Medicolegal Issues in Obstetrics and Gynaecology

Swati Jha
Emma Ferriman
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This book is dedicated to my Father who introduced me to Pandora's box and made me the Doctor I am today and my Mother who gave me the values by which I live my life.

Swati Jha

Preface

The UK is experiencing a dramatic increase in medico-legal claims. The four main reasons for litigation are accountability, the need for an explanation, concern with standards of care and compensation. However the decision to take legal action is determined not only by the original injury but also by a failure to provide information, an explanation and an apology. **Insensitive handling of an injury and poor communication** after the original incident **increases the risk of litigation** and erodes the patient-doctor relationship. Doctors almost never deliberately cause harm to patients; however increasingly claims are being prosecuted successfully.

Medicine has always been an imperfect science and as humans we will make mistakes. Whereas the principle of "Six Sigma" can be applied to certain areas of medical practice, surgery involves so many variables that it would be impossible to apply those principles. It is also true that a single failure rarely leads to harm but in complex systems, which is what surgery involves, it is usually the Swiss cheese model of accident causation that results in suffering for the patient. Unfortunately this is also what often results in successful litigation.

Obstetrics and gynaecology in particular has always had a reputation for being a highly litigious specialty. However for all those in the practice of obstetrics and gynaecology, we are in the specialty because we enjoy it and have chosen it *in spite of* it being a litigious specialty and have obviously not been deterred by this fact. Awareness of issues related to litigation however makes us more aware of how best to avoid injury and harm to our patients and at the same time protects us from accusations of clinical negligence.

The aim of this book is to highlight minimum standards relating to the management of different conditions in the practice of obstetrics and gynaecology. We also highlight clinical governance issues and common causes of litigation. A section on how to avoid litigation is provided in each chapter followed by a case study. This should be of use to clinicians and lawyers alike and raise awareness of how to avoid facing clinical negligence claims in our day-to-day practice.

Sheffield, UK — Swati Jha

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1.1 The Difference Between the Law and Ethics

Good law should follow ethical principles, and in day to day life we usually act ethically if we follow the law. But in complex dilemmas the ethically correct action cannot automatically be determined by reference to current law. This is obvious when we consider past laws; in many countries and for many periods slavery was legal, but it was never ethical. Similarly termination is legal in some jurisdictions and illegal in others, so its moral status cannot be judged simply by appeal to local laws; it must be judged by appeal to more fundamental principles.

However, philosophical thinking is hard, there is often insufficient time to do it properly, and individuals easily fall prey to self-interest and self-deception. For everyday decisions the law, and paralegal bodies such as the GMC, provide simple guidance that any doctor should be able to follow.

The rest of this book describes the law and the above day to day rules. In this chapter we consider the philosophical principles that underpin them.

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1.2 Ethical Principles

Medical practice should respect the following principles:

Beneficence

A doctor should act in the best interests of the patient

Non-maleficence

First, do no harm

Autonomy

The patient has a right to choose or refuse their own treatment

Justice

Resource allocations between competing individuals should be made justly.

Problems typically arise in two ways. Firstly, if one principle conflicts with another. For example, termination of pregnancy puts respecting the autonomy of the mother with acting non-maleficently to the fetus. In UK law, the rights of the fetus cannot supersede the autonomy of the mother. However, the fetus does have some 'rights' or else there would be no need to regulate termination of pregnancy. Secondly, around the issue of justice. People arguing for a just allocation of resources often appeal to two different conceptions of justice. On the one hand, justice as entitlement, e.g., a kidney should be allocated in accordance with the wishes of the person to whom it rightfully belongs, for example, the donor. On the other hand, justice as fairness, it should be allocated by a fair process for example

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equal shares for all, or by lottery, or to the person who will benefit most.

Many philosophers and religious leaders have attempted to resolve such dilemmas by appeal to a universal moral law, the Golden Rule. Immanuel Kant expressed it as his categorical imperative "act only in accord with those rules which you can, will that it become universal moral laws" [1]. Richard Hare, considering the termination decision, added "and as we are glad was done to us when we were in the same situation" [2].

1.3 Case Scenario

A young woman requests termination of pregnancy. She reports that her last menstrual period was 8 weeks ago. On scan she was found to be 25 weeks gestation. The doctor explained that in the UK it is illegal for a doctor to perform a termination beyond 24 weeks unless there is a substantial risk to the mother's life, or fetal abnormalities. The patient found a clinic abroad that would offer late termination and booked flights to go.

1.3.1 Termination Ethics

The ethics around termination of pregnancy remain as controversial today as they did in 1967 when the Abortion Act was enacted in English Law. The central argument against termination is that following the principle of non-maleficence, killing innocent people is wrong. The fetus is a person. Therefore termination is wrong. The central argument for termination is that if we respect autonomy, people should be allowed to do what they like with their own bodies, and the mother should be allowed to empty her uterus/have a termination. The self-described "pro-lifer" resolves the conflict this way: when one person's desire to do what they like with their own body conflicts with another person's desire not to be killed, not killing takes precedence. The self-described "pro-choicer" usually finds fault with this in two ways, either by disputing the status of the fetus as a person, or by arguing that respecting bodily autonomy takes precedence over not killing.

1.3.2 Personhood

One of the central issues to the debate is the status of the human fetus. At what point in its development from a zygote to an autonomous, mature person does a human acquire a "right to life".

First we need to define person. Let's be circular, and define it as a "being who may not be unjustly killed". The obvious answer is humans, members of the species Homo sapiens. On that definition the fetus is a person and, on the face of it, termination is wrong. However, although it makes intuitive sense, the Homo sapiens claim does not bear close examination. It is "speciesist", in the same sense as it would be racist to claim that only whites are persons. They are both distinctions based on morally irrelevant criteria, namely skin colour, or species membership. The reason we don't immediately perceive the speciesist claim as such, is that on this planet the only undisputed contenders for personhood are members of the species, Homo sapiens.

We need a thought experiment to clarify things. Imagine a spacecraft landed outside your house one day. How would you decide in what sense to have the occupants to dinner? Would you eat them, or sit down together and share a meal? Remember they are making the same decision about you. The answer is obvious. You would not decide on the basis of their species. You would assess their mental state. Are they conscious, self-aware, do they want to live, would they be deprived of anything by painlessly dying? If the answer is yes, you should not kill them, and if they've made the same judgment about you, they also should let you live.

So now we have a better definition—consciousness, self-awareness, wanting to live, are what makes people, people. For now we need not go into the precise definition any further. If we take this argument, the fetus does not make the cut. Or if it does we are already being unfair to many other animals.

On this definition personhood/non-personhood is a continuum. Some higher animals, primates, dolphins and whales probably also fulfill some criteria for personhood. Maybe they are conscious, aware of themselves and grieve when their family members are killed. This is a strength of our definition; we should be careful how we treat such higher animals.

But however we look at it, on the basis of this argument, the 12-week fetus say, is not even a borderline person on this definition, so termination is permitted.

One problem is that this argument appears to commit us to permit infanticide. Newborn babies are not self-aware, and don't, as far as we can tell, care about their future life. Can we also kill them if they are inconvenient?

Some philosophers would argue yes, if no other person is prepared to make the effort to look after them (e.g. Singer). The value of newborn babies lies in the importance other people give them. They are precious in the way an inanimate, but otherwise important painting like the Mona Lisa is precious. It is not a person, but destroying it would be wrong. Killing a newborn baby is not the same as killing an adult, but so long as its mother, or the nurses looking after it, want it to live then it is still wrong.

But imagine if no-one cared enough to expend effort looking after a particular newborn baby. Perhaps its mother had other concerns, or it was so premature that the only nurses who could look after it, also had other concerns. Perhaps they needed time with their own families. This might happen as technology for saving the lives of premature babies grows more complex. At that point we would surely allow the last neonatal intensive care nurse to switch off the ventilator with a clear conscience.

Other societies, such as the Spartans, have permitted infanticide in the past, and some, India and China, tolerate it even today. Such societies are different but not immoral.

Many people will argue that this is the wrong way to think about the fetus. They would argue that any argument which leads to a conclusion that newborn babies are not people and do not have a right to life should be rejected as absurd. Several religions take the stance that the human fetus is special because it has a soul, given by God from the moment of conception. Termination is therefore prohibited. However no adult should impose their religious belief on another. So a belief that the fetus is special is an excellent reason for a believer to forego termination. But it's a bad reason to prohibit an unbeliever, or a believer in a different tradition, from choosing one.

However not all those who are anti-termination argue from a religious standpoint. Tom Huffman argues that a fetus has rights worthy of protection: "It is proper to consider a woman's right to employ a physician in self-defence against an unwanted fetus, then it is equally proper to consider an interested third-party exercising the fetus' right of self-defence on its behalf against a women who intends to abort. The fetus is … a moral patient who has a right to life but must rely upon others to protect it against those who would threaten its interests" [3]. In other words because the human fetus cannot themselves exercise rights whereas the mother can and does exercise her rights, should make us sensitive to the protection of whatever rights the fetus may have.

If a fetus only has rights when it is born then the following difficulty emerges: if a doctor may be sued on behalf of a child who suffered harm due to negligence on the part of that doctor while the child was a fetus in utero then did those rights exist at the time of the negligence? Can the child's rights only be exercised retrospectively after the birth?

If we reject the notion that a newborn baby is not a person with no rights to protect, then at what stage of pregnancy is termination permissible. A former US Surgeon General Koop said "I do not know anyone among my medical confreres, no matter how pro-abortion he might be, who would kill a newborn baby the minute after he was born….My question is this: would you kill this infant a minute before that, or a minute before that, or a minute before that?....At what minute can one consider life to be worthless and the next minute consider that same life to be precious". A fetus may not function in the same way as an adult "consciousness, self-awareness,

wanting to live" but that fact alone may not remove the fetus from the status of a person.

1.3.3 Bodily Autonomy Versus Not Killing

Some people have argued that termination is permitted even if the fetus is as much a person as you and me. After all we don't force women to give a kidney, or even a pint of blood to save an adult life. Why should we force them to carry a pregnancy? But perhaps that's not a fair analogy. The philosopher, Judith Jarvis Thomson, came up with a better one [4]. Her thought experiment is an analogy with termination for rape, but not limited to that.

A famous violinist, i.e. not just a person who valued his own life but someone whose life was also valued by many others, develops a fatal kidney disease, which can only be treated by connection to the circulation of another person for 9 months. He has a rare blood group and it is difficult to find someone with the right group who is also willing to be connected. A Society of Music Lovers hear about the problem, search for a suitable person and find you. Rather than asking if you would agree to be connected, they kidnap you and connect you to the violinist's circulation. The next day you wake up and the clinic director explains what has happened. You demand to be disconnected, but the director says his hands are tied. He can't disconnect you without killing the violinist, an undisputed person with his own right not to be unjustly killed. Should you stay connected? Obviously it would be kind of you to do so. But must you?

Thomson says that if after due consideration you decided that you couldn't cope with 9 months connection, you should be allowed to disconnect. If so we should also permit termination for rape victims, whatever our belief about the personhood of the fetus.

It's only a small step to extend this line of argument to termination for a woman whose contraception has failed? Imagine it was well known that the Music Lovers were on the hunt for a suitable victim in your town. The police warned people to not travel home alone. And imagine that you decided to cross the local park to take the pleasure of exercise, or of viewing the sunset, and the Music Lovers jumped out of the bushes, abducted and connected you. Would it make any sense for the clinic director to say, "I would have disconnected you, but I can't because you brought this on yourself by your reckless behaviour"? Surely not. By analogy taking sexual pleasure does not commit you to bearing the pregnancies that occasionally result, whatever the personhood of the fetus.

There are many critics of Thomson's analogy. Some argue that we do not have the same obligation to sustain a stranger who is plugged into us as the obligation to sustain our own offspring. Koukl argues that were a woman to be surgically plugged into our own child, it's unlikely she would be willing to cut off the life-support so easily. He criticises Thomson's assumption that a mother has no more duty to her own offspring than a stranger. Others have argued that the comparison between disconnecting support or withholding support is not a fair comparison with termination of pregnancy as the former is a case of letting die and the latter is a case of killing. Some have argued that the burden of being bedridden and connected to a stranger for 9 months is not a fair comparison with 9 months of a mobile, healthy pregnancy.

1.3.4 Taking Potentiality Seriously

Many people find the above arguments unconvincing. Their intuition is different from Thomson's, or they object to the personhood arguments on the grounds that the fetus, unlike animals, has the potential to become a person. If we do nothing it will likely become a paradigm person. The philosopher Richard Hare took such potentiality claims seriously, arguing from the Golden Rule; "Treat others as you were glad that you were treated when you were in the same situation" [2]. Since most mothers would not have wanted to be aborted when they were fetuses, termination is, on the face of it, wrong; even for a fetus with spina bifida who is likely to

be handicapped, because if we were that fetus we would choose life in a wheelchair rather than no life at all.

But, Hare says, imagine that the mother plans a family of just one child. If she carries this pregnancy she will bear a child with spina bifida. If she aborts she can have a normal child who would not otherwise exist. That "replacement child" would wish the termination to happen. The mother cannot act as both the spina bifida and the replacement child would wish. Hare asks what you would choose if you had to live through the lives of both children? Reject termination and get one life in a wheelchair and one non-life. Abort, and get one non-life and one replacement life in full health. You'd obviously choose the latter, so the mother should abort. At least for a predictably handicapped fetus where the mother is fertile and likely to have a replacement pregnancy, termination is in the interests of the replacement child.

Hare then asks us to consider how this type of argument plays out with the more usual types of termination; those considered by young women not ready for a baby. They probably will have another child later. How much better will that later child's life be? Will it be better or worse if the mother has the first termination? There are more people to consider than just this child now and possible replacement/future children. All children affect other people's lives. Not just in big ways, by marrying them, or taking the job they wanted, but in all the minor ways in which each of us improves or harms the welfare of others.

Consider how all these other people would view the termination, the decision becomes rather like deciding whether to reproduce at all. The high likelihood that the present fetus will exist without termination creates a presumption that termination is usually wrong, but it's hardly a knock down argument. In an overpopulated world, if the mother would struggle to look after the baby, or if the present fetus will be handicapped, termination might be the right choice.

Imagine what terminations we would choose if we were as yet unconceived, i.e. from behind a veil of ignorance. If we did not know whether we would be conceived and live, conceived and aborted or be a replacement fetus after another termination. We would know the chance of being a boy or girl, being handicapped, being unwanted, born to a single parent, living in an underpopulated or over crowded world. Hare thinks we think we might be fairly liberal.

Or perhaps it is too complicated to judge. Thinking about future people and replacement fetuses is tricky. But the complications are similar to those faced by people deciding whether to reproduce at all. We solve them by leaving the decision to parents. They, especially the mother, are probably best placed to act in their future children's best interest.

1.3.5 Deprivation of Futures

An American Philosopher Don Marquis set out his arguments against termination (except in rare circumstances) [5]. He sets out that termination is wrong because it deprives an individual of their future: "what primarily makes killing wrong is neither its effect on the murderer nor its effect on the victim's friends and relatives, but its effect on the victim. The loss of one's life is one of the greatest losses one can suffer…. [It] deprives one of all the experiences, activities, projects and enjoyments that would otherwise have constituted one's future". He argues that just as killing an adult is wrong due to the loss of their future experiences, termination too is wrong because it is presumed that the fetus has a future of value.

Fortunately, few other common ethical dilemmas are as tricky to resolve as the pregnancy termination dilemma. Most others, are solvable with clear thinking. The following is one such.

1.4 Case Scenario

A 49 year old woman presented with a history of right iliac fossa pain, dyspareunia and dysmenorrhoea. An ultrasound revealed a 5 cm complex right ovarian cyst. Her Ca-125 was elevated and her risk of malignancy index was 300. She was booked to undergo a total abdominal hysterectomy and bilateral salpingo-oophorectomies.

The patient was a Jehovah's Witness. She was fully counselled about the risks of surgery in particular bleeding and an advanced directive stating her refusal of all blood products was completed. At the operation the patient was found to have extensive endometriosis. The operation was difficult and there was significant venous bleeding. Five hours later, despite the assistance of a vascular surgeon, it became clear that the woman had lost 5 L of blood and was going to die. The patient was kept ventilated and died surrounded by her family. The husband, who was not a Witness was grateful to the gynaecologist that he had respected the patient's wishes and acknowledged that it must be a very difficult situation for him. The woman's parents were furious with the JW community.

The striking ethical principle in this case is autonomy. The patient had a clear wish to avoid all blood products. She was fully aware that the operation she was going to have had a risk of bleeding and that without blood products that bleeding could be potentially life threatening. She was resolute in her wishes and had capacity to make a decision about her treatment. The other principle which arises is beneficence. The gynaecologist and vascular surgeon failed to give a transfusion which at little cost would, in their eyes, have done much good by saving her life. However, the patient was well informed and competent and had judged that the "benefit" of following the tenets of her church outweighed saving her life. For a well-informed competent adult, respecting autonomy trumps doing good.

Conclusion

For the vast majority of decisions clear ethical thinking gives a clear answer. In the case of a fully informed, competent Jehovah's Witness experiencing life threatening bleeding, the decision not to give blood while difficult for all involved is the right decision. The ethics of termination are deeply contentious but we hope this article has set out some of the important philosophical arguments for and against.

When it comes to ethical considerations: think long and carefully; talk to colleagues; record your thought process and justify your decision making.

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Why Doctors Get Sued

2

Eloise Powers

2.1 Introduction

In this chapter, an overview of the main categories of clinical negligence claims which are typically brought against medical professionals in England and Wales will be provided, namely: consent, errors of treatment (including surgical errors) and errors of diagnosis. This is not intended to be an exhaustive categorisation of cases, but it covers the majority of clinical negligence cases which doctors are likely to encounter in practice. Other types of cases include secondary victim claims and systemic/procedural failings. In each category, key legal principles are set out, a case example is given and advice is provided on how doctors can avoid litigation. The guidance set out in the chapter can only be regarded as generic in nature and does not constitute legal advice.

The advantages of avoiding litigation are self-evident. For doctors, the litigation process is time-consuming, difficult and distressing. For patients, the consequences of clinical negligence are often devastating. For the NHS, the costs of litigation are burdensome: NHS Resolution's stated strategic objective is *"a move to an organisation which is more focused than before on prevention, learning and early intervention to address the rising costs of harm in the NHS"* [1]. For all concerned, it is clear that prevention is better than cure.

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Most clinical negligence claims in England and Wales are brought against Trusts or other organisations rather than against individual doctors. The vast majority of claims do not proceed to trial: in 2015–16, the NHS Litigation Authority (now part of NHS Resolution) stated that *"fewer than 1% of the claims we resolved went to trial"* [2]. It seems empirically likely that the cases which do proceed to trial are closer to the borderline (in terms of merits) than the cases which settle or are discontinued by claimants. Under these circumstances, it is important to consider typical examples of cases which settle.

Obstetric claims deserve special consideration: 33% of NHS Resolution's annual expenditure (10% of claims received) comes from obstetrics [3]. Claims involving birth injuries, such as cerebral palsy claims, are often of very high value involving lifelong care claims. Obstetric claims can often span two or three of the categories considered in this chapter: for example, in a shoulder dystocia case, a claimant may allege a failure to obtain properly informed consent followed by the use of excessive traction in effecting the delivery.

2.2 Consent

2.2.1 Key Legal Principles

Following the 2015 case of *Montgomery* [4], a doctor is under a duty to obtain a patient's informed consent to treatment in the following manner:

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- Take reasonable care to ensure that the patient is aware of any **material** risks involved in any recommended treatment.
- Take reasonable care to inform the patient of **any reasonable alternative or variant treatment**, and of the material risks of the reasonable alternative or variant treatment.

The concept of "material" risk is defined as follows: *"whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it."*

Importantly, it will not be a defence to establish that the failure to warn of the material risk would be accepted as proper by a responsible body of medical opinion. When a patient makes a choice about medical treatment, it inevitably involves making value judgments. The Supreme Court held that these value judgments should be made by the patient, not the doctor. Under the circumstances, the Bolam approach becomes inappropriate in consent cases.

In circumstances where a doctor reasonably considers that disclosure of information would be *"seriously detrimental to the patient's health,"* or in circumstances of *"necessity"*, doctors will not be required to obtain informed consent.

The effect of the *Montgomery* judgment is to move away from a paternalistic model of the relationship between doctor and patient. As the Court of Appeal observed in *Webster* [5]. *"What they point to is an approach to the law which, instead of treating patients as placing themselves in the hands of their doctors (and then being prone to sue their doctors in the event of a disappointing outcome) treats them so far as possible as adults who are capable of understanding that medical treatment is uncertain of success and may involve risks, accepting responsibility for the taking of risks affecting their own lives, and living with the consequences of their choices."* The implication is that the *Montgomery* approach may (in the long run) serve to reduce litigation once it has been fully assimilated into medical practice.

Case Study: Ms. A

Ms. A presented with a complaint of significant post-menopausal bleeding. Her medical history included two caesarean section deliveries, Crohn's disease and a right hemicolectomy, cholecystectomy and hepaticojejunostomy and post-surgical pelvic adhesions. She underwent an endometrial biopsy, which revealed no evidence of residual hyperplasia of the endometrium. She was offered a hysterectomy to resolve the bleeding.

Ms. A was appropriately advised of the routine risks associated with a hysterectomy, but she was not advised of the significant risk to her bowel and biliary reconstruction due to her complex medical history. Further, she was not advised about alternative treatment options including hormonal treatment with progestogen, continuous HRT or a Mirena IUS. She was not advised that the bleeding would be likely to stop within around a year even if she did not undergo treatment.

Unfortunately, Ms. A sustained a small bowel injury during her hysterectomy. She thereafter suffered a chain of complications including fistula and sepsis. Her condition deteriorated, she went into multi-organ failure and died at the age of 57.

This case illustrates the dangers of taking a "standardised" approach to the consenting process. Ms. A needed to know that she was at significantly increased risk of serious complications if she underwent a hysterectomy, and needed to know that there were far safer options available to treat her vaginal bleeding.

Avoiding Litigation

- The consenting process does not start and finish with the consent form. Be aware that a Court will review *the whole consenting process*, including the records of your pre-treatment discussions with the patient and correspondence.
- As Baroness Hale observed in *Montgomery*, *"it is not possible to consider a medical procedure in isolation from its alternatives."* Make sure that you have discussed *alternative procedures*, and the risks and benefits of these procedures, with your patient, and make a record of these discussions.
- Where appropriate, advise your patient that having *no treatment/conservative treatment* is available as an option.
- The consenting process is *patient-specific* and should take account of the risks, benefits and alternative treatments applicable to each individual patient.
- Where your patient has a history which puts her at *additional risk* if she undergoes the proposed treatment, you should discuss the additional risk with the patient, quantify the additional risk where possible and make a record of the discussion.
- When managing labour/delivery, present the pros and cons of different modes of delivery in an *objective manner* (regardless of your personal beliefs or preferences).

2.3 Errors of Treatment or Surgery

2.3.1 Key Legal Principles

The 1957 case of *Bolam* [6] established the following touchstone: whether the doctor is acting in accordance with a practice of *"competent respected professional opinion."* A doctor who acts in accordance with a standard of practice recognised as proper by *a responsible body of medical opinion* will not be held to be negligent merely because another body takes a contrary view.

In the 1997 case of *Bolitho* [7], the House of Lords held that in applying the *Bolam* test, the court has to be satisfied *"that the exponents of the body of opinion relied on can demonstrate that* ***such opinion has a logical basis.***" Experts should direct their minds to the question of comparative risks and benefits and reach a defensible conclusion on the matter.

Case Study: Ms. B

Ms. B suffered a perineal tear classed as 3b following the protracted and difficult delivery of her first child. The tear was repaired shortly after delivery. Two months later, Ms. B re-presented with symptoms of an ano-perineal fistula, which was confirmed upon MRI and upon ano-rectal physiology. The doctors who performed the ano-rectal physiology strongly recommended that Ms. B should be referred to a colorectal surgeon to perform the repair.

The repair procedure nevertheless proceeded under the supervision of an urogynaecologist. The procedure was performed incorrectly, resulting in far more extensive damage than was necessary: the vaginal wall was opened, the perineum was opened till the fistula, the anus was opened and the fistula track was excised. The correct procedure would have been to treat the fistula with a seton (loose or cutting).

Ms. B suffered permanent and disabling incontinence and requires ongoing treatment by way of inserts.

This case demonstrates the importance of following correct procedures, and of ensuring that patients are referred to the most appropriate specialist for their condition.

Avoiding Litigation

- Familiarise yourself with up-to-date *guidelines and literature*. The National Institute of Clinical Excellence (NICE) and the Royal College of Obstetricians and Gynaecologists (RCOG) guidance documents are routinely scrutinised in the course of treatment/ surgical claims.
- In situations where you are deviating from best practice guidance, ensure that you have fully thought through and documented your *rationale* for doing this, and that you have obtained clear and comprehensive *consent* from your patient.
- Where a particular procedure falls outside your specialism or is usually undertaken by a different specialism, consider *referring your patient to a relevant specialist*.
- In obstetrics, midwives should be aware of the circumstances in which an *obstetrician's opinion* is needed.
- In gynaecological surgery, consider involving a colorectal specialist in cases where there is an *increased risk of bowel injury*.
- *Discuss difficult cases* with colleagues/ at a multi-disciplinary team meeting, and record your discussions.

2.4 Errors of Diagnosis/Delayed Diagnosis

2.4.1 Key Legal Principles

In the 2017 first instance case of *Muller* [8], Mr. Justice Kerr considered whether the *Bolam* principle applied to cases involving errors of diagnosis or failure to make a diagnosis (as distinct from cases involving the exercise of professional judgement about treatment or surgery). He concluded—in his words, *"with some regret"*—that the principles in *Bolam* and *Bolitho* do indeed apply to cases involving errors of diagnosis. At the time of writing, and pending any further developments in the higher courts, the legal principles relating to errors of diagnosis are the same as the legal principles relating to errors of treatment.

Case Study: Ms. C

During a period lasting over a year, Ms. C attended various appointments with her GP and at the colposcopy clinic. She had a sore, macerated area on her right labium majorum, and experienced vulval pain to the extent that she was unable to tolerate the colposcopy speculum. Despite this, she was not referred to a gynaecologist for over a year. When she was eventually referred to a gynaecologist, she was diagnosed with vulval cancer.

Due to the delay in diagnosis, Ms. C was advised to undergo a radical vulvectomy rather than a simple removal of the lesion. She suffered disabling lymphoedema and has lost all sexual function at a young age.

This case demonstrates the importance of being alert to incidental findings, and the importance of taking action within a reasonable time-frame where a patient has potentially worrying symptoms.

Avoiding Litigation

- Be alert to the patient who repeatedly presents with *symptoms which are difficult to explain*. Discuss such patients at MDT meetings, and make referrals where appropriate.
- Take action quickly (investigations, referral to other specialists, treatment) where a patient makes a *poor recovery after surgery*.
- Have a high index of suspicion for the investigation and treatment of *cancer*. A large number of clinical negligence cases arise out of delayed diagnosis of cancer.
- Be alert to *sepsis* and take rapid action where appropriate [9]. Failure to diagnose and treat sepsis generates a

significant number of clinical negligence cases, often with tragic consequences.
- Encourage junior staff to *escalate patients with troubling symptoms* as soon as possible.

Key Points: Why Doctors Get Sued

- Plan the patient's treatment in conjunction with the patient.
- Advise the patient of alternative treatment options/no treatment.
- Take a patient-specific approach when advising about risks.
- Be objective when advising about the pros and cons of different birth options.
- Familiarise yourself with best practice documents.
- Clearly consider and document your rationale for any departure from best practice in a particular case.
- Discuss complex or puzzling cases at an MDT or with professional colleagues, and record your discussions.
- Work within your competence and refer patients to the most appropriate specialist.
- Investigate or refer patients with ongoing unexplained symptoms.
- Take action quickly where a patient fails to recover as expected after surgery.
- Be alert to sepsis.
- Investigate potential cancer cases rapidly.
- Follow up upon any concerns about your patients.
- Encourage junior staff to escalate patients with concerning symptoms.

References

1. *"Delivering fair resolution and learning from harm": Our strategy to 2022. NHS Resolution,* p4.
2. NHS Litigation Authority Annual report and accounts 2015/16, p16.
3. "Delivering fair resolution and learning from harm": Our strategy to 2022. NHS Resolution, p12. Note that these statistics do *not* seem to include gynaecological claims other than obstetrics.
4. *Montgomery v Lanarkshire Health Board* [2015] UKSC 11. The facts of the *Montgomery* judgment are considered in more detail in [chapter dealing with case law].
5. *Webster v Burton Hospitals NHS Foundation Trust* [2017] EWCA Civ 62, para 81.
6. *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 583, p587.
7. *Bolitho v City and Hackney Health Authority* [1998] AC 232, p1158.
8. *Muller v King's College Hospital NHS Foundation Trust* [2017] EWHC 128.
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Consent After Montgomery: Clinical Considerations

3

Helen Bolton

3.1 Background

In March 2015 the UK Supreme Court ruled on a landmark case that confirmed patients' right to autonomy [1]. During her first pregnancy Nadine Montgomery, a petite, diabetic woman, expressed anxieties on several occasions about her forthcoming delivery, as scans had identified a large baby. She did not specifically request caesarean section. The delivery was complicated by shoulder dystocia and consequently her son developed cerebral palsy.

Mrs. Montgomery had not been advised of the potential risks of vaginal delivery or shoulder dystocia. Nor had the option of a planned caesarean section been discussed. Defending her practice, the obstetrician claimed that although the risk of shoulder dystocia was significant, the absolute risk of grave injury resulting from it was minimal, and therefore she was not obliged to discuss it. Moreover, she claimed such discussions are not standard practice, and that if all diabetic women were told of these risks then they would inevitably choose caesarean delivery, which would not be in their best interests. As Mrs. Montgomery had not asked about caesarean, she had been under no obligation to discuss it with her.

Mrs. Montgomery claimed that had she been advised of the risks of shoulder dystocia and offered caesarean section, then she would have chosen that option, thus avoiding vaginal birth and her son would have been healthy. The case was won on appeal at the Supreme Court. She received around £9 m in damages.

Prior to *Montgomery*, consent cases were tested by traditional tests of negligence, i.e., doctors only failed in their duty in consent cases if it could be proven that their practice was not in line with how a body of responsible practitioners would act (the *Bolam* [2] principle). Doctors were only obliged to inform patients of risks if these were perceived by the doctor to be significant (*Sidaway* [3]). The *Montgomery* ruling now enshrines in case law that it is no longer up to the doctor to decide the extent of disclosure about risk. Rather, it up to the patient to decide.

3.2 Requirements for Consent

Doctors have an ethical and legal duty to obtain a competent patient's consent before embarking on treatment, unless there are exceptional circumstances [4]. Competent patients have an absolute right to accept or refuse treatment, without any need to justify their decision. A patient is free to withdraw her consent at any time.

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The *Montgomery* ruling has not altered the fundamentals of consent. It remains the case that for consent to be valid the patient must [5]:

1. Have capacity to give their consent to make that particular decision,
2. Be provided with sufficient information (clarified in *Montgomery*)
3. Be free from coercion, and able to give their decision voluntarily.

The Mental Capacity Act 2005 provides clear guidance on capacity and clinicians must be familiar with this [6]. It is good practice for consent to be documented in writing, especially for interventions such as surgery, although this is not usually a legal requirement.

3.3 Consent After Montgomery: What Constitutes Sufficient Information?

The judgment in *Montgomery* clarifies that it is the patient, not the doctor, who determines how much information is required for sufficient consent. This is a clear departure from previous case law, where the doctor was required only to impart the information that a reasonable body of medical opinion thought appropriate. Although the *Montgomery* ruling has been perceived to have changed the landscape of medical consent, the same overriding principles have been enshrined in GMC guidance for many years [5].

Since *Montgomery*, the new test for sufficient information is now as follows [1]:

1. The doctor is under a duty to take reasonable care to ensure that the patient is aware of any material risk involved in the treatment, and be informed of any reasonable alternative treatments, including no treatment.
2. The materiality test is whether, in the circumstances of that particular case, a reasonable person, in that patient's position would be likely to attach any significance to that risk, or the doctor is, or should reasonably be aware, that the particular patient would be likely to attach significance to it.

What constitutes a 'material risk' cannot be defined simply by percentages. The judges gave clear guidance that the significance of each risk for the individual patient is likely to reflect a range of factors other than just its magnitude. The significance of the risk should be assessed by:

1. The nature of the risk
2. The effect that it would have on the life of the patient
3. The importance of the potential benefits of the treatment to that particular patient
4. The alternatives available (including no treatment)
5. The risks involved in those treatments

Therefore, the assessment of material risk requires both facts about the risk itself, in addition to knowledge about the characteristics and wishes of the patient. This requires clear dialogue with the patient, and doctors must take time to have a discussion with the patient about risks and to establish (within reason) which risks will matter for that particular patient. Substituting dialogue with written information, or overwhelming the patient with technical information is not acceptable. To avoid future litigation, it is essential to document what was discussed in as much detail as possible, and how the patient responded to the information.

Although *Montgomery* requires doctors to discuss alternative options with the patient, it does not require the doctor to provide that treatment. It remains the doctor's responsibility to advise patients on which treatment may be medically preferable, but ultimately it is up to the patient to decide.

3.3.1 Exceptions to Provision of Information

There are three situations where it may not be necessary to discuss material risks:

1. Where treatment is provided out of necessity in an urgent situation
2. The therapeutic privilege exception—this is the rare situation where a doctor has the right to withhold information about risks if it is believed that the patient will be seriously harmed by knowledge of that risk. This only applies in very exceptional cases, and withholding information just to prevent upsetting or worrying a patient is not acceptable, as upset and worry do not constitute serious harm.
3. The right of the patient not to know—a patient can decide that they do not wish to be aware of the risks, and a doctor is not obliged to discuss them when a patient makes it clear that she does not wish to discuss the matter. The GMC guidance provides further advice on how to manage patients in this situation [5]. Although patients have the right not to know, this can be problematic, as the patient doesn't know what they do not want to know.

3.3.2 Birth Choices Post-*Montgomery*

Mrs. Montgomery won her case because she had not been advised of the risks of vaginal birth or offered the option of caesarean section. She had not specifically enquired about caesarean section, however the judge ruled that her obstetrician still had a duty of care to discuss this option with her. In her ruling, the judge intimated that the medical team may have viewed vaginal delivery as morally superior than caesarean section, and that this view had dominated their thinking. She also stated that '*gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also a right to act as a genuinely autonomous human being*' [1]. It remains to be seen what impact *Montgomery* will have on future litigation. However, obstetricians must be mindful of a woman's right, now enshrined in case law, to decide which type of delivery she wishes.

3.4 Court Decisions Since Montgomery

3.4.1 A v East Kent Hospitals University NHS Foundation Trust [2015] EWHC 1038

Mrs. A brought a claim alleging that her obstetricians had failed in their duty to warn her of the possibility that her child may have a chromosomal abnormality. Routine screening tests for trisomy 13, 18 and 21 had estimated a very low risk of abnormality, and there were no structural anomalies at her 20-week scan. The fetus was shown to be small on scan measurements and subsequently she underwent serial growth scanning and monitoring until delivery by caesarean section at 37^{+6} weeks. Unfortunately the baby was born with severe disabilities secondary to a rare unbalanced chromosome translocation. Mrs. A claimed that had she been advised of the risk then she would have elected for amniocentesis, thus detecting the abnormality, and consequently she would have chosen to terminate the pregnancy. The key issue in this case was resolving whether or not there was evidence that there was a material risk that the baby may be suffering from a chromosomal abnormality. If so, in keeping with the *Montgomery* case, it was agreed that the doctors ought to have raised that material risk with Mrs. A. However, on review of the evidence presented by the defendants and expert witnesses the court concluded that there was no material risk that the baby had a chromosomal abnormality, over and above the background risk. There was nothing to suggest that this was a risk to which a reasonable patient, in the position of Mrs. A, would have attached any significance. Indeed, the judge noted that Mrs. A had already accepted the very low background risk given in her screening tests and continued with the pregnancy. Medical practitioners do not have to warn patients about theoretical risks.

3.4.2 Spencer v Hillingdon Hospitals NHS Trust [2015] EWHC 1058

Although not strictly concerning consent, this case is of relevance because the judge applied the *Mongtomery* materiality test in determining the duty to provide advice to a patient during the post-operative period. Mr. Spencer brought a case claiming that the hospital had failed in its duty to warn him of the possibility of post-operative venous thromboembolic events (VTE). He underwent elective surgery to repair an inguinal hernia. Shortly after discharge he experienced calf pain. He attributed this to inactivity due to being generally unwell after surgery, and did not specifically seek medical attention until several weeks later when he presented with severe shortness of breath and palpitations. He was diagnosed with bilateral pulmonary emboli. It was proven in court that the hospital had failed to provide him with any specific information, either oral or written, with respect to the risks and symptoms of VTE. Instead he had simply been advised to report 'any problems' after his discharge. The judge acknowledged that Mr. Spencer was in a low risk group for VTE, and that VTE is a rare event. However, in applying the basic principles defined in *Montgomery*, the judge concluded that a reasonable patient, such as in Mr. Spencer's case, would expect to be advised about the symptoms and signs of VTE given the potential seriousness of the condition. By not warning Mr. Spencer of specific signs and symptoms of VTE, the Trust had failed in its duty of care. He was awarded £17,500 in damages, as the judge also concluded that had Mr. Spencer been properly advised (confirming causation), he would have sought medical attention earlier.

Key Points: Consent After Montgomery

- The *Montgomery* judgment requires a patient-centered approach to consent, and is entirely in keeping with GMC guidance on consent.
- Doctors must take reasonable care to ensure the patient is made aware of any material risk involved in the proposed treatment.
- The materiality test is individual to the specific patient and their circumstances, and requires dialogue between patient and doctor.
- Written information, and/or overwhelming the patient with excessive information does not constitute proper consent.
- Doctors must discuss alternative options with the patient, including the risks and benefits associated with those options.
- Detailed documentation of discussions is essential to avoid litigation. A written consent form alone is insufficient documentation.
- When considering birth options, women must be informed of the material risks associated with vaginal delivery, including risks to the mother as well as the baby.

References

1. Montgomery v Lanarkshire Health Board [2015] UKSC 11.
2. Bolam v Friern Management Committe [1957] WLR 582.
3. Sidaway v Board of Governors of the Bethlem Royal Hospital [1985] AC 871.
4. RCS. Consent—Supported Decision Making—a good practice guide. 2016.
5. GMC. Consent: patients and doctors making decisions together. 2008.
6. GOV.UK. Mental Capacity Act 2005 Code of Practice. 2007.

4 Consent After Montgomery: Legal Considerations

Elizabeth Thomas and Bertie Leigh

4.1 Introduction

The present law of consent is shaped by the 2015 judgment of *Montgomery* [1]. The Supreme Court in *Montgomery* relied heavily on guidance published by the GMC in 2008 [2]. However, Mrs. Montgomery was treated in 1999. This suggests that in order to advise practitioners how to counsel their patients today we have to anticipate the position of the regulators and courts many years hence, something we attempt to do by analysing whether the current system of consent reflects optimal medical practice.

4.2 Use of a Consent Form

The consent form was devised as a defence to battery i.e. unlawful touching, to prove the patient consented to the doctor's touch. It is now used as evidence of an informed choice to a specific treatment. For that consent to be *Montgomery*-compliant the form should evidence discussions of alternatives, including various material risks and benefits including no treatment. However, typically the information the patient is given on the form is specific to the agreed treatment and recorded in untidy handwriting with acronyms and abbreviations that mean nothing to most lay people. For example, most forms mention the risk of bleeding: patients will think they are likely to bleed if their skin is cut; we have no record that they were told how much bleeding there might be and whether it might be difficult to arrest. Such a form may be a useful *aide memoir* to the doctor of what they have said in relation to that specific procedure, but it does not provide objective evidence that the patient understood what was meant, had time to assimilate the information or that it was conveyed in an appropriate fashion.

Sometimes the evidence we need is haphazardly recorded in clinic letters describing *Montgomery* discussions and the decision to proceed. But we need a structured record of the decision process. The current focus on consent forms is because it is the only place where the patient makes a physical entry in the notes by their signature - a reassuring but often empty disclaimer for the doctor that it is the patient's informed choice to proceed.

For the avoidance of doubt, should the consent form (currently seen as the pinnacle of the consent process) be presented to a patient shortly before an intervention we say it is *prima facie* evidence of malpractice, if not professional misconduct. This is because:

1. It implies that consent was sought at the wrong time. The patient has long since already made their decision, they have

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arranged to take time off work and made arrangements for their domestic responsibilities to be disposed of. They have mentally adjusted themselves so as to undergo an intervention and it is quite wrong to suppose that a *Montgomery* explanation of risks/benefits/alternatives can sensibly be presented to them long after the decision to proceed has been taken.

2. Such consent is sought at the wrong time emotionally. The patient will be anxious if not frightened by the imminence of surgery, and so it is unlikely that they will be able to absorb significant information that is of relevance to the important decision that they are being asked to take. Mentally they are already committed to the operation.

4.3 Future Law

We suggest that when the Supreme Court next considers a case of consent to treatment it will go beyond analysing whether all the appropriate risks/benefits and alternatives were mentioned: it will be considering how and when they were described. It will examine the doctor's discharge of their role as a teacher. It will be asking whether the necessary information was given in an appropriate fashion. If the patient was counselled in the wrong language, or at the wrong time, or if the information was unlikely to have been understood because the doctor was rushed or spoke in a technical fashion, then the process will be found wanting even if all the right risks and alternatives were mentioned.

Simple utterance of *Montgomery* information does not discharge the doctor's duty of care. For a decision system to be fit for purpose it needs to be able to identify objective evidence that the individual patient has understood the information provided and made a decision based on that understanding. Counselling may need as much skill as diagnosis or performing a procedure.

4.4 The Decision Record

Lawyers work on the principle that if it is not written down it did not happen. Therefore, we need to find a way for doctors to record not only the information that has been conveyed to the patient but also the fact that the patient has understood what has been said. To fend off future litigation surrounding consent we need to replace the current system with a decision record. However, it seems to us that an optimal process will not take place in most time-poor NHS clinics. If the matter is to be done properly it has to be done without time pressure, probably in the comfort of the home.

We suggest that a great deal of the information that needs to be conveyed as well as the recording of the patient's understanding can best be achieved with technology. For example, an online/downloaded programme could contain the information that the doctor wishes to convey, with the opportunity for patients to learn even more. If the process were linked to the treating centre there could be a record of the information accessed and that spurned.

An algorithm could be written so as to highlight anomalous answers with alarms triggering invitations to attend an additional clinic. This could require the presence of the treating clinician but equally it could be with a nurse-counsellor—the process of learning must be recorded and scribbled notes avoided. Alternatively it could all be done online with an invitation to access further information. The variations that could be devised are vast.

Such a programme could utilise cartoons, diagrams and videos describing the anatomy, the lesion or the disease and the modalities of treatment. There could be graphs and statistical tables presenting data that the patient may want to understand. Crucially the system could be in the patient's own language.

Not all medical decisions call for this pattern of counselling. In dire emergencies all that the patient really needs to know is that if they do not consent to the proposed treatment imminent death is a certainty. There are also patients who

are so cognitively impaired that we stray into best interests territory and those unable to access technology will need assistance. However, we have to describe an optimal process of counselling before we identify the deviations that will be appropriate in certain circumstances.

We advocate that the profession should develop these procedure-specific decision records. If the text is agreed by the profession through the Royal Colleges and the professional societies then we will have the advantage of consistency in different centres as well as avoiding multiple repetitions of the work of preparation. That does not mean that it should be immutable. Through use we anticipate it would be re-written and adapted - it should be a living, growing thing, responding to the way in which it is used by patients and to reflect changing science and treatment options.

Incidentally the technology could also usefully record the patient's view of the process in retrospect; recording whether the treatment and the outcome corresponded to the patient's expectations. This would of course provide a means of reviewing both the counselling provided and the skill of the clinician and so allowing the continuing development of both.

Conclusion

The consent form was devised as a defence to battery—unlawful touching—the patient consented to the doctor's touch. It is now used as evidence of an informed choice to a specific treatment. However, we do not need a record of what is self-evident from the fact that the patient is willingly lying on the bed, but a record of the process by which they came to take the decision to be there. We need a record of the fact that the hospital has played its part in helping the patient to take that decision in a *Montgomery*-compliant fashion. We also need a process that reflects the importance of recording advice given to patients when surgery is not in issue or an alternative to surgery is chosen. It is our opinion that the current system of discussions in rushed clinics with the handing out of leaflets and consent evidenced by a scribble on a consent form is not fit for purpose and will not withstand future forensic scrutiny by the courts. This is not because there is anything in the law that says it is wrong, but because it is not part of an optimal medical practice. Trying to shoe-horn a defence to battery into a decision record is simply misguided.

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2. GMC, Consent: patients and doctors making decisions together. 2008.

Duty of Candour

5

Helen Bolton

5.1 Background

The duty of candour is about being open and honest when things go wrong. There are two types of duty, professional and statutory. The professional duty of candour is defined by the General Medical Council (GMC) as 'a professional responsibility to be honest with patients when things go wrong'. In contrast, the statutory duty of candour is a legal duty to be open and honest, and applies to all health and social cares organisations that are registered with the regulator, the Care Quality Commission (CQC) in England. Although there is considerable overlap, there are important distinctions between the two. Clinicians must understand these differences to ensure they can fulfill both their professional and legal responsibilities to their patients.

5.2 Professional Duty of Candour

It is well established that healthcare professionals have an ethical responsibility to be open and honest with their patients, and this is enshrined in the GMC's guidance for doctors 'Good Medical Practice' [1]. Recognising that doctors, nurses and midwives work closely together, the GMC and the Nursing and Midwifery Council (NMC) have published more detailed joint guidance on the matter setting out clear expectations for health care professionals [2]. The joint guidance covers both the professional's individual duty to patients, and the professional's responsibilities to the organisation for which they work. The duty to the patient arises when something goes wrong during a patient's treatment or care, that causes, or has the potential to cause, harm or distress. In such a case the healthcare professionals must:

- Tell the patient (or, where appropriate, their family or carer) that something has gone wrong
- Apologise—stating what happened, what can be done to deal with any harm caused, and what will be done to prevent this happening again
- Offer an appropriate remedy or support to put matters right, if possible
- Provide a full explanation of the short and long term effects of what has happened

As was noted immediately above, the professional duty of candour applies whenever patients have suffered harm or distress when something has gone wrong with their care. Unlike the statutory duty of candour (see below), there is no defined threshold of harm that needs to be met for the duty to arise. In circumstances, where a 'near

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miss' has occurred (i.e. care has gone wrong, but fortunately the patient came to no harm) the GMC advises clinicians to use their professional judgement when deciding whether to tell patients about the error. When there is uncertainty it may be helpful to seek advice from senior colleagues or healthcare teams.

The patient should be spoken to as soon as possible after it has been realized that something has gone wrong. Doctors should not be afraid of apologizing to patients when things have gone wrong. An apology does not automatically mean that the clinician is taking personal responsibility for the error, nor is it an admission of legal liability. The NHS Litigation Authority actively encourages healthcare organisations to apologise, and will never withhold legal cover for a claim because an apology of explanation has been given [3]. Any uncertainties must be explained and all questions answered honestly. Discussions should be fully documented, with notes made contemporaneously whenever possible.

The GMC also mandates doctors that the duty of openness and honesty extends beyond just patients, to include candour with their colleagues, employers, organisations and regulators. This includes an expectation to report adverse incidents, to cooperate fully with reviews and investigations, and to express concerns where appropriate. Doctors must support and encourage each other to be open and honest, and not to stop others from raising concerns.

5.3 Statutory Duty of Candour (CQC-Registered Healthcare Organisations, England)

Healthcare organisations in England that are registered with the regulator, the Care Quality Commission (CQC) have an organizational duty to be open and honest when things go wrong [4]. In contrast to the professional duty, the statute applies only when a 'notifiable safety incident' has occurred, where a threshold of moderate harm or worse is met. The regulations define these incidents as any event that has appeared to have caused, or has the potential to cause, moderate or severe harm, death, or prolonged psychological harm. Prolonged psychological harm means that it must be experienced for 28 days or more.

Once a notifiable safety incident has been identified, the statute requires that:

- The patient should be informed, in person, as soon as reasonably practical
- A full explanation is given, including what further investigations will be carried out
- Offer an apology and provide reasonable support to the patient
- Organisations must keep a written record of the notification to the patient
- The patient must be provided with a written account of the discussion and copies of correspondence must be kept by the organisation

Although the ultimate responsibility for complying with the statutory duty of candour resides with the healthcare organisation, individual healthcare professionals have a key role in working with their organisation to ensure the legal obligations are fulfilled. Senior doctors are most likely to be the organisation's representative, and to lead the discussions with the patient. All CQC-registered healthcare organisations should have a named manager responsible for statutory duty of candour.

In some cases it can be difficult to determine if an incident reaches the threshold of harm for statutory notification. Guidance suggests that harm should be assessed in the 'reasonable opinion of a healthcare professional' with the emphasis on being open if there is any doubt [5]. Individual clinicians should be encouraged to seek advice from appropriate colleagues and their organisation's managers in cases where there is uncertainty. Clinicians must be mindful that their professional threshold for duty of candour is low, and that they are obliged to be open and honest with their patients even when the harm caused may seem insignificant, or does not meet the threshold for statute.

5.4 Consequences of Not Complying with Duty of Candour

For the patient a lack of openness and honesty erodes trust and can cause significant distress. Doctors who fail to act in accordance with the GMC guidance on candour may find themselves with sanctions from the GMC, including restrictions on their licence to practice. Organisations that do not comply with the statutory duty of candour will incur regulatory action from the CQC, and in serious or persistent cases could even face criminal prosecution.

5.5 Case Study: Bladder Injury

A patient attended the delivery unit at 4 am with contractions. She had previously had one caesarean section. Shortly after emptying her bladder, her membranes ruptured. The CTG showed an acute bradycardia, and vaginal examination revealed that she was 5 cm dilated with a cord prolapse. The attending midwife kept the fetal head elevated manually by upward vaginal pressure and she was transferred immediately to theatre for delivery by category I (immediate) caesarean section under general anaesthesia. An attempt by the midwife to catheterise the bladder failed, so the registrar decided to proceed to delivery of the baby, and to insert the catheter after delivery, reasoning that the patient had just been to the toilet and that further delays should be minimized. Apart from some scarring due her previous caesarean, the procedure was apparently uncomplicated, and the baby was born in good condition within 20 min of the initial cord prolapse. Frank haematuria was noted in recovery, but no action was taken and she was later transferred to the post-natal ward. The midwives expressed concerns that the haematuria persisted, but were reassured by the junior medical staff and advised to remove the catheter the following day. She was discharged home on day 3. On day 10 she re-presented with constant leakage of urine, and further investigations revealed a vesico-vaginal fistula. This had occurred as a consequence of unrecognized bladder injury.

The attending registrar informed the duty consultant of the events. They immediately went together to see the patient, and explained her bladder had been damaged during her caesarean, and advised that she would need further treatment to fix the injury. They explained that it appeared there had been a delay in recognising the injury, and that in hindsight the presence of blood in her urine should have triggered earlier investigations, which may have avoided her developing the fistula. In keeping with their professional duty of candour, they offered her an apology, and answered her questions. She was also advised that her case would be reviewed at the local governance meeting, and that she would be kept informed of the results of the review. A midwife was present throughout the conversation, who then stayed with her to provide additional support to ensure she had fully understood the explanation. Contemporaneous notes of the discussions were recorded in the clinical notes. The clinicians reported the injury as a patient safety incident, following their hospital's governance guidelines.

The Consultant then notified the manager responsible for statutory duty of candour. Referring to the CQC guidance, it was confirmed that the injury was a notifiable safety incident, and that the degree of harm had reached the threshold required for notification under the statutory duty of candour. It was agreed that the discussion and apology that had already taken place were appropriate and sufficient to have complied with the statutory requirements. It was also agreed that the consultant would write to the patient, summarizing what had happened. The local governance meeting concluded that the injury may have been avoided if the bladder had been catheterised, and identified earlier if the staff had acted on the frank haematuria. As a consequence, teaching sessions were arranged to ensure the medical, midwifery and theatre staff were aware of the importance of catheterisation prior to caesarean delivery and of the potential significance of blood in the urine. This outcome was included in the letter, along

with another apology, and she was invited back to see the consultant in clinic to debrief several weeks later. The patient had made a good recovery and expressed her thanks to the staff for their honesty. She was grateful that her baby had been delivered safely. The consultant documented the discussion, and copied correspondence to the manager to ensure the hospital's notification process was complete.

Key Points: Duty of Candour

- Professional duty of candour is an individual responsibility. The statutory duty is an organisational responsibility.
- The professional duty of candour requires doctors to be open and honest with their patients when things go wrong, and also within their organisation by reporting and learning from adverse incidents.
- The statutory duty of candour (England) applies to care organisations registered with the CQC. Individual professionals have a responsibility to cooperate with the organisation to ensure the legal obligations are met.
- The statutory duty applies when a notifiable safety incident has occurred that have (or have the potential to) resulted in moderate harm or worse.
- Offering an apology does not mean that the healthcare professional is accepting personal responsibility for the error, and must not be a barrier to saying sorry.
- Where there is any doubt, the professional and statutory duties advise that clinicians err on the side of being open and honest.

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Leading Cases

6

Fiona Paterson

The aim of this chapter is to provide the reader with an overview of the leading cases in relation to two matters; namely negligence (or breach of duty) and causation. They are the two components of liability or put simply, if a patient is to sue a healthcare professional successfully, he/she must first prove that the care was negligent and second, that the negligence in question caused him/her harm. Many of the leading cases arise from treatment in areas of clinical care other than obstetrics. Nevertheless, they remain relevant to obstetrics and midwifery care.

6.1 Negligence

6.1.1 What Constitutes Negligence?

Bolam v Friern Hospital Management Committee [1] is often cited as the seminal case in medical negligence, Mr. Justice McNair,

"*…where you get a situation which involves the use of some special skill or competence, then the test as to whether there has been negligence or not is not the test of the man on the top of a Clapham omnibus, because he has not got this special skill. The test is the standard of the ordinary skilled man exercising and professing to have that special skill. A man need not possess the highest expert skill; it is well established law that it is sufficient if he exercises the ordinary skill of an ordinary competent man exercising that particular art.*"

That definition was refined by the House of Lords in *Sidaway v Governors of Bethlehem Royal Hospital* [2] who recognised that in many situations there may be a range of acceptable practice. The judgment stated,

"*a doctor is not negligent if he acts in accordance with a practice accepted at the time as proper by a responsible body of medical opinion even though other doctors adopt a different practice.*"

But a note of caution was sounded subsequently by the House of Lords in *Bolitho v City and Hackney Health Authority* [3]—finding an expert who was supportive of his/her actions was not enough for a clinician facing allegations of negligence to escape liability. Lord Browne—Wilkinson stated,

"*…the court has to be satisfied that the exponent of the body of opinion relied upon* [by the clinician facing an allegation of negligence] *can demonstrate that such opinion has a logical basis… the judge before accepting a body of opinion as being responsible, reasonable or respectable, will need to be satisfied that, in forming their views, the experts have directed their minds to the question of comparative risks and benefits and have reached a defensible*

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conclusion on the matter…in some cases, it cannot be demonstrated to the judge's satisfaction that the body of opinion relied upon is reasonable or responsible. In the vast majority of cases the fact that distinguished experts in the field are of a particular opinion will demonstrate the reasonableness of that opinion…. But if, in rare case, it can be demonstrated that the professional opinion is not capable of withstanding logical analysis, the judge is entitled to hold that the body of opinion is not reasonable or responsible…"

The law has continued to evolve from these judgments in response to the specific circumstances of individual cases which have come before the courts, the most significant of which has been *Montgomery v Lanarkshire Health Board (General Medical Council intervening)* [4]. The judgment is now regarded as pivotal in matters of consent. The facts are particularly pertinent to obstetrics and midwifery. The Supreme Court (formerly the House of Lords) **recognising the social and legal developments, which meant that medical paternalism was no longer condoned, stated that** at the heart of obtaining a patient's consent must lie a recognition that he/she is entitled to decide what risks he/she is willing to take. Critically, defining the ambit of how far a clinician had to go in enumerating and explaining the risks associated with any procedure was now a matter for the courts and not the medical profession:

"*…The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a person's rights rests with the courts, not with the medical professions.*"

The decision undoubtedly represents a seachange from the deference by the courts towards the medical profession which was seen in cases such *Bolam* and *Sidaway.* A clear signal was sent by the Supreme Court; that when obtaining consent a doctor's role is to inform rather than determine or influence what should happen to a patient. Patients should now be treated as autonomous individuals allowed, possibly even encouraged to take an active role in any decisions about their care. The ultimate arbiter of how far they should be allowed to inquire and insist is now the court rather than the clinician. Understandably, that may be a somewhat sobering message for clinicians and a departure from an approach with which they are accustomed. For advice on how to approach matters of consent in light of this, see the chapter "*Why doctors get sued*".

6.2 Causation

It is sometimes easier to recognise a causal link between a doctor's alleged negligence and any harm suffered by the patient, rather than to define what the legal test for causation actually is. Over the years, the courts have formulated various tests, all of which have subsequently evolved through amendment and sometimes erosion by the later decisions of other courts.

The following two cases (decided by the Court of Appeal) have been selected due to their seminal nature.

In *Bailey v Ministry of Defence* [5] the patient had undergone an unsuccessful procedure in a Ministry of Defence Hospital to remove a gallstone. Her problems were compounded by inadequate care post-operatively. She then developed pancreatitis and continued to deteriorate and was transferred to the Intensive Care Unit where she underwent two further procedures. The patient was then moved to the renal ward of another hospital, where she aspirated on her vomit, which in turn, led to a cardiac arrest that caused her to suffer hypoxic brain damage. The court had to grapple with whether there was a sufficiently strong causal link between the inadequate post-operative care at the Ministry of Defence Hospital.

The Court of Appeal acknowledged that the cardiac arrest which caused the hypoxic brain

damage had been caused by a combination of negligent care and bad luck. But was that sufficient for the patient to win or did she have to show that the negligent care had been the dominant cause? The Court of Appeal decided that if the patient could prove that "but for" the impact of the negligence (as opposed to the bad luck), the injury would probably not have occurred, the claimant should win. The issue was then, what did the evidence actually demonstrate or prove on the facts of the patient's case? In a dose of judicial pragmatism, the Court of Appeal decided that where medical science could not establish the probability that "but for" a negligent act the injury, would not have happened, but could establish that the contribution of the negligent cause "*was more than negligible*," the patient should succeed. In the present case, the patient had crossed that hurdle.

In *Wright v Cambridge Medical Group* [6] a child, aged 11 months, had developed a bacterial superinfection in hospital and been discharged home undiagnosed. Her mother contacted a GP, who negligently failed to refer the child to hospital until 2 days later. It was not until three further days later that the child was correctly diagnosed in hospital, by which time her hip had become infected. As a result, she had permanently restricted movement, and a leg length discrepancy. Proceedings were brought on behalf of the child against the GP only.

Perhaps surprisingly, the judge decided that GP's negligence had not caused the child any harm, as, even if she had been admitted to hospital 2 days earlier, she would not have been treated properly and would have suffered the same permanent damage. The child's litigation friend appealed to the Court of Appeal who decided that the GP's negligence was a causative factor of the child's permanent injury. The reasoning behind the decision was that the hospital's treatment of the child (even though it was negligent) was not so serious or unusual as to destroy the causative link between the GP's negligence and the child's injury.

Both the parties (in the proceedings) agreed that, if the child had been admitted to hospital 2 days earlier, and given the same treatment as she ultimately received, it was very likely that there would have been significantly less permanent damage and possibly no permanent damage. However, the damage suffered as a result of GP's negligence was identifiable and divisible from the damage caused by the hospital's negligence. Consequently, there was no way that the hospital could be held liable for the earlier damage and the GP should not be liable for the whole damage.

The Court of Appeal went even further and looked at the case in terms of a loss of opportunity to secure a better outcome. It held that where a doctor had negligently failed to refer his patient to a hospital, and, as a consequence, she had lost the opportunity to be treated as she should have been by a hospital, the doctor could not escape liability by establishing that the hospital would have negligently failed to treat the patient appropriately, even if promptly referred.

The implications of these two cases has been the subject of much discussion and debate within the legal press and in subsequent decisions. In most cases, causation will be considerably simpler and will turn largely on a combination of expert evidence and a judge's sense of what is fair, just and reasonable in the circumstances.

In conclusion, the leading cases summarised above should give the reader a snap shot of how the law currently stands. What is clear though, is that the tectonic plates of judicial reasoning are shifting in relation to the practice of medicine. Even 10 years ago the idea of a court making the bold statements made by the Supreme Court in Montgomery would have been unthinkable. The decisions of the appellate courts over the next decade, (particularly in an area as emotive as obstetrics), are likely to involve a judicial balancing act of the patient's rights and a recognition that clinicians do not offer a consumer service, but care to the sick and vulnerable, in often highly pressured circumstances.

Conclusion

Clinicians need to familiarise themselves with the rulings of these landmark cases as they have a bearing on patient care and management, and will continue to be the leading authorities in respect of all areas of clinical practice.

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2. [1985] AC 871.
3. [1998] AC 232.
4. [2015] AC 1430.
5. [2008] EWCA Civ 883; [2009] 1 WLR 1052.
6. [2011] EWCA Civ 669 [2013] QB 312.

The Claim Journey

7

Karen Ellison and Emma Ferriman

7.1 Introduction

In a recent poll of all doctors in the United States 60% of them had been through the medical litigation process at some point in their career. When this was broken down by specialty 85% of obstetrics and gynaecology doctors had been sued. Of the cases that went forward 35% were settled prior to trial, 21% were withdrawn by the Claimant, 14% ruled in favour of the doctor, 11% were dismissed by the court, 3% settled at the trial; leaving only 3% where the court ruled against the doctor [1]. Litigation seriously affects doctors leaving them feeling hopeless, doubting their own competence with a fear of exposure and humiliation by their peers. This can lead to isolation and loneliness with negative effects on relationships and their family. In addition, the process is often lengthy taking doctors away from their patients [1, 2].

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7.2 Letter Before Action

The first step in the litigation process will be a letter from a patient's solicitor, this usually occurs without warning and is often unpleasant containing criticism of the doctor and is usually written in an aggressive and adversarial style. It is important to keep this in perspective, to acknowledge the emotions experienced and to seek support and advice from a colleague. When faced with this situation it is important that the doctor seeks advice from their defence organisation and does not respond directly [3]. The defence organisation will provide a buffer between the doctor and the claimant's solicitor in the legal process. It is important that the doctor provides their full co-operation with the process to enable it to progress [2].

For a clinical negligence claim to be successful the claimant has to prove on the balance of probabilities that the doctor owed a duty of care, that there was a breach in that duty and that harm occurred as a result of that breach (causation). The clinical management in a case is assessed by independent experts in the relevant field using the Bolam standard. This standard considers the clinical management of the doctor against that of a reasonable body of doctors practicing in the same field. The claimant must prove that the doctor's care fell below a reasonable standard and that this resulted in the claimant sustaining harm. Experts are therefore required to provide both reasonable

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and logical evidence that will stand up to scrutiny. A doctor must respond quickly to any complaint and provide medical records within a timely manner. Following this however, there may be a long period of waiting, months or even years, when the claimant takes advice and makes a decision on whether to proceed with their case. If the claimant does proceed with the case, then a strict timetable will be drawn up which must be followed. Formal proceedings must be brought within a three-year timescale. This three-year period may run either from the date of the incident or from the date of knowledge. The date of knowledge is the date at which the patient became aware that the injury sustained could be attributable to clinical negligence. There are two exceptions to this; in the case of children and in those patients with reduced mental capacity for example as a result of cerebral palsy. A child has up to their twenty-first birthday (i.e. 18 years plus 3 years) to issue proceedings. In the case of a minor legal action is usually brought by a close relative who becomes the child's litigation friend. For claimants with impaired mental capacity there is no time limitation on claims.

7.3 Letter of Claim

When a doctor is notified of a claim it is important to contact their defence organisation and the litigation department within their trust. The letter of claim should be shared with the defence union as well as any medical records and a record of the doctor's involvement in the case. Medical records should be available within 40 days of their request from the claimant's solicitors. Having instructed a defence organisation all correspondence should be directed through them so that the doctor has no direct contact with the claimant's solicitors. Any documentation received directly should be forwarded immediately to the doctor's representative whilst maintaining a photocopy of any relevant information. Accurate record keeping is essential. The doctor should write a factual account of the event for their own records. This record should detail their involvement in the incident and their direct recollection. Where the doctor cannot recall the precise nature of their involvement the doctor should document this and describe their usual clinical practice. Where the doctor does have a good recollection of events the account should be as detailed as possible. Remember the claimant has a number of years to bring their claim and recollections will fade with time, so the time spent preparing the account may be invaluable at a later date.

7.4 The Response

The legal process will begin with a pre-action protocol where disclosure of the medical records is requested (Fig. 7.1) [4]. Following disclosure of the medical records the claimant will take expert advice and make a decision whether to proceed. In these cases, the trust or their representatives will receive a letter of claim and this will be forwarded to the doctor involved. The letter of claim gives a detailed description of the alleged failings of the doctor. The claimant should not issue formal proceedings until 4 months after the letter of claim. The trust's representatives are obliged to issue a formal letter of response within 4 months of the letter of claim. A doctor involved in this process may take advice from the hospital's representatives or from their own defence organisation regarding preparation of a suitable response. For those claims that are denied, clear and detailed reasons will be provided to the claimant in order for them to consider their position. Arguments should be reasoned and logical in an attempt to facilitate a withdrawal of the claim and to settle any dispute informally. For those claims that are not resolved the claimant will issue formal proceedings.

7.5 Formal Proceedings

A doctor involved in a case where formal proceedings have been issued will be supported by the hospital's representatives if the case has occurred in the NHS or by the legal representatives of agencies working in the private sector. In the NHS, all claims are ultimately overseen by

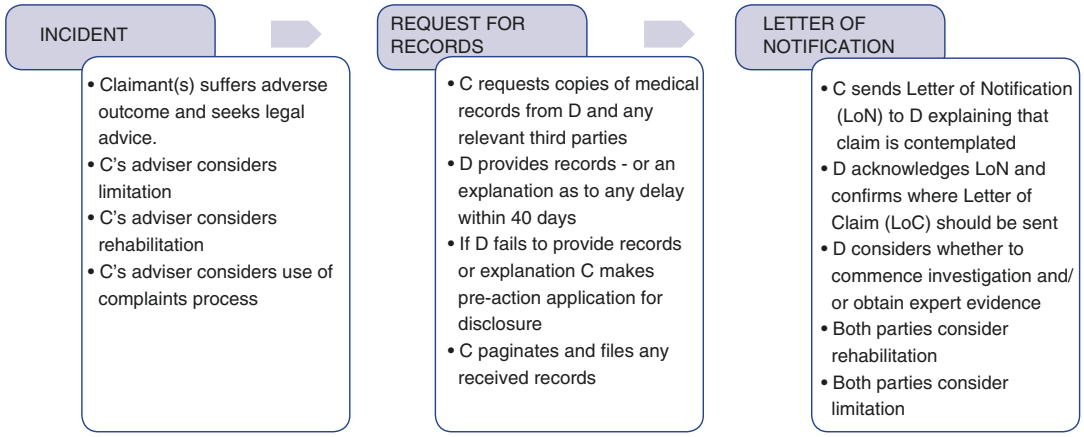

Fig. 7.1 The legal process simplified

the NHS Litigation Authority (NHSLA) in England, the NHS Wales shared services partnership in Wales, the Central Legal Office (CLO) in Scotland and The Directorate of Legal Services (DLS) in Northern Ireland. In addition, the doctor can be supported by a representative from their defence organisation. A detailed defence document will be produced with the doctor's own witness statement as a key component. The witness statement is the doctor's signed factual account of their involvement in the case and will be lodged with the court, so it is imperative that the doctor involved is entirely happy with the contents of the statement. The doctor is also required to sign a statement of truth as part of this document.

7.6 Doctors Witness Statement and Exchange of Witness Statements

The process of medical litigation is lengthy and time-consuming. Any doctor involved in this process will be expected to liaise directly with the hospital's representatives and to provide information in a timely manner. This information may consist of evidence of adequate accreditation and training and so it is imperative that a doctor keeps detailed evidence in their appraisal documentation. As the process proceeds the doctor will be asked to comment upon any allegations, to read expert reports in the exchange of evidence and to attend conferences with counsel. They are obliged to sign a statement of truth as part of the documentation.

The reports of experts instructed by the defense and claimants are exchanged, and either may present questions to the other about their report. Experts may be required to meet and prepare a joint statement. The objective of such meetings is to resolve as much of the case before trial as possible to save on time and costs. Where the defense is persuasive the claim may be discontinued by the claimant.

7.7 Trial

Some cases will be settled out of court usually without admitting liability, but on occasion a breach of duty will be admitted to achieve an out of court settlement.

For those few cases that do proceed to trial (less than 1%) [5] the process can be lengthy depending on the complexity of the case and it is important that a doctor involved in this process has adequate professional and personal support.

Doctors involved in medical litigation commonly ask whether all cases are referred to the General Medical Counsel (GMC). GMC referral rarely occurs [5]. The GMC will investigate those cases where there are significant concerns regarding patient safety and where a doctor's fitness to

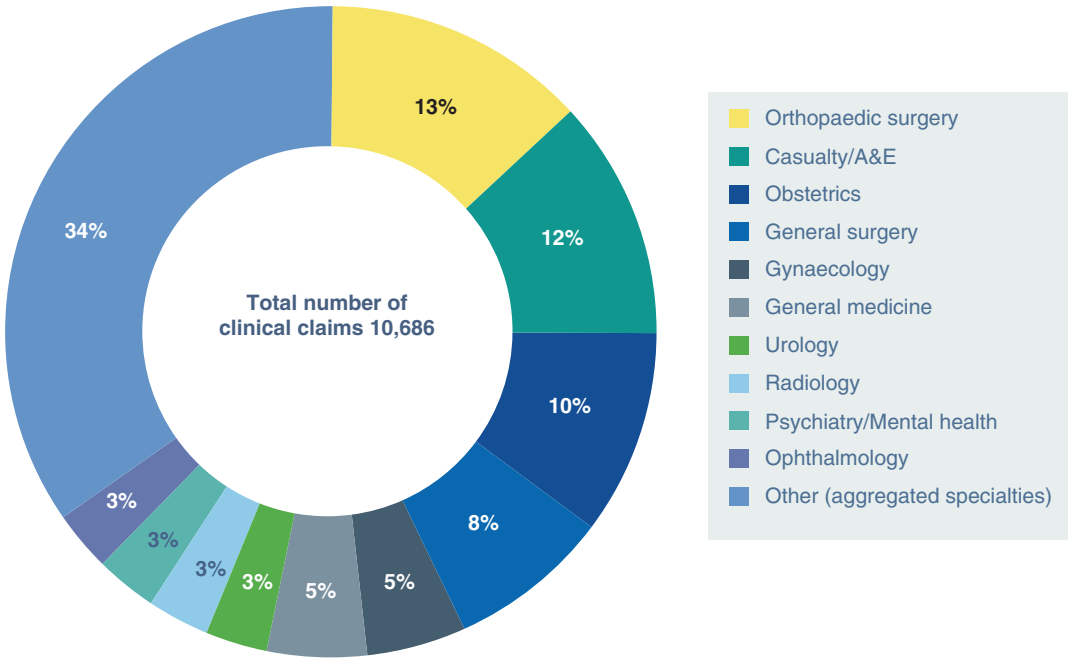

Fig. 7.2 The number of clinical negligence claims received in 2016/2017 by specialty

practice may be impaired. Another issue for some doctors involved in litigation is where the claimant remains a patient of the doctor thus providing a potential conflict. The GMC states that a doctor must not allow a complaint to prejudice a patient's care. There are instances however, where the doctor-patient relationship is deemed to be irrevocably damaged and where the patient may be better receiving care form an alternative healthcare professional [6].

Doctors will never avoid being sued. It is highly likely in a high-risk specialty such as obstetrics and gynaecology (see Fig. 7.2) [7] that a doctor will become involved in a formal patient complaint and medical litigation. What a doctor can do is put themselves in a stronger position by being able to defend their treatment for example by following local and national guidelines. Good record keeping and detailed correspondence regarding a patient's care is imperative. Cases where documentation is poor are more difficult to defend whereas cases in which the documentation is of a high standard are more difficult for the claimant to dispute [5]. Another key factor is good communication with the patient and their family especially in the face of complications or adverse outcome. Time spent explaining in detail is invaluable and although this process wont completely dispel all medical litigation it may help to alleviate a patient's concerns or anxieties. Adverse incidents can be reduced, but not eradicated by clinical risk management. For an individual doctor this means practicing within their own area of expertise, knowing their personal limitations, and communicating effectively with patients and colleagues and writing good contemporaneous notes [8].

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GMC Referral

8

Katherine Sheldrick and Angela Pilling

8.1 Background

The General Medical Council ("GMC") is the regulatory body responsible for maintaining the register of medical practitioners, setting standards in medical education and practice, 5 year revalidation, and investigating concerns which may put patient safety or the public's confidence in the profession at risk. It regulates all registered medical practitioners across the UK. Since 2012 the investigatory and hearing (or adjudication) functions of the GMC have been separated. If you are subject to a GMC investigation and your case is referred for a hearing, the hearing will take place before a Panel of the Medical Practitioners Tribunal Service ("MPTS"). The MPTS is a Statutory Committee of the GMC established under the Medical Act 1983 [1].

8.2 GMC Guidance

The GMC publishes and updates its guidance and standards periodically. Its overarching guidance is entitled "Good Medical Practice" (GMP) (last updated in 2014). It sets out the duties and core professional standards of all registered doctors broken down into four domains (knowledge, skills and performance; safety and quality; communication, partnership and team work; maintaining trust). In addition, the GMC publish more detailed explanatory guidance which shows how the principles of GMP apply in specific circumstances. All registered medical practitioners are expected to be aware of and follow the GMC's current guidance and to maintain their continuing professional development. The standards set out in its guidance are applied by its investigators and experts in determining the seriousness of any alleged departure from GMP and whether it may call into question a practitioner's fitness to practise medicine.

8.3 GMC Statistics on Number and Outcome of Referrals

The most recently published data for 2016 [2] records the GMC reviewed 9140 concerns or referrals in the context of almost 240,000 licensed and registered medical practitioners. The annual level of referrals has remained fairly constant over the last 5 years, at between 9 and 10,000. Of these concerns in 2016, almost 74% were closed at the initial triage stage without further investigation. This may be because they do not raise a serious concern or the concern does not relate to a doctor's fitness to practice. If a concern is closed at the initial triage stage, you are unlikely to be informed of the fact or be made aware that there was a concern.

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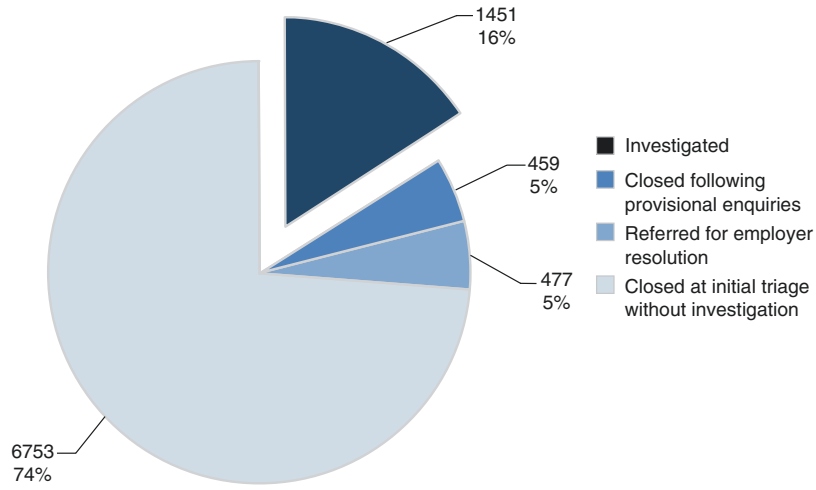

Fig. 8.1 GMC investigation of concerns in 2016. Data from GMC Annual Report 2016

Of the remaining 2387 concerns which were not closed at triage, just over 60% (1451) were investigated, 20% (477) were referred to the doctor's employer for local resolution and the balance (459) closed following provisional enquiries.

Of the investigations concluded by the GMC in 2016, 54% were concluded with no further action. Just over 13% (245) cases were referred for an MPTS hearing. The remainder of the cases concluded with advice, a warning or undertakings. Warnings and undertakings are recorded on the doctor's registration (see Sanctions section below) (Fig. 8.1).

8.4 Sources of Referral

Anyone can refer a medical practitioner to the GMC. Thus a referral can be made by a colleague/whistleblower, patient (or their Solicitor), relative, member of the public, Coroner, their employer's Responsible Officer, Police, pharmacist, CQC or NHS Protect amongst others. In addition, a medical practitioner may be under a regulatory duty to self-report or the GMC may commence an investigation in the absence of referral, for example, where there has been adverse press reporting.

If you are a manager, colleague or responsible officer and are considering making a referral, you may wish to consider the GMC thresholds guidance [3] before doing so.

8.5 When You Should Self-Report?

GMP identifies three situations [4] in which practitioners should self-refer where:

1. their health may put patients at risk;
2. they have been cautioned or convicted by the police anywhere in the world: and/or
3. where they have been criticised by an official inquiry (including by a Coroner).

Practitioners must protect patients and colleagues from any risk posed by their health. A practitioner cannot rely upon their own assessment of risk but must consult a suitably qualified colleague and follow their advice about any changes/limitation to their practice or to refrain from work while they are unwell.

8.6 What Type of Concerns Are Investigated?

The concerns:

- Must raise issue of impairment of fitness to practise
- Be made within the last 5 years (unless in public interest to investigate older cases)
- Single clinical incidents may be investigated

- Repeated/pattern of concerns about clinical care and practice likely to lead to invitation for performance assessment
- Concerns of lack of knowledge of English language will lead to invitation for formal assessment
- Concerns regarding a practitioner's own health will usually lead to assessment by two independent health assessors
- Presumption that five categories of serious concern will be fully investigated

The GMC will only investigate concerns which raise an issue of impaired fitness to practise. Within their guidance they give examples of concerns which will not be investigated including minor motoring offences not involving drugs or alcohol, a delay of less than 6 months in providing a medical report, a minor non-clinical matter or a complaint about the cost of private medical treatment.

They cannot investigate concerns which took place over 5 years ago unless they determine there is a public interest in doing so despite the fact it has been made late [5].

Isolated concerns which do not raise an issue of impairment, for example, about the quality of treatment where there is no serious risk to the patient or a poor attitude to a patient, will not be fully investigated but are likely to be disclosed to the practitioner and RO to be dealt with at appraisal to ensure there is no repetition.

Single clinical incidents which resulted in patient harm will be investigated and usually an expert opinion obtained to determine whether the management falls below or seriously below the standard to be expected of a reasonably competent practitioner. Where it is alleged that the practitioner has fallen seriously below the standard to be expected, the threshold for presumption of impairment will be reached which means the level has been reached for imposition of a sanction (see below for an explanation of the sanctions which are available to the GMC Case Examiners/MPT).

Where any further concerns are notified, they will also be investigated fully. If there is a pattern or area of concern identified relating to clinical competence, a practitioner is likely to be invited to undergo a performance assessment. Such an assessment will include written examinations, observed simulated clinical examinations (OSCEs) and interviews with the practitioner and other third parties.

Concerns may be referred about a practitioner's knowledge of the English language either spoken and/or written. Such concerns will lead to an invitation to sit further examinations to test the practitioner's language skills. The current GMC criteria require a valid (taken within the last 2 years) IELTS certificate showing:

- A score of at least 7.0 in each testing area (speaking, listening, reading and writing), and an overall score of 7.5.
- You got these scores in the same test
- You took the academic version of the test
- The original stamp and test report form (TRF) number
- You obtained the scores in your most recent sitting of the test.

Similarly concerns about physical or mental health will be investigated by inviting the practitioner to undergo an independent assessment usually by two specialists who are instructed to provide their opinion on the practitioner's health, diagnosis and fitness to practise with or without restriction.

There are some categories of concerns that will inevitably be investigated fully. These include allegations of:

1. Sexual assault, indecency or sexually motivated examination
2. Violence
3. Inappropriate relationships with patients
4. Dishonesty including fraud
5. Practising without a licence

Practitioners need to be aware that any allegations (including those arising in their personal lives) which fall into any of the categories 1, 2 or 4 above will be fully investigated by the GMC irrespective of whether they directly involve patients or their care as they give rise to a pre-

sumption of impaired fitness to practice because of their seriousness.

8.7 Notification of Criminal Investigations

In accordance with the Common Law Police Disclosure arrangements [6], the police will disclose to the GMC details of any practitioner who is arrested or charged with an offence where they consider there is a "pressing social need" to do so and there is a public protection risk. In such cases, police notification to the GMC is usually the source of the concern and their investigation. Having received such information the GMC will ask a Case Examiner to decide whether a practitioner should be referred for an MPT Interim Orders Tribunal (IOT) hearing (see below) to consider whether interim restrictions should be placed on the practitioner's registration whilst an investigation is ongoing. The IOT can make no order, impose conditions or suspend the practitioner's registration.

8.8 IOT Hearings

If a practitioner receives correspondence listing an IOT hearing they should seek urgent advice. The minimum notice period is 24 h in urgent cases but usually a practitioner will be given a week or 10 days notice. It is important to ensure that your registered address is kept up to date so that you receive correspondence in a timely manner. A bundle of papers will be disclosed which sets out the concerns raised with the GMC. This may be the first indication a practitioner has received of any concern. Ordinarily, the practitioner will be expected to attend the hearing and/or attend with their legal representative. The hearing can proceed in the absence of the practitioner if the Panel is satisfied the doctor has been served with notice of the hearing. The GMC will instruct a lawyer to attend the hearing and present their case. The GMC should confirm what order they seek in advance of the hearing to assist preparation of the practitioner's case. No oral evidence is permitted except in exceptional circumstances but oral representations are made on behalf of the GMC and the practitioner to the IOT Panel. In addition, documentary evidence can be submitted in advance or at the hearing, for example, references from colleagues, CV, appraisal documents. The hearing is held in private unless the practitioner requests it is held in public. All IOT hearings are routinely listed at the MPTS offices in Manchester.

To make an interim order restricting a practitioner's registration, the Panel must determine it is necessary for protection of members of the public and/or otherwise in the public interest and/or in the doctor's own interests. The latter ground is usually applied in cases of health concerns. The "public interest" includes maintaining public confidence in the profession and good standards of conduct and performance. The IOT cannot accept undertakings offered by the practitioner.

If conditions are imposed by the Panel, they will be taken from the suite of "standard conditions" set out in IOT conditions bank available on the GMC and MPTS websites [7].

The maximum length of interim order which can be imposed by the Panel is 18 months. Any further extensions require High Court approval. Further interim order hearings will be listed at 3 or 6 monthly intervals (depending on the circumstances). They may not require attendance at a hearing and may be dealt with on the papers in certain circumstances. A practitioner or the GMC can request an early review hearing if there has been a change in circumstances.

8.9 GMC Investigation

Once a GMC investigation is opened, the GMC will notify you of the fact and disclose (some) details to you of the concern(s) raised. This is known as a "Rule 4" letter. The GMC may anonymise the concern. You will be asked to provide information about your current work/employer(s) (called a Work Details Form) and invited to respond to the concern.

You should notify your medical defence organisation immediately upon receipt of any

GMC correspondence. You should also notify your employer(s) (and Deanery if you are a doctor in training) of the GMC investigation. The GMC will contact them on receipt of your completed form, disclose the complaint and ask them to confirm whether they have any concerns about you. It is, therefore, in your interests that they are aware prior to receiving GMC correspondence. The GMC will set a deadline for you to provide a completed Work Details Form and if you fail to do so without good reason, the failure may be included as an additional concern as you are expected to cooperate with your regulator. The form includes a declaration that the information is complete and accurate and it is therefore important that you ensure that it is. Incorrect or incomplete information may give rise to additional concerns about your probity and honesty.

You should take advice from your medical defence organisation and/or solicitor about whether it is in your interests to provide a response at this very early stage of the GMC investigation. You are not obliged to respond at this stage.

The GMC will undertake investigations to obtain documentary and witness evidence to support the concern(s) and expert evidence to confirm their seriousness. If the concerns relate to the practitioner's health or performance, the GMC will usually invite the practitioner to undergo an assessment. Any unreasonable refusal to agree to undergo an assessment is likely to be included in the allegations against the practitioner and will be considered as demonstrating a lack of insight. It may also lead to an IOT referral (see above).

Once the GMC have concluded their investigation, they will determine whether the evidence they have obtained supports an allegation of impaired fitness to practise. If the evidence does not, the GMC investigation will be concluded and you will be notified. Where the evidence supports an allegation of impairment, the GMC will set out formal allegations in what is referred to as a "Rule 7 letter". The practitioner has 28 days to respond to the allegations. An extension of time may be needed to prepare the practitioner's response. You should take advice on what (if any) allegations should be admitted and what evidence should be submitted with any response. This will depend on the nature of the allegations and may include testimonial references, evidence of focussed CPD, appraisal documents, reflective statement and/or expert evidence.

Once a response has been served or the deadline has passed, two GMC Case Examiners (one medically qualified and the second lay) will be asked to review the case and determine whether the case should be referred for a hearing before a Medical Practitioners Tribunal (MPT) or concluded in another way (see below). Both Case Examiners must agree to any decision. If the Case Examiners are unable to agree, the matter will be referred to the Investigation Committee. Where cases fall within one of the following seven headings, unless there are exceptional reasons, a referral for a hearing will be made:

1. Sexual assault or indecency
2. Violence
3. Improper sexual/emotional relationships
4. Knowingly practising without a licence
5. Unlawfully discriminating
6. Dishonesty
7. Gross negligence or recklessness about a risk of serious harm to patients

The Courts have determined that cases in these categories where the practitioner has not been prosecuted or has been acquitted in a criminal court can still be investigated by the GMC, referred for hearing and sanctioned [8].

8.10 Referral to a MPT Hearing

Following notification of the Case Examiners decision to refer your case, a timetable will be set at telephone hearings for steps (known as directions) to be taken to prepare the case for hearing. A hearing date will be set within 6 months of the first telephone hearing.

The directions may include deadlines for disclosure of evidence (documentary, witness and expert) by each party, a meeting of experts, exchange of documents setting out legal arguments to be raised at the beginning of the hearing (called preliminary arguments). These hearings

are in public and do attract press attendance and publicity. The GMC will present their case first by calling witnesses and introducing documents. Usually a witness's statement will be taken as their evidence in chief. Witnesses will then be cross examined by the other party and asked questions by the Panel. When the GMC has called all of it's evidence (subject to any legal arguments), the practitioners case will then be presented. The practitioner may give evidence or choose not to do so. Evidence can be called on his/her behalf to rebut the allegations and submissions on facts.

At the conclusion of the practitioner's case, the Panel will go into private session to decide what facts are found and which allegations they find proved. They will then announce their findings and hear submissions from both parties, first on whether or not the findings amount to impairment and secondly, if they do, what sanction is appropriate. The Panel can impose a warning (see below) even if they determine that there is no impairment. The sanctions available to them where impairment is found are:

- Acceptance of undertakings (see below)
- Conditions for up to 3 years
- Suspension for up to 12 months or
- Erasure from the medical register

The practitioner may appeal a decision of the FTP Panel to the Administrative Court. Any appeal must be lodged at Court within 28 days of the determination.

Before the expiry of any conditions or suspension period, a review hearing will be listed to determine whether the practitioners fitness to practise remains impaired (in which case further sanctions may be imposed) or is unimpaired and the sanction will expire.

8.11 Resolution of Cases Not Referred to a MPT Hearing

Where the Case Examiners determine that a case should not be referred to a MPT hearing they may:

- Conclude the case with no further action
- Conclude the case with written advice to the practitioner
- Agree undertakings with the practitioner
- Invite the practitioner to accept a warning

Undertakings are promises made by the practitioner usually to take certain steps or restrict their practice. They are of unlimited duration and are reviewed at least annually by the GMC. On average, they remain in place for 2–3 years. Any breach of undertakings will be investigated by the GMC and may result in further action being taken. The undertakings will appear on the medical register except those relating to health which remain private.

Warnings can be offered where the Case Examiners decide that there is no impairment but there has been a serious departure from GMP. The GMC will provide a draft of the proposed warning. Representations can be made about the contents of any proposed warning. If you do not agree to accept a warning or the proposed terms of any warning, you can elect for a hearing before the GMC Investigation Committee. They have the power to impose a warning.

If a warning is accepted, it will be published on the medical register in the terms agreed for a period of 5 years and will be disclosed on request by any employer indefinitely.

8.12 Things to Remember

1. Don't ignore correspondence from the GMC
2. Keep your registered address up to date to ensure you receive correspondence
3. Be aware of GMP and the GMC's updated guidance
4. Seek advice and assistance as soon as possible
5. Notify your employer(s)
6. Keep everything you are sent and copies of any documents you provide to the GMC
7. Seek support—it is likely your colleagues have been part of a GMC investigation or know someone who has

References

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4. GMP guidance April 2014, paragraphs 28 and 75.
5. GMC Guidance for decision makers on Rule 4(5) 11 January 2016.
6. Which replaced the Notifiable Occupations Scheme (NOS) in 2015.
7. GMC: www.gmc.org.uk MPTS: www.mpts.org.uk.
8. Rv Metropolitan Police Commisioner ex parte Redgrave [2003] 1 WLR 1136 and clarified in Bhatt v GMC [2011] EWHC 783 (Admin) and Ashraf v GDC [2014] EWHC 2618 (Admin).

Report Writing

9

Eloise Powers and Sallie Booth

9.1 Introduction

This chapter contains advice and guidance for clinicians who are instructed to provide expert reports for use in civil legal proceedings. It will encompass the following areas: the legal and ethical framework for expert witnesses; pitfalls and risks for expert witnesses; positive advice and guidance for expert witnesses.

9.2 Legal and Ethical Framework

All expert witnesses should familiarise themselves with Part 35 of the Civil Procedure Rules [1], the Practice Direction to Part 35 of the Civil Procedure Rules [2], and the Civil Justice Council's Guidance for the instruction of experts in civil claims [3]. These documents are publicly available online and should be read in full. What follows is a summary of some of the most important principles:

Key Legal and Ethical Principles

- Experts owe a duty to exercise reasonable skill and care to those instructing them, and to comply with any relevant professional code. However, they have an **overriding** duty to help the court.
- Experts must provide opinions that are **independent,** regardless of the pressures of litigation. A useful test of independence is that the expert would express the same opinion if given the same instructions by another party. Experts should not see themselves as advocates.
- Experts should confine their opinions to matters which are **material to the disputes**.
- Experts should only provide opinions in relation to matters which **lie within their expertise**.
- Experts should take into account **all material facts before them.**
- Experts should inform those instructing them without delay of **any change in their opinions on any material matter and the reasons for this.**
- An expert's report must comply with the formal requirements set out at **Practice Direction 35, 3.1–3.3.**
- Where there is a range of opinion on matters dealt with in the report, experts

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should **summarise the range of opinions and give reasons for the expert's own opinion.**
- Experts should **keep facts and opinion separate.**
- Where the facts are in dispute, experts should express **separate opinions based upon each version of the facts.**
- Experts should not express a view in favour of one or other version of the facts, *unless* they regard one set of facts as being less probable **based upon their own particular expertise and experience.**
- A **summary of conclusions** is mandatory.

9.3 Pitfalls and Risks

In extreme cases experts can face criminal sanctions if they commit perjury, or can face sanctions for contempt of court if they mislead the court. Experts can also be reported to their professional body. Such cases will by their nature be unusual, and are unlikely to arise unless an expert acts unethically. However, the existence of such sanctions serves to underline the importance of being aware of the overriding duty to the court.

Prior to 2011, expert witnesses enjoyed an "immunity from suit" in relation to their participation in legal proceedings. Following the Supreme Court's judgment in *Jones v Kaney* [4], expert witnesses are no longer immune from being sued for breach of duty in relation to the evidence which they give in court or for the opinions which they have expressed in anticipation of court proceedings.

Jones v Kaney: **The Facts**

In Jones v Kaney, a claimant suffered physical and psychiatric injuries in a road accident. Ms. K, a clinical psychologist, was instructed by the claimant's solicitors. She examined the claimant and gave the opinion that he was suffering from post-traumatic stress disorder (PTSD). In a second report, she gave the opinion that the claimant was still suffering from depression and some of the symptoms of PTSD. The defendant in the road accident case contended that the claimant was deceptive and deceitful.

A joint meeting took place between the experts for both sides. Ms. K signed a joint statement in which she confirmed agreement to the following: (a) the claimant's psychological reaction to the accident was no more than an adjustment reaction, and (b) she agreed that the claimant's behaviour was suggestive of "conscious mechanisms" that raised doubts about whether his reporting was genuine.

Ms. K thereafter gave the following account of what had happened: (a) She had not seen the reports of the opposing expert at the time of the telephone conference; (b) The joint statement, as drafted by the opposing expert, did not reflect what she had agreed in the telephone conversation, but she had felt under some pressure in agreeing it; (c) Her true view was that the claimant had been evasive rather than deceptive; (d) It was her view that the claimant did suffer PTSD which was now resolved; (e) She was happy for the claimant's then solicitors to amend the joint statement.

The road traffic case subsequently settled at an undervalue, and the claimant issued proceedings against Ms. K. At first instance, the proceedings were struck out on the basis that Ms. K enjoyed immunity from suit. The Supreme Court reversed this decision and held that expert witnesses no longer benefit from immunity from suit; this judgment allowed the claim against Ms. K to proceed.

A practical consequence of the judgment in *Jones v Kaney* is that it becomes even more important for expert witnesses to have professional

indemnity insurance in place which specifically covers their work as an expert witness.

At a more fundamental level, the decision in *Jones v Kaney* underlines the importance of taking reasonable care when providing a professional opinion as an expert witness. Lord Brown observed as follows: *"Suffice to say that in my opinion the most likely broad consequences of denying expert witnesses the immunity… will be a* ***sharpened awareness of the risks of pitching their initial views of the merits of their client's case too high or too inflexibly*** *lest these views come to expose and embarrass them at a later stage."*

Reassuringly for experts, Lord Brown also observed as follows: *"I would urge the courts to be alert to protect expert witnesses against specious claims by disappointed litigants – not to mention to stamp vigorously upon any sort of attempt to pressurise experts to adopt or alter opinions other than those genuinely held."* Notwithstanding this reassurance, what follows is some practical advice for experts in avoiding risks and pitfalls:

Avoiding Pitfalls: Advice for Experts

- Ensure that you have read the relevant documents. Be prepared to **ask for any relevant documents which are missing,** or refer in your report to key documents which you have not received.
- Ensure that the opinion which you reach is **well-founded** right from the start. Have you thought it through? Have you considered the counter-arguments and the other side's case?
- A well-founded opinion should be based upon an understanding of the **facts** of the case and upon any relevant **scientific literature and guidelines**, as well as upon your own professional opinion. **Reasons** in support of your own opinion should be provided.
- It can be useful to ask yourself whether you would be prepared to defend your opinion **under oath in court.**
- If your opinion is honestly and genuinely held, you should not change it merely because you are put **under pressure to do so** (in the absence of any good reason).
- **Avoid "cutting and pasting"** text from one opinion into another. At worst, cut and paste mishaps could lead to Data Protection Act proceedings. At best, cut and paste mishaps will cast doubt upon whether you have paid sufficient attention to the case.

9.4 Positive Advice

Bearing in mind all of the caveats above, what positive steps are experts able to take in order to assist those who instruct them? Answering this question will require some understanding of the reasons why expert reports are obtained and the purposes to which they are put. In medical negligence cases, we can divide expert reports into three main categories: (1) breach of duty, (2) causation, (3) condition and prognosis.

Breach of duty: A breach of duty report addresses the question of whether or not the care received by a claimant fell below a reasonable standard of care. Lawyers will make use of the breach of duty report when drafting pleadings, such as the Particulars of Claim or Defence. When writing a breach of duty report, it is helpful to bear the following points in mind:

- For all the reasons set out above, it is crucial that your opinion is well-founded and sustainable. Contrary to popular belief, responsible lawyers would rather be presented with a well-founded negative opinion than a poorly-founded positive opinion. In addition to the overriding ethical considerations which are set out above, there are practical considerations: it can cost the client a significant amount of money and time to bring, or to defend, a weak claim, so the client needs to know from the outset if their position is weak.

- If you are identifying a breach of duty, you should pinpoint a specific act (or acts) upon a specific date (or dates) which fall below a reasonable standard of care. If you are critical of a delay, you should identify the point in time at which the delay becomes unjustifiable. This information makes it easier to draft pleadings.
- If there are relevant authoritative guidelines in place (NICE, RCOG or similar), you should cite the material parts of the guidelines.

Causation: A causation report addresses the question of whether the identified breach of duty made a material difference to the course of events. Lawyers will make use of the report when drafting pleadings and also as a basis for quantifying damages. When writing a causation report, it is helpful to consider the following points:

- You are likely to be asked to comment upon what "would have happened" but for the negligence. This question is inherently hypothetical, and can pose difficulties for scientifically-trained experts. In answering this question, you should be aware that the civil standard of proof is the balance of probabilities: in other words, you are only being asked to provide the *most likely* scenario.
- In answering the hypothetical question of what "would have happened", it is helpful to take a step-by-step approach, going through the treatment which would normally be provided and the outcome which would normally be expected. Medical literature which provides outcome data is often of great assistance.
- You will sometimes be faced with the task of reporting on causation in a case where the claimant has multiple medical conditions. In such a case, you will be asked to distinguish between the symptoms which can be causally linked to the negligence and the symptoms which cannot be causally linked to the negligence. It is helpful to consider whether examination of the claimant is necessary in order to answer this question. When answering this question, it is important to present a clear and well-founded opinion.

Condition and Prognosis: A condition and prognosis report is usually based upon an examination of the claimant. It addresses the claimant's present condition and medical prognosis. Lawyers will make use of the condition and prognosis report when quantifying the claim and when instructing further experts (such as a care expert, occupational therapist or accommodation expert). It is helpful to bear the following points in mind:

- When examining the claimant, please set out and explain the methodology which you are using. Your conclusions upon issues such as future treatment needs and ongoing assistance needs should be consistent with the history and your findings upon examination.
- It is extremely important to be as precise as possible when addressing issues such as the costs of further treatment or the particular restrictions upon activity faced by a claimant. Providing detail and justification is essential: your report is likely to be used as the basis for bringing or defending a claim for significant amounts of money.
- Where a claimant has co-morbidities, it is important to distinguish between the effects of the negligence and the effects of the co-morbidities. Where appropriate, you may need to defer to other expert opinion; alternatively, you may be in a position to address this issue yourself. You should address the question of what needs the claimant has which are "qualitatively or quantitatively" different from the needs which s/he would have had in any event [5].
- It is helpful to be as specific as possible about the severity and duration of any symptoms caused by the breach of duty (even where these symptoms have resolved) as this will assist the lawyers tasked with quantifying the case.

Key Points: Report Writing

- Experts have an overriding duty to the court and should provide opinions which are independent, regardless of the pressures of litigation.
- Experts can be sued for breach of duty in relation to the evidence they give in court or in anticipation of court proceedings.
- Experts should have *"a sharpened awareness of the risks of pitching their initial views of the merits of their client's case too high or too inflexibly"*.
- When writing a breach of duty report, it is helpful to pinpoint any breaches of duty by identifying specific acts and specific times.
- When writing a causation report, it is helpful to take a step-by-step approach when addressing what would have happened but for the breach of duty.
- When writing a condition and prognosis report, it is particularly important to perform a thorough examination and provide detail about any restrictions or needs which the claimant may have.
- Above all, expert opinions should be well-founded and supported by reasons.

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Being an Expert Witness

10

John Reynard

10.1 Background

For a court to accept expert evidence, it must be assured that the criteria of admissibility (when should expert evidence be accepted) and competence (is the expert qualified to give it) have been fulfilled.

For the criterion of admissibility to be fulfilled, the evidence must be outside the experience of the tribunal—the judge in a civil case and the judge and jury in a criminal case. Evidence that is not sufficiently intelligible to judge and jury, because it relates to a field of *specialised* knowledge, requires the input of the expert witness in order that it can be made intelligible to the judge and/or jury. Evidence that is within the experience of the 'man on the street', and therefore by definition can be understood by judge and jury, requires no such input.

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10.2 Definition of an Expert Witness

The pragmatic approach adopted by the English Courts in determining expertise means that there is no general requirement for expert witnesses to have formal qualifications or to be accredited by professional bodies. By virtue of the formalized process of acquiring entry to the established professions, it is easy for the Courts to assess expertise. Consequently, the "… academically-based sciences such as medicine, geology or metallurgy, and the established professions such as architecture, quantity surveying or engineering, present no problem. The field will be regarded as one in which expertise may exist and any properly qualified member will be accepted without question as expert" [Bingham LJ 1991 in *R. v Robb* [1991] 93 Cr. App. R. 161] [1].

The competence of an expert witness to give evidence lay at the heart of arguably one of the UK's worst miscarriages of justice and so it is an issue of great importance. In the case of Sally Clark, wrongly accused of murdering her two sons, Professor Sir Roy Meadow, expert though he was in matters of child abuse, was not an expert in the interpretation of statistical data. His misinterpretation of statistical data led to her wrongful conviction for murder:

"Even when an infant dies suddenly and unexpectedly in early life and no cause is found at autopsy, and the reason for death is thought to be

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an unidentified natural cause (Sudden Infant Death Syndrome) … it is extremely rare for that to happen again within a family … such a happening may occur in 1:1000 infants, therefore the chance of it happening twice within a family is 1:1 million. Neither of these two deaths can be classified as SIDS. Each of the deaths was unusual and had the circumstances of a death caused by a parent" (*Clark (Sally)* [2004] EWCA Crim 1020) [2].

Professor Meadows failed to appreciate (because he was not an expert in statistics) that squaring the odds of deaths of 1:1000 for one death to 1:1 million for two deaths, is only valid if each of the deaths is truly independent of the other without the shared genetic and environmental circumstances of the children being members of the same family. Professor Meadow later went on to conclude that the chances of two natural deaths, given the social circumstances of Mrs. Clark's family, were actually even slimmer at 1 in 73 million, likening this to the chances of winning at the Grand National 4 years in a row on a horse with odds of winning of 1 in 80. At the initial trial this wrongly interpreted 'evidence' proved compelling and the jury concluded that she was guilty of murder.

Mrs. Clark's father complained to the GMC alleging serious professional misconduct on the part of Professor Meadow. A Fitness to Practise Panel of the GMC concluded in July 2005 that Professor Meadow was guilty of serious professional misconduct and ordered that his name be erased from the register. Professor Meadow appealed to the High Court and in February 2006 Collins J allowed his appeal and quashed the order of the GMC.

The GMC in turn appealed against that judgment (*GMC v Meadow* [2006] EWCA Civ 1390) [3]. The appeal was dismissed, but only by a 2-1 majority and Sir Anthony Clarke MR's dissenting judgment is instructive:

> "Professor Meadow is not a statistician and had no relevant expertise which entitled him to use the statistics in the way he did … he made a mistake which other non-statisticians have made … He gave the evidence as part of his expert evidence and, moreover, did so in a colourful way which might well have been attractive to a jury … to support the prosecution's case that the children had both died from unnatural causes. He knew that he had no such experience and should have expressly disclaimed any. To my mind, that amounts to serious professional misconduct".

The *Clark* and *Meadow* cases thus highlight the importance of experts constraining their opinions to areas in which they are genuinely expert, but it also raised the important question of principle of whether an expert witness should be entitled to immunity from disciplinary, regulatory or fitness to practise proceedings in relation to evidence given by the expert in legal proceedings.

In *Pearce v Ove Arup* [2001] EWHC Ch 455 Justice Jacob J concluded [4]:

> "I see no reason why a judge who has formed an opinion that an expert had seriously broken his Part 35 duty should not, in an appropriate case, refer the matter to the expert's professional body… Whether there is a breach of the expert's professional rules and if so what sanction is appropriate would be a matter for the body concerned".

Normally, evidence given honestly and in good faith would not merit a referral. It is unlikely that a single case involving a poor report or evidence would on its own show that the practitioner was unfit to practise and so a danger to the public. However, criticism of an expert by a judge quite apart from being a most serious matter in its own right may well discourage solicitors from instructing that expert again. Such matters have a habit of spreading rapidly, and a hitherto successful Medicolegal career may be ruined.

10.3 Duty of the Expert Witness

The expert is therefore well advised to take heed of the Civil Procedure Rules (CPR 35.3) which state:

1. It is the duty of experts to help the court on matters within their expertise;
2. This duty overrides any obligation to the person from whom experts have received instructions or by whom they are paid.

The basis of the Civil Procedure Rules is that it would be contrary to the public interest for the expert to undertake to confine an opinion that

was in the client's interest only and to refrain from saying anything to the court to which the client might take objection.

At one time experts were immune from prosecution for the views expressed in their reports or in Court. However, the Court of Appeal in the *Meadow* case indicated that there was no absolute immunity.

The absence of immunity from prosecution was further emphasized in *Jones v Kaney* [2011] UKSC 13 [5]. The background was that Dr. Kaney, instructed on behalf of the claimant, expressed an initial view that the claimant Mr. Jones was suffering from post-traumatic stress disorder or 'PTSD'. The psychiatrist instructed by the insurers defending the claim opined that Mr. Jones was exaggerating the effects of his physical injuries. In the joint statement signed by both experts after a joint discussion, Dr. Kaney conceded ground on a number of issues, so weakening the claim considerably. Specifically, Dr. Kaney agreed that the claimant's psychological reaction was only an adjustment reaction, not PTSD. Mr. Jones therefore had to settle the claim for significantly less than he had been seeking.

Dr. Kaney then herself became the subject of a claim by Mr. Jones who accused her of having negligently signed the joint from statement, the allegation being that she did not have sufficient reason to retreat from her diagnosis that Mr. Jones was suffering from PTSD. The Supreme Court concluded that experts do not enjoy immunity from civil claims arising out their preparation and presentation of evidence for the purpose of court proceedings: *Jones v Kaney* [2011] UKSC 13 [5].

It is therefore essential that you are objective and are careful to both sides of the argument, as advised by Cresswell J in *The Ikarian Reefer* ([1993] 2 Lloyd's Rep. 68) [6, 7]:

"An expert witness should provide independent assistance to the court by way of objective unbiased opinion in relation to matters within his expertise… He should not omit to consider material facts which could detract from his concluded opinion".

Formulate your opinion only on the basis of reasoned argument, for once you have convinced your instructing solicitor and the appointed barrister of the merits of the case, they may not take kindly to changes in opinion when your opinion has initially been supportive of the case, especially when such changes occur late in the day. If, however, the other side comes up with a compelling and well-reasoned argument that is contrary to your initial opinion, then of course be prepared to give ground and concede a point.

Some expert witnesses are tempted to please their instructing solicitors by preparing a report weighted in favour of the claimant's or defendant's case, and refuse to budge from this opinion. The expert is well advised to avoid such an approach. At the very least if the case cannot hold up to reasoned argument your instructing solicitor and his or her barrister will be irritated to have wasted hours of effort in prosecuting a case, only to find this out in court.

Worse than this though is for the expert to face criticism from a judge for a partisan report. Such criticism has the potential to destroy your medicolegal practice, for who will wish to instruct you again.

In the recent case of *Harris v Johnston* [2016] EWHC 3193 an expert witness for the Claimant was described by Andrews J as having an "intransigent mind set" [8]. The judge found that the reasoning of one of the Claimant's expert witnesses "was unreliable" and that the expert's "general intransigence … sloppy attention to detail and … failure to abide by [*the*] duties … [*of*] … an independent expert did not just lead me to question [*the expert's*] reliability, it left me with no confidence in [*the expert*]". Accordingly, the judge could not rely on any of the expert's evidence and unsurprisingly the claimant lost. The judge described the Defence expert on the other hand as "the model of an independent and impartial expert, balanced, fair and objective".

It is crucial to declare any potential conflict of interest from the outset, to your instructing solicitor and to make this very clear in any report. In *EXP v Barker* [2015] [9] EWHC 1289 (QB) it transpired during the court case that the defendant's neuroradiology expert had a long and close relationship with the defendant, having trained him, written a paper together and having assisted him in securing a job. The judge concluded:

"Failure to make early disclosure [*of a pre-existing relationship between an expert and a*

party] may lead to the kind of chaotic situation that has arisen in this case, where the nature and extent of the conflict became clear only in the course of the trial and led to a submission, after all the evidence was heard, that the evidence of the defendant's expert, upon which the defence in the event ultimately depended, should be ruled inadmissible by the court".

Conclusion

None of the above 'rules' of being a good expert are difficult. The critical thing for the medical expert is to remember that their role is to interpret evidence that lies outside the experience of the judge and/or jury and to provide an objective and unbiased opinion, expressing the pros and cons of each view. It is not to act as the judge. The expert's opinion must be logical and capable of withstanding reasoned argument.

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The Obstetrician/Gynaecologist in Coroner's Court

11

A. R. W. Forrest

11.1 History

The Office of Coroner was first established in 1194 as a means of maximising the revenue of the Crown at a time when the Treasury was burdened with finding a ransom, some 2½ times the annual revenue of the Crown, for King Richard I who was being held captive by the Duke of Vienna. The original duties of the coroner were as custodian of the pleas of the crown (*custos placitorum coronae*). This involved the collection of a variety of fines and fees, including fines of a community where a person was found dead and it could not be proved he was English rather than Norman. The coroner's role was crystallised in the next century by an act of Edward I [1]. Arguably, not much changed until the passage of the Coroners and Justice Act 2009.

11.2 Current Position in England and Wales

The coroner is a judge in a court of record who investigates deaths reported to him which require investigation in the circumstances set out in the Coroners and Justice Act 2009. Strictly speaking, it is not the death which is reported, but rather the presence of a dead body in the coroner's area. Where the coroner has reason to suspect that the deceased died either a violent death or unnatural death, or the cause of death is unknown, or the deceased died in custody or otherwise in state detention then he must open an investigation into the death. At present, only the Registrar of Births, Deaths and Marriages has a statutory duty to report such a death to the coroner. A typical example where the Registar makes such a report would be where the medical certificate indicates that the death was due to industrial disease, which is regarded as an unnatural death, and the death has not been reported to the coroner. There is a common law duty on householders and others who may be about the person at the time of death to report a death, which engages the coroner's duty to investigate, to the coroner. It is a GMC requirement to report such a death [2]. Section 2 of the Coroners and Justice Act 2009 deals with reform of the death certification process and includes provisions mandating the reporting of certain deaths to the coroner. The reforms also include the appointment of Medical Examiners who will review all medical certificates of the cause of death. However, some 9 years after the Act was passed these reforms have yet to be implemented. Early 2019 has been suggested as a possible implementation date [3].

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11.3 The Investigation

Once informed of a death the coroner initiates a three-stage process; first preliminary enquiries to establish whether an investigation should be initiated, then an investigation which may show that the cause of death is natural in which case an inquest is not required and finally the inquest. The inquest is an enquiry in court to establish who the deceased was, when they died and how they came to their death. If the circumstances of the death require an investigation into a possible breach of the rights set out in the European Convention on Human Rights (ECHR), which are incorporated into English law in the Human Rights Act 1998, then the inquest is extended to inquire into the circumstances of the death. Most of the developments in judge made coronial law over the last few years have involved such extended inquests. They are often referred to as "Article 2" or "Middleton inquests" [4], Article 2 of the European Convention on Human Rights being the "right to life" section, which gives a right to have one's death independently investigated when the State, by omission or positive action, has contributed to the mechanism of death. This right has been interpreted quite widely [5].

11.4 The Inquest

The coroner occupies an unusual position in English law. He is a judge, appointed by, and funded by, the local authority for his coroner's area. His court is an inquisitorial one. Unlike a civil or criminal court there are no parties trying to make their case with the judge holding the ring. The coroner oversees the investigation and in court takes the witnesses through their evidence. When the coroner has concluded his questioning, then "properly interested persons" or their legal representatives, may question the witness. Among those classified as properly interested persons are persons whose conduct might be called into question in respect of the death. That may include clinicians who are called to give evidence other than as witnesses to fact or as experts. The questioning of witnesses must be confined to the matters the inquest has to determine—who the deceased was, where, when and how they came to their death and, where it is an "Article 2" inquest, the broad circumstances of the death. Advocates for the family may try to extend the questioning into other areas to gather evidence for adversarial proceedings in other courts. The coroner should not allow this.

When the evidence has been heard, the coroner will ask the interested persons if they wish to address him on matters of law. He will then sum the evidence up, briefly if he is sitting without a jury, addressing the jury on the conclusions that are available. These can be either short form conclusions, such as "accident", "natural causes" or "stillbirth", or a narrative verdict. A narrative verdict is a succinct, neutral, account of how the deceased came to their death. However, the conclusion is formulated it must not include opinion on anything other than how, or in what circumstances in an Article 2 inquest, the deceased came to their death and must not appear to determine any question of criminal liability on the part of a named person or civil liability.

Once the conclusion has been announced the Coroner will consider if the evidence has disclosed a situation that, unaddressed, may lead to future deaths [6]. If it has he has a non-discretionary duty to make a report to a person who can do something about it. This is known as a Regulation 28 Report. The addressee of the report has 56 days to respond, saying what action they propose to take, or, if they are going to take no action, why not. The response is published on the Judiciary website. In general, Hospital Trusts will try to argue against the submission of such a report if it relates to a situation within their Trust.

11.5 Conclusions

What used to be described as the "Verdict" is now known as the "conclusion". Whilst there is a statutory list of short form conclusions [7], the coroner has a discretion to use other formulations, provided they do not impugn criminal

responsibility or civil liability. Some conclusions of concern in obstetrics and gynaecology practice are discussed below.

11.6 Unnatural Death

An unnatural death will require an investigation by the coroner. But what is an unnatural death? One definition is "Death wholly or partly caused or accelerated by any act, intervention or omission, other than a properly executed measure intended to prolong life" [8]. So, during medical care, acts of intervention or omission can convert a natural cause of death into an unnatural cause requiring an inquest. For example, an unconscionable delay in an ambulance attending a young girl with severe asthma was held to convert a death from natural disease into an unnatural death requiring an inquest [9]. A similar situation was a case where a woman was delivered of twins, did not have her blood pressure taken after delivery and went on to die of fulminant eclampsia [10].

Deaths occurring as a result of a well-known complication of treatment can still be considered an unnatural death in coroner's law [11]. In practice coroners may take into consideration the opinion of the pathologist in deciding whether or not the death is a natural one in the circumstances. The decision is the coroner's not the pathologist's and pathologists and other experts should avoid the phrase "this is a death due to natural causes" in their reports to the coroner. When a person is suffering from a fatal condition and medical treatment simply does not prevent death from the condition then the appropriate conclusion is "natural causes". If the treatment causes death, say as a result of an adverse drug reaction, then conclusions of accident or misadventure may be recorded.

11.7 Accident/Misadventure

Whilst the higher courts have said that there is no distinction between these two conclusions, there is a difference. An accident can be defined as an unintended consequence of a human act, whilst misadventure is an unintended consequence of an intended human action. Misadventure may be particularly relevant to deaths occurring in medical treatment. For example, where a patient is being treated for a condition that does not threaten life and a mishap leads to death, then misadventure may be the conclusion recorded. Coroners vary in their approach to these two conclusions.

11.8 Unlawful Killing

The commonest reason for an unlawful killing conclusion in medical practice is gross negligence manslaughter. There are three elements to this, there was a duty of care to the deceased, there was a breach of that duty of care causing death and the breach of the duty of care was so egregious that it requires punishment by the State, not just monetary compensation. There may be a fine margin in a particular case between misadventure and gross negligence manslaughter. In fact, such cases rarely reach the coroner's court, the matter typically being dealt with by the criminal courts. After a criminal trial where the facts that would be explored at an inquest have been canvassed, the coroner has a discretion as to whether or not to proceed to an inquest. Where the facts haven't been fully explored in the trial, for example if there is a guilty plea, the coroner may proceed to an inquest.

When the inquest is being heard with a jury, in his summing up the coroner will explain that a conclusion of "natural causes" does not imply the clinicians were without fault, just as a conclusion of "accident/misadventure" does not imply that the clinicians were at fault.

11.9 Stillbirths

A still birth is defined as "a child which has issued forth from its mother after the twenty-fourth week of pregnancy and which did not at any time after being completely expelled from its mother breathe or show any other signs of life" [12].

In order to die you have to live in the first place and in law a still born infant has never lived. So, a stillborn child's remains cannot be the subject of an inquest. However, the coroner may inquire into whether or not the infant showed any signs of life after complete expulsion form the mother's body. Whilst the coroner's duty to investigate in such circumstances has been established for nearly 200 years [13], it still generates controversy. The coroner's right to inquire as to whether a child was born alive or stillborn was recently confirmed in a case where a 19 year old woman presented at hospital with a dead baby in a shoe box after an unattended delivery 6 days earlier. The coroner initiated an investigation to establish whether or not the child was born alive. The Court of Appeal confirmed he was correct [14].

There is a view that the coroner's jurisdiction should be extended to encompass deaths *in utero* in the last trimester of pregnancy. This would require new legislation. Whilst a submission has been made to the Law Commission to that effect such a change is unlikely for some time, if ever.

There can be disagreement between those present at birth as to whether or not an infant has shown any sign of life after complete expulsion from its mother's body. There can also be disagreement as to whether or not an agonal e.c.g rhythm can be regarded as a sign of life. My own view is that it should be considered a sign of life. The legal definition is clear. "Any" sign of life includes chaotic cardiac electrical activity.

11.10 Abortion

The short form conclusion "Abortion" refers to the cause of death of the mother, not the infant.

A particularly difficult situation is where an infant shows signs of life on delivery after a therapeutic termination of pregnancy. When this occurs, those attending have a duty to care for the child and provide appropriate treatment in its best interests. In one case where treatment was delayed the gynaecologist involved was prosecuted for attempted murder. The magistrates held that there was no case to answer [15]. When a death occurs in such circumstances the coroner must be informed. An inquest will usually result. There are a large range of conclusions that the coroner might return after such a death. A narrative verdict may be appropriate.

11.11 Preparing for the Inquest

When a clinician is called to appear before the inquest, it is important to establish if it is to give simply evidence of fact or if he is a "properly interested person" whose conduct may be called into question at the inquest. In either case, the clinician should immediately contact their defence organisation. The importance of properly completed, contemporaneous case notes that are dated and signed cannot be over emphasised. Moreover, making sure the case notes and any relevant laboratory reports do not disappear into a hospital oubliette is very important. When going to the Inquest, be sure to get there in plenty of time, dress appropriately, make sure you have read and re-read any statement or report you have produced and if you have referred to any papers or authoritative texts in your report take them with you to court. The advice from your defence organisation about the specific case will be invaluable.

Key Points: The Obstetrician/Gynaecologist in Coroner's Court

- The Coroner's main duty is to investigate possibly unnatural deaths.
- Deaths that appear to a clinician to be natural may be unnatural in law.
- The Procedure in the coroner's court is inquisitorial not adversarial. There are no parties in the coroner's court putting their sides of a case against each other. Rather it is an enquiry conducted by the coroner to establish four simple truths, who the deceased was, where they died, when they died and how they came to their death. When Article 2 of the European Convention on Human Rights is engaged the remit of the Inquest is extended to exploring the circumstance of the death.
- The Inquest is not a forum where criminal responsibility or civil liability are canvased.

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12 Intimate Examinations and Chaperones

Janesh K. Gupta

12.1 Background

It is every clinician's duty to provide a good standard of care when assessing, diagnosing and treating patients. As part of this duty we are sometimes obliged to conduct intimate examinations. These include examination of breasts, genitalia and rectum, but for some patients other close contact may also be regarded as intimate. Intimate examinations can be embarrassing and distressing for patients and we are obliged as a result to respect their dignity and privacy [1, 2].

A chaperone is an independent person, appropriately trained, whose role is to observe the examination/procedure undertaken by the doctor/health professional to assist in maintaining the appropriate doctor–patient relationship.

When an intimate examination is to be conducted, the patient should be offered the option of having a chaperone present. This applies irrespective of the genders of the doctor and patient. A chaperone should fulfill the following criteria:

- Usually be a health professional (do not have to be medically trained)
- Be sensitive and respect the patient's dignity and confidentiality
- Reassure the patient if they demonstrate signs of distress/discomfort
- Familiarise themselves with what the procedure involves
- Be present for the duration of the examination and be able to see what the doctor is doing (where practical)
- Be willing to raise concerns if necessary

In addition to intimate examinations, other situations where a chaperone may be beneficial are as follows:

- Anxious or vulnerable patients
- Patients with whom there may have been a misunderstanding or difference of recollection of events in the past
- Patients reviewed by trainee doctors or students
- Where religious or cultural issues which may affect the physical examination

Having a chaperone present has several advantages, including:

- Provides assistance to the health professional in the examination including passing instruments when required
- Provides emotional comfort and reassurance to the patient
- Acknowledges a patient's vulnerabilities and ensures the patient's dignity is preserved.

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– Add a layer of protection for the doctor: it would be rare for an allegation of impropriety be made when a chaperone was present.

In order to avoid litigation in this area, the GMC has provided clear guidance for practising clinicians, and it is important that clinicians follow these principles carefully.

12.2 Minimal Standards and Clinical Governance Issues

Before performing any intimate examination, explain why it is required and the nature of the examination to allay any fears. The patient should be given the opportunity to ask questions. It is important to explain what the examination involves, including the fact that it may cause pain or discomfort. The patient should have a clear idea of what to expect before starting.

The patient's permission to proceed should be obtained and documented in the notes. Patients should be offered a chaperone for all intimate examinations. A relative or a friend is not a suitable chaperone, but where the patient requests the presence of a friend or relative they may be present in addition to a chaperone. The chaperone's identity should be recorded in the medical notes.

To ensure a patient's dignity, she should be allowed to undress herself in a private room, she should be provided with a cover and she should not be helped to undress, unless she specifically asks for assistance. If the examination is obviously too uncomfortable or if the patient asks for the examination to be stopped it must be ceased immediately. No personal comments should be made during the examination. All discussions during the examination should be relevant.

Where a chaperone is not available (home visits or in the out of hours setting) it is important to consider the clinical urgency of the examination. The examination can be postponed to a later date as long as there is no adverse impact on the patient's clinical needs.

If the patient refuses a chaperone a clear explanation should be given why a chaperone is required and this fact recorded in the medical records. When a patient continues to refuse a chaperone, it is at the discretion of the doctor whether or not to proceed and will be a decision based on both clinical need and the requirement for protection against any potential allegations of an unconsented examination/improper conduct. It is imperative to document that a chaperone was offered and declined.

As the treating doctor if you are unwilling to proceed consideration should be given to referring the patient to another doctor/colleague. This may be a doctor of the same gender as the patient if this is the basis for refusing the examination. Any delay should not adversely affect the patient's health.

There is a duty to report any inappropriate sexual behaviour of a colleague with a patient (Sexual behaviour and your duty to report colleagues (2013).

Where an intimate examination is required on an anesthetised patient or when supervised students wish to carry out such an examination, written patient consent should be obtained in advance.

Where the examination involves a child or young person, their capacity to consent should be assessed and where this is lacking, permission from the parents should be obtained. At 16 a young person should be presumed to have the capacity to consent.

There may be exceptions to when a chaperone is not required, i.e., in an emergency, when the patient's clinical needs must be the priority.

12.3 Reasons for Litigation

The main reasons for litigation are patient complaints and allegations of inappropriate sexual behaviour or sexually motivated intimate examinations, usually because there is an absence of a chaperone. It should be remembered that there is a duty to report any inappropriate sexual behaviour of a colleague with a patient [3].

Where an allegation of sexual misconduct has been made the local police force is duty bound to investigate. Such investigations may result in a criminal case being brought against the doctor. Because of the seriousness of the offences that are likely to have been alleged the trial will normally take place in the Crown Court in front of a panel of 12 jury members and one Judge. In most cases the doctor's defence organisation will provide a defence.

12.4 Avoidance of Litigation

It is important that the above guidance from the GMC is followed and to maintain professional boundaries between patient and doctor [4]. In addition to offering patients a chaperone, the doctor must be competent in performing the relevant examination and must be clear that it will help the diagnosis.

12.5 Case Study

A 25-year-old woman had a vulval abscess that was treated by incision and drainage at the local hospital. She was followed up by her General Practitioner, who performed examinations of the vulva and vagina on three separate occasions, 1 week apart. At each of these examinations a chaperone was not present. As the abscess resolved, the patient alleged that the examinations became more sexually motivated, as each examination became more prolonged and the last examination allegedly involved stimulation of the clitoris. In a criminal court hearing the doctor was cross-examined and eventually acquitted as he was able to convince the court that a chaperone was offered at each visit but refused by the patient. However, the doctor had failed to record these offers in the medical records and despite his acquittal his case was referred to the General Medical Council for further investigation into his Fitness to Practice.

Key Points: Intimate Examinations and Chaperones

- Chaperones should be used wherever possible, for the protection of both the patient and doctor and patients should be offered a chaperone for all intimate examinations.
- Ensure training for all chaperones.
- Although it is not mandatory for a chaperone to be present, the presence of a chaperone decreases the risk of an allegation of inappropriate behaviour.
- If a patient refuses to have a chaperone, the doctor can refer to a colleague.
- If the doctor continues with the examination without a chaperone, the offer of a chaperone and the reasons for continuing with the examination should be clearly documented in the medical records.
- Be sensitive to a patient's ethnic/religious and cultural background. The patient may have a cultural dislike to being touched by a person of another sex or undressing in front of such a person.

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Part II

Anaesthesia in Obstetrics and Gynaecology

Swati Jha and Danny Bryden

Pain Relief

13

Jeremy P. Campbell and Felicity Plaat

13.1 Background

Provision of pain relief in labour has humanitarian intent but additional medicolegal considerations. The indications, contraindications and complications of non-regional (pharmacological and non-pharmacological methods) and regional techniques for labour analgesia are discussed below. The issue of informed consent and the implications of antenatal birth plans are also described.

13.2 Minimum Standards and Clinical Governance Issues

Attitudes towards pain relief in labour are influenced by cultural factors, peer group pressure and personal expectations. The woman's partner and other family members are frequently involved in the choice of pain relief. If expectations are not met or complications arise, complaints and litigation are likely. It is essential that appropriate information is given and analgesia is tailored to the individual parturient.

The Royal College of Anaesthetists (RCoA) [1], Obstetric Anaesthetists' Association (OAA) [2] and the National Institute for Health & Care Excellence (NICE) [3] describe standards of care for the provision of regional analgesia for labour. Failure to achieve these standards increases vulnerability to litigation.

13.3 Reasons for Litigation

13.3.1 Non-pharmacological Analgesia in Labour

A variety of psychological and physical methods are available. Although apparently safe, evidence of efficacy is lacking. Such methods can be promoted by care-givers and offered by Trusts. Anaesthetists should be aware of what is available and provide unbiased information. A summary of the existing evidence can be found in the Cochrane Database of systematic reviews [4].

13.3.2 Pharmacological Analgesia in Labour

13.3.2.1 Inhalational Analgesia (Entonox)

Entonox (a mixture of 50% nitrous oxide in oxygen) is widely used as an analgesic in labour. It may cause nausea, light-headedness and drowsiness. Although not a potent analgesic, studies have suggested that it provides sufficient analgesia for many women [5].

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13.3.2.2 Systemic Opioids

Pethidine remains the most commonly used opioid for labour analgesia, although use of diamorphine is increasing. Both are given intramuscularly and are predominately sedative and anxiolytic rather than analgesic [6] and up to three quarters of women require additional analgesia. Pethidine readily crosses the placenta and may cause neonatal respiratory depression if delivery occurs within 1–2 h of administration. Its use has been associated with subsequent neonatal behavioural and feeding problems.

13.3.2.3 Patient Controlled Analgesia

Patient controlled opioid analgesia (PCA) may be offered if regional analgesia is contraindicated. Both fentanyl and remifentanil have been used. Remifentanil is potentially superior because it has a rapid onset and a short duration of action, providing rapid analgesia with quick recovery between contractions [7]. Fetal exposure is minimal due to rapid metabolism. The woman requires supplemental oxygen and continuous oxygen saturation monitoring. There have been case reports of life-threatening respiratory depression in labour.

13.3.3 Regional Analgesia

Regional analgesia provides better pain relief in labour than other methods. Combined spinal-epidurals (CSE) provide quicker pain relief than epidurals. Indications and contraindications are given in Table 13.1.

13.3.3.1 Timing of Analgesia

A common cause of complaint by women is that they did not receive regional analgesia when requested, or that it did not work adequately.

Both the RCoA and the OAA suggest that the anaesthetist should attend within 30 min of a request for analgesia in units providing a 24-h

Table 13.1 Indications and contraindications for regional analgesia in labour

Indications for regional analgesia
1. Maternal request
2. Maternal cardiovascular and respiratory disease
Regional analgesia reduces the cardiovascular stress associated with painful uterine contractions.
3. Obstetric indications
(a) Pre-eclampsia. *Effective analgesia helps reduce blood pressure and improves renal and placental blood flow.*
(b) Multiple pregnancy. *Use of regional analgesia is associated with improved acid-base status of the second twin and facilitates operative delivery if required.*
4. Anaesthetic indications
(a) Obesity *Early establishment of regional analgesia can be extended to provide anaesthesia in an emergency reducing the need for general anaesthetic.*
(b) Predicted difficult airway *Reduces the need for general anaesthesia (and therefore the risk of failed tracheal intubation) in an emergency.*
Contraindications to regional analgesia
• Maternal refusal
• Allergy to local anaesthetic or opioid drugs
• Lack of resuscitation equipment and trained staff to care for the woman
• Inability to gain large-bore (16-G) intravenous access
• Local infection at site of insertion
• Significant coagulopathy or anticoagulation (see later)
• Cardiovascular instability
• Raised intracranial pressure (intrathecal injection or accidental dural puncture with an epidural needle may cause coning)
Special circumstances:
1. *Anticoagulants or aspirin*
Aspirin: this is not a contraindication to regional analgesia.
Low molecular weight heparin (LMWH), e.g. enoxaparin, dalteparin:
Following a prophylactic dose of LMWH, an epidural should not be sited, or an epidural catheter removed, for 12 h. After a treatment dose of LMWH 24 h should elapse before siting a regional block or removing a catheter. If LMWH is to be given after removal of an epidural catheter, a minimum of 4 h should elapse.

Table 13.1 (continued)

2. *Thrombocytopenia*
If a patent has thrombocytopenia secondary to pre-eclampsia, the platelet count can fall rapidly. It is therefore essential to have a recent platelet count before siting an epidural, (within 6 h). A platelet count above 80×10^9/L is considered sufficient if associated with normal coagulation studies. A lower threshold may be safe in women with idiopathic thrombocytopenia as platelet function is normally good. A haematologist should be consulted if in doubt.
3. *Infection*
If a woman is systemically septic, epidural analgesia may exacerbate hypotension due to peripheral vasodilatation, as well as risk introduction of micro-organisms into the neuraxial space. We avoid regional analgesia in women who are overtly septic with hypotension. Woman who are asymptomatic but pyrexial should receive intravenous antibiotics prior to epidural placement. It may be prudent to avoid dural puncture in these circumstances.

epidural service [1, 2]. Frequently, factors beyond the control of the anaesthetist are responsible for delays in providing analgesia. The need to transfer a woman, staffing and communication issues may be responsible. It advisable that the anaesthetist record the time of the request, the time he or she attended, and whether there were factors delaying the provision of analgesia.

There is no evidence for withholding regional analgesia in early labour. NICE states that it should be provided to women in the latent stage who request it [3]. Equally, regional analgesia should not be withheld in the second stage of labour.

13.3.3.2 Preventing Inadequate Analgesia

Studies suggest up to 24% of epidurals provide less than adequate analgesia at some point during labour. Table 13.2 lists factors associated with inadequate analgesia.

The CSE technique provides more rapid analgesia than plain epidurals, and is recommended when speed is essential [3]. There is some evidence that a CSE is associated with greater maternal satisfaction, fewer re-sites and less need for rescue top-ups compared with an epidural. Insertion of the block in the sitting position is associated with a higher success rate although the incidence of venous puncture (bloody tap) is increased. Use of ultrasound for insertion may improve success rates. 4–5 cm of the catheter should be inserted into the epidural space: too little and the risk of displacement is increased; too much and the likelihood of a one-sided block (the most common cause of inadequate analgesia) is increased. Addition of opioids to local anaesthetic improves the quality of analgesia. Low concentrations of local anaesthetic (<0.25% bupivacaine) should be used [3] and analgesia maintained with intermittent epidural top-ups. Top-ups may be staff-administered, or given via a patient controlled device (patient controlled epidural analgesia [PCEA]). Both reduce the incidence and intensity of motor block compared with epidural infusions, and PCEA may increase maternal satisfaction. Motor block reduces maternal satisfaction and contributes to the increased length of the second stage of labour and the higher incidence of instrumental delivery.

Table 13.2 Factors associated with inadequate regional analgesia in labour

Patient factors
Spinal deformity/spinal surgery
Obesity
Anaesthetic/management factors
Failure of the initial dose
Length of catheter in epidural space <2 cm or >8 cm
Lack of operator experience
Continuous infusion to maintain analgesia
Inadequate frequency of top-ups
Inadequate volume of top-ups
Obstetric factors
Duration of labour >6 h
Malposition of fetus

13.3.3.3 Management of Inadequate Analgesia

Units should have guidelines on the management of inadequate analgesia. Regular monitoring of the adequacy of analgesia as well as the block level is recommended.

If analgesia is inadequate, the woman should be reassured that analgesia can be improved. Larger volume, low concentration top-ups may help inadequate spread of the epidural block. Additional opioids may help when the spread of the block is adequate but pain relief is not. One-sided blocks may be corrected by lying the woman on the unblocked side and topping up the epidural, and/or withdrawing the epidural catheter by 1 cm. However, if these measures are not successful they should not be repeated and instead the epidural should be re-sited.

13.3.3.4 Side Effects and Complications of Regional Analgesia

These are largely the same for regional anaesthesia and are discussed in the following chapter.

Hypotension is rarely a problem with the low-dose regimens recommended for labour as long as aorto-caval compression is avoided. Serious sequelae from accidental intravenous injection of local anaesthetic and high block are also less likely.

Accidental dural puncture occurs in 0.5–2% of epidurals. Approximately 70% of women who have an accidental dural puncture with a 16-G epidural needle will suffer a low pressure headache, which may be extremely debilitating. Long-term sequelae include cranial nerve palsies and subdural hematomata [8]. It is essential that any woman who suffers a dural puncture be actively followed up by an anaesthetist to assess for headache. Litigation is likely if the woman had not been warned of this complication, if she was not properly followed up and was not offered an epidural blood patch in a timely manner.

When neurological symptoms present postnatally there is a tendency to implicate anaesthetic interventions, but the majority of cases are due to the mechanics of labour or fetal pressure on nerves. Permanent neurological damage due to regional techniques occurs in 1 in 80,000–1 in 320,000 [9]. Delay in obtaining imaging and referral for surgery when compressive lesions are present may lead to permanent neurological deficit which is hard to defend and a tragedy for the new mother.

13.3.4 Consent for Regional Analgesia in Labour

As with any procedure, it is essential to seek consent for regional analgesia. For consent to be valid, adequate information should be provided, the woman must have capacity and not be coerced. Although someone in great pain or under the influence of analgesic drugs may be considered to lack capacity, the extent in the obstetric setting has yet to be determined. In a case involving a woman refusing caesarean section in labour, the Court ruled that despite receiving opioids she remained competent to make that decision [10].

It is inappropriate to burden women suffering painful contractions with large amounts of information. This should be provided antenatally instead. However, at the time of a request for analgesia, the anaesthetist should provide the woman with basic details which should be documented. Table 13.3 lists the risks and complications which are commonly discussed. An information card, produced by the OAA (including translations in over 40 foreign languages)

Table 13.3 Risks and complications discussed and documented prior to instituting regional analgesia in labour

Failure/one-sided block/re-site
Motor block/immobility/urinary catheter
Hypotension/nausea and vomiting
Prolonged second stage of labour/increased risk of assisted vaginal delivery
Headache
Temporary/permanent neurological damage
Infection

NB It is worth pointing out that whilst backache is common after childbirth, the evidence shows no causal relationship to regional analgesia in labour

can be downloaded to facilitate discussion (labourpains.com).

13.3.5 Birth Plans

The NHS Choices website describes a birth plan as '*a record of what you would like to happen during your labour and after the birth*' including pain relief. Women are advised to '*keep an open mind*' as '*you may find that you want more pain relief that you'd planned*' [11].

A particular challenge is a birth plan that states the woman should not be given an epidural even if she requests one in labour, and then presents in labour desperate for one. If she is deemed to have capacity it is appropriate to proceed, although it may be wise to ask for written consent. Postnatally or even once the epidural is effective the woman (and her partner) may be resentful of the anaesthetist who aided her 'labouring self' to overrule the wishes expressed in her birth plan. A debrief may help the woman to accept events [12]. If the woman lacks capacity, the birth plan (if written clearly, signed and witnessed) should be considered evidence of an Advance Decision, and must be respected. In such circumstances, it is wise to make sure that a witness (usually the midwife) is present, everyone agrees with the decision and that this is documented. If a trainee is faced with a situation such as this, it is advisable to involve senior input early.

13.4 Avoidance of Litigation

Risks of litigation can be reduced by ensuring that labouring women and attendants are provided with appropriate information and analgesia in a timely manner. Labouring women should be presumed to have capacity and discussions of treatment or any delays should be carefully documented. Analgesic inadequacy or complications should be acted upon as soon as you become aware of them. Follow-up after delivery can be helpful and may avoid later complaints.

13.5 Case Study

A multiparous woman requested regional analgesia for labour. The cervix was 5 cm dilated when she had last been examined 1 h previously. She was very distressed. An anaesthetic core trainee attempted to site the epidural. He was finishing his second week on Delivery suite in preparation to beginning a job at ST1 level. He made 3 attempts to site the epidural and there was an obvious dural tap at the final attempt. The supervising consultant attended promptly and sited an epidural with difficulty in the space above that provided good analgesia for the remainder of the labour. Subsequntly the woman developed a disabling, positional headache. Blood patching was delayed for 48 h. Although it relieved the headache, the woman claimed to have subsequently suffered recurring headaches, backache and brought a case against the anaesthetist and Trust.

Solicitors for the woman claimed that the initial procedure for siting the epidural had been carried out negligently, the trainee anaesthetist was not qualified to undertake the procedure and had been inadequately supervised. Furthermore it was claimed that the woman had not been warned of the possibility of PDPH and would not have had an epidural had she been told. Finally it was claimed that by delaying the blood patch, the woman's suffering was prolonged increasing the risk of developing long term problems.

There was clear documentation of the risks discussed, including PDPH and the issue of consent was dropped. The trainee involved had had a run of dural taps in the week previously was supposed to be directly supervised but at the time the consultant was in theatre with a category 2 CS. On the basis of this the allegation that the trainee was inadequately supervised could not be defended and the case was settled for a modest sum as the delay in blood patch is accepted practice, and the evidence for long term sequelae uncertain.

Key Points: Pain Relief

- Management of pain needs to be individualised to suit patient expectations.
- Patients should be made aware of the various options so that they can make an informed decision.
- For invasive procedures which have risks, adequate consent is necessary.
- Timely provision of analgesia (within 30 minutes of the request being made) and good documentation of reasons for delay should be made.
- When analgesia is inadequate, this should be appropriately topped up.
- Complications should be identified and managed promptly.

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Regional Anaesthesia

14

Sujata Handa and David Bogod

14.1 Background

Regional anaesthesia techniques have revolutionised surgical approaches and pain relief in Obstetrics & Gynaecology. In obstetric anaesthesia, the trend towards regional techniques over general anaesthesia for caesarean section has been one of the leading causes of reduction in maternal mortality. Effective postoperative pain relief allows enhanced recovery as a result of early mobilisation and reduces the likelihood of post-operative complications; e.g. infection, deep vein thrombosis. Regional anaesthesia techniques include spinal, epidural, combined spinal-epidural (CSE) and transverse abdominis plane (TAP) blocks.

14.2 Minimum Standards and Clinical Governance Issues

Intravenous access and standard AAGBI (Association of Anaesthetists of Great Britain and Ireland) monitoring should be in place before commencing any procedure. Regional anaesthesia techniques are performed in sitting or lateral position. The procedure is done with strict aseptic precautions. Ultrasound scanning provides real-time images and can be useful to guide placement of needle for central neuraxial blockade. Opioids are very commonly mixed with local anaesthetics to improve the quality and duration of analgesia.

Absolute contraindications to central neuraxial blocks include coagulation disorders, local site infection or severe sepsis, known allergy, raised intracranial pressure and patient refusal.

Spinal anaesthesia—Spinal anaesthesia results in a rapid onset of block, thought to act mainly at the spinal nerve roots. Hypotension and post-dural puncture headache are common complications. Early recognition and treatment is key to treatment. The spinal cord ends at the level of first lumbar vertebra. The spinal needle should be introduced below this level to avoid damage to the spinal cord.

Epidural anaesthesia—Main advantages of an epidural are related to the use of an epidural catheter allowing control over the onset, extent and duration of blockade. However, the likelihood of missed segments and local anaesthetic toxicity is higher when compared to a spinal. The risk of inadequate block or failure is higher in patients with morbid obesity, previous back surgery and anatomical abnormalities of the musculoskeletal system.

Combined Spinal Epidural—CSE technique combines the benefits of both procedures. The spinal component provides a rapid onset of a predictable block, while the indwelling epidural catheter provides the ability to extend the block

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by titrating the dose of local anaesthetics to the desired effect.

Transversus abdominis plane block—TAP block has been shown to reduce the need for postoperative opioid use and provide more effective pain relief after general anaesthesia, while decreasing opioid related side effects such as sedation and postoperative nausea and vomiting. It is a useful technique for postoperative analgesia following abdominal and gynaecological procedures involving T6-L1 distribution, the innervation of the abdominal wall.

14.3 Reasons for Litigation

The reasons for litigation following regional anaesthesia are most commonly related to

- Inadequate information disclosure during the process of consent
- Pain during caesarean section
- Nerve damage
- Failure to diagnose, investigate and treat complications
- Failure to follow-up

14.4 Avoidance of Litigation

- Document all options discussed with the patient at the time, including general anaesthesia.
- Check and document level of block achieved to cold and light touch as well as motor blockade.
- Listen to and empathise with the patient—believe she is in pain, if she so states. Discuss options available—supplement anaesthetic or conversion to GA.
- Postoperative follow-up and debrief with patient, partner and midwife.

Consent—As it is the patient who carries the burden of risk, it is imperative that she is fully informed of all material risks and alternative options available along with their risks. Statistical significance should not be used to decide disclosure, but a severe risk, however rare should be mentioned, especially if, when it materialises, it will affect the patient's life or livelihood.

Paraplegia, vertebral canal abscess, vertebral canal haematoma, meningitis, spinal cord ischaemia and death must be mentioned during consent. Uncommon complications such as failure, severe headache and significant drop in blood pressure should also be mentioned.

Regional anaesthesia information leaflets should be given to all patients in the anaesthetic preoperative or antenatal clinic.

Information given should be adequate in its scope, content and presentation and the anaesthetist should take steps to make sure it is understood and documented.

Nerve damage—The incidence of neurological complications after a spinal block is estimated to be 1:13,000 and 1:25,000 after an epidural block [1]. National Audit Project 3 estimated the rate of permanent harm after central neuraxial block in the obstetric population to be between 1:320,000 (optimistically) and 1:80,000 (pessimistically) [2]. Pain and/or paraesthesia during needle or catheter insertion should alert the anaesthetist to stop. A change of direction of needle or use of a different inter-spinous space may be required. Neuropraxia or neuropathy can be coincidental due to lithotomy or head down position during laparoscopic procedures, fetal head position or forceps during instrumental delivery and peripheral nerve compression by tissue oedema.

A thorough neurological examination is mandatory and 'red flag' signs such as progressive motor block should prompt urgent radiological investigations to rule out spinal cord compression causing nerve damage. Compression as a result of haematoma or abscess warrants immediate surgical treatment.

Pain during caesarean section—a thorough assessment of the adequacy of the block before surgery, with confirmation of a block extending above the T6 dermatome (underside of breasts)

to a fine touch stimulus usually avoids this situation. However, if pain occurs, patients should be offered different options of supplementing the anaesthetic. The options can be in the form of Entonox, bolus doses of intravenous short acting opioids, Ketamine, local anaesthetic infiltration by surgeon or institution of general anaesthetic. If a patient feels significant pain even before delivery, this is a strong indication that general anaesthesia will be necessary. General anaesthesia should not be withheld in this situation unless it carries significant maternal hazard well beyond the 'usual' risks associated with the technique.

14.5 Case Study

Mrs. ABC was scheduled for an elective caesarean section. She consented to a combined spinal-epidural as the anaesthetic technique. During the insertion of CSE, she felt severe low back pain and electric shock type pain in her right leg. This lasted for almost a minute and she was extremely distressed with the experience. The block height was tested with ethyl chloride spray for sensation of cold, followed by a pair of forceps used to test sharp pain. The patient could feel the forceps on her lower abdominal wall; albeit a slightly dulled sensation as compared to sensation on the upper abdomen or lower part of chest.

She felt severe pain with the surgical incision and the epidural component was topped up at this stage. Despite three attempts at topping up the epidural, adequate block height was not achieved. She was in pain and extremely upset that general anaesthesia was needed and that she would therefore be unable to experience the birth of her baby.

Documentation of the block height was minimal on the anaesthetic chart and there was no mention of the pain during insertion of CSE.

The case went to court, however, settlement (in the order of £60,000) was reached between the parties before the evidence was concluded.

Key Points: Regional Anaesthesia

- Adequate preoperative assessment should include discussion of all options of anaesthetic techniques available.
- Key elements of the discussion should be recorded on the anaesthetic chart.
- Patient choice based on information disclosed about risks and benefits of each technique.
- Strict adherence to asepsis and maintain AAGBI standards for monitoring and conduct of anaesthesia.
- Prompt recognition and treatment of complications.
- Adequate follow up of patients.

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General Anaesthesia

15

Samuel Hird and Rehana Iqbal

15.1 Background

General anaesthesia is still commonly used for gynaecological surgery but its use in obstetric surgery has largely been replaced by regional anaesthesia due to a lower maternal risk. In spite of this decline litigation has increased. Recognised standards exist to reduce the risk of complications.

General anaesthesia was used for 50% of caesarean sections in the 1970s [1] compared with 8% in 2013 [2]. In obstetric practice general anaesthesia is now mostly administered in emergency situations, due to adverse maternal or fetal physiology, or where regional anaesthesia has failed [3]. This selects a cohort of increasingly comorbid and technically challenging patients in which medicolegal issues are more likely to arise. Despite the dramatic reduction in general anaesthesia use in obstetrics the absolute number of claims for obstetric general anaesthesia has increased [4] to an average of 2.5 claims per year. These claims are more likely to lead to a cost when compared to regional anaesthesia and result in a higher cost per claim [5].

This chapter will outline the standards for general anaesthesia and present the common reasons for litigation and how to avoid it.

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15.2 Minimum Standards and Clinical Governance Issues

There are a number of relevant guidelines.

Consent must be given and documented before anaesthesia [6]. Material risks should be discussed to which a reasonable person in the patient's position would attach significance. This may be challenging in emergency obstetric anaesthesia with time critical decisions needing to be made when there may be pain, distress and concern over fetal wellbeing.

The Association of Anaesthetists of Great Britain and Ireland (AAGBI) produce minimum standards for monitoring and staffing [7, 8]. Local hospital guidelines may also exist and be used in cases of litigation to define expected standards of local practice [9].

The Obstetric Anaesthetists Association (OAA) website [10] publishes several examples of hospital guidelines in relation to obstetric general anaesthesia and highlight that the following areas should be considered and addressed:

A pre operative assessment of the airway
Antacid prophylaxis
Rapid sequence induction with preoxygenation and cricoid pressure
Measures to avoid awareness particularly before skin incision
Planning of extubation
Reduction in the hypertensive response to intubation

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15.3 Reasons for Litigation and Avoidance

Common reasons for litigation include the following:

15.3.1 Accidental Awareness under General Anaesthesia (AAGA)

AAGA is a distressing experience existing on a spectrum from brief episodes of awareness without pain to prolonged episodes of paralysis and surgical pain [2]. Late severe psychiatric sequale may develop in up to a third of those who experience AAGA [11].

The incidence of AAGA is approximately 1 in 8000 when neuromuscular blockade is used [2]. However, AAGA is over represented in obstetric anaesthesia by a factor of 10 [2] with an incidence of up to 1 in 670 for caesarean section [2]. Twenty-three cases were reported via the NHS litigation authority (NHSLA) over a 12-year period [11] with obstetric anaesthesia representing 30% of all AAGA claims [11].

Risk factors for awareness are common in obstetrics and include emergency surgery, rapid sequence induction with neuromuscular blockade and a short interval from induction of anaesthesia to start of surgery [2]. Detection of AAGA in the parturient may be difficult with differing baseline physiological variables and an absence of tachycardia and hypertension in 20% of cases of AAGA [2]. At present there is no gold standard depth of anaesthesia monitor with NICE and AAGBI guidance only going as far as suggesting EEG based monitoring as an option in high risk cases [7, 12]. Depth of anaesthesia monitors may become the standard of care in the future.

Failure to provide a state of unconsciousness when providing general anaesthesia is most commonly due to human error and is considered unacceptable with few exceptions [13]. Dosing errors are the most common and tend to be reflective of substandard care [2], most commonly simple syringe swaps [11] (e.g. antibiotic with thiopentone) [2]. These errors tend to result in brief awake paralysis and universally result in a payout.

Claims have been made for AAGA attributable to inappropriately low doses of induction agents due to disconnection or reflux back up intravenous lines. As IV induction agents such as thiopentone tend to be short acting, prolonged attempts at intubation may have contributed up to 30% of cases of awareness in the Royal College of Anaethetists (RCoA) 5th National Audit Project on AAGA (NAP 5) [2]. Inhaled maintenance anaesthetic agents take time to 'wash in' so an adequate gas flow and availability of an additional syringe of IV hypnotic is recommended [2].

Preoperative communication of the risk of AAGA is appropriate in those with risk factors and is specifically recommended by the NAP 5 report [2, 11]. If a patient is led to believe they will be unconscious without question then should AAGA occur they are more likely to feel a duty of care has been breached [2].

Management of a suspected case of AAGA should include:

- Documentation of the presence or absence of common aspects of recollection which may include conversations heard, sensations of choking, breathlessness or pain.
- The anaesthetic chart should be reviewed to determine any likely cause.
- An apology and an explanation should be given to the patient as soon as possible, ideally before discharge.
- Appropriate follow up which may include counselling should be arranged. Appropriate follow up reduces the psychological disease burden of AAGA and potential medicolegal issues. The NHSLA claims database specifically mentioned a lack of interest, concern or emotional support in five cases of litigation [11].

Medical expert review would determine the satisfactory conduct of the following

- Patient monitoring
- Intraoperative management of signs of distress
- Timing and dose of drugs used including volatile end tidal concentrations and flows

- Appropriateness of choosing a general anaestehtic technique
- Documentation of this information is essential

15.3.2 Airway

Airway management is fundamental to administering safe general anaesthesia. Issues may arise from failed intubation or ventilation, aspiration or damage to local structures via instrumentation.

Preoperatively an airway assessment should include a review of previous anaesthetics for intubation difficulties and an examination of the airway. In an emergency a verbal history and examination may be all there is time for.

Failed intubation occurs in 1 in 2000 [14] elective cases which rises to approximately 1 in 390 in the obstetric population [3]. There are well recognised guidelines for its management in the general adult population [15] with specific obstetric guidelines [16]. Failed intubation may be associated with difficult or failed ventilation during which hypoxia may ensue. Task fixation over intubation is a risk and repeated unsuccessful attempts at intubation may make ventilation more difficult and hypoxia more likely. In this situation guidelines describe techniques to facilitate ventilation and oxygenation which culminate in an emergency surgical airway. Preoxygenation is important to prolong the time before hypoxia occurs.

In the event of failed intubation but successful ventilation the patient can be woken up and an alternative plan for anaesthesia made. In the case of emergency caesarean section, the decision whether to proceed or wake the mother must be made. Theoretical scenarios on whether to proceed with an unsecured airway divides opinion [3]. The latest obstetric failed intubation guidelines include a list of factors to consider rather than a didactic algorithm [16] which includes the threat to the mother and fetus, difficulty of surgery, risk of aspiration and potential for alternative regional anaesthesia or airway strategies. When faced with reality, case series suggest that most (73%) anaesthetists continue and this has increased over time [3] however the individual situation must be taken into account.

In the event of litigation, it will need to be established if an airway assessment occurred and an appropriate strategy for securing the airway performed with minimization of the risk of complications e.g. aspiration. The sequence of events following complications would be scrutinised against national guidelines for failed intubation/ventilation. Data from critical monitoring such as end tidal CO2 would need to be documented along with strategies used to maintain anaesthesia and oxygenation.

Blood pressure should be well controlled prior to induction of anaesthesia however in emergency situations this may not always be possible. If the balance of risk favours proceeding with surgery, drugs to blunt the hypertensive response to laryngoscopy include short acting opiates and IV betablockers [17]. Magnesium has antihypertensive properties but should not be seen as an adequate antihypertensive in women with severe hypertension [18] Invasive arterial monitoring may be required to obtain beat to beat analysis.

Aspiration of gastric contents into the lungs is a risk when consciousness is reduced with anaesthesia. Risk factors include lack of fasting, intra abdominal pathology and masses including pregnancy. The standard of care in those with risk factors is to induce general anaesthesia with a rapid sequence induction (RSI) technique to minimise the risk of aspiration [19] and administration of antacids preoperatively to minimise damage should aspiration occur.

Oesophageal intubation may occur due to difficult laryngoscopy and may be associated with damage or perforation of the oesophagus. Subsequent ventilation will fail to ventilate the lungs and will instead inflate the stomach increasing the risk of aspiration. Failure to obtain a correct capnography trace should prompt doubt over the position of the endotracheal tube. If left unrecognized morbidity and mortality due to hypoxia is high [18, 20–22]. Four claims for oesophageal intubation were made in the 12 years to 2007 to the NHSLA [20]. Of these 3 died and 1 suffered memory loss [1]. Oesophageal intuba-

tion regularly comes up on the CMACE report as a cause of death [21, 22].

Hypoxic injury resulting in brain damage or death may be the common end pathway from a failure to mitigate from the above complications.

Damage to surrounding structures typically includes the oropharynx and teeth however the trachea and oesophagus may also be involved. Anaesthetists should be familiar and trained on the airway equipment and adjuncts available in their department.

15.3.3 Hypertensive Intracranial Haemorrhage

A specific cause of maternal brain injury is hypertensive intracranial haemorrhage which may be precipitated by the hypertensive response to laryngoscopy. Poor perioperative blood pressure control is a contributing factor [22].

15.3.4 Patient Deaths

Anaesthesia is not a disease but an intervention and harm or death as a result of anaesthesia can be considered iatrogenic and potentially avoidable [23]. Death can result in the physician facing criminal charges e.g. manslaughter. Anaesthetists have been convicted of manslaughter for gross negligence administering general anaesthesia [24] and the number of doctors charged with manslaughter is increasing [24]. In order to demonstrate a doctor is guilty of manslaughter it must be established that there was a duty of care that was breached by standards that fell so far below expected that it amounted to a crime. Breaches may be via acts or omissions and must have made a significant contribution to the death [9].

15.3.5 Neonatal Harm

This can occur due to either a delay in administering general anaesthesia or maternal complications resulting from general anaesthesia.

It is widely acknowledged that general anesthesia in the parturient poses a greater risk than in the non pregnant patient. Inappropriate delay in administrating anaesthesia either as a reluctance to perform general anaesthesia or inappropriately long attempts at regional anaesthesia have been reported [4]. Other causes of delay are a failure to communicate the urgency of delivery to the anaesthetist. Fetal monitoring until the administration of general anaesthesia is essential.

Complications of maternal anaesthesia with inability to oxygenate the mother may result in fetal hypoxia [4] causing brain damage or neonatal death.

15.3.6 Nerve Injury

General anaesthesia is not without neuronal risk. Poor patient positioning can result in neuropathies, [13] most commonly involving the ulnar nerve [25]. The lithotomy position is associated with a 1 in 3600 rate of long standing lower limb neuropathies. The common peroneal nerve is the most frequently injured in the lower limb but sciatic and femoral injuries may also occur. Risk of injury increases with prolonged positioning over 4 h, increasing age, smoking and diabetes [26].

15.3.7 Post Operatively

Anaesthetic duty of care extends into the post operative period [13] with the need for appropriate disposition and planning. Following surgery strong opioids may be required. Post operative deaths from opiate toxicity have appeared in multiple CMACE reports [23, 27] as well as deaths due to bronchospasm in obese asthmatics [28]. The record of intra and post operative observations may be scrutinised to assess if the appropriate post operative level of care was selected along with appropriate post operative management.

15.4 Case Study

As most cases are settled out of court this is an adapted case. J (Claimant), a 25 year old obese primip in labour underwent a category 1 caesarean section in 2001 for cord prolapse. R (defen-

dant) induced anaesthesia with thiopentone and rocuronium and established maintenance with sevoflurane in an oxygen nitrous mixture. Intubation was documented as difficult requiring two separate attempts. Alfentanil and morphine were given for analgesia after delivery and reversal was administered at the end.

The next day J became increasingly distressed due to a recollection of awareness during the operation. She was seen by the anaesthetist who documented her experiences along with an apology, explanation and plans for followup. J recalls the sensations of her abdomen being cleaned followed by a sharp severe pain and pulling before blacking out due to the pain.

Expert opinion considered the following: It was likely that Js recollection of cleaning occurred before the induction of anaesthesia. It is possible the experiences of pain and pulling may have occurred on emergence of anaesthesia however in this case they were thought to be a true reflection of intraoperative awareness as they were supported by a documented rise in heart rate and blood pressure to above her baseline. The choice of general anaesthesia and the doses of induction drugs used were appropriate. There was a failure to document the end tidal concentrations of sevoflurane which was used for maintenance of intraoperative anaesthesia. It was likely that due to the prolonged time at intubation there was a delay in establishing volatile anaesthesia allowing the induction drug to wear off. There was also the possibility of inadequate dosing of intraoperative anaesthesia although the lack of documentation could not support or refute this. The case was settled out of court.

Key Points: General Anaesthesia

- Minimum standards of monitoring, number of staff and consent from the patient must be adhered to regardless of the state of emergency.
- A pre-operative assessment of the airway is required with appropriate management strategies and adherence to national guidelines in the event of unanticipated difficulty.
- Careful consideration is required on whether to proceed with caesarean section in the event of an unsecured airway taking into account maternal, fetal and surgical factors.
- Antacid prophylaxis and rapid sequence induction with cricoid pressure should be used in those at risk of aspiration, as in obstetrics
- Strategies to blunt hypertensive response to laryngoscopy in those at risk include opiates and IV beta blockers. Invasive arterial monitoring may be required.
- Appropriate Induction drug dosing, volatile anaesthesia concentrations and flows must be administered and documented. Vigilance is required at induction for human error and equipment malfunction to avoid AAGA.
- An apology, explanation, follow up and counselling is essential for those who experience AAGA.
- Patients must be positioned with care whilst anaesthetised to avoid nerve damage.
- Emergence and extubation requires consideration of potential difficulties. Stomach decompression should be considered in non fasted cases.
- Appropriate post operative level of care should be considered.

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Part III

Obstetrics

Emma Ferriman and Swati Jha

Prenatal Screening and Diagnosis

16

Emma Ferriman and Dilly Anumba

16.1 Background

In the United Kingdom, it is mandated that all pregnant women are offered fetal screening tests that meet agreed standards for the three major chromosomal abnormalities—trisomy 18, 13 and 21. They should also be offered an ultrasound scan between 18 and 21 weeks' gestation to check for fetal structural abnormalities. The UK National Screening Committee which is responsible for setting the standards for the national screening programme mandates that all women are provided with information regarding their prenatal fetal screening options. The screening programme is implemented by the fetal anomaly screening programme (FASP) which ensures uniform and equal access to high quality fetal screening services across the UK, so that women can make informed choices regarding which screening tests they want to undergo [1].

NICE guidance for antenatal care for uncomplicated pregnancies recommends the combined test (a combination of ultrasound and blood markers) in the first trimester and the quadruple or triple test in the second trimester [2]. In addition, there is an increasing demand for highly accurate non-invasive prenatal testing (NIPT). Women deemed to be at risk of chromosomal abnormalities may then opt for a diagnostic test such as an amniocentesis or chorionic villus sample (CVS).

Failure to avail women of information and options for fetal screening may lead to litigation should an adverse fetal outcome result. In a recent 10-year report of medicolegal claims published by the National Health Service Litigation Authority (NHSLA) in 2012, there were 230 claims as a result of antenatal investigations, comprising 4.5% of the total claims for maternity services, and costing £144,811,665 (4.8%) of all claims [3].

16.2 Minimum Standards

Minimum standards set to assure high quality fetal screening services emphasise the need to identify the target population for screening, provide them with accurate information, and to periodically assess coverage or uptake of screening tests. Services are also required to attain high rates of predictive accuracy of screening as well as follow-on diagnostic tests, all of which should be provided in a timely fashion. Standards to minimise harm through accurate reporting, staff education and training are also stipulated. For instance, a standardised detection rate of 85% for Trisomy 21 and 80% for Trisomy 18 and 13 are currently stipulated and a screening test turnaround time of three working

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days is recommended. Women deemed to be screen positive on the basis of a threshold (currently a risk greater than 1 in 150) should be offered a diagnostic test. For women undergoing invasive tests, turnaround times should be within three calendar days for rapid diagnostic tests and within 14 days for full karyotyping [1]. For diagnostic tests women should be informed that the miscarriage rate for both CVS (performed from 11 weeks) and amniocentesis (performed from 15 weeks) is between 0.5% and 1%. The operator should perform enough procedures per year to maintain proficiency and should keep records of procedure-related loss rates [4].

16.3 Clinical Governance Issues

The sources of error in prenatal screening and prenatal diagnosis have been recently reviewed [5]. Although data is sparse, mistakes may occur in relation to counselling, tissue sampling, laboratory testing and quantification, or pregnancy dating. Healthcare providers may fail to offer recommended screening tests to a pregnant woman or to manage the uptake of such tests. Women undergoing first trimester screening should be made aware of all the available options for screening, including more accurate tests which may need to be privately funded (such as NIPT at present) and the implications of having a positive test. They should also be made aware of the difference between a screening and a diagnostic test. Women should enter the screening pathway early so that they can access all available tests. Patients with positive screening results should be given the relevant information on how to proceed further. NIPT has a high detection rate and a low false positive rate, but parents should still be counselled that this is a screening test for which a positive result would require confirmation by a diagnostic test. Patients who opt for an invasive diagnostic test should be made aware of the two tests available—either CVS from 11 weeks or amniocentesis from 15 weeks. These procedures should be performed in centres with appropriate facilities and staffing, and by practitioners who maintain competence by performing enough procedures annually.

16.4 Reasons for Litigation

- Failure to provide access to screening in the first trimester due to delayed referral to the midwife or the hospital.
- Failure to appreciate that screening is not diagnostic and that even with a low-risk result there is a chance that the baby may be affected.
- Failure to provide patients with all the information regarding available screening tests
- Failure to give patients all the available options once a high-risk result is identified
- Failure to obtain informed consent regarding invasive procedures including miscarriage rates
- Failure to counsel patients regarding mosaic results
- Failure to provide genetic counselling in patients with chromosomal abnormalities with an impact on future pregnancies
- Failure to provide results of screening or diagnostic tests promptly, or not at all.
- Incorrect pregnancy dating leading to wrong screening risk estimation.

16.5 Avoidance of Litigation

Claims for "wrongful birth" are typically brought by a parent or guardian on behalf of a minor child with a congenital disorder. The claimant usually alleges negligence of the health care provider in the prenatal period by failing to diagnose the congenital condition. Such a breach of duty must directly result in the birth of an affected baby in a situation where the parents would have opted to discontinue the pregnancy had the abnormality been detected. Claims of "wrongful birth" are highly emotive and are typically of significant financial cost as they involve the long-term care of the child as well as potential loss of earnings and lifestyle changes for the parents. To minimise the chance of successful litigation parents should be provided with good information regarding the screening options and approaches, as early during pregnancy as practicable. Screening services must ensure that they practice to the minimum stan-

dards and "fail-safe" guidelines recommended by the FASP. Ideally screening information should be written and available in the parents' own language. In view of the high profile of NIPT and its proposed introduction into the NHS for women screening high risk on first trimester screening in October 2018, patients who wish to receive information regarding NIPT should have access to it. When there is a failure of the screening system this should be reported and fed back to providers. This may involve auditing services to ensure national standards are met and to ensure that results are communicated to patients in a timely manner so that prompt referrals may be made to access tertiary centres where applicable. Claims are often made in situations where there are no unit protocols. Each unit should therefore, adopt into their local protocol the minimum national standards for Down's syndrome screening and anomaly scanning. Regular audit and service evaluations by provider units will help identify systematic errors and gaps in practitioner knowledge that need addressing [5].

16.6 Case Study

Mrs. P was a 42-year-old lady in her first pregnancy who attended a private clinic for a non-invasive prenatal test (NIPT). She was counselled, and she signed a consent form. The consent form clearly stated that the test was a screening test with a 99% detection rate for Trisomy, 21, 18 and 13 and a 0.1% false positive rate. In addition, Mrs. P opted to have fetal sex chromosome testing and wished to know the gender of her baby. Blood was taken at 13 weeks gestation and sent for analysis. The NIPT result showed the baby had a high risk of Turner's syndrome (45 XO). Following counselling the patient opted to have an amniocentesis. The long-term culture confirmed a normal female karyotype 46XX. Mrs. P proceeded with a litigation case based on the fact that she had been inadequately counselled regarding the NIPT. She alleged that she had not been told of the false positive rate of 0.1% and the potential reasons for a false positive result such as placental mosaicism. A preliminary ruling was given that Mrs. P had been counselled and signed a consent form that clearly stated the test was not diagnostic and had a false positive rate. No breach of duty was identified in this case.

Key Points: Prenatal Screening and Diagnosis

- Early entry to the screening pathway to ensure access to all available tests whether NHS or private sector tests
- Accurate information regarding screening and prenatal testing including detection rates
- Ensure parents are aware of the differences between a screening test and a diagnostic test
- Ensure efficient communication of abnormal results
- Ensure a robust risk management system to highlight detection rates and screening failures
- Ensure prompt referral for parents needing tertiary centre investigations
- Ensure informed consent for women undergoing diagnostic procedures

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The 20-Week Anomaly Scan

17

Emma Ferriman and Dilly Anumba

17.1 Background

In the United Kingdom, it is mandated that all pregnant women are offered an ultrasound scan between 18 and 21 weeks' gestation to check for fetal structural abnormalities. Such screening offers women the choice to discontinue pregnancies affected by serious fetal abnormalities. Where they opt to continue the pregnancy antenatal detection of a serious anomaly may enable parents and care-givers to prepare better for the birth of a baby with congenital abnormalities. The non-detection of a serious fetal abnormality can lead to claims of "wrongful birth" by parents who would have opted to terminate the pregnancy had they been informed of an anomaly in early pregnancy.

However, it should be realised that it may not always be possible to distinguish between non-detection of a fetal abnormality owing to a negligently conducted ultrasound scan and non-detection of an abnormality that does not lend itself to easy visualisation despite a carefully conducted imaging examination. Some fetal abnormalities lend themselves to easier detection by ultrasound than others. Published detection rates for fetal abnormalities vary with organ of affectation, the nature of the sonography service, whether the ultrasound scan was carried out in the context of a secondary level screening service or of a tertiary level diagnostic and therapeutic unit [1]. Detection rates may also vary with the gestational time point at which the scan was carried out, and with the severity of the malformation screened for.

Failure to recognise the complexities of detecting structural anomalies leads to considerable litigation in the UK. Fetal anomaly scans were examined in the National Health Service Litigation Authority (NHSLA) report published in October 2012. There were a small number of claims compared to the total number of scans performed, but the litigation costs were substantial. At the time of the report £10,080,500 had been paid in damages to claimants and a further £39,994,773 was reserved for claims yet to be concluded. In addition to this, legal costs of £1,793,735 had been paid to claimants' solicitors and experts, and £667,746 had been paid to solicitors and experts acting on behalf of the NHSLA [2]. The medical negligence claims all centred around failure to diagnose a severe abnormality on the 20-week scan, but claims are usually unsuccessful unless the issue of 'wrongful birth' can be proven, and the parents are able to demonstrate that if the abnormality had been detected they would have terminated the pregnancy, and that they were denied the option of this decision by the non-detection of the anomaly antenatally.

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17.2 Minimum Standards

The fetal anomaly scan forms part of the NHS Fetal Anomaly Screening Programme (FASP). This programme sets minimum standards for the provision of a high-quality screening service against which performance is often judged. The over-arching aim is to provide all pregnant women access to high quality, but uniform screening tests. In addition, all eligible women should be provided with high quality ultrasound screening information in order that they can make informed choices in a timely manner [1]. Women may opt to undergo ultrasound screening for fetal anomaly or they may chose to opt out of screening. The ultrasound examination is usually performed between 18^{+0} and 20^{+6} weeks to check for a base-set of 11 structural fetal anomalies (see Table 17.1).

The minimum standards set to assure high quality fetal anomaly scanning require that consent is sought and documented to conduct the scan, and that the limitations of the scan are clearly explained. Women should be advised not to opt for an anomaly scan if they do not wish to be informed if anomalies are found. Where image quality of the first scan is suboptimal (reasons for this will include, raised maternal BMI, poor fetal position, uterine anomalies such as fibroids or previous surgery), a further scan may be offered by 23^{+0} weeks gestation in order to complete the fetal anomaly scan. Failure to obtain adequate views should be clearly documented and the reason stated.

The required images for the 20-week anomaly scan are listed in the FASP handbook in appendix 1 [3].

Table 17.1 This is taken from The Fetal Anomaly Screening Handbook and shows the 11 conditions screened for as a minimum on the 20-week scan

Conditions	Detection rate (%)
Anencephaly	98
Open spina bifida	90
Cleft lip	75
Diaphragmatic hernia	60
Gastroschisis	98
Exomphalos	80
Serious cardiac anomalies include the following: • Transposition of the Great Arteries (TGA) • Atrioventricular Septal Defect (AVSD) • Tetralogy of Fallot (TOF) • Hypoplastic Left Heart Syndrome (HLHS)	50
Bilateral renal agenesis	84
Lethal skeletal dysplasia	60
Edwards' syndrome (Trisomy 18)	95[a]
Patau's syndrome (Trisomy 13)	95[a]

[a]Detections rates will be reviewed following implementation of screening as part of the combined screening strategy

17.3 Clinical Governance Issues

Errors relating to ultrasound screening for structural fetal anomalies often result from failure to offer women fetal scans, and to counsel them about its fallibility. Women should be made aware of ballpark scan detection rate estimates for common significant abnormalities, as missed or incorrect diagnosis of fetal abnormalities during any pregnancy trimester can occur despite scrupulous fetal imaging evaluation.

Operator-dependent errors can occur when operators have insufficient training or skill to perform an anomaly scan. They may be at an early phase of a learning curve for providing such a service independently. Pressures on a service with severely limited allotted scan times for sonographers may also contribute to errors. An anomaly scan should be scheduled to last no less than 30 min for a singleton pregnancy.

Obesity is associated with an increased risk of some congenital abnormalities, and also contributes to errors in the detection of fetal abnormalities. The compromised acoustic window resulting from adipose tissue markedly attenuates ultrasound signals, requiring optimum ultrasound machine settings to facilitate the anatomic survey.

17.4 Reasons for Litigation

Overall there are a small number of claims annually arising from the 20-week scan compared to the large number of ultrasound examinations

performed. This is primarily because ultrasound is a good screening tool and will detect approximately 80% of severe or lethal abnormalities in a low risk population [4]. In the NHSLA report there were recurring themes for litigation and these included:

1. Non-adherence to local protocols detailing minimum standards for the examination
2. Human error featured in 72.5% of claims
3. Poor training and education
4. Failure to get a second opinion
5. Substandard equipment
6. Inadequate documentation

17.5 Avoidance of Litigation

Litigation in this area will always be a feature of obstetric practice and this is because ultrasound is a screening tool that is not infallible. It is also highly operator dependent and open to interpretation. However, there are some strategies that will make the screening system more robust and help to reduce error.

1. Adherence to local and national guidelines—in the NHSLA report only 60% of units had undertaken scans according to guidelines. Local guidelines should reflect national recommendations. Every unit should have a protocol in accordance with local guidance to ensure minimum standards are reached.
2. Prevention of human error—all units should have systems in place to audit all examinations and compare detection rates to national standards. Where the diagnosis is missed, these cases should be reviewed within the department as per local clinical governance pathways and investigated accordingly to determine whether the error was knowledge or protocol-based.
3. Education and training—all personnel performing the ultrasound examinations should be adequately trained. The heath provider must ensure education and training occurs within the department and that personnel are also funded to participate in external continuing professional development (CPD).
4. Referral policy—in cases where there is a concern, operators should have access to a second opinion from a senior colleague. Trainee sonographers should have a period of supervision until they are competent to perform examinations unaided. Finally, there should be a robust referral pathway for specialist fetal medicine opinion.
5. Equipment—all equipment should be fit for purpose, regularly serviced and updated to provide adequate imaging.
6. Documentation—in 52.5% of cases reviewed in the NHSLA report, documentation was inadequate. Although the previous recommendation was that only abnormal images should be stored, the current FASP recommendation is that all the images required as a baseline for a complete 20-week scan (both normal and abnormal) should be stored as an electronic record. The images should have an accompanying electronic report. Both of which should be accessible on an electronic reporting system for review and audit.

17.6 Case Study

A 28-year-old woman in her second pregnancy was referred to a specialist fetal medicine unit at 20 weeks following diagnosis of an abdominal wall defect on the anomaly scan. The scan confirmed a small exomphalos containing bowel only. The couple were counselled regarding the association with chromosomal abnormality and other structural defects. The couple opted for amniocentesis which showed a normal male karyotype. A fetal echocardiogram confirmed a structurally normal heart. It was recommended that the claimant delivered in the tertiary centre where the baby would have surgery to repair the hernia. As part of a multi-disciplinary approach the Claimant also received prenatal counselling by the Paediatric Surgeons. Further scans conducted every 4 weeks in the tertiary unit showed good fetal growth and unchanged appearances of the exomphalos. Labour was induced at 39 weeks gestation. At delivery, it was noted that the baby not only had an exomphalos, but a small bladder

exstrophy and ambiguous genitalia. The baby was transferred to a supra-regional centre for ongoing treatment. The Claimant successfully sued the Trust for wrongful birth based on the fact that had the full extent of the fetal abnormality been detected antenatally the Claimant would have opted for termination. The Claimant and her husband had been counselled that an uncomplicated exomphalos with normal chromosomes and no other structural anomalies would do well in 90% of cases and require one operation. The baby required multiple operations, some of which were complex, at a supra regional centre necessitating that the Claimant leave her job and move her home. The judge in the case ruled in the Claimant's favour because although the abnormality was rare and complex, the fetal medicine scan was targeted to detect complex anomalies. The judge also ruled that although the baby was much loved he believed that the Claimant would have opted for termination had the full extent of the anomalies been detected antenatally.

Key Points: 20-Week Anomaly Scan

- Offer an anomaly scan between 18^{+0} weeks and 21^{+6} weeks
- Written information should be provided regarding the limitations of ultrasound
- For those patients in whom the first examination is incomplete offer a second scan at 23 weeks
- Ensure the examination is performed by trained personnel
- Agreed protocols for second opinions and specialist referral
- Maintain and update ultrasound equipment according to agreed standards
- Provide adequate documentation and electronic reports for the examination
- Ensure required images are taken, captured and stored on an electronic system
- Regular audit of examinations should be performed and compare the unit's performance to agreed national standards
- Report all missed diagnoses as per local clinical governance protocols

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Induction of Labour

18

Myles J. O. Taylor

18.1 Background

Induction of labour is the process whereby the uterus is stimulated to deliver prior to the spontaneous onset of labour. Over the last decade, the incidence of induction has increased from approximately 1 in 5 to over 1 in 4 of all pregnancies in England [1]. Critics argue that this represents an adverse development reflecting an ever-increasing medicalisation of labour when labour should be regarded as a normal physiological process. They also argue that increased rates of induction will inevitably result in increased rates of interventions such as emergency caesarean section. On the other hand, recent evidence suggests that induction of labour, in all conditions studied, improves perinatal outcome whilst also being associated with unchanged or reduced medical intervention rates.

The main reason underlying a decision to induce labour is that on balance, at that stage of the pregnancy, it is appreciated that the risks to the mother or fetus of continuing with the pregnancy exceed those of delivery. In reaching this decision, the pregnancy needs to be regarded from both fetal and maternal perspectives.

From the maternal perspective, factors which need to be assessed include the safety of induction of labour. For example, a previous history of caesarean section will increase the risk of scar rupture, or a very large baby may increase the risk of a failed induction. Such reasons may be persuasive in making a decision to avoid induction altogether, instead opting for elective caesarean section.

From the fetal perspective, the gestation of induction is of particular importance. For example, a clinical presentation of mild tailing off of fetal growth may be all that is required to trigger a recommendation of induction of labour at term where the risks of neonatal morbidity and mortality are low. In contrast, at gestations less than 28 weeks, the same clinical features would probably prompt close surveillance of the pregnancy in the hope of achieving a higher gestation of delivery, hence reducing the substantial neonatal risks at this early gestation.

18.2 Minimum Standards

Prior to offering induction of labour women should be informed about the reasons for induction, when, where, and how the induction process will be carried out, and the arrangements for analgesia. They should also be aware of the alternative arrangements if the mother does not opt for induction and the risks and benefits of induction of labour in specific circumstances (e.g. when there has been a previous caesarean

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section). Women also need to be made aware that induction of labour may not be successful and what the mother's options would be under these circumstances. Indications and contraindications for induction of labour are documented in Table 18.1.

The complications of induction of labour should be explained. This is commonly achieved by patient information leaflets. Complications include hyperstimulation of the uterus in which uterine contractions are either too frequent (greater than 5 contractions in 10 min) or too strong. Under these circumstances, there is a risk that impaired blood supply to the uterus and placenta will result in fetal distress. Even without hyperstimulation, the use of oxytocin can result in fetal distress, particularly if the baby is vulnerable, for example in growth restricted babies who may not able to withstand the stress of labour. Uterine rupture, a life-threatening event to mother and fetus, in which part of all of the uterine wall is disrupted, is rare in the unscarred uterus (less than 1 in 10,000 pregnancies). However, after a previous caesarean section, the incidence of this complication is increased to approximately 0.68% and 1.91% in induced or augmented labours respectively [2].

Table 18.1 Indications and contraindications for induction of labour

Indications
Prolonged pregnancy
Prolonged rupture of membranes
Chorioamnionitis
Multiple pregnancy
Maternal disease—Diabetes, hypertension, cardiac disease, sickle cell disease, deteriorating mental health, malignancy
Fetal compromise—Fetal growth restriction, non-reassuring CTG, reduced fetal movements, rhesus disease
Oligohydramnios/polyhydramnios
Fetal death
Previous stillbirth
Previous precipitate delivery
Severe symphysis pubis dysfunction
Social indications including partner overseas or childcare logistics
Contraindications
Placenta praevia/accreta or vasa praevia
Transverse fetal lie
Previous adverse reaction to induction agent
Cord prolapse in a viable pregnancy
Previous classical uterine incision
Previous myomectomy where uterine cavity breached
Previous uterine perforation
Active genital herpes
Invasive cervical carcinoma

For many women, however, there are concerns that induction of labour will inevitably lead to a more medicalised and less natural or physiological end to their pregnancy. For example, women are often concerned about induced labour being more painful than spontaneous labour and also of feeling less in control [3]. Mothers may also be disappointed that labour and delivery is advised in an Obstetrician-led maternity unit rather than at or home or in a low risk midwifery-led birthing centre.

All methods of labour induction are designed to either ripen the cervix or stimulate uterine contractions, recognising that labour is essentially a combination of uterine contractions in the presence of a dilating cervix. Methods of induction of labour can be divided into non-pharmacological and pharmacological [4]. Non-pharmacological methods include stretching and sweeping the cervix, artificial rupture of membranes (ARM) and use of intra-uterine balloons which both stretch and stimulate the cervix. Pharmacological methods include the use of synthetic oxytocinon or prostaglandin analogues.

Once the uterus is contracting, the cervix dilating, and labour is established, both mother and fetus are monitored according to established care pathway guidelines. Observations are designed to ensure that sufficient progress in labour is being achieved. Oxytocin, if not already being used, can be employed to augment labour. Women undergoing induction of labour with oxytocin require continuous electronic fetal monitoring.

18.3 Clinical Governance Issues

Before the availability of cervical ripening agents, the use of ARM and oxytocin were associated with a very high risk of a failed induction—defined as not having delivered vaginally within

24 h. Thus, in nulliparous women whose induction was commenced with a very unripe cervix, or low "Bishop" score, the incidence of emergency Caesarean section for failed induction of labour exceeded 45% [5]. In contrast, with modern ripening agents, the failure rate, even in the presence of an unfavourable cervix is only around 15% [4].

The chief advantage of induction of labour is that it reduces the length of time that the fetus or mother is exposed to the risks of pregnancy itself or to the complications that have arisen. For most women, the decision to opt for induction of labour to avoid adverse consequences of maternal or fetal disease is straightforward. Similarly, the offer of induction of labour when the pregnancy goes overdue (i.e. between 41 + 0 and 42 + 0 weeks) has become routine and uncontroversial as there is widespread recognition that a pregnancy which goes beyond 40 weeks of gestation is associated with increased prenatal risks which can be largely avoided by induction of labour. In any event, women at this late gestation frequently find the burden of pregnancy increasingly challenging and often welcome the relief that delivery will bring.

Routine induction of labour before 41 weeks gestation is not currently offered or recommended in the UK. However, this situation is changing, with some clinicians now lowering their threshold for induction of labour as the methods of induction have improved and the risks of late still-birth are better appreciated. For example, in many units, despite the lack of any national guidance to recommend it, mothers are routinely offered induction of labour for increased maternal age [6] (>40 years at booking) or if a large baby is suspected (>5 kg anticipated birth weight in non-diabetic pregnancies). As a result, there is an increasing debate on whether all women should be offered induction of labour at 38–39 weeks gestation, principally to avoid the risk, albeit low, of late still-birth. A catalyst for this change in clinical practice has been the recent Montgomery ruling by the Supreme Court [7] on informed consent which suggests that doctors and midwives should inform mothers of the "material" risks of continuing with the pregnancy and awaiting spontaneous labour versus the risks of induction of labour or having an elective caesarean section.

When assessing the risks of stillbirth at term, it is important to consider the risks as a proportion of the ongoing pregnancies at a particular gestation [8]. If one simply regards the risks of stillbirth at a particular gestational age, this misses the point that the population at risk from continuing the pregnancy comprises all ongoing pregnancies rather than just the babies born that week. The risks of stillbirth vary according to gestational age with a peak at 41–42 weeks gestation (Fig. 18.1) and also increase according to maternal age. Thus, the risk of still birth per 1000 pregnancies at 41 weeks gestation for women younger than 35 years, 35–39 years and over 40 years old are 0.75, 1.29 and 2.48, respectively [9]. In the UK, Cotzias

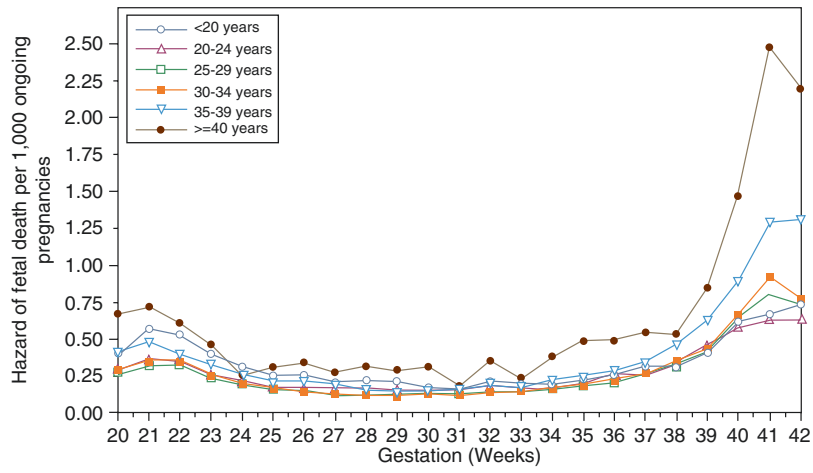

Fig. 18.1 Risk of stillbirth for congenitally normal singleton births by gestational age, 2001–2002 (from Reddy et al. [9])

et al. [10] found that the overall prospective risk of still-birth after 38 weeks is 1 in 529—similar to the risk of perinatal death in pregnancies that continue beyond 41 weeks when delivery is usually offered or recommended (2–3/1000) [4]. However, the principal argument against the routine offer of induction of labour at term to all women is that this would not be feasible and would overload already hard-pressed maternity units. Strategies to reduce workload include induction of labour in an out-patient setting. In addition, many maternity units allow low risk mothers in whom the induction process has commenced, but who then labour without ARM or oxytocin, to labour in a low-risk setting without continuous CTG monitoring. In addition, the use of oral rather than vaginal agents may make induction of labour more acceptable to mothers and the use of mechanical rather than pharmacological techniques may also increase the safety by reducing the risk of uterine hyperstimulation.

With modern methods of induction, far from increasing it, induction of labour probably reduces or makes no difference to the emergency caesarean rate. Thus in a randomised controlled trial of women induced for maternal age (≥35 years) [6], the emergency Caesarean section rate was not increased in the induction group compared to controls. Similarly, recent meta-analysis of randomised trials for induction of labour at or beyond term [11, 12], emergency Caesarean section rates [11] were reduced by 11–17% in women induced compared with expectant management.

Overall with the improved safety and efficacy of the induction process the day may approach when all women will be offered induction of labour at 38 weeks gestation.

18.4 Reasons for Litigation

- Failure to recognise when induction of labour is indicated
- Failure to offer or recommend induction of labour
- Failure to expedite induction of labour in a timely manner
- Failure to follow local protocols or guidelines for induction of labour
- Failure to inform women of the potential risks of induction of labour
- Failure to instigate appropriate monitoring once labour is established
- Failure to recognise and treat uterine hyperstimulation
- Failure to abandon induction when labour is not progressing

18.5 Avoidance of Litigation

Many complaints arise from delayed induction. Women are not informed of the potential length of the induction process and have unrealistic expectations of the timescales involved. Ideally this issue should be managed through a documented discussion regarding the induction process and its potential complications as well as through patient information leaflets. It is good practice for maternity units to audit their induction policies including indications for induction, failed induction rates and delay between induction and delivery. In most hospitals inductions are prioritised on a daily basis to ensure that those pregnancies with the most pressing needs are prioritised above less urgent indications.

In low-risk pregnancies, ensure that guidelines on the management of post maturity are followed. In low risk pregnancies, induction of labour is normally only offered if the pregnancy goes overdue. Thus, failure to offer induction of labour at 41–42 weeks is substandard. Conversely, if a woman, declines induction of labour, proper counselling and good documentation about the risks of fetal demise and the need for increased fetal surveillance in such cases is mandatory.

In high-risk pregnancies ensure that the pros and cons of continuing with the pregnancy versus induction of labour or caesarean section are properly assessed and discussed with the mother. Failure to recommend induction in high risk situations, or to recognise that the pregnancy has become high risk, and hence induction should be recommended, are common areas of litigation. On the other hand, if a mother,

despite the identified risks to herself or her baby declines induction of labour, then proper counselling must be given, and good documentation of this decision made.

When complications arise, such as hyperstimulation, or uterine rupture, close inspection of the management of the case may reveal substandard care; either in failing to follow local protocols or in failing to respond properly to the complications when they arose. All such cases should be examined as part of the risk management process with an opportunity for staff education and training. Where an adverse outcome has occurred, the parents should be involved in the process and any reports fed back to them open and honestly.

When a late still-birth occurs—particularly after 38 weeks gestation—it is inevitable that bereaved mothers will question the wisdom of maternity services not offering induction of labour routinely at this earlier stage—choosing instead to offer induction of labour only until 2–3 weeks later at 41–42 weeks gestation. Currently, there are no national guidelines to suggest that women over the age of 40 years or indeed that all women after 39 weeks should be offered induction of labour. This means that according to the Bolam test, it remains the case that since a reasonable body of Obstetricians would not routinely offer induction of labour to women over the age of 40 years, let alone to all women, it cannot be said that failure to offer induction of labour to such women represents substandard care. On the other hand, it seems logical that if the increase in perinatal mortality after 42 weeks is sufficient to prompt an offer of induction of labour, it follows that at 38 weeks, where the prospective risk of still-birth is similar, then the material risks of continuing with the pregnancy >38 weeks should also be discussed with mothers and the option of induction of labour discussed, in keeping with the Montgomery ruling. Viewed from this perspective, failure to offer all women induction of labour at 38 weeks gestation, particularly those over 40 years, should be regarded as substandard care. Time will tell whether the Court will favour a Bolam or Montgomery viewpoint in such cases.

18.6 Case Study

Mrs. A conceived dichorionic diamniotic (DCDA) twins in her second ongoing pregnancy having had a normal vaginal delivery previously which was complicated by the development of pre-eclampsia. At 33 weeks gestation, an ultrasound scan was performed which demonstrated significant growth discordance of 24% but normal liquor volumes and normal umbilical artery Dopplers. At 36 weeks, Mrs. A developed pre-eclampsia. Despite national guidance on hypertension in pregnancy, national guidance on the management of DCDA twins, and also the development of significant growth discordance, the pregnancy was allowed to continue to 39 weeks gestation. When Mrs. A presented at 39 weeks for delivery, one twin had demised. The Trust concerned admitted that there was a failure to recommend and expedite delivery by induction of labour, or Caesarean section, at 37 weeks. This case was settled on the grounds that the clinician failed to recognise that induction of labour was indicated in accordance with national guidelines and the clinician failed to offer delivery or induction of labour in a DCDA twin pregnancy at 37 weeks gestation.

Key Points: Induction of Labour

- Documentation regarding the indication for induction of labour
- Discussion regarding the pros and cons of induction of labour versus abdominal delivery
- Document possible complications including failed induction, hyperstimulation and uterine rupture
- Expedite induction in those women requiring urgent delivery
- In women declining induction arrange suitable monitoring of mother and baby
- Ensure continuous fetal monitoring in high-risk inductions

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Diabetes in Pregnancy

19

Alexander M. Pirie

19.1 Background

Diabetes in pregnancy significantly increases the risks of miscarriage, fetal abnormality, placental dysfunction, preeclampsia, sepsis, stillbirth, cerebral palsy, macrosomia, shoulder dystocia, birth injury, operative delivery and maternal death. Diabetes mellitus affects about 1 in 20 pregnancies: 87.5% of which are gestational diabetes (with later-life risk of type II diabetes), 7.5% have type I diabetes and 5% have type II diabetes. As obesity increases and women become older, both gestational and type II diabetes are becoming much more common.

The Hyperglycaemia and Adverse Pregnancy Outcomes (HAPO) study [1], since adopted by the World Health Organisation, has lowered the threshold for the diagnosis of gestational diabetes. NICE updated their 2008 guidelines in 2015 [2] to reflect this and these should be consulted for full details.

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19.2 Minimum Standards

19.2.1 Pre-existing Diabetes

These women should be seen for preconceptual counselling regarding the risks associated with pregnancy and provided with information and advice. This patient education programme should start from booking and continue throughout pregnancy. The aim is to stabilise preconceptual glucose levels between 5 and 7 mmol/L on wakening or 4–7 mmol/L before meals. The glycosylated haemoglobin levels (HbA1c) should be less than 6.5% to reduce the risk of congenital abnormality. Patients should be advised to take 5 mg daily of folic acid preconceptually until 12 weeks gestation. All patients should have a nephropathy screen prior to pregnancy and be referred to a renal physician if there is evidence of significant renal compromise.

At booking Aspirin 75 mg should be recommended to reduce the risk of preeclampsia. For those women with pre-existing hypertension on angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor antagonists these medications should be converted to alternative medications with a good safety profile in pregnancy to minimise the risk of teratogenesis. Any women on statins should be discontinued before pregnancy or soon as confirmed. Metformin can be used preconceptually and throughout pregnancy either singularly or as an adjunct to insulin. Other oral hypoglycaemic

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agents should be stopped and exchanged for insulin. HbA1c levels should be performed at booking to determine glycaemic control and the level of risk for congenital abnormality. Women should be offered nephropathy and retinopathy screening if these have not been performed within the last 3 months.

Patients should monitor their capillary glucose levels and aim for fasting levels of 5.3 and 7.8 mmol/L, 1 hour after meals or 6.4 mmol/L, 2 hours after meals. Isophane (NPH) insulin is the preferred long acting insulin; long acting insulin analogues can be used if there is good glucose control before pregnancy. For women where multiple injections are failing to control their blood sugars an insulin pump should be offered. Unwell patients with hyperglycaemia require urgent testing for ketonaemia to exclude ketoacidosis. Patients should be warned about the risk of hypoglycaemia and advised to keep a glucose source available. Glucagon should be considered for type 1 diabetics.

Obstetric care should be structured with review one to two weekly in a joint obstetric diabetes clinic. A 20-week detailed fetal anomaly scan should be offered to include a detailed cardiac scan and thereafter serial ultrasound assessments for fetal growth and liquor volume at 28, 32, 36 and 38 weeks gestation.

The mode of delivery should be discussed, highlighting the pros and cons of vaginal versus abdominal delivery. A detailed plan for the management of glycaemic control in labour should be documented aiming to maintain capillary glucose measurements between 4 and 7 mmol/L in labour. Delivery should be planned for between 37 + 0 and 38 + 6 weeks for **uncomplicated** type I or type II diabetes, but delivery should be considered before 37 weeks if maternal, fetal or metabolic complications arise. For women attempting vaginal delivery there should be continuous CTG monitoring in labour and it should be noted that diabetes is not a contraindication to attempting vaginal birth after caesarean section (VBAC). In women who present with preterm labour or require delivery prior to 36 weeks gestation, steroids for fetal lung maturation can be used in conjunction with an additional insulin regime to control maternal glucose levels. Betamimetics should not be used for tocolysis in diabetic pregnancy.

In the postnatal period infants born to diabetic mothers should be screened for neonatal hypoglycaemia. Mothers should be aware that the initiation of breastfeeding improves glucose control.

19.2.2 Gestational Diabetes

Gestational diabetes (GDM) should be diagnosed if the fasting glucose is above 5.6 mmol/L or above 7.8 mmol/L, two hours after a 75 g glucose load (glucose tolerance test). Women should be screened for GDM if their body mass index (BMI) exceeds 30 kg/m^2, they have a first degree relative with diabetes, a previous pregnancy complicated by GDM, a previous baby weighing greater than 4.5 kg or they are in a high risk ethnic group. New recommendations state that glycosuria of 1+ on two or more occasions or a single occasion of 2+ or more, should lead to further testing for GDM. Women with GDM in a previous pregnancy should be offered self-monitoring of capillary glucose levels and a GTT as soon as possible. Delivery should be planned no later than 40 + 6 weeks for **uncomplicated** gestational diabetes. Following delivery, a fasting glucose level should be taken at between six and thirteen weeks and they should be advised to have annual HbA1c estimations. For women with gestational diabetes whose blood sugars return to normal after birth they should be counselled regarding their future lifestyle including weight optimisation, diet and exercise.

19.3 Clinical Governance Issues

Women with diabetes in pregnancy should be managed in a specialist obstetric diabetic clinic with a multi-disciplinary team including an obstetrician, endocrinologist, specialist midwife, specialist diabetic nurse and dietician.

There should be local protocols for the management of both pre-existing diabetes in pregnancy and gestational diabetes based on national guidance. Women should be managed in accordance with these guidelines. Patients should have access to a specialist Midwife or a diabetic nurse specialist to ensure adequate blood sugar monitoring and enable early access to the maternity unit if required.

19.4 Reasons for Litigation

- Consent: Montgomery case (see below) upholds earlier GMC guidance on ensuring patient is aware of all 'material risks' and can decide her options
- Failure or delay in stopping teratogenic drugs such as ACE inhibitors
- Failure to screen for or to diagnose gestational diabetes
- Failure to inform the women of risks and options for pregnancy and delivery
- Failure to diagnose placental insufficiency
- Failure to diagnose macrosomia and recognise risks of sensitivity to hypoxia and birth injury, especially shoulder dystocia
- Failure to deliver by appropriate mode at appropriate time
- Instrumental operative birth, attempted or actual, and birth injury and cerebral palsy
- Prolonged labour, delay in recognition of significance of CTG abnormality and timely delivery by appropriate means and cerebral palsy
- Continuous CTG monitoring should be continued during transfer to theatre for emergency Caesarean section and appropriate fetal heart rate monitoring during siting of epidural anaesthesia
- Delays in acting on concern, delays in transfer to theatre or delays in theatre, including dynamic reassessment of risk to baby and mother
- Failure to institute appropriate postnatal thromboprophylaxis at dose appropriate to weight

19.5 Avoidance of Litigation

In diabetes, periods of maternal hyperglycaemia are associated with fetal hyperinsulinemia causing fetal plasma potassium and glucose to fall as these are driven intracellularly, with risks of fatal fetal cardiac arrhythmia and intrauterine death, hence one benefit of good glucose control. Likewise, when the umbilical cord is cut at delivery, the hyperinsulinaemic fetus is now cut off from the maternal glucose oversupply and can become neuro-hypoglycaemic. Fetal osmotic polyuria can cause polyhydramnios with risks of preterm labour and cord prolapse. Macrosomic babies in maternal diabetes are not just large with higher oxygen and energy requirements, but they use oxygen less efficiently and so are more sensitive to injury by transient hypoxaemia.

The Confidential enquiries into maternal deaths as published by MBRRACE(UK) [3] remind us:

- Diabetes is a risk factor for maternal death
- Hypertension due to nephropathy, pre-eclampsia and, subarachnoid haemorrhage are commoner in diabetic pregnancy
- Diabetes is a risk factor for sepsis
- Ischaemic heart disease is commoner at any age in diabetes
- Chest pain requires careful evaluation
- Breathlessness requires careful evaluation for pulmonary oedema, cardiomyopathy, heart failure.

19.6 Case Study

Montgomery v Lanarkshire Health Board [2015] UKSC 11 radically complements the Bolam test ('body of reasonable medical opinion') and Bolitho principle ('rational course of action') in the standard of care around consent. The seven judges in this Supreme Court Judgment indicate that Bolam is the correct standard for medical negligence, but the standard for consent is not what a body of reasonable medical people do, but rather what the 'person in the street'

would want to know about all of their options and all 'material' risks involved. (For accuracy, Hunter v Hanley is the reference case law in Scotland rather than Bolam).

Mrs. Nadine Montgomery had studied molecular biology at Glasgow University, and worked in the pharmaceutical industry. She was a woman with insulin-dependent diabetes when she had her first baby on 1st October 1999. She had small stature and the baby was suspected to be large. Although it was known that there was an approximately 10% risk of shoulder dystocia, she was not offered a caesarean section but endured a vaginal birth by forceps after a prolonged induced labour. Shoulder dystocia occurred lasting around 12 min, and her son suffered brachial plexus injury and hypoxia. He was later diagnosed with cerebral palsy, and he has grown up with severe disabilities.

The risk of shoulder dystocia in this case is around 10%. The risk of a significant brachial plexus injury, in cases of shoulder dystocia involving diabetic mothers, is about 0.2%. In a very small percentage of cases of shoulder dystocia, the umbilical cord becomes compressed within the mother's pelvis. This can cause prolonged hypoxia, particularly in a macrosomic baby with higher oxygen requirements, thus resulting in cerebral palsy or death. The risk of this happening is less than 0.1%.

Initially, the Scottish Court did not find breach of duty in keeping with the medical expert testimony, as not offering caesarean section was within the range of practice of many obstetricians of the time, and therefore not a breach of duty. The Court also concluded that her case failed also on causation, because even if Mrs. Montgomery had been given advice about the risk of serious harm to her baby, it would have made no difference in any event, since she would probably not have elected to have her baby delivered by caesarean section. That decision was upheld by the Inner House of the Court of Session, which is the Appeal Court in Scotland.

Mrs. Montgomery proceeded to take her case to the Supreme Court, where seven judges upheld her appeal, 16 years after the birth. They said that as an intelligent woman, it is probable that she would have chosen caesarean section had she been made aware of the risks, thus upholding the case for causation. On breach of duty, they determined that the wrong standard had been applied for judging issues of consent. This is best illustrated by the following quotes from the Supreme Court Judgment:

> '*An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it*.' Paragraph 87

> *'The doctor is however entitled to withhold from the patient information as to a risk if he reasonably considers that its disclosure would be seriously detrimental to the patient's health. The doctor is also excused from conferring with the patient in circumstances of necessity, as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision. It is unnecessary for the purposes of this case to consider in detail the scope of those exceptions.*' Paragraph 88

> *'…it follows from this approach that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.*' Paragraph 89

> *'…the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is comprehensible.*

The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.' Paragraph 90

'…the guidance issued by the General Medical Council has long required a broadly similar approach. It is nevertheless necessary to impose legal obligations, so that even those doctors who have less skill or inclination for communication, or who are more hurried, are obliged to pause and engage in the discussion which the law requires. This may not be welcomed by some healthcare providers; but the reasoning of the House of Lords in Donoghue v Stevenson [1932] AC 562 was no doubt received in a similar way by the manufacturers of bottled drinks. The approach which we have described has long been operated in other jurisdictions, where healthcare practice presumably adjusted to its requirements.' Para 93

The Montgomery judgment sent shock waves through much of the medical profession because it adds legal muscle to drive fully informed patient choice; it is no longer 'doctor knows best'. The three domains of the patient's values, the patient's risk preferences and patient's personal gut-feeling should be carefully explored to make an acceptable shared decision. Arguably, the best medicine was always about working in partnership with patients: matching choices to each individual patient's profile of values, specific risk adversity and intuition.

Key Points: Diabetes in Pregnancy

- Ensure patients have access to preconception counselling, information and education
- Inform patients regarding the potential risks involved with diabetes in pregnancy
- Offer high-dose folic acid and low dose aspirin.
- Stop ACE, AR antagonists and statins
- Screen for GDM in high-risk women
- Offer additional GTT for women with glycosuria
- Ensure appropriate glucose monitoring and control
- Arrange serial ultrasound assessments for fetal growth
- Counsel women fully regarding the timing and mode of delivery
- Maintain continuous electronic fetal heart monitoring in labour
- Monitor babies of diabetic mothers for neonatal hypoglycaemia
- Offer postnatal screening for diabetes and lifestyle advice

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Cardiac Disease in Pregnancy

20

Philip J. Steer

20.1 Background

Cardiac disease is currently the major cause of death associated with pregnancy in the United Kingdom. This places a premium on giving accurate preconception advice, and ensuring management during pregnancy which is consistent with current standards. This is best done by the multidisciplinary team including an obstetrician, cardiologist, anaesthetist, midwife, and cardiac nurse. The principles of management focus on minimising avoidable stress in pregnancy, particularly during delivery. These patients require an agreed management plan for pregnancy and delivery that is accessible to all healthcare professionals involved in their care. It is essential to respect patient autonomy, even when they make decisions about their care which carry avoidable risk.

20.2 Minimum Standards and Clinical Governance

Up to the mid-2000s it was customary for authorities such as the American College of Cardiology/American Heart Association/European Society of Cardiology to strongly discourage pregnancy in women with certain severe cardiac conditions such as pulmonary hypertension and advise termination should pregnancy occur [1]. However, the development of drug therapies such as sildenafil and prostenoids has improved the prognosis [2], as has a multidisciplinary approach to care involving obstetricians, cardiologists, anaesthetists and midwives [3]. Recent papers have suggested a substantial improvement in prognosis, with mortality rates possibly falling to as low as 5% [4–6].

Clinical practice is constantly being updated. Cardiac disorders are not a homogeneous group, and management varies substantially depending on the specific diagnosis, so that there are no randomised clinical trials. It is therefore necessary to keep up-to-date by reading all reported case series relevant to individual patients. It is mandatory to maintain regular communication and discussion with colleagues looking after similar groups of patients. A clinician looking after a high-risk patient with a relatively uncommon condition will be expected to either have significant personal experience of management of such cases, or at least take extensive advice from colleagues who have such experience. The recent UKOSS survey of women with mechanical heart valves who went through pregnancy reported a 9% mortality and 47% poor fetal outcome [7]. In an associated commentary Cauldwell and Steer highlighted the fact that 19% were not referred to either tertiary care or to a specialist obstetric

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S. Jha, E. Ferriman (eds.), *Medicolegal Issues in Obstetrics and Gynaecology*,
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cardiology service during their pregnancy [8]. An obstetrician without the relevant experience who fails to refer such a patient for appropriate care is likely to be found guilty of substandard practice.

In patients with impaired cardiovascular function a key point in their management is the maintenance of a stable cardiovascular system at times of acute stress. This is particularly important around the time of delivery, for example using slow incremental epidural anaesthesia to relieve pain (to avoid sudden hypotension). Delivery, whether by assisted vaginal delivery or caesarean section, needs to be done as gently as possible, avoiding unnecessary manipulation such as manual removal of the placenta (controlled cord traction is preferred), and minimising traction on the peritoneum at caesarean section. It is important to have an experienced obstetrician involved in the care who recognises the need to take care at delivery and to avoid procedures likely to provoke acute cardiovascular collapse.

20.3 Reasons for Litigation

- Failure to give accurate, up to date information to women with congenital heart disease
- Failure to allow women autonomy in decision making in their pregnancy
- Failure to refer women with complex cardiac disease to a tertiary centre
- Failure to provide care as part of a multidisciplinary team
- Failure to document a detailed plan of care both antenatally and for delivery
- Failure to nominate a contactable lead for the patient
- Failure to maintain the most stable cardiovascular environment during delivery
- Failure to recognise the haemodynamic changes involved in the postnatal period

20.4 Avoidance of Litigation

Litigation may arise as a result of preconception counselling, or when a woman presents in early pregnancy with a previously undiagnosed cardiac lesion. The clinician has a moral and legal duty to give up-to-date and accurate information about prognosis for the individual and the implications for the fetus, including the risks of preterm birth, fetal growth restriction, and recurrence of congenital heart disease. A thorough review of the most recent literature on each particular condition is therefore imperative. This can often be done effectively using the internet during the consultation. A valuable source is OMIM - Online Mendelian Inheritance in Man—https://www.omim.org/. The importance of accurate preconception counselling has recently been emphasised in a number of publications [9–11].

It is important to stress the value of the multidisciplinary team approach. Ideally patients with complex cardiac disease should attend a joint consultation with all the relevant team members present. This means that patient, cardiologist, anaesthetist, midwife and cardiac nurse all hear exactly what the obstetrician is saying, and each of the professionals and the patient can contribute to the discussion in their turn. Opinions on cardiac function coming from a cardiologist are always more authoritative than those from an obstetrician, however experienced. Only the patient has a full perspective on her preferences and priorities. Such an approach requires honesty and openness, and far from causing concern or alarm to the patient or her family instils a greater confidence in patient care, knowing that no issues are being hidden, and that the entire team is comfortable with the advice being given. Joint consultation ensures unanimity in policy-making and avoids inadvertent conflicts of advice. Moreover, each member of the team has their knowledge of the other specialties regularly updated, which benefits all members. This approach will also allow the opportunity to make a detailed plan of care in both the hospital records and in the woman's handheld maternity records. This detailed contemporaneous recording of the issues discussed is of substantial medicolegal value. It helps the individual professionals to cope with the responsibility for any decisions that are made, because they know that any inadvertent error in advice or management is likely to have been picked up by colleagues. Moreover,

in the event of a poor outcome, the responsibility for any decision made is shared, which is not only comforting to the individual but is also a great strength if the decision is subsequently questioned in court.

The issue of autonomy in decision-making is a major medicolegal issue in relation to pregnancy in women with heart disease. The traditional approach to care has been paternalistic, often with strong recommendations being made to women about the decisions they should make. Such an approach is no longer acceptable, and this has been emphasised by the Montgomery ruling [12]. The responsibility of the doctor is to make sure that the facts that they provide to enable their patients to make decisions appropriate for them as individuals are correct. If the outcome is adverse, failure to ensure that they have given accurate and up-to-date advice is likely to result in successful litigation against them.

20.5 Case Study

Mrs. A knew that she had pulmonary hypertension and so in the late 1990s attended a meeting of the Grown-Up Congenital Heart charity (GUCH, now replaced by the Somerville Foundation, www.thesf.org.uk). The meeting was addressed by an obstetrician with experience of managing pregnancy in women with heart disease, who explained the risk of mortality but also emphasised the importance of informed choice. She subsequently attended the obstetrician's clinic for detailed preconception counselling. A letter from the GP said that Mrs. A was an intelligent woman who was "making a brave decision to go ahead with pregnancy". She had seen a cardiologist at a tertiary level centre who had written that the course of pulmonary hypertension in pregnancy is very unpredictable and "there is a possibility she could lose her life". However, it also stated that there was a "low risk of death, perhaps it could be 5%". Mrs. A became pregnant and antenatal echocardiograms were reassuring although they confirmed a pulmonary artery pressure of 50 mmHg. She was asymptomatic until 32 weeks gestation, when she started to complain of mild breathlessness and soon thereafter she was admitted for observation. At 34 weeks she had a brief period of unconsciousness. However, she was very concerned about the effect of early delivery on the baby, and therefore expectant management was continued despite repeated episodes of unconciousness. At thirty six weeks there was spontaneous rupture of the amniotic membranes. Although good contractions were generated by a low-dose oxytocin infusion, the cervix failed to dilate and a caesarean section was performed. The baby was delivered in good condition but following their usual practice, the delivering obstetrician performed a manual removal of the placenta and immediately afterwards the mother developed a supraventricular tachycardia which progressed to cardiac arrest. Resuscitation failed.

At the subsequent inquest, there was considerable discussion about the level of risk posed by pregnancy in women with pulmonary hypertension. In the 1980s and 1990s, the risk of maternal mortality was estimated to be between 30 and 56% [13]. There was some criticism of the relatively low level of risk quoted in this case. However, the supervising cardiologist pointed out that Mrs. A had a number of favourable features including good exercise tolerance, and that detailed antenatal care had been provided. The coroner in summing up pointed out that a 5% risk of maternal mortality was still 1 in 20, some 500 times higher than the average for a pregnant woman, and for that 1 in 20, death was 100%. However, he also stressed the importance of giving the most accurate information possible to enable women to make fully informed choices.

Key Points: Cardiac Disease in Pregnancy

- Offer pre-pregnancy counselling to women with cardiac disease
- Ensure information provided is the most up to date and accurate
- Provide accurate documentation of all counselling and consultations
- Best results are achieved with a multidisciplinary team approach

- Inform the patient and her family of all the material risks
- Provide a detailed individualised care plan for pregnancy and delivery with a named lead professional
- During childbirth maintain as stable a cardiovascular environment as possible
- Incremental epidural anaesthesia may be useful
- Shorten the second stage of labour/assisted delivery if indicated
- Avoid manual removal of placenta where possible

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Pre-eclampsia and Hypertension

21

Alexander M. Pirie

21.1 Background

Preeclampsia is the commonest medical disorder of pregnancy. It can manifest as no symptoms, odd symptoms, or the classical headache, epigastric pain, swelling, nausea and visual aura. Worldwide, it's a major cause of maternal death, neonatal brain damage and litigation. Outcomes have significantly improved in the UK with better antenatal monitoring, multidisciplinary team working, and the consistent use of antihypertensive agents, antenatal steroids and early delivery. This has largely been driven by the NICE guidelines published in 2010, and the Confidential Enquiries into Maternal Deaths published triennially since 1952, now run by MBRRACE (UK). Between 2009 and 2014, there were 14 maternal deaths in the UK associated with hypertensive disorders, compared with 37 deaths in each of the two previous 6-year periods. Of those 88 hypertensive deaths, 41 were due to intracranial hemorrhage, 18 hepatic necrosis, 15 acute fatty liver, 9 eclampsia/cerebral oedema, 3 hepatic rupture, and 3 pulmonary oedema (one mother in two categories). Confidential assessors found that almost all those deaths may have been prevented by better care [1]. In the most recent 2013–2015 report there were eighty eight direct maternal deaths of which three were attributable to pre-eclampsia and eclampsia.

21.2 Minimum Standards

In 2010, NICE produced national guidelines for the Investigation and Management of Hypertensive Disorders of Pregnancy [2]. The diagnosis of hypertension in pregnancy includes new hypertension occurring after 20 weeks (gestational hypertension), new hypertension with proteinuria (pre-eclampsia) and chronic hypertension (present before 20 weeks).

Chronic hypertension may have unknown aetiology (sometimes unhelpfully referred to as essential hypertension) or a specific cause such as nephropathy, Cushing's and Conn's disease, coarctation of the aorta, renal artery stenosis or phaeochromocytoma. Women with pre-existing medical conditions should be managed by an obstetrician with experience in maternal medicine and an appropriate general physician. Ideally these women should be seen for pre-conception counselling.

There should be accurate risk assessment at booking. Women at high risk of hypertension in pregnancy include those with a previously affected pregnancy, chronic hypertension, chronic renal disease, diabetes, systemic lupus erythematosus (SLE) and antiphospholipid syndrome (APS). In chronic hypertension, patients should be counselled regard-

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ing the embryopathic effect of angiotensin converting enzyme (ACE) inhibitors and aim to convert to labetalol, methyldopa or nifedipine within 2 days, under expert guidance. In women with chronic hypertension, the blood pressure should be kept below 150/100 mmHg, or below 140/90 mmHg if there is target organ damage. More recent evidence from the CHIPS trial suggests that a diastolic of 85 mmHg is more protective against the effects of severe hypertension [3].

Women with two or more moderate risk factors for hypertension at booking should also be offered aspirin 75 mg from 12 weeks until birth. Moderate risk factors include first pregnancy, maternal age greater than 40 years at delivery, pregnancy interval of more than 10 years, family history of preeclampsia, multiple pregnancy, body mass index (BMI) of more than 35 kg/m^2. Blood pressure and urinalysis should be checked at each antenatal clinic visit. Women should be made aware of the importance of hypertension-related symptoms including headache, visual aura, swelling, pain below the ribs, vomiting and reduced fetal movements, and the need to seek advice.

In mild gestational hypertension (140/90–149/99 mmHg), no treatment is required other than monitoring weekly. This should be twice weekly if there is a high risk of preeclampsia or if the pregnancy is less than 32 weeks. In moderate gestational hypertension (150/100–159/109 mmHg), labetalol is the first line agent and twice weekly monitoring is appropriate. Other agents used with apparent safety in pregnancy are nifedipine and methyldopa (although methyldopa should be discontinued postnatally due to its association with tiredness and postnatal depression). In severe gestational hypertension (160/110 mmHg or higher), hospital admission is required with four times daily BP monitoring. A diagnosis of significant proteinuria is made when the Protein-Creatinine Ratio (PCR) is more than 30 mg/mmol. Antenatal corticosteroids should be given if preterm delivery is anticipated.

A care plan should be agreed between a senior obstetrician and the woman and documented in the notes. This should cover the frequency and type of monitoring required and the treatment and side effect profile of any prescribed medication. If preterm delivery is anticipated there should be neonatal involvement and a discussion regarding the pros and cons of vaginal versus abdominal delivery and the timing of delivery. For acutely unwell patients with unstable blood pressure not responding to oral therapy, intravenous labetalol or hydralazine may be required with the addition of magnesium sulphate. Monitoring of these patients should occur in an obstetric high dependency setting with staff appropriately trained in acute medical emergencies. Careful attention should be paid to both adequate blood pressure control and fluid monitoring, avoiding fluid overload and the precipitation of pulmonary oedema. Clinicians should be aware that the postnatal patient remains at high risk of eclampsia.

21.3 Clinical Governance Issues

The booking assessment should included an appropriate risk assessment for hypertension and aspirin prescribed accordingly. Blood pressure and urinalysis should be performed at every antenatal visit and should be documented. Blood pressure should be measured using an approved, appropriately calibrated device by a standard method. Two measurements of blood pressure of >140/90 mmHg or a single blood pressure measurement of >160/110 mmHg constitute hypertension and warrants investigation and treatment. There should be recognition and prompt escalation of referral if the blood pressure exceeds 140/90 mmHg, if proteinuria develops or relevant symptoms are reported. There should be patient education regarding the recognition of symptoms and appropriate investigation of any potential signs for hypertension. For women diagnosed with hypertension in pregnancy there should be good communication with the woman and shared decision making regarding pregnancy management. It is important to recognise the risk of psychological 'threshold avoidance' by medical and midwifery staff; this is where important symptoms are discounted or dismissed, or where the blood pressure is re-checked until a normal reading is

obtained to avoid crossing the thresholds for action in a patient who doesn't want to be admitted. Outpatient monitoring by either the community midwife or in an antenatal day unit setting may reduce the numbers of women requiring hospital admission although these modalities should be used appropriately. It is also essential that the results of any investigations performed in these settings are followed up in a timely manner and escalated where necessary.

All midwifery and medical staff should be aware of the need for an appropriate response to any women with hypertension in pregnancy presenting with reduced fetal movements or any degree of antepartum haemorrhage. There should be appropriate use of serial ultrasound assessment of fetal growth, liquor volume assessment and Doppler studies. Abnormal fetal growth may prompt referral to a specialist for ongoing pregnancy care. The pregnancy should be managed according to both maternal and fetal well-being. At gestations, less than 28 weeks this may present difficult decisions for clinicians and patients, but all decisions should be made in collaboration with the wider team and clearly documented. Consideration to thromboprophylaxis may also be required based on risk stratification, BMI, intervention status and hypostasis during hospital admissions [4].

Adverse outcomes should be reported and investigated in a robust manner with sharing of learning for all staff involved and dissemination to the wider team for ongoing education. Any investigation reports should be shared with parents in an open and honest manner.

21.4 Reasons for Litigation

- Failure to appropriately risk assess at booking
- Failure to offer low dose aspirin in high-risk women
- Failure to manage women with underlying medical problems jointly with an appropriate physician
- Failure to measure blood pressure and perform urinalysis at each antenatal visit
- Failure to respond appropriately to patient symptoms including headache, oedema and epigastric pain
- Failure to instigate appropriate treatment
- Failure to recognise the need for both maternal and fetal monitoring
- Failure to offer delivery in women with worsening pre-eclampsia or essential hypertension with superimposed pre-eclampsia
- Failure to offer monitoring in an obstetric high dependence unit post delivery
- Failure to continue to observe women with hypertension in the postnatal period including blood pressure and fluid input/output
- Failure to instigate a follow up plan for women discharged back to primary care

21.5 Avoidance of Litigation

Most claims arise from delay in diagnosis, delay or failure of treatment or negligent treatment. They relate either to maternal or neonatal injury, cerebral palsy, loss of a baby or loss of maternal life. These events require formal investigation as per local and national guidance.

The commonest cause of maternal death in hypertensive pregnancy is subarachnoid haemorrhage (SAH). The most sensitive and specific symptom for SAH is the suddenness of the onset of the headache, rather than its severity or location. Small herald subarachnoid bleeds present with sudden-onset headache hours to days before the fatal bleed, and the clinical art is to detect the herald bleed allowing the neurosurgeon or vascular radiologist to secure the small berry aneurysm and prevent the big bleed. Only 10% of sudden onset headaches will turn out to be SAH, but all sudden-onset headaches require investigation by CT and lumbar puncture if the latter is negative. This means accepting that 90% of your CT/LP investigations will be negative, but that this is worthwhile to detect the 10% which are positive. All headaches in pregnancy requires careful evaluation, especially in hypertension. Some causes of headache are listed in Table 21.1.

For patients presenting with hypertension in pregnancy consideration must be given to the pos-

Table 21.1 Causes of headache in pregnancy with symptom clues

Pre-eclampsia (but beware sudden onset headache)
Migraine (visual or epigastric aura)
Tension headache
Dehydration
Post dural headache (worse on standing)
Head trauma
Cerebral venous thrombosis
Intracranial hypertension (vomiting)
Subarachnoid haemorrhage (sudden onset)
Ischaemic stroke
Vasculitis
Brain tumour (worse on wakening)
Benign intracranial hypertension (obesity, pulsatile tinnitus)
Meningitis/encephalitis (neck stiffness, pyrexia or hypothermia, altered consciousness)
Sinusitis
Cranial neuralgias
Pituitary apoplexy (tunnel vision)

sibility of hypertension secondary to an undiagnosed medical condition. Clinicians should look out for the characteristic sodium/potassium patterns in Cushing's, Conn's, primary and secondary hyperaldosteronism and renal artery stenosis. Consider radio femoral delay and ventricular heave in coarctation of the aorta and consider the palpitations and diaphoresis of phaeochromocytoma. All clinicians should be aware that the increased blood flow and haemodilution of pregnancy resets the normal reference range downwards for urea and creatinine when assessing renal glomerular function. In ultrasound, look out for the small smooth kidneys of chronic glomerulonephritis or the small irregular scarred kidneys of 'chronic pyelonephritis' (chronic vesioc-ureteric reflux). Adult polycystic kidneys carry an additional risk of subarachnoid haemorrhage.

Appropriate investigations need to be instigated in these scenarios with involvement from other non-obstetric physicians. Common pregnancy symptoms may also mimic more sinister diagnoses. For example, epigastric pain is common in normal pregnancy presumably due to mechanical and hormonal factors. But foregut structures like the liver refer pain to the epigastrium, so it may be due to liver involvement in pre-eclampsia or HELLP syndrome (as well as gastritis, gastric ulcer, pancreatitis or gallstone disease). There may be evidence of haemolysis in the form of rising bilirubin, falling haemoglobin, rising reticulocyte count (with rising MCV and RDW), falling haptoglobin and the presence of haemoglobin in the urine. Haemoglobinuria will show on a dipstick as a smooth positive on the blood window, not to be confused with haematuria which shows as a speckled positive. In pre-eclampsia, the transaminases may be elevated due to hepatocyte *structural* damage, whereas hepatocyte *functional* damage may be seen in abnormal glucose, bilirubin, albumin levels and deranged clotting indices.

In women with orthopnea and paroxysmal nocturnal dyspnea consideration should be given to pulmonary oedema. In preeclampsia, this results from the reduced oncotic pressure from the hypoalbuminaemia of haemodilution and impaired hepatic synthesis combined with myocardial dysfunction and increased vascular permeability, and can be fatal if excess fluid is given.

Once a diagnosis of hypertension in pregnancy has been made a clearly documented management plan should be constructed detailing frequency of monitoring for both mother and baby, treatment regimens and the timing and mode of delivery. A multi-disciplinary approach with early involvement of anesthetic staff, intensivists, haematologists and neonatologists will improve outcome in sick patients. Most importantly delivery should be planned with stabilisation of the maternal condition prior to commencement of surgical intervention.

21.6 Case Study

AW v Greater Glasgow Health Board [2015] ScotCS CSOH_99

Mrs. AW was a 30-year-old healthy non-smoker in her first pregnancy whose antenatal care was booked with the community midwives. Around 30 + 6 weeks, she developed tiredness, headaches, facial swelling and blurred vision.

Community midwives made an appointment to visit her at home at 31 + 2 weeks but they did not appear. A new home visit appointment was

made for 2 days later, when they phoned to say they would be delayed but again did not appear. The midwives attended a further 2 days later, and Mrs. AW explained her symptoms, as well as an altered pattern of fetal movements. The midwife reassured her that many of these symptoms were common in pregnancy. The patient and her husband noted that the two attending midwives had just been attending a home birth, and that their mood was 'jokey with lots of banter', with them referring to Mrs. AW as the 'boring patient'.

Both Mrs. AW and her husband stated that no measurement of blood pressure or urinalysis was performed by the midwives, and there is no record of blood pressure in the case notes. The urinalysis section of the notes has the abbreviation 'c/c' which the midwife stated in Court meant 'clear of sugar, clear of protein'. On hearing evidence under cross-examination in Court, the Judge determined that the Claimant was correct in that no blood pressure or urinalysis was performed by the midwives, despite the midwives' insistence to the contrary.

At 32 + 2 weeks, Mrs. AW reported her symptoms to the physiotherapist at an antenatal class, who arranged immediate medical assessment. Mrs. AW had an ultrasound scan of the baby showing growth restriction, abnormal Dopplers and an impaired biophysical profile. She was also found to be hypertensive with single plus proteinuria on dipstick testing. Immediate delivery was performed by caesarean section after stabilisation of her blood pressure. Unfortunately, her son went on to develop cerebral palsy.

After hearing 51 days of evidence, from 30 witnesses, including four obstetric experts, as well as experts in midwifery, neonatology, paediatric neurology and neuroradiology, the Judge decided that there was a clear breach of duty on the part of the midwives for not measuring and recording blood pressure, urinalysis or responding to Mrs AW's symptoms. However, the case failed on causation as the Judge found the cause of the cerebral palsy was longstanding fetal growth restriction, and that the Claimant had not successfully proven to the Court that early delivery would have improved the outcome. The four eminent obstetric experts had vastly different opinions. The outcome was upheld at appeal in 2017. The enormous time, emotion and expense could have been avoided by the simple recording of blood pressure and urinalysis.

Key Points: Pre-eclampsia and Hypertension

- Familiarity with national and local guidelines by midwifery and obstetric staff
- Appropriate care pathways for community midwives and GPs
- BP and urinalysis at every visit for all pregnant women
- Recognition of relevant symptoms
- Appropriate investigation of sudden onset headache
- Exclude other neurological causes of headache
- Orthopnea and paroxysmal nocturnal dyspnoea may suggest pulmonary oedema
- Timely follow up and response to blood results
- Appropriate escalation pathway for BP or symptoms crossing thresholds
- Senior Obstetrician to make care plan in conjunction with woman
- Appropriate timing and mode of delivery
- Accurate documentation and retention of data

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Umbilical Cord Prolapse

22

Susana Pereira and Edwin Chandraharan

22.1 Background

Umbilical cord prolapse (UCP) occurs when the umbilical cord descends through the cervix and either lies beside the presenting part (occult) or beyond it (overt) in the presence of ruptured membranes [1]. Cord presentation occurs when the cord is present between the presenting part and the cervix with or without ruptured membranes. The overall incidence varies between 0.1 and 0.6% of pregnancies [2]. The incidence may be as high as 1% in breech presentations. There is some evidence that the incidence has reduced over the last 40 years due to the reduction in grand multiparity and the rising rates of caesarean section [2]. UCP is a major obstetric emergency and may be associated with increased rates of perinatal morbidity and mortality. Perinatal mortality is associated with prematurity and congenital fetal malformations. Perinatal morbidity is primarily due to fetal birth asphyxia. Birth asphyxia occurs by either compression of the umbilical cord and/or vasospasm in the umbilical artery. This appears to be an all or nothing event, either causing a major neurodevelopmental impact or little in the way of cerebral injury [2]. Perinatal death is also seen in term babies especially when a diagnosis of UCP is made at home. Adverse outcomes are reported when transfer to the hospital is delayed. The management of UCP is one of the labour ward minimum data set skills required by the Clinical Negligence Scheme for Trusts (CNST) in England, Welsh Risk Pool in Wales and the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) in Scotland.

22.2 Minimum Standards

There are a number of risk factors for UCP that are listed in Table 22.1. Obstetric interventions are a significant factor and may play a part in up

Table 22.1 Risk factors for umbilical cord prolapse

General	Procedure related
Multiparity	ARM with high presenting part
Low birthweight <2.5 kgs	Manual rotation with ruptured membranes
Preterm labour <37 weeks gestation	External cephalic version
Congenital fetal anomaly	Internal podalic version
Breech presentation	Stabilising induction of labour
Transverse, oblique, unstable lie	Insertion of intrauterine pressure catheter
Second twin	Balloon catheter induction of labour
Polyhydramnios	
Free presenting part	
Low lying placenta	

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to 50% [3]. There is an increased risk associated with external cephalic version (ECV), internal podalic version, manual rotation and artificial rupture of membranes when the presenting part is free. These interventions should be discussed with the woman and the associated risks clearly documented. For those women at an increased risk of UCP, hospital admission is recommended; unstable or transverse lie from 37 weeks gestation or prelabour rupture of membranes where the baby is not cephalic. Clinicians should avoid performing amniotomy when the presenting part is high. Amniotomy with a high presenting part should be performed where there is immediate recourse to emergency caesarean section. When there is a cord presentation with intact membranes delivery by caesarean section is usually indicated.

The management of UCP will depend on the setting in which it occurs. In the hospital environment when UCP is diagnosed before full dilatation of the cervix caesarean delivery is indicated. There should be minimum handling of the umbilical cord to prevent vasospasm of the umbilical artery. The presenting part can be elevated manually or by filling the bladder and a knee-chest position may also alleviate cord compression. For cases where there are fetal heart rate abnormalities in the presence of uterine activity tocolytics agents such as terbutaline can be used [4], however these manoeuvres should not delay delivery. When UCP occurs at full dilatation the practitioner has the option of instrumental delivery if this can be performed safely and quickly. If cord prolapse occurs following internal podalic version of the second twin, breech extraction may be indicated. Due to the risks of fetal acidosis a neonatal team should be present at delivery and paired umbilical cord gases should be taken. In a community setting immediate transfer to the nearest consultant unit in the knee-chest position with either manual elevation of the presenting part or elevation by filling the urinary bladder should occur.

Where UCP occurs at the limits of viability between 23 and 24 + 6 weeks detailed discussions should occur between the parents and both the obstetrician and the neonatal team. Expectant management is usually the main stay of management. There is no evidence for manually replacing the umbilical cord within the uterine cavity.

22.3 Clinical Governance Issues

The diagnosis and acute management of an UCP can be a very traumatic event for the woman and her family. The parents should be fully debriefed by the obstetrician explaining the reasons why the UCP occurred whether it was predictable and the reasons for emergency management.

All staff caring for pregnant women should receive regular emergency drill training in the management of all obstetric emergencies including UCP [5]. Emergency drill training will reduce the decision to delivery interval and improve neonatal outcomes [6]. All cases should be reported via the risk management pathway as a clinical incident. This is a CNST requirement in England. The NHS resolutions report looking at the litigation cases where babies developed cerebral palsy were critical of route cause analysis investigations. Their recommendations included increased involvement in the investigation process for patients and their families, improved support for staff involved in difficult cases, polarisation of reports focusing on system changes that are more likely to improve outcomes and for independent external reviews to occur to ensure a robust and fair process [7].

Litigation cases are much more difficult to defend where there is evidence of poor documentation as often occurs in an acute emergency situation. The RCOG advocate the use of preformatted scribe sheets to improve the documentation in obstetric emergency scenarios. These accurately record the personnel present and the timings for the individual manoeuvres [1].

22.4 Reasons for Litigation

- Failure to recognise antenatal risk factors
- Failure to recommend hospitalisation in high risk cases
- The performance of amniotomy with a high presenting part or in breech presentations

- Failure to document risks of UCP as a result of obstetric manoeuvres such as ECV, internal podalic version and manual rotation
- Failure to perform controlled ARM in high risk cases such as polyhydramnios
- Delayed in the diagnosis of UCP
- Excessive handling of the cord leading to vasospasm
- Delayed transfer to theatre for delivery
- Delay in achieving delivery
- Failure to ensure neonatal resuscitation team present at delivery

22.5 Avoidance of Litigation

It is important to anticipate umbilical cord prolapse when risk factors are identified, which include polyhydramnios, preterm delivery, breech delivery, multiple pregnancy or a 'non-engaged presenting part' during labour (i.e. cases where there is an 'ill-fitting' presenting part). Careful examination immediately after rupture of membranes may help in timely diagnosis. The CTG trace may show repetitive atypical variable deceleration or a single prolonged deceleration, which may culminate in a terminal bradycardia secondary to the total occlusion of the umbilical cord. If the cervix is fully dilated, an urgent operative vaginal delivery should be carried out immediately. If this is not possible or if the cervix is not fully dilated, an immediate 'Category 1' caesarean section should be carried out. Measures to improve fetal oxygenation by avoiding compression of the prolapsed umbilical cord should be attempted if the fetus is found to be alive. The umbilical cord should not be handled to avoid causing spasm of the umbilical blood vessels. If the operating theatre is occupied or if there is an anticipated delay in transferring to the operating theatre, acute tocolysis should be employed to abolish ongoing uterine contractions so as to relieve repetitive or sustained compression of the umbilical cord [4].

Human factors play a crucial role in optimising intrapartum outcomes and the Human WORM (deficiencies in Workmanship, Omissions, Relationships and Mentorships) have been reported to contribute to approximately 80% of serious incidents in obstetric practice [8]. Intense staff training to reduce 'workmanship' errors, learning from root cause analysis to avoid 'omissions', improving effective team working and communication and appropriate and timely senior input are essential to reduce the adverse impact of human factors.

Regular skills and drills, improvement in knowledge of fetal physiology and detailed record keeping and documentation as well as addressing the human factors may help minimise the errors and the likelihood of litigation. Many of these incidents may be preventable by identifying system failures during intrapartum care and then ensuring timely and appropriate corrective action. In order to achieve a 'medico-legal risk free' environment, it is vital to have an open culture towards human error, to investigate the incidents and learn from them (Fig. 22.1) [9].

22.6 Case Study

Mrs. P was in her third pregnancy having had two previous uncomplicated vaginal deliveries. At 38 weeks, she was found to have an unstable lie and was admitted to hospital due to the risk of umbilical cord prolapse. Mrs. P went into spontaneous labour at 39 + 6 weeks gestation, her baby was in a transverse lie. A specialist registrar examined Mrs. P in view of regular uterine contractions every 5 min. On vaginal examination, the cervix was 3 cm dilated, with the membranes intact. The doctor contacted the Consultant on call by telephone who recommended an external cephalic version (ECV) followed by artificial rupture of membranes. The specialist registrar attempted an ECV and the membranes ruptured leading to an umbilical cord prolapse. The doctor attempted to push the fetal head up to reduce the risk of cord compression. The case was again discussed with the on-call Consultant. The Consultant advised he would attend with a view to perform either an instrumental delivery or a caesarean section. There was 40-min delay from the time of the diagnosis of cord prolapse to delivery by emergency caesarean section.

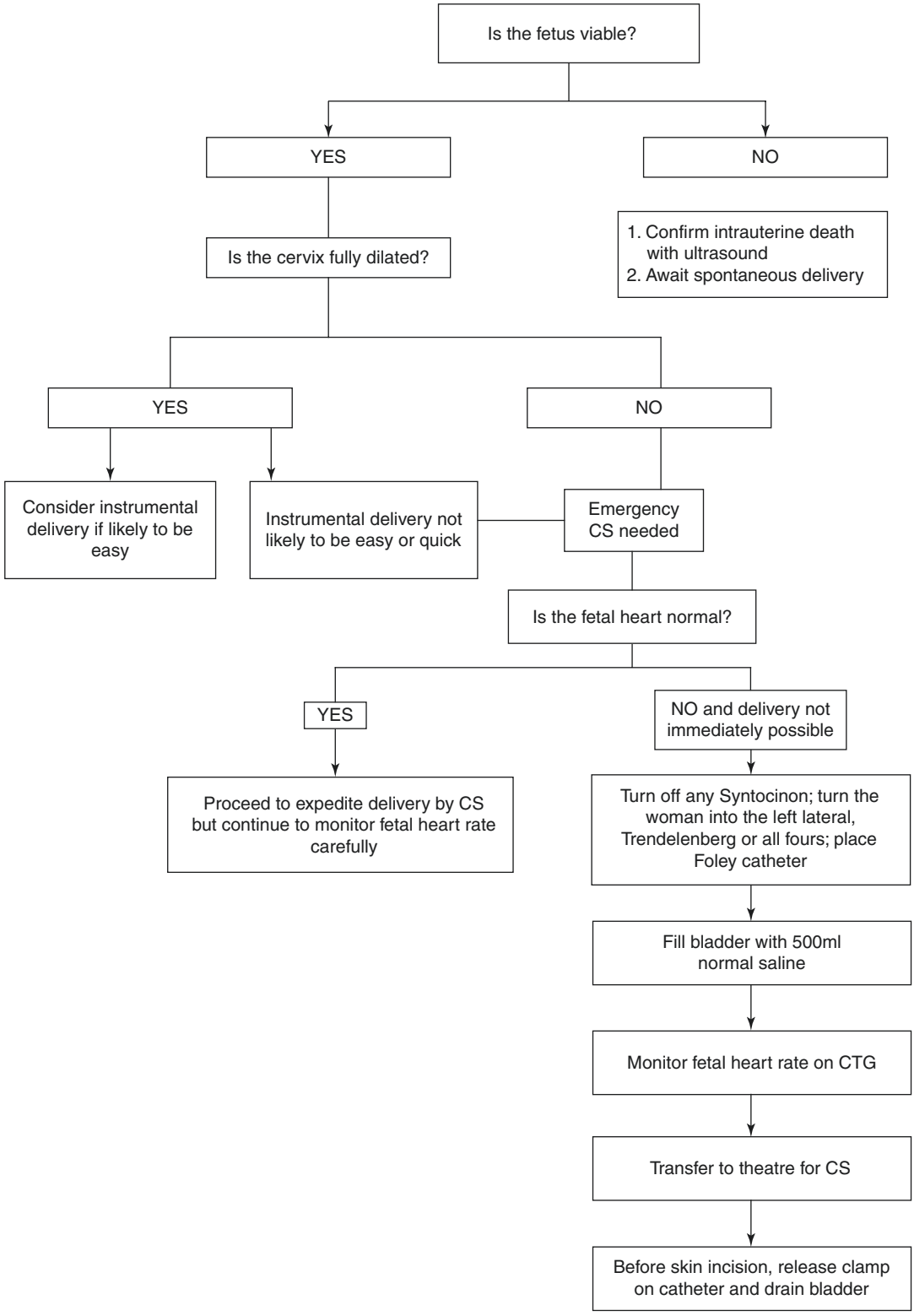

Fig. 22.1 Algorithm for management of umbilical cord prolapse. MOET Handbook third edition 2014 [10]

The baby was born in poor condition with Apgar scores of 4 at 1 min, 6 at 5 min and 7 at 10 min. The baby was admitted to the neonatal unit and suffered seizures within the first 12 h of life. The baby required transfer to a tertiary neonatal unit for cooling. He suffered profound birth asphyxia and has consequently developed athetoid cerebral palsy.

The Judge ruled in the Claimant's favour due to a failure of the obstetric team to arrange adequate plans for delivery following Mrs. P's admission. It was alleged that had an experienced obstetrician devised a management plan for the delivery, an elective caesarean section would have been advised. In that event, neither cord prolapse nor any brain injury would have occurred. In the alternative, it was alleged that if a stabilising induction and artificial rupture of membranes was appropriate, proper preparations for delivery by caesarean section would have been made. In that scenario, it was alleged that had umbilical cord prolapse occurred, the baby would have been delivered by caesarean section well before any injury to his brain. As a consequence of the negligence the boy now suffers from involuntary movements affecting his arms and legs and cannot stand and walk. Nor can he use his arms effectively in many circumstances. The hospital admitted that the actions of the doctors were negligent. During the course of the legal action, various offers were made that culminated in an offer of £5 million. As the Claimant preferred a periodical payment scheme, the hospital made an alternative offer in the form of a £1.3 m sum, together with periodical payments of £120,000 each year.

Key Points: Umbilical Cord Prolapse

- Identify antenatal risk factors for UCP
- Hospitalise women with unstable and transverse lie from 37 weeks
- Ensure amniotomy is indicated and the presenting part is fixed in the pelvis
- Be aware that certain obstetric interventions increase the risk of UCP such as ECV, internal podalic version and stabilising induction
- For women at risk of UCP where amniotomy is indicated ensure immediate access to category 1 caesarean section
- Be familiar with the manoeuvres required to reduce cord compression
- If UCP occurs at full dilatation consider instrumental delivery
- If UCP occurs at incomplete cervical dilatation perform category 1 caesarean section
- Ensure neonatal team present at delivery
- Accurate documentation using a preformatted scribe sheet
- Ensure staff training in obstetric emergencies

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Fetal Growth Restriction (FGR)

23

William L. Martin

23.1 Background

In essence, fetal growth restriction (FGR) may be placentally mediated, or not. FGR due to non-placental problems is likely to have an early onset and thus lead to a symmetrically small baby, with the head circumference (HC), abdominal circumference (AC), femur length (FL) and estimated fetal weight (EFW) all below the 10th centile. The aetiology is more likely to be a genetic or chromosomal issue, or congenital infection with early onset FGR. Placentally mediated problems usually manifest later and thus are more likely to lead to asymmetric FGR with the HC and FL preserved but the AC and EFW measuring less than the 10th centile.

Babies born weighing less than the 10th centile for gestation are referred to as small for gestational age (SGA). Of these, the majority will be constitutionally small but around 30% will have FGR or intrauterine growth restriction (IUGR) and be at higher risk of adverse outcome. It is important to appreciate that some babies born over the 10th centile will have failed to reach their full growth potential and thus are at similar risk of adverse outcome as a baby with FGR born below the 10th centile.

It is the identification of genuine FGR that is the holy grail of antenatal care. Once identified, underlying causes for FGR need to be sought. Ultimately timely delivery is the aim of management, after steroids and magnesium sulphate, if appropriate. These currently remain the only treatment options.

In managing these cases, it is important to follow local guidelines, which should be based on the Royal College of Obstetricians and Gynaecologists (RCOG) Green-top guideline Number 31 [1]. Irrespective of the underlying cause of FGR, the diagnosis and management may be difficult. The majority of FGR babies will be normal, small babies that will survive to term. To over-investigate may medicalise a pregnancy and cause a couple significant psychological stress. To under-investigate, however, could lead to intrauterine death or delivery of a compromised baby that failed to cope with labour due to placental insufficiency. This would clearly be a much worse outcome for a couple. If accepted practice is followed, then litigation through mishap will be minimised, and any actions taken defensible.

23.2 Minimum Standards

The causes of FGR are many and varied and the definitions used are similarly diverse, making for abundant, but often confusing literature. The

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standard of management of these babies has thus been variable. Babies with FGR feature disproportionately in perinatal mortality statistics, with 50% of unexplained stillbirths being less than the 10th centile. Reducing still birth is a mandated directive from the government to NHS England forming part of the NHS business plan 2015–2016. The NHS England "Saving Babies' Lives" care bundle is an integral part of reducing stillbirth rates with risk assessment and surveillance for FGR a key element of the care bundle [2].

The RCOG green-top guideline is a comprehensive distillation of the current evidence available at the time of writing, relating to SGA babies and thus should be the basis for local guidelines for the detection and management of SGA. Any reasons for variance in those guidelines from established practice, should be clearly documented and agreed at senior level in the Trust.

The guidelines propose an assessment tool to be applied to all pregnancies at booking to aid identification of pregnancies at high risk for FGR (Fig. 23.1). The guideline also discusses how established SGA should be managed. There is also an algorithm that summarises the management of these patients (please see Fig. 23.2).

Screening of all pregnant women should be offered. The optimal methods of screening are crude meaning that only 50–60% of cases will be identified at best. Screening utilises history (for example of a previous FGR baby, maternal smoking or maternal medical problems); examination using symphysis-fundal height (SFH) plotted on population or customised growth charts; and investigation, such as serial growth scans and Doppler velocimetry. Once FGR is suspected, further management should be directed to establishing a cause, monitoring the pregnancy; treating with steroids and magnesium sulphate and timing the delivery.

23.3 Clinical Governance Issues

Adherence to the local guidance should be audited to include detection rates. Accepting that ultrasound for estimated fetal weight has a sub-

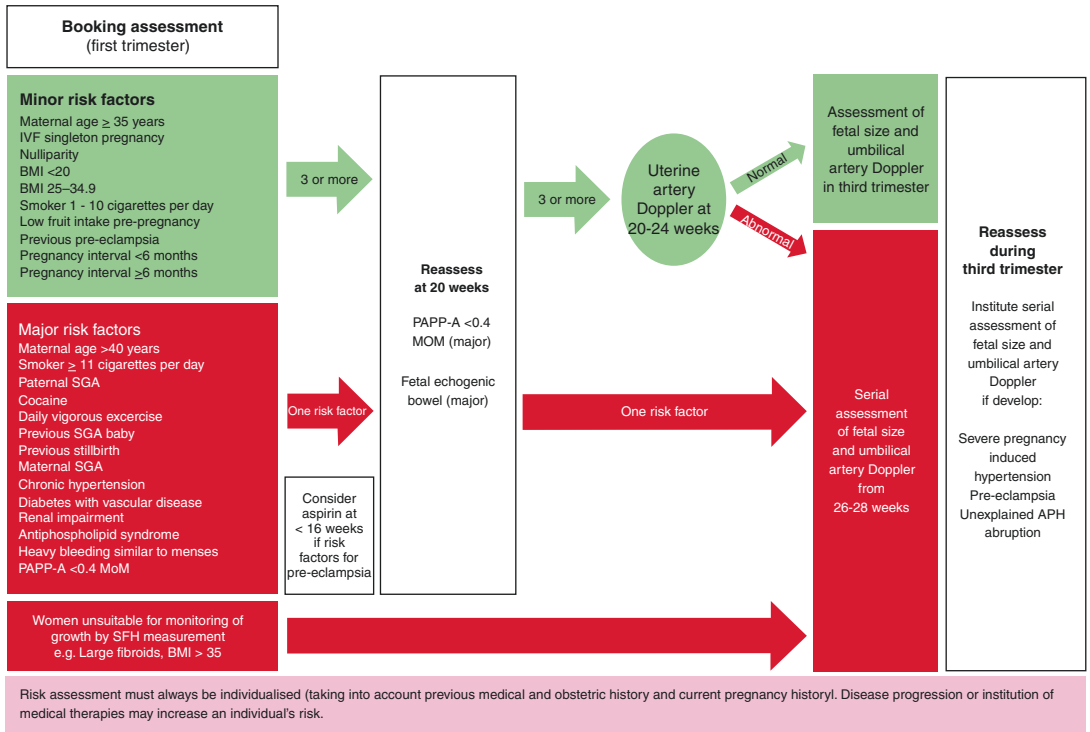

Fig. 23.1 Screening pathway for the small for gestational age baby (RCOG Green-top guideline No. 31)

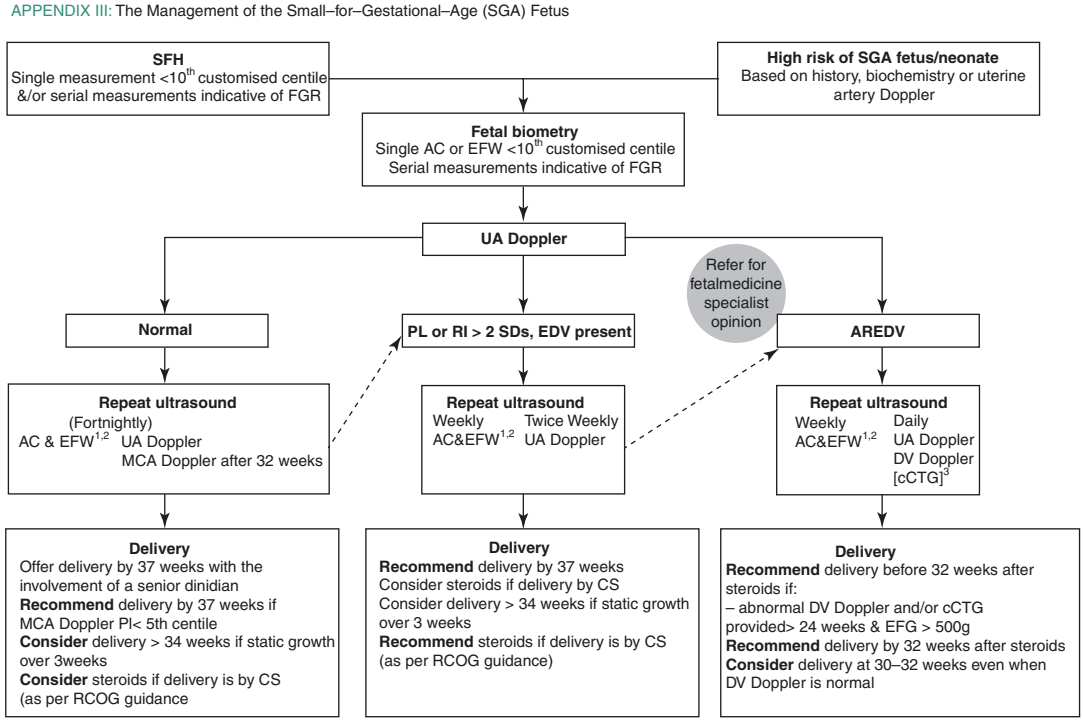

Fig. 23.2 Management of the small for gestational age baby (RCOG Green-top guideline No. 31)

stantial error of ±15–20%, then detection cannot be 100%, but is likely to be improved with regular image review, feedback to staff, and ongoing training of sonographers.

Regular, on-going audit of the detection of SGA should be carried out within every maternity unit. Benchmarking nationally would be ideal but relevant data collection is difficult and thus robust national detection rates (including false positive and negatives) do not currently exist. As such local targets are generally (and somewhat arbitrarily) developed.

Risk reporting is an important part of establishing a culture of clinical governance within an organisation. Staff should feel they can report missed cases without risk of recrimination, and learn from feedback on their practice.

Training in the detection methods such as SFH use in screening for SGA or more advanced Doppler measurements in the management of suspected SGA, should be taught to relevant staff throughout an organisation by appropriately trained staff.

23.4 Reasons for Litigation

The number of claims related to SGA is small but potentially very costly if wrongful birth can be proved.

Reasons for litigation may include:

- Not following guidelines thus inadequate detection/management of SGA
- Lack of appropriate investigation
- Failure to identify SGA leading to stillbirth
- Failure to identify fetal anomaly or congenital infection as a cause of SGA
- Inadequate training of staff
- Failure to refer for a second opinion

- Not referring in a timely manner to an appropriate level of neonatal unit
- Poor documentation

23.5 Avoidance of Litigation

There are many controversial areas in the management of this group of patients, a full discussion of all of these is not possible here. Before discussing a couple of examples, it is worth considering that there are circumstances where management is not a source of significant debate but care is often found wanting. For example, the RCOG guideline makes the care of women at 37 weeks with a baby below the 10th centile quite clear. Once term is reached (at 37 weeks), induction should be offered. If this advice is not given and fetal or neonatal complications arise, there is little defence to offer. In the event that the patient declines the offer, a clear discussion of the risks including explicitly stating that stillbirth is a possible outcome by not following the advice should be undertaken. As always, contemporaneous documentation for that discussion should be recorded.

Two examples of more controversial areas for further consideration here are:

- very early onset FGR (<23 weeks) or suspected structural anomalies.
- delivery at extreme prematurity (<26 weeks) or very low (estimated) birth weight (<500 g)

In the first instance, the RCOG guideline recommends a referral for a detailed anomaly scan by a fetal medicine specialist to be offered. This may lead to the offer of further tests (invasive and non-invasive) and consultations with other specialists such as a geneticist, paediatric neurologist or neonatal surgeon. Findings may lead to difficult choices for the couple. Throughout, the counselling needs to be frank and comprehensible, with the various courses of action which may include continuing with or termination of pregnancy being made clear. It is important to ensure the couple understand the counselling, with the help of translators (not including relatives) where necessary. Failure to do so (and fully document), may lead to law suits for wrongful birth.

Ultimately the only "treatment" for FGR is delivery. After 32 weeks, this decision is relatively easy and the outcome likely to be favourable. However, perinatal outcome is predominantly determined by gestational age and fetal weight. They are especially important at early gestational age (<26 weeks); or when the estimated fetal weight is low, around 500 g. These are difficult circumstances in which the decision whether to deliver or not will need to be considered. Where time and availability permits, counselling should involve senior colleagues, fetal medicine subspecialists and especially neonatal colleagues. This will provide valuable information to help a couple come to an informed decision. Depending on the availability of the appropriate level of neonatal care, the place of birth is also important. It is well accepted that *in utero* transfer is better in terms of outcome than *ex utero*. The use of steroids and magnesium sulphate also should be discussed [3]. These are interventions for which there is a well-established neonatal benefit and to fail to use them appropriately (which may include not giving them too early) may be regarded as substandard care.

A decision in obstetrics is often dynamic and so should be reviewed regularly. A decision made a few days previously, may no longer be appropriate as a scan may demonstrate fetal growth over 500 g or a gestation is reached where it may be considered appropriate to give steroids, magnesium sulphate and to deliver.

Finally, on the often-repeated basis that: "If it's not recorded, it didn't happen" discussions should be comprehensively documented. A recurrent theme in unsuccessful defences is that documentation was poor and patient information and understanding was inadequate. The converse does not always hold true, but well recorded (legible), contemporaneous notes will aid a defense case.

23.6 Case Study

A 38-year-old woman in a consanguineous marriage (1st cousins) presented in the index pregnancy at 12 weeks for booking. This was her second pregnancy; her first baby was well grown.

She underwent an amniocentesis for maternal age, the result was normal. The 20-week anomaly scan was normal with all measurements above the 5th centile. At 26 weeks, a SFH measurement was 23 cm and at 30 weeks was 27 cm. In neither case was the measurement plotted on a customised growth chart (although there was one in the notes). There were normal fetal movements. At 34 weeks, the SFH was 31 cms, again the growth was not plotted. A junior doctor arranged for a growth scan but due to lack of availability it was done 2 weeks later. The HC, AC and FL were all on the 5th centile. Liquor volume was reduced (maximum pool depth 1.5 cm) and there was absent end diastolic velocity on Doppler examination of the umbilical artery. The patient was admitted and delivered by Caesarean section that day as the cervix was unfavourable. The baby's birthweight was less than the 10th centile. The child developed cerebral palsy.

A case was brought against the Trust for mismanagement of the pregnancy. Whilst it is clear that there were missed opportunities to offer ultrasound and the antenatal care was substandard, developmental delay was not felt by the neonatal expert to be due to antenatal events rather the likely diagnosis was a metabolic condition, thus the case was settled in favour of the Trust.

Key Points: Fetal Growth Restriction

- Each pregnancy should be assessed for risk factors for FGR and appropriate monitoring instituted to screen for and then manage FGR if identified.
- In early onset FGR (<23 weeks) or where fetal structural anomalies are suspected, referral should be made to a specialist in fetal medicine.
- Pregnancies may start as low risk and change to high risk, thus each antenatal contact should be used as an opportunity to reassess the assigned risk for that pregnancy.
- Steroids, magnesium sulphate, timing and place of delivery are the only treatment options in suspected FGR. Where the baby is suspected to be very small or very early in gestation, the decision to deliver will need to be made in consultation with the family, senior obstetrician (s) with referral to other specialists (such as fetal medicine and neonatal colleagues) as deemed necessary.
- Counselling should be comprehensive and comprehensible. Appropriate language should be used including, where necessary, translators.
- Documentation of all discussions and the decisions arising from them should be made. These decisions need to be reviewed regularly in light of any new information.

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Placenta Praevia, Placenta Accreta and Vasa Praevia

24

Jeremy Brockelsby

24.1 Background

Placenta praevia occurs when the placenta is inserted wholly or in part into the lower segment of the uterus. If the placenta lies over the internal os it is a major praevia, but if the leading edge of the placenta is in the lower segment, but not covering the internal os it is a minor or partial praevia. The reported incidence of placenta praevia is about 0.5% at term.

The morbidly adherent placenta describes three pathological variants where part of or all of placenta invades into the uterine wall (see Table 24.1); if this occurs then the placenta will then not undergo the normal physiological separation at the time of delivery. The incidence of placenta accreta is increasing and is reported to be around 1:550; studies have observed this is mirroring a rising caesarean section rate [1]. As well as previous caesarean section, other risk factors include any surgical interventions that increases damage to the uterine architecture including myomectomy, vigorous dilatation and curettage and Asherman's syndrome. Vasa praevia occurs when fetal vessels pass through the fetal membranes over the internal cervical os and below the presenting part of the baby unprotected by placental tissue or umbilical cord. This can occur secondary to a velamentous cord insertion or when the vessels run between the lobes of a bipartite placenta. The incidence is between 1 in 2000 and 6000 pregnancies [2]. Both placenta praevia and placenta accreta can lead to obstetric haemorrhage and its complications; coagulation defects, effects of massive transfusion, multi-organ failure, hysterectomy and surgical injury to adjacent structures. Maternal death can occur despite optimal planning, transfusion management, and surgical care. Vasa praevia carries a significant risk to the fetus if the vessels are ruptured.

Table 24.1 Classification of the morbidly adherent placenta

Type	Findings
Accreta	Invasion into the inner third of the myometrium
Increta	Invasion through the myometrium and serosa
Percreta	Invasion through the myometrium and serosa and into adjacent organs such as the bladder

24.2 Minimum Standards

All women should be offered placental site screening as part of their routine anomaly scan to exclude a low-lying placenta. In women with a low-lying placenta on ultrasound scan and a

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previous caesarean section, placenta accreta should be excluded. In asymptomatic women with a minor praevia on scan a follow up scan should be arranged at 36 weeks gestation. For asymptomatic women with a major praevia on the 20-week scan a further scan should be performed at 32 weeks. If the placenta remains within the lower segment these women should be seen and counselled by a senior obstetrician regarding the implications and possible risks including mode and timing of delivery. Women with a placenta more than 2 cms form the internal cervical os can opt for vaginal birth [2].

The main screening method is transabdominal ultrasound, although this has a false positive rate of up to 25% for placenta praevia. This has led to transvaginal ultrasound becoming the gold standard for accurate localisation of placental site where there is diagnostic uncertainty on transabdominal scanning. The ultrasound report must accurately document the relation of the placenta to the internal cervical os in cms and whether the placenta is anterior or posterior. This is important as the location of the placenta may influence the surgical approach and outcome. The anteriorly orientated placenta increases the risk of excessive blood loss and transfusion, as the surgeon may be required to cut through it at the point of delivery. Placenta praevia is important to diagnose, because it inevitably requires a caesarean section and potentially more radical surgical interventions such as hysterectomy. It is imperative that the patient is fully counselled for these complications.

Anterior placenta praevia with a previous caesarean section scar will also increase the risk of a morbidly adherent placenta. The risks of a morbidly adherent placenta increase with the number of caesarean sections or uterine surgery and the presence of a low-lying placenta; therefore, all women should be offered screening if they have these risk factors. This initial screening should be with ultrasound and be undertaken by an operator with experience in assessment of the placenta and its abnormalities. Grayscale ultrasonography has been demonstrated to be sensitive enough and specific enough for the diagnosis of morbidly adherent placenta. When colour Doppler and Three-dimensional power Doppler are added the detection rates increase further [3]. Over the last decade there has been increased utilisation of magnetic resonance imaging (MRI) as a diagnostic tool. However, studies comparing these modalities have failed to demonstrate any added maternal benefit over ultrasound [3]. It may be useful where ultrasound is technically difficult such as in the obese patient.

Any cases where the diagnosis of placenta accreta has been raised and there are suspicious ultrasound or MRI findings, should be managed as such. Caution at the time of operation is preferable to being unprepared. The diagnosis of the morbidly adherent placenta prior to delivery allows multidisciplinary planning with the aim of minimising both the maternal and neonatal morbidity and mortality.

For both placenta praevia and placenta accreta the antenatal prevention and treatment of maternal anaemia is recommended by the RCOG [2], in view of the risks of haemorrhage at the time of delivery. Outpatient management is the preferred option for women and has been shown to be safe [3]. However, both the RCOG [2] and Royal Australian and New Zealand College of Obstetricians and Gynaecologists [4] recommend that women at risk of antepartum haemorrhage should remain close to the hospital in the third trimester. However, neither defines a geographical limit and this remains the decision of the clinician and the patient. As a rule, asymptomatic women who have a minor placenta praevia may be managed as an outpatient and women with a major praevia who have bled previously are advised admission from 34 weeks.

For both placenta praevia and placenta accreta problems arise when these patients present out of hours, either due to haemorrhage or a missed antenatal diagnosis. For those women in whom the diagnosis is known there should be a clear management plan outlined in the antenatal and maternity notes. Consultant staff should be informed and attend as soon as possible. Resuscitation follows the basic principles of airway, breathing, and circulation. Two large bore cannulas should be inserted to allow rapid blood transfusion and fluid resuscitation. The

availability of blood and blood products is mandatory with a low threshold for escalation to the major obstetric haemorrhage protocol.

Although risk factors allow the identification of most cases during the antepartum period, the diagnosis is occasionally discovered at the time of delivery. If this is the case then the surgical team has no option but to expedite delivery, unless there are no maternal or fetal concerns when it would be reasonable to halt and summon the appropriate personal to attend theatre, with the aim of reducing the maternal morbidity. Even when it is not safe to pause it is essential that all relevant on call staff are summoned as a matter of urgency as these cases can become complicated from an early stage.

There are a number of surgical approaches that may be employed for placenta praevia and placenta accreta. In general, opening the uterus at a site distant from the placenta and delivering the baby without disturbing the placenta is preferred [2]. This will allow conservative management of the placenta or elective hysterectomy if placenta accreta is confirmed [2]. Delivering through the placenta results in increased blood loss and a higher chance of hysterectomy. In some instances, conservative management of placenta accreta may be possible with local resection, however in women in whom there is already bleeding, conservative treatment is unlikely to be successful. In women where the placenta does not separate following delivery it is preferable to leave the placenta in situ and close the uterus. These women can be managed conservatively or by hysterectomy; both of these options are associated with a reduction in blood loss [5]. Where the placenta partially separates the placenta will need removal. Adherent portions may be left in situ, but blood loss can be torrential. For women in whom placental tissue is left behind they should be warned of the risks of infection and further haemorrhage. Surgical management must be individualised and although, planned delivery is the goal, a contingency plan for an emergency delivery should be developed for each patient, which would incorporate a local protocol for the morbidly adherent placenta and the management of massive obstetric haemorrhage.

Vasa praevia is unlikely to be diagnosed clinically in women who are asymptomatic although occasionally the fetal vessels are palpated through the membranes on vaginal examination. In the presence of bleeding following membrane rupture delivery should not be delayed as rapid fetal exsanguination will occur. Vasa praevia can be diagnosed reliably with colour Doppler ultrasound [6]. The diagnosis should be confirmed on transvaginal ultrasonography and repeated in the third trimester as 15% of cases may resolve [7]. Cases of vasa praevia confirmed in the third trimester should have antenatal admission from 28 to 32 weeks [2]. Delivery should occur by elective caesarean section.

24.3 Clinical Governance Issues

Detailed consent should be taken antenatally and should include the RCOG guidance for consent to caesarean section [8], but in addition women should be warned that the risk of massive haemorrhage is approximately twelve times more likely with a placenta praevia. The risk of hysterectomy is also increased and rises when associated with a previous caesarean section. In the pilot series of the RCOG care bundle [9] 33% of women required a hysterectomy. Silver et al. documented the link between the number of previous caesarean sections and the risk of placenta accreta, placenta praevia and hysterectomy documented in Table 24.2 [10].

Any woman with a known placenta praevia should be delivered by the most experienced obstetrician and anaesthetist on duty. As a minimum requirement during a planned procedure, a consultant obstetrician and anaesthetist should be present on delivery suite. Junior doctors should not be left unsupervised when caring for these women.

The diagnosis of morbidly adherent placenta prior to delivery allows multidisciplinary planning with the aim of minimising the maternal and neonatal morbidity and mortality. Multidisciplinary antenatal planning should include the following personnel; Consultant Obstetrician, Consultant Anaesthetist, Consultant Haematologist, Consultant

Table 24.2 Number of previous caesarean sections and risk of placenta accreta, placenta praevia and hysterectomy [11]

No previous caesarean sections	No of women	No with placenta accreta	Risk of placenta accreta if placenta praevia (%)	No of hysterectomies
0	6201	15 (0.24%)	3	40 (0.65%)
1	15,808	49 (0.31%)	11	67 (0.42%)
2	6324	36 (0.57%)	40	57 (0.9%)
3	1452	31 (2.13%)	61	35 (2.4%)
4	258	6 (2.33%)	67	9 (3.49%)
5	89	6 (6.74%)	67	8 (8.99%)

Gynae-Oncologist, Consultant Interventional Radiologist. A Consultant Urologist (if the bladder is considered to be involved) and a Consultant Neonatologist if delivery is likely to be very preterm. The use of a care bundle for placenta praevia and accreta is now considered good practice. The key elements are documented in Table 24.3. All obstetric units should have locally or regionally devised protocols for the diagnosis, management and treatment of these patients. These should outline all the requirements for the safe delivery of this group of women, with both personnel requirements, surgical and radiological options. Ideally it would have an accompanying check list of personnel and equipment required for these births.

Clinical incident forms should be completed for all adverse events these will include all cases of massive obstetric haemorrhage, peri-partum hysterectomy and any unexpected admission to the intensive care unit. All cases should be examined after the event for learning and guidelines redesigned based on these observations.

Postnatal follow up should include a debrief surrounding the delivery, any complications or unexpected events and any implications for future pregnancy and fertility.

All staff involved in the care of these women should receive training with regard to massive obstetric haemorrhage and acute fetal compromise. Staff performing antenatal imaging should have adequate training in the screening, diagnosis and recognition of placental variants such as placenta praevia and placenta accreta, bi-lobed placenta, velamentous cord insertion and vasa praevia. There should be a robust referral pathway for the use of MRI where the ultrasound features suggest a morbidly adherent placenta.

Table 24.3 Care bundle for women with placenta praevia and placenta accreta

Consultant obstetrician planned and directly supervised delivery
Consultant anaesthetist planned and directly supervised anaesthetic at delivery
Blood and blood products available
Multidisciplinary involvement in pre-op planning
Discussion and consent includes possible interventions (such as hysterectomy, placenta left in situ, cell salvage and interventional radiology)
Local availability of a level 2 critical care bed

24.4 Reasons for Litigation

24.4.1 Placenta Praevia and Placenta Accreta

- Failure of diagnosis.
- Failure to adequately consent the patient.
- Failure to adequately prepare for the potential issues.
- Failure to prepare adequately for the surgery.
- Avoidable damage to adjacent organs—bladder/bowel
- Failure to involve a senior surgeon at an appropriate stage.
- No follow up of the patient

24.4.2 Vasa Praevia

- Failure to perform TV scan to confirm diagnosis
- Failure to repeat TV scan in the third trimester
- Failure to offer admission from 28 to 32 weeks gestation

- Delay in performing category 1 caesarean section following membrane rupture

24.5 Avoidance of Litigation

Imaging for placenta praevia and placenta accreta should be performed according to local and national guidelines [2]. Sonographers should be aware of the risk factors for placenta praevia and placenta accreta. Where appropriate images are not obtained transabdominally, a transvaginal approach should be employed. MRI scanning may aid diagnosis and a clear pathway for referral should be in place. Imaging for vasa praevia should include a colour Doppler transvaginal scan with a repeat examination in the third trimester.

Once the diagnosis has been made or suspected, women should be referred to a consultant Obstetrician for the detailed planning of delivery. Ideally there should be an agreed management pathway in place involving the multidisciplinary team.

The pathway should detail management options that would allow any competent clinician to manage these cases. These guidelines should have a clear list of the required personnel. Any case where placenta accreta has been raised as a potential and there are suspicious findings on either ultrasound scan or MRI, should be managed as such. These cases require a multidisciplinary approach with a planned caesarean section when all available staff can be present.

Women should receive detailed explanation of all the possible complications and management strategies including massive obstetric haemorrhage, cell salvage, blood transfusion, tamponade balloons, interventional radiology in women declining blood products, hysterectomy, retention of placental tissue and surgery to adjacent structures including bladder and bowel. The preferred management options should be detailed and written consent for any additional procedures obtained. Women generally seek compensation in view of the long-term complications that occur as a direct result of the surgical interventions that may be necessary. These may be unavoidable even with careful pre-operative planning but if planning has occurred and been comprehensively documented then the patient will consider that all has been done to reduce the risks.

Good communication with the patient during the pre-operative period will reduce litigation as patients will have their expectations managed; they will appreciate that this is a serious complication of pregnancy, which carries a high level of morbidity and potentially mortality. It is important that these patients are debriefed by a senior clinician who can address any unresolved issues.

24.6 Case Study

A 34-year-old woman was booked in her second on going pregnancy. A fetal anomaly scan was undertaken; this demonstrated that the placenta was within the lower uterine segment. Therefore, a further ultrasound assessment was arranged for 32 weeks. At this scan the placenta was documented as now not being low lying, however a succenturiate lobe was noted on the posterior wall of the uterus with the main body of the placenta on the anterior uterine wall. The fetal vessels connecting the two parts of the placenta appeared to pass over the uterine cervix; therefore, the possibility of vasa praevia was raised. In view of these ultrasound findings a further ultrasound assessment was arranged for 34 weeks, at this scan the question of a vasa praevia was again raised but no referral was made to the Obstetric team. At 39 weeks, the women went into spontaneous labour where upon she started to bleed per vaginum; she was rushed to hospital, where on arrival the fetal heart rate demonstrated a pathological pattern. An emergency Caesarean section was undertaken, at birth the baby was pale and unresponsive; fetal bloods demonstrated that the baby was profoundly anaemic. Resuscitation was initiated and the baby transferred to the neonatal unit; unfortunately, despite prolonged resuscitation the baby died 2 hours after birth. Placental histology demonstrated a placenta with a succenturiate lobe, connected with fetal vessels that had ruptured. The diagnosis of vasa praevia was confirmed.

Expert evidence was obtained to support the case that Defendant trust had negligently failed in its duty of care to the mother for the following reasons:

(a) To perform a transvaginal scan at either the 32 or 34 weeks scan that would have confirmed the diagnosis
(b) To plan an elective caesarean section at 37/38 weeks gestation following the diagnosis.
(c) Arranged inpatient management of this case from 34 weeks.

The Defendant Trust settled the case.

Key Points: Placenta Praevia, Placenta Accreta and Vasa Praevia

- All women should be screened for placenta praevia
- Screening for vasa praevia is not appropriate
- Vasa praevia should be confirmed on TV colour Doppler ultrasound with a repeat in the third trimester
- Women with confirmed vasa praevia should be offered antenatal admission in the third trimester and be delivered by elective caesarean section
- All women with risk factors for placenta accreta should have a detailed scan conducted by a person with the relevant expertise.
- All women with a placenta praevia should be counselled by an obstetrician with regard to risks and mode of delivery.
- All women where the diagnosis of a placenta accreta is raised should be managed as such.
- All women with either a placenta praevia or accreta should have blood products readily available.
- Consent for either praevia or placenta accreta should document all the risks for the procedure.
- Where possible these procedures should be undertaken electively with all relevant staff either in theatres or directly available.

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CTG Interpretation

25

Vikram Talaulikar and Sabaratnam Arulkumaran

25.1 Background

The NHS Litigation Authority (NHS LA) report 'Ten Years of Maternity Claims' has highlighted cardiotocograph (CTG) interpretation as a major source of litigation, with the main allegations focusing on the failure to recognise an abnormal CTG and act on it [1]. Failure to refer appropriately and poor documentation were also commonly recognised in the report. In the UK litigation arising from Obstetrics accounts for 60 to 70% of the total sum paid out by the NHSLA, but comprises only 26% of the workload. This disproportion occurs because claims relating to cerebral palsy and hypoxic damage may total in excess of £1 million due to the cost of lifelong care for a child with a severe brain injury.

25.2 Minimum Standards

Continuous fetal monitoring by CTG should not be performed on low risk women in labour. It is essential that Obstetricians be aware of the indications for continuous fetal monitoring. These include:

- Fetal growth restriction or fetal abnormality
- Maternal BMI >35
- Previous caesarean section
- Preterm labour
- Maternal diabetes
- Multiple pregnancy
- Maternal pulse >120 beats per minute
- Severe chorioamnionitis, sepsis or a temperature greater than 38 degrees in labour
- Severe hypertension (160/110 mmHg or above)
- Syntocinon use
- The presence of meconium stained liquor
- Vaginal bleeding occurring in labour
- Prolonged membrane rupture exceeding 24 hours
- Delay in the first or second stage in labour
- Regional anaesthesia
- Fetal heart rate below 110 beats per minute or above 160 beats per minute
- Polyhydramnios or oligohydramnios
- Decelerations heard on intermittent fetal auscultation

For women in whom continuous monitoring is required any decisions in labour should be made assessing the whole clinical picture rather than on the CTG alone. This will include antenatal and intrapartum factors, current fetal and maternal wellbeing as well as the progress of labour. The

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woman should have one to one care and an assessment of the CTG should be made regularly; hourly if the trace is reassuring, but more frequently if there are concerns.

The main principle for intrapartum CTG interpretation is to categorise the trace based on baseline fetal heart rate, variability greater than 5 beats per minute, the presence or absence of decelerations and the presence or absence of accelerations. CTGS should be categorised according to the NICE guidelines [2];

1. Normal or reassuring features
2. Non-reassuring features
3. Abnormal features

(See Table 25.1 for CTG classification according to NICE and management guidance)

If a CTG has abnormal features the clinician should try and establish possible causes and instigate corrective measures in an attempt to normalise the trace. Such measures will include a change in maternal position or mobilisation, encouraging fluid intake, administration of antipyretics, modification of contraction frequency in patients on oxytocin and consideration of tocolysis with Terbutaline. If the CTG continues to be suspicious or pathological the clinician should consider fetal blood sampling or to expedite delivery.

25.3 Clinical Governance Issues

CTG traces need appropriate interpretation and this can only be achieved with implementation of education and training. This training and education will form part of all mandatory training for both Midwives and Obstetricians annually. This may be achieved by Obstetric induction packages, monthly departmental morbidity or mortality meetings based on CTG review or via e-learning programmes such as StratOg by the RCOG or K2 teaching systems or by face-to-face workshops such as The CTG Master class. Where a CTG is difficult to interpret early involvement of senior colleagues should be encouraged. Strategies such as telemetry may allow earlier review of abnormal CTGs.

CTG tracings need to be of good quality and this may be affected by maternal body mass index or pain in labour. More advanced fetal monitoring systems such as Monica or STAN may help to achieve better quality tracings. In addition these systems are more helpful in distinguishing between maternal and fetal pulse rate, a common error encountered in litigation cases. It may be that external monitoring is not possible and that a fetal scalp electrode will improve the quality of fetal monitoring.

CTG tracings need to be adequately stored and kept as part of the patient record for up to 21 years. With the advent of the electronic patient record this will become more efficient allowing safer storage and a reduction in the deterioration of CTG traces over time. In addition CTGs need to contain unique patient identification with accurate timings and dates. This requires the CTG machine's inbuilt clock to be regularly checked and updated. CTGs must also have any significant events recording accurately upon them including examinations, bleeding, the presence of meconium, the placement of epidural anaesthesia etc.

Any maternity unit employing CTG monitoring must have twenty-four access to accurate fetal blood sampling via a microblood gas analyser. An abnormal fetal heart rate pattern may warrant fetal blood sampling and indeed serial samples if initial readings are normal, but the CTG abnormality persists.

Finally paired umbilical cord samples should be taken from all deliveries where there is concern for fetal wellbeing. These will include caesarean section in labour, instrumental deliveries and babies born with poor Apgar scores.

25.4 Reasons for Litigation

The reasons for litigation with CTG interpretation includes [2]:

- Misinterpretation of CTG traces
- Inappropriate or delayed response
- Failure to provide one to one care once a CTG is required due to inadequate staffing

– CTG recordings of inferior quality making accurate interpretation difficult
– Managing the patient according to the CTG and not taking into account the whole clinical picture
– Failing to perform regular reviews even on normal CTG traces
– Calling for senior input when the CTG is abnormal or difficult to interpret
– Failing to appreciate changes in the clinical scenario for example progress in labour, bleeding in labour or meconium staining of the liquor

Table 25.1 The NICE guidance for CTG classification is summarised in the tables below

	Feature		
Description	Baseline (beats/min)	Baseline variability (beats/min)	Decelerations
Normal/reassuring	100–160	5 or more	None or early
Non- reassuring	161–180	Less than 5 for 30–90 min	Variable decelerations: • Dropping from baseline by 60 beats/min or less and taking 60 s or less to recover, • Present for over 90 min • Occurring with over 50% of contractions OR Variable decelerations: • Dropping from baseline by more than 60 beats/min or taking over 60 s to recover • Present for up to 30 min • Occurring with over 50% of contractions OR Late decelerations: • Present for up to 30 min • Occurring with over 50% of contractions
Abnormal	Above 180 Or Below 100	Less than 5 for over 90 min	Non-reassuring variable decelerations (see row above):• Still observed 30 min after starting conservative measures • Occurring with over 50% of contractions OR Late decelerations • Present for over 30 min • Do not improve with conservative measures • Occurring with over 50% of contractions OR Bradycardia or a single prolonged deceleration lasting 3 min or more
NICE make the following recommendations for the management of CTG traces			
Category	**Definition**	**Interpretation**	**Management**
CTG is normal/ reassuring	All three features are normal/reassuring	Normal CTG, no non-reassuring or abnormal features, healthy fetus	• Continue CTG and normal care. • If CTG was started because of concerns arising from intermittent auscultation, remove CTG after 20 min if there are no non-reassuring or abnormal features and no ongoing risk factors.

(continued)

Table 25.1 (continued)

Description	Feature		
	Baseline (beats/min)	Baseline variability (beats/min)	Decelerations
CTG is non-reassuring and suggests need for conservative measures	1. non-reassuring feature AND 2. normal/reassuring features	Combination of features that may be associated with increased risk of fetal acidosis; if accelerations are present, acidosis is unlikely	• Think about possible underlying causes. • If the baseline fetal heart rate is over 160 beats/min, check the woman's temperature and pulse. If either are raised, offer fluids and paracetamol. • Start 1 or more conservative measures: – Encourage the woman to mobilise or adopt a left-lateral position, and in particular to avoid being supine – Offer oral or intravenous fluids – Reduce contraction frequency by stopping oxytocin if being used and/or offering tocolysis. • Inform coordinating midwife and obstetrician.
CTG is abnormal and indicates need for conservative measures AND further testing	1. abnormal feature OR 2. non-reassuring features	Combination of features that is more likely to be associated with fetal acidosis	• Think about possible underlying causes. • If the baseline fetal heart rate is over 180 beats/min, check the woman's temperature and pulse. If either are raised, offer fluids and paracetamol. • Start 1 or more conservative measures (see 'CTG is non-reassuring...' row for details). – Inform coordinating midwife and obstetrician. – Offer to take a FBS (for lactate or pH) after implementing conservative measures, or expedite birth if an FBS cannot be obtained and no accelerations are seen as a result of scalp stimulation – Take action sooner than 30 min if late decelerations are accompanied by tachycardia and/or reduced baseline variability. • Inform the consultant obstetrician if any FBS result is abnormal. • Discuss with the consultant obstetrician if an FBS cannot be obtained or a third FBS is thought to be needed.
CTG is abnormal and indicates need for urgent intervention	Bradycardia or a single prolonged deceleration with baseline below 100 beats/min, persisting for 3 min or more[a]	An abnormal feature that is very likely to be associated with current fetal acidosis or imminent rapid development of fetal acidosis	• Start 1 or more conservative measures (see 'CTG is non-reassuring...' row for details). • Inform coordinating midwife • Urgently seek obstetric help • Make preparations for urgent birth • Expedite birth if persists for 9 min • If heart rate recovers before 9 min, reassess decision to expedite birth in discussion with the woman.

Abbreviations: *CTG* cardiotocography, *FBS* fetal blood sample

[a]A stable baseline value of 90–99 beats/min with normal variability may be a normal variation (having confirmed that this is not the maternal heart rate); obtain a senior obstetric opinion if uncertain

– Inappropriate use of Oxytocin
– Poor documentation
– Poor communication and team working

25.5 Avoidance of Litigation

Litigation in this area will never be completely avoided, but there are some strategies to reduce risk. These include regular education and training for all staff either through mandatory training or external courses. Any CTG in labour needs to be formally classified according to NICE recommendations [2]. Suspicious or pathological CTGS need to be assessed and appropriate management instigated. It is of paramount importance that communication occurs between health professionals and when there is doubt escalation to a senior Midwife or Obstetrician should occur at an early stage. Other strategies to ensure more robust CTG interpretation include the introduction of 'buddying' systems and CTG stickers. In these cases CTGs are reviewed regularly by two professionals to ensure agreement with regard to classification and ongoing management, and a sticker in the patient's case record documents this review. Where there is a difference in opinion this will prompt a more senior review.

25.6 Case Study

Mrs. T was a 26-year-old teacher in her first pregnancy. During the antenatal period, she had a number of ultrasound scans that showed no obvious fetal abnormality with an appropriately grown baby with normal liquor and Doppler. At the final ultrasound scan at 38 weeks gestation a comment on the ultrasound suggested the placenta showed some calcification. The estimated fetal weight was on the 15th centile for gestational age. Mrs. T underwent induction of labour for post maturity. She was induced with prostaglandin gel followed by artificial rupture of membranes (ARM) and oxytocinon infusion. During labour the CTG was categorised as normal despite some periods where there was reduced variability. Mrs. T made good progress to full dilatation, she pushed for 1 hour and as delivery was not imminent was delivered by uncomplicated vacuum assisted delivery. A live female baby was delivered. The baby was noted to have poor tone at delivery with Apgar scores of 6 at 1 min and 7 at 5 min. Cord gases were normal. The baby was breathing spontaneously and did not require intubation. On examination, there was a small mark from the ventouse cup, but no evidence of subgaleal haemorrhage or cephalohaematoma. Subsequently the baby was found to have an absence of primitive reflexes and tendon reflexes, was dysmorphic and had a small ventricular septal defect. The baby showed seizures in the first 12 hours of life. The baby was diagnosed with severe hypotonic cerebral palsy with global developmental delay. A CT scan at 3 months of age showed no significant abnormalities in the brain parenchyma, but the suggestion of a small interventricular haemorrhage.

The parents brought a claim against the hospital based on:

1. Failure to consider placental calcification as abnormal and deliver by caesarean section
2. Failure to interpret the intrapartum CTG correctly and deliver by caesarean section
3. Failure to offer caesarean section due to meconium-stained liquor

The claim was successfully defended. The expert opinion was divided regarding the interpretation of the CTG, but overall the Judge believed there was no evidence to suggest an intra partum insult and that the baby had an underlying neurological condition that predated the pregnancy. The evidence for this was the normal CTG in labour, normal cord gases at delivery and an MRI and CT scan postnatally showing no evidence of hypoxic injury.

Key Points: CTG Interpretation

- Classification of CTGs into normal, suspicious and pathological is essential to plan appropriate management.
- Employment of simple measures such as change in maternal position, rehydration, treatment of pyrexia, reduction or stopping syntocinon infusion may convert the CTG to normal.
- Use of tocolytics may be indicated to improve uteroplacental bed perfusion and prevent the baby becoming hypoxic
- Immediate delivery is indicated in profound fetal bradycardia in excess of 9 min
- All staff members should have annual CTG updates

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Operative Vaginal Birth

26

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26.1 Background

Operative vaginal birth (OVB) as an intervention is undertaken with the purpose of enabling better maternal and/or neonatal outcomes than would result from the alternatives—a caesarean section or not intervening at all. OVB, when performed correctly, in an appropriate setting by an experienced and trained practitioner, usually results in better outcomes for women and their babies than a caesarean section. Compared to OVB, caesarean section performed at full cervical dilatation is associated with increased rates of; major haemorrhage (RR 2.8), prolonged hospital stay (RR 3.5) and admission to the neonatal intensive care (NICU) (RR 2.6). However caesarean section is associated with lower rates of neonatal trauma (RR 0.6) [1]. Moreover, operative vaginal birth, when successful requires reduced analgesia requirements, can be expedited more quickly [2] and women are much more likely (>80%) to have a spontaneous vaginal birth in their next pregnancy [3, 4]. In addition, repeat caesarean section may limit maternal choices in future pregnancies, increases the risk of abnormal placentation that carries significant maternal risks [5] and is associated with an increased risk of unexplained stillbirth in future pregnancies with a hazard ratio of 1.5 [6].

The rate of OVB in the UK is stable at around 12% of total births per annum. This correlates to around 70,000–80,000 women having an OVB within the UK every year—a significant group of women and babies and it is therefore important that obstetricians know how to, and are able to, provide good patient care in this high-risk environment. Furthermore, poorly performed OVB has a significant litigation cost: each case settled by NHS Resolution, between April 2000 and March 2010, had a mean value in excess of £580,000 [7], and accounted for 3% of all maternity claims by value (not including those in which the baby developed cerebral palsy due to failures in duty of care during an OVB).

26.2 Minimum Standards

OVB can often be the best option for the mother and baby in the second stage of labour but it is essential that the accoucheur performs a careful, accurate and comprehensive clinical assessment to confirm that the prerequisite conditions are met for safe vaginal operative delivery. Furthermore, an OVB should be performed by a practitioner with the appropriate training,

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experience and skills, who can formulate and put in place appropriate back-up plans (such as access to a theatre), know when to discontinue attempts at delivery, and anticipate and manage any potential complications. The prerequisites for OVB have been identified by The Royal College of Obstetricians and Gynaecologists (RCOG) as seen in Fig. 26.1.

The operator should be aware that there are higher rates of complications, including failure, shoulder dystocia, haemorrhage and fetal injury associated with a maternal body mass index (BMI) >30, an estimated fetal weight > 4000 g, fetal malposition and a mid-cavity delivery or where head is 1/5th palpable per abdomen [8].

Operative vaginal births where any of the above factors are present should ideally be performed in an operating theatre where there is immediate recourse to caesarean section.

A practitioner's choice of instrument should be made on the basis of the clinical examination and their own personal experience and training [8]. However, within this there is considerable scope for tailoring of the instrument to the clinical situation, and a competent practitioner should be aware of the relative advantages and disadvantages of different instruments and communicate this, along with the rationale for choosing it, to the woman and her family prior to starting the procedure. The ventouse creates a negative pressure seal on the fetal head and uses this as an anchor point to apply traction. When compared with forceps delivery the use of the ventouse is more likely to fail and therefore require a secondary caesarean section (RR 1.7). In addition, there is a risk of cephalohaematoma (RR 2.4) and retinal haemorrhage (RR 2.0) [8]. However, a recent systematic review has found that although common, retinal haemorrhage at birth almost always resolves by 6 weeks of age [9]. The risk more commonly associated with forceps is an increased risk of maternal trauma (OR 1.6), however the use of forceps is more likely to achieve a vaginal birth than vacuum assisted delivery (OR 0.3) [8].

A rotational operative birth is any birth in which the orientation (position) of the fetal head requires correction by the obstetrician prior to delivery. These births are associated with a greater risk of failure [8, 10] and are acknowledged as being technically more complex requiring a sufficiently experienced operator [11]. However, despite this background, there is good evidence that in skilled hands rotational operative births are safer than the alternative (a caesarean section) [12]. Therefore, it is reasonable for these births to be attempted, provided certain criteria

Full abdominal and vaginal examination	Head is ≤1/5th palpable per abdomen vertex presentation. Cervix is fully dilated and the membranes ruptured. Exact position of the head can be determined so proper placement of the instrument can be achieved. Assessment of caput and moulding. Pelvis is deemed adequate. Irreducible moulding may indicate cephalo–pelvic disproportion.
Preparation of mother	Clear explanation should be given and informed consent obtained. Appropriate analgesia is in place for mid-cavity rotation deliveries. This will usually be a regional block. A pudendal block may be appropriate, particularly in the context of urgent delivery. Maternal bladder has been emptied recently. In-dwelling catheter should be removed or balloon deflated. Aseptic technique.
Preparation of staff	Operator must have the knowledge, experience and skill necessary. Adequate facilities are available (appropriate equipment, bed, lighting). Back-up plan in place in case of failure to deliver. When conducting mid-cavity deliveries, theatre staff should be immediately available to allow a caesarean section to be performed without delay (less than 30 minutes). A senior obstetrician competent in performing mid-cavity deliveries should be present if a junior trainee is performing the delivery. Anticipation of complications that may arise (e.g. shoulder systocia, postparum haemorrhage) Personnel present that are trained in neonatal resuscitation

* Adapted from the Society of Obstetricians and Gyneaecologists of Canada 2004[41] and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2009[27,28]

Fig. 26.1 Prerequisites for OVB

are met. The delivery should be performed by a suitably trained and experienced operator, in theatre (dependent on operator experience) and the operator should be aware of the potential complications (such as shoulder dystocia) that may arise [13]. Rotational OVBs can be conducted using either rotational (Kielland's) forceps, rotational ventouse or using manual rotation followed by direct forceps application. There is no conclusive evidence as to which of these methodologies is superior to each other, although some recent studies and a meta-analysis have found that rotational forceps are superior to manual rotation followed by direct forceps, and there is a lower failure rate than ventouse delivery [13, 14].

The RCOG recommends that the procedure should be abandoned where there is no evidence of progressive descent with moderate traction during each contraction or where birth is not imminent following three contractions of a correctly applied instrument by an experience operator.

The RCOG guideline for OVB also explains that the bulk of malpractice litigation results from failure to abandon the procedure at the appropriate time, particularly the failure to eschew prolonged, repeated or excessive traction efforts in the presence of poor progress. If there is difficulty in applying the instrument correctly, no descent with each traction, birth is not imminent following three pulls and/or a reasonable time has elapsed since the decision for intervention has been made, then the attempt at operative vaginal birth should be abandoned.

Failure to deliver the baby using the primary instrument will then necessitate the use of either a second instrument or a caesarean section—both of which are associated with significantly poorer outcomes than a successful primary delivery using any single instrument [1, 15]. The use of sequential instruments is associated with greater harm than either a successful primary OVB, or a primary caesarean section [15]. However, following a failure to deliver using the first instrument (usually a ventouse), if there has been significant descent of the head, it may be safer and therefore reasonable to proceed to use a second instrument (usually forceps), due to the significantly increased complexity and potential trauma associated with a caesarean section when the fetal head is deeply engaged within the pelvis. While such a decision to proceed with a second instrument may be reasonable, it should be explicitly justified and documented by the practitioner [8]. It would not usually be justifiable to use ventouse after the failure of an attempted forceps birth.

Following successful delivery, the condition of the baby should be assessed with both Apgar scores and paired umbilical cord gases. The perineal trauma should be accurately documented and repaired accordingly. Where the procedure has resulted in a third or fourth degree tear this should be repaired in theatre under appropriate conditions.

26.3 Clinical Governance Issues

Clinical governance issues will be focussed around comparison of the operative vaginal delivery rate to the national figures, rates of failed procedures and the use of sequential instruments. Where failure of operative delivery occurs, these cases should be reviewed by the risk management team to ensure all prerequisites for safe instrumental delivery have been met, that appropriate documentation exists for the use of sequential instruments and whether the procedure has been abandoned appropriately. There should be documentation of women sustaining third and fourth degree perineal tears and investigation into those babies sustaining significant fetal trauma such as subgaleal haemorrhage, brachial plexus injury, fractures, facial nerve palsies or intracranial haemorrhage. In addition, all babies delivered with Apgar scores <7 at 5 min or an arterial cord gas of <7.1 should have a case review to ensure appropriate management. Other themes to be assessed may be appropriate analgesia and the number of pulls required to achieve the delivery.

Documentation remains a key issue. This should include informed consent. Deliveries occurring within the delivery room do not usually have documented consent forms whereas theatre deliveries have an appropriately completed consent form documenting all the material risks of the procedure (Fig. 26.2). Obstetric practice

Serious risks	
Maternal Third and fourth degree tears Extensive or significant vaginal/vulval tear	**Fetal** Subgaleal haematoma 3-6/1000 Intracranial haemorrhage 5-15 in 10 000 Facial nerve palsy (rare)
Frequent risks	
Maternal Postpartum haemorrhage 1-4 in 10 (very common) Vaginal tear/abrasion (very common) Anal sphincter dysfunction/voiding dysfunction	**Fetal** Forceps marks on face (very common) Chignon/cup marking on the scalp (practically all cases of vacuum-assisted delivery) (very common) Cephalohaematoma 1–12 in 100 (common) Facial or scalp lacerations, 1 in 10 (common) Neonatal jaundice /hyperbilirubinaemia, 5 – 15 in 100 (common) Retinal haemorrhage 17–38 in 100 (very common

Fig. 26.2 Risks associated with operative vaginal birth adapted from Consent Advice No. 11, Royal College of Obstetricians and Gynaecologists 2010

appears to be moving away from procedures performed without documented consent in an increasingly litigious society. Documentation regarding the procedure should ideally be recorded on a pre-printed proforma that is completed by the operator immediately after delivery (Fig. 26.3). The documentation should be detailed and accurate especially in cases where operative vaginal delivery has failed leading to a full dilatation caesarean section.

A recurring theme in obstetrics is the training and experience of the operator. Experience will be gained by direct supervision on the labour ward until competence is achieved, but also in the setting of formal skills training as provided by such courses as ROBUST and MOET. For operators where there is a high incidence of failure, repeated use of sequential instruments and repeated evidence of both fetal and maternal trauma this should raise concerns and further support and supervision instigated until competence is achieved.

The importance of a comprehensive debrief by a senior clinician cannot be stressed enough. Women and their partners may find the delivery traumatic and suffer psychological sequelae. A detailed explanation of the indications for the procedure and the procedure itself may be helpful to reduce concerns or complaints. Finally, women who have experienced an operative vaginal birth should be encouraged to attempt a vaginal delivery in a subsequent pregnancy as 80% will be successful.

26.4 Reasons for Litigation

- Failure to obtain informed consent with full explanation of the material risks
- Inexperienced operator
- Use of sequential instruments
- Allegations of excessive traction and multiple pulls
- Fetal trauma
- Maternal trauma
- Baby born in poor condition as evidenced by poor paired cord gases
- Evidence of a significant birth asphyxia following the delivery

26.5 Avoidance of Litigation

Failures to provide adequate explanation and consent are major contributors to litigation associated with operative birth [16]. In 2017, the General Medical Council Consent Guidelines recommended: "The doctor uses specialist knowledge and experience and clinical judgement, and the patient's views and understanding of their condition, to identify which investigations or treatments are likely to result in overall benefit for the patient. The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but

Patient Details

Date .....
Operator Name .... Grade .....
Supervisor Name .... Grade .....

Indication(s)for delivery: ....
Classification of OVD: outlet / low / midcavity
Rotation > 45o: yes / no
Fetal wellbeing: CTG: normal / suspicious / pathological
Liquor: clear / meconium

Prerequisites:
Place of delivery: room / theatre
Analgesia: local / pudendal / regional
Consent: verbal / written
Catheterised: yes / no

Examination
1/5th per abdomen: .....
Dilatation: .....
Position: .....
Station: .....
Mou lding:.....
Caput: .....

Procedure
Instrument used:
Vacuum extractor : silastic / Kiwi / metal anterior / metal posterior
Forceps: rotational / non-rotational / outlet
Number of pulls: ....
Traction: easy / moderate / strong
Maternal effort: minimal / moderate / good
Placenta: CCT/ manual
Episiotomy: yes / no
Perineal tear: 1st degree ☐
2nd degree ☐
3rd / 4th degree ☐ (complete pro forma)
Other ☐ (complete suturing pro forma if necessary)
EBL:.....

Multiple instrument use: yes / no
Examination before second instrument
1/5th per abdomen:.....
Position: .....
Station: .....
Moulding: .....
Caput:.....
Reasons for second instrument:
.....
.....
.....

Baby: M / F Birth weight: ..... (kg) Apgar: 1..... 5..... 10..... **Cord pH:** Arterial..... Venous.....
Post-delivery care:
Level of care: routine / high dependency
Syntocinon infusion: yes / no
Catheter: yes / no Remove .....
Vaginal pack: yes / no Remove .....
Diclofenac 100 mg PR: yes / no Analgesia prescribed: yes / no
Thromboembolic risk: low/ medium / high
Thromboprophylaxis prescribed: yes / no

Signature: ..... Date: .....

Fig. 26.3 Operative vaginal delivery record

they must not put pressure on the patient to accept their advice" [17].

In the post-Montgomery era the decision-making process is a shared process between the patient and clinicians [18], which requires clinicians to both provide the information and also assimilate it, as well as to explain the risks and benefits of a recommended course of action (and alternative options). This may not always be practicable given that most, if not all operative births are performed as either an emergency, or at least an urgent intervention. For this reason the RCOG recommends that women should be informed in the antenatal period about operative vaginal delivery, particularly during their first pregnancy [8].

With this background, and in a post-Montgomery context, while OVB is often undertaken in an emergency, and can be safer than a caesarean section, it is vital that women receive appropriate counselling prior to the procedure. Appropriate counselling should include an explanation of the most severe, but uncommon complications as well as the most frequent for the procedure in question. In addition alternative management options should be given and consent should ideally be provided in written form [17].

Defending a potential claim can be extremely difficult unless there is good documentation for the operative birth, including: indications, examination findings and performance of the operative vaginal birth.

Experts or judges reviewing a case often deem that meticulous documentation reflects meticulous care and also 'If it isn't documented then it didn't happen'. The quality of documentation can reflect a clinician's level of professionalism and forms the basis of any successful defence of a claim or complaint. Claims are twice as likely to be successfully defended if documentation is judged to be adequate. Good record keeping is also essential for education, clinical audit and risk management purposes. In this respect, the use of a standardised proforma may be of benefit.

26.6 Case Study

Mrs. J, was a 29-year-old lady in her first pregnancy. She was admitted in spontaneous labour at term and made slow progress to full dilatation. Mrs. J pushed for one and a half hours and the baby was not delivered. The specialist registrar was asked to attend with a view to an instrumental delivery. The doctor performed a vaginal delivery; the cervix was fully dilated; the fetal head was at spines in a left occipito transverse position. There was a significant amount of caput and moulding present. The CTG was normal. The doctor opted to take Mrs. J to theatre for a trial of forceps delivery and if this was unsuccessful to proceed to caesarean section. Informed consent was obtained. Mrs. J has a spinal anesthetic. The doctor examined Mrs. J and performed a manual rotation from left occipito transverse to a left occipito anterior position. The doctor then applied Neville Barnes Forceps that locked easily. The doctor then proceeded to deliver the baby with forceps over five contractions with five pulls. A live male baby was delivered with evidence of extensive facial bruising at delivery. Cord gases were normal at delivery. A case was brought against the hospital for a forceps delivery that was prolonged and involved the use of excessive force. The baby had a permanent scar over the right eye, significant discoloration to the right cheek bone and significant indentations in front of both ears. The Judge was critical of the delivery for the following reasons:

1. There was poor documentation of the procedure
2. The number of pulls was not documented by the doctor, but the Midwife in attendance noted five pulls.
3. There was no documentation regarding the degree of decent of the fetal head within the pelvis over successive pulls.
4. An appropriately performed procedure would not leave permanent scarring to a baby's face and from this evidence the Judge concluded that the doctor had achieved the delivery with unnecessary force.

The Judge ruled in favour of the Claimant supported by his mother and legal friend. The case was settled on a full liability basis with £11,150 being awarded to the Claimant.

Key Points: Operative Vaginal Birth

- Ideally women should be counselled in the antenatal period regarding OVB.
- Informed consent should be obtained detailing all the risks associated with the procedure for both mother and baby.
- All prerequisites for operative vaginal delivery should be met.
- A suitably skilled operator should conduct the delivery.
- The decision for a trial of operative delivery in theatre should be guided by factors that may increase the likelihood of failure.
- The choice of instrument should be made according to the clinical situation and the operator's experience.
- There should be documented evidence of continued decent of the fetal head throughout the procedure.
- The decision to use sequential instruments should be documented appropriately.
- A paediatrician should be present at delivery.
- Paired cord gases should be taken.
- An operative delivery proforma should be completed immediately after delivery.

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Caesarean Section

27

James Johnston Walker

27.1 Background

The medical legal problems of caesarean section (CS) relate to complications of the procedure itself or where there is a delay in delivery of the baby in a situation of fetal compromise. There are also potential long-term risks for both the mother and the baby. These various factors produce the dilemma of the balance of risks and benefits to the mother and the baby. This has been further complicated by Montgomery v Lanarkshire Health Board findings on the role of consent [1]. Advances in medical practice means that CS delivery is now almost as safe as vaginal birth leading to a change in the balance of risks and rising rates. CS is now seen as less of a medical procedure and more of a treatment choice in which the mother has a significant role. Despite the relative safety, CS remains at the centre of maternity medical litigation. The NHSLA recently published figures showing that there have been 674 claims related to caesarean section since 2000. This led to a litigation cost of £2,126,167,223 (Table 27.1). The majority of claims are for complications of the procedure, but the costs are related mostly to delay in the carrying out the procedure leading to complications for the baby such as hypoxic ischaemic encephalopathy (HIE) and cerebral palsy (CP) [2, 3].

27.2 Minimum Standards

There are various documents that cover aspects of caesarean section and the decisions to carry them out, including NICE Clinical guideline (CG132) [1] and NICE Quality standard (QS32) [2, 3].

A consultant needs to be involved in the decision to carry out an elective or emergency CS. The mother needs to be involved in the decision-making process and be fully informed of the risks.

Planned caesarean sections should be carried out at or after 39 weeks, unless an earlier delivery is necessary because of maternal or fetal indications.

Much of the reasons behind litigation involving CS relates to delays in carrying out the procedure. The decision to delivery interval is based on the classification of CS (Table 27.2) of which only the first two are relevant here. Category 1 is an emergency CS delivery as soon as possible. The aim is for a decision to delivery interval of 30 min. Category 2 is a CS requiring delivery within a reasonable timescale without taking risks. The aim is for a decision to delivery interval of between 30 and 75 min depending on the level of concern.

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Table 27.1 Reasons, numbers and claims associated with caesarean section

Reason	Number	Litigation cost (£)	Cost per claim (£)
Complications of procedure	533	45,099,097	84,614
Delay in procedure	115	154,736,115	1,345,531
Other	26	16,332,011	628,154
Total	674	2,126,167,223	320,589

Table 27.2 Classification for urgency of caesarean section [4]

Grade	Definition
1. Emergency	Immediate threat to life of woman or fetus
2. Urgent	Maternal or fetal compromise which is not immediately life-threatening
3. Scheduled	Needing early delivery but no maternal or fetal compromise
4. Elective	At a time to suit the woman and maternity team

Lucas DN, Yentis SM, Kinsella SM, Holdcroft A, May AE, Wee M, Robinson PN. Urgency of caesarean section: a new classification. J R Soc Med. 2000;93:346–50

In the classification system by Lucas et al the classification refers to the timing of the decision to operate. For example if a case was booked as an elective procedure for malpresentation, the classification would be a grade 4, but if she went into labour before the chosen date (or even if she didn't go into labour, but had delivery before the scheduled date) the classification would change to 3. Similarly if there was fetal bradycardia which responded to treatment and the patient needed subsequent delivery for failure to progress, it would be classified as grade 3 rather than a 2. Caesarean section is a surgical procedure and as such is associated with the complications of any major surgery. Prior to surgery there should be an assessment of haemoglobin to identify anaemia.

If the risk of bleeding is high, blood transfusion services should be available and cell salvage should be considered. Regional anaesthesia is the preferred option although the decision will be based on both obstetric and anaesthetic considerations as well as taking into account maternal preference where possible. An indwelling urinary catheter should be placed to prevent over-distension of the bladder and remain in situ until the patient is mobile. To prevent inhalation injury, antacids and drugs to reduce gastric volumes and acidity should be given. If a general anaesthetic is used than pre-oxygenation, cricoid pressure and rapid sequence induction should be carried out to reduce the risk of aspiration. The WHO surgical safety checklist for maternity cases should be used (see Fig. 27.1). The operating table should have a lateral tilt of 15° to avoid aortocaval compression. Safe surgical practice should be followed to reduce the risk of HIV infection of staff. Prophylactic antibiotics should be given before skin incision according to local antibiotic guidelines. A risk assessment for venous thromboembolism (VTE) should be undertaken and thromboprophylaxis given as per existing guidelines. The skin incision will vary according to the clinical indication for the procedure, but in general a transverse abdominal incision should be used, 3 cm above the symphysis pubis with subsequent tissue layers opened bluntly and extended with scissors. The lower uterine segment should be extended by blunt extension of the uterine incision. The baby will be delivered either manually or with the use of Wrigley's forceps. Both venous and arterial cord pHs should be performed after all CS for suspected fetal compromise, to allow review of fetal wellbeing and guide ongoing care of the baby. The placenta should be removed using controlled cord traction and not manual removal as this reduces the risk of post-partum complications including uterine inversion. The uterine cavity should be checked and ensured it is empty. The uterus should then be closed in two layers with an absorbable suture with closure in layers for the rectus sheath and the skin.

A senior obstetrician should be present for complicated caesarean sections including full dilatation sections where there may be difficulty in delivery of the baby's head from the pelvis. Pushing the baby's head up from below may aid delivery, but it can also lead to a "ping-pong ball" skull fracture in the baby. In addition, a section at full dilatation carries an increase in both maternal and fetal complications [6]. Other indications for a senior obstetrician to be present include major placenta praevia or accreta, extreme prematurity with

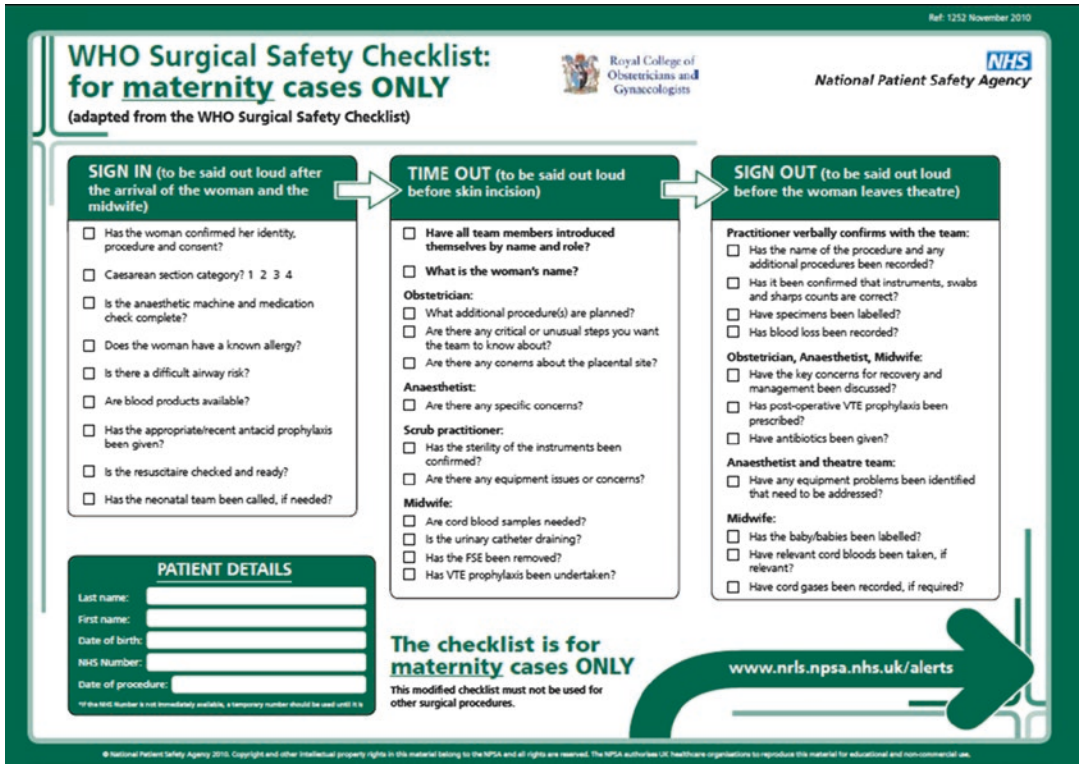

Fig. 27.1 WHO surgical safety checklist for maternity cases only [5]

or without ruptured membranes, raised body mass index, previous difficult operative procedure and large maternal fibroids. When a midline abdominal incision is used, mass closure with slowly absorbable continuous sutures should be used.

Women undergoing caesarean section whether as an emergency or electively should be aware of the material risks [7]. The risk of fetal lacerations is about 2%. Particular care should be taken when the CS is being carried out after rupture of the membranes and at full dilatation when the uterine wall is thin. Short term risks include wound infection and breakdown sometimes leading to sepsis, injury to the bladder, bowel and other structures and the potential need for blood transfusion. There is increasing evidence of long term sequelae to CS, with risk of infertility, ectopic pregnancy or rupture of the uterus in subsequent labours. The explanation of these risks need to be part of any informed consent process. For category 1 caesarean sections where there is no time to get written consent, verbal consent is permissible.

27.3 Clinical Governance Issues

All complications of caesarean section should be reported according to the maternity guidance. The RCOG suggests a number of triggers for incident reporting in Obstetrics as detailed in Table 27.3 [8]. The clinical governance issues surrounding caesarean section can be broadly divided into maternal, fetal and organisational. Maternal governance issues will include failed operative delivery leading to full dilatation caesarean section, blood loss greater than 1500 mls, caesarean hysterectomy, intensive care admission, return to theatre, anaesthetic complications including inadequate analgesia and uterine rupture or dehiscence. Fetal complications will include fetal lacerations and birth trauma, low Apgar scores, low cord gases and unexpected admission to the neonatal unit. Organisational issues may include delayed delivery, unavailability of a theatre or theatre staff or equipment failures.

Table 27.3 RCOG Clinical governance advice No.2 [8]

Suggested trigger list for incident reporting in maternity		
Maternal incident	Fetal/neonatal incident	Organisational incident
Maternal death Undiagnosed breech Shoulder dystocia Blood loss > 1500 mL Return to theatre Eclampsia Hysterectomy/laparotomy Anaesthetic complications Intensive care admission Venous thromboembolism Pulmonary embolism Third-/fourth-degree tears Unsuccessful forceps or ventouse uterine rupture Readmission of mother	Stillbirth > 500 g Neonatal death Apgar score < 7 at 5 min Birth trauma Fetal laceration at caesarean section Cord pH < 7.05 arterial or < 7.1 venous Neonatal seizures Term baby admitted to neonatal unit Undiagnosed fetal anomaly	Unavailability of health record Delay in responding to call for assistance Unplanned home birth Faulty equipment Conflict over case management Potential service user complaint medication error Retained swab or instrument Hospital-acquired infection Violation of local protocol

All such events should be examined by the risk management process. The process of investigation should include patients and their families and there should be an open and honest approach when things go wrong. Documentation is a key concern. There should be appropriate documentation concerning the risks of caesarean section on the consent form and there should also be detailed operation notes for complicated procedures. Claims are easier to defend where good documentation exists. Where themes are identified these should be investigated and are particularly concerned with operative complication rates or returns to theatre that may identify an individual requiring support, supervision or further training.

27.4 Reasons for Litigation

- The indication to perform a caesarean section
- The delay in carrying out the procedure
- Maternal complications of the procedure
- Fetal complications occurring during delivery
- Short and long-term sequelae
- Failure to document all the material risks on the consent form
- Poor documentation of complicated procedures
- Inadequate anaesthesia
- Failure to request a neonatal team at delivery
- Inadequate resuscitation at delivery

27.5 Avoidance of Litigation

Avoidance of litigation is based on the appropriate preparation starting with informed consent. The mother needs to understand the complications of the procedure and the risks of alternative interventions. Hospitals need to have robust escalation processes to allow for the identification of fetal compromise, rapid escalation and transfer to theatre, with an aim to delivery within 30 mins.

Although speed is important, this should not be at a cost of increased risk to the mother or baby.

The operator should have the appropriate skills and experience or supervision to carry out the procedure. Particular risks should be assessed, and plans put in place to mitigate them. Such situations include placenta praevia or accreta where preparation with the appropriate clinicians present improves the response to complications. Training should concentrate on good surgical practice and particularly on the delivery of the baby's head from the pelvis. The use of skills and drills training help to provide experience of situations that are rare but that have potentially serious outcomes if not dealt with appropriately.

27.6 Case Study

Jac Richards v Swansea NHS Trust (2007) EWHC 487 (QB) 13/3/07 [9, 10].

Jac Richards was delivered by caesarean section at 14:25 on 15 May 1996. At the age of 10 years he was severely disabled resulting from an acute hypoxic ischaemic insult to the brain at or around the time of delivery. The medical experts in court agreed the ischaemic insult began 15–20 min before birth. The judgement relied heavily on the existing guidelines and the judge pragmatically determined that 'once the decision had been taken to deliver Jac by emergency caesarean section, the defendant owed a duty of care to Jac to deliver him as quickly as possible with the aim of trying to deliver him within 30 min. If the failure to deliver him within 30 min had been shown to be due to the limited resources of the defendant or constraints on those attending Mrs. Richards, e.g. the need to deal with other pressing cases, the primary claim would have failed, but no evidence of matters affecting the speed of Jac's delivery was placed before the court. Therefore, the defendant had negligently failed to deliver the claimant as quickly as possible whereas, had it not been negligent, the claimant would have been born without disability. Therefore, the Claimant had established on the balance of probabilities that his delivery some 55 min after the decision had been taken to carry out the Caesarean amounted to a breach of duty.

Key Points: Caesarean Section

- Adequate preparation before the procedure including patient choice
- Decision to delivery interval appropriate to the risk
- Procedure undertaken by adequately trained surgeons with the appropriate supervision if required
- Good surgical technique with prompt recognition of complications and their management
- The risk of complications such as placental position, full dilatation or a deeply impacted fetal head should be assessed and plans put in place prior to starting the procedure
- Accurate documentation and operation notes detailing all complications
- Appropriate use of antibiotics and thromboprophylaxis
- The presence of a neonatal resuscitation team if there is evidence of fetal compromise
- Appropriate follow up of patients

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Shoulder Dystocia

28

Tim Draycott and Jo Crofts

28.1 Background

Shoulder dystocia is defined as a vaginal cephalic birth that requires additional obstetric manoeuvres to assist the birth of the infant after gentle traction has failed [1]. Shoulder dystocia occurs when either the anterior shoulder impacts behind the maternal symphysis or, less commonly, the posterior shoulder impacts over the sacral promontory.

There is wide variation in the reported incidence of shoulder dystocia. Recent data sets have reported that there are significant differences in the rates of shoulder dystocia reported from the US and outside the US: US rates were 1.4% whereas the reported rate was 0.6% outside the US [2].

Shoulder dystocia remains a largely unpredictable event and can result in serious long-term morbidity for both mother and baby. This personal harm notwithstanding; poor outcomes can result in very significant litigation costs: in the USA shoulder dystocia is the second most commonly litigated complication of childbirth [3]; it is the most commonly litigated problem in Saudi Arabia [4], and in England the NHS Litigation Authority paid more than £100 million in legal compensation over a decade from 2000 to 2009 for preventable harm associated with shoulder dystocia [5]. Clearly, this is an enormous loss of resource to health care in general, and also a perverse incentive against best care [6].

Medical theories and expert opinions about the causal relationships between birth, management of shoulder dystocia and neonatal brachial plexus injuries have ebbed and flowed over the last two decades. Opinions have ranged from res ipsa loquitor, through the more recent propulsion theories to recent data that suggest that a substantial majority of brachial plexus injuries related to shoulder dystocia can be prevented with accurate management of the shoulder dystocia following RCOG national guidance [7, 8].

The literature on causation of obstetric brachial plexus palsy has influenced recent judicial decisions regarding the causation of obstetric brachial plexus injury. Based on this literature and case law, a template was proposed to provide guidance for those assessing issues of causation in clinical negligence claims [9].

28.2 Minimum Standards

Evidence based algorithms for the management of shoulder dystocia recommend resolution manoeuvres. A reduction in injury rates has been associated with an increase in correctly managed labours [10]. It is important to demonstrate that

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the correct manoeuvres were performed, ideally in the order of the RCOG algorithm [1] (Fig. 28.1).

Best practice recommendations for the management of SD have led to the development of standard protocols, which require McRobert's as a first-line manoeuvre. McRobert's positioning is currently recognized as the single-most effective intervention, relieving up to 39% of SDs [8].

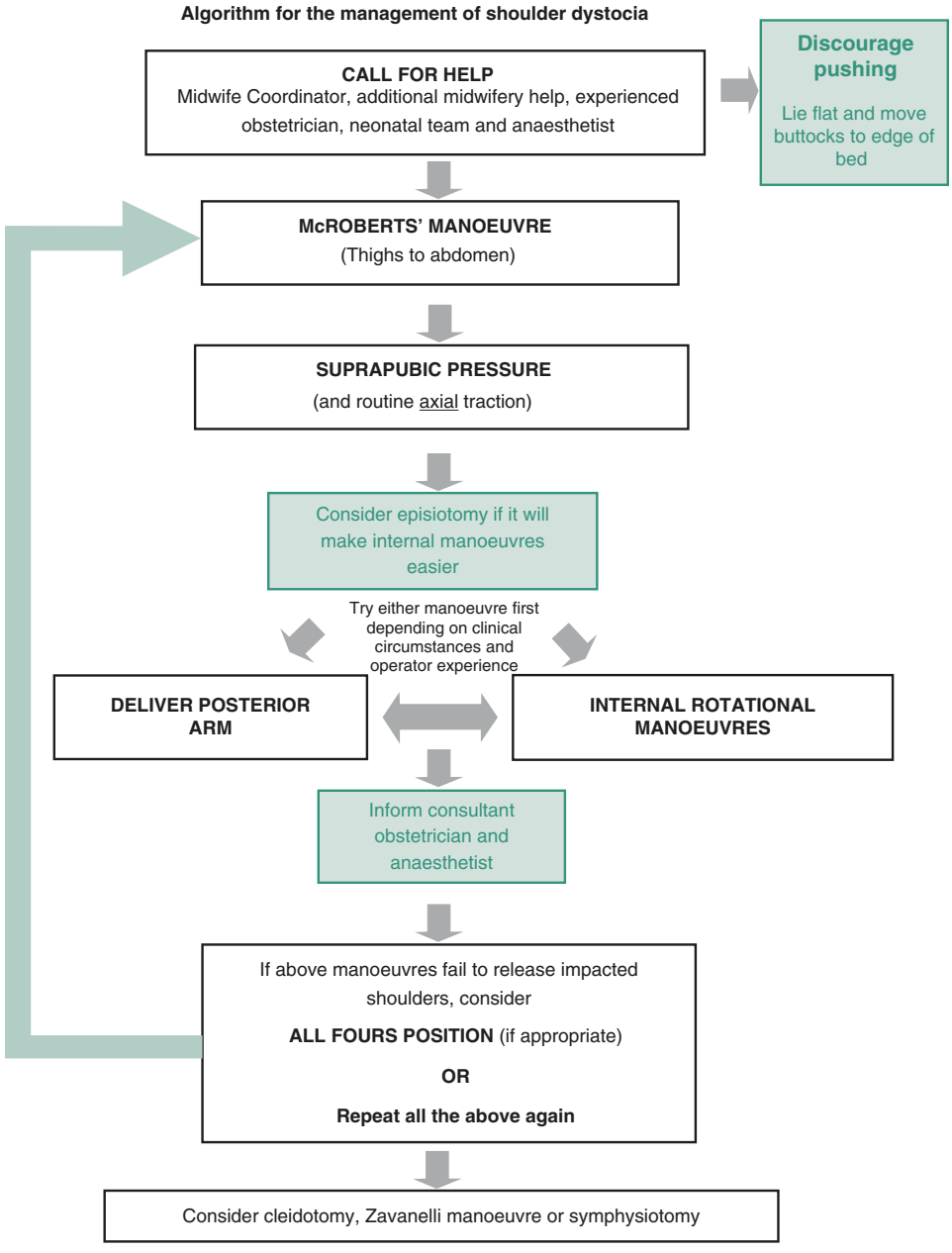

Fig. 28.1 Algorithm for the management of shoulder dystocia [1]

Lithotomy is not the same, as McRobert's and the legs should be actively removed from the lithotomy supports. To perform McRobert's manoeuvre accurately requires one person to manage the delivery and two to abduct and flex the hips into the McRobert's position and possibly another to apply suprapubic pressure. Therefore, where there are less than three birth attendants it is unlikely that the manoeuvres could have been executed properly.

McRobert's is often combined with suprapubic pressure (Rubin's I) and the success rate improves to 54%. Suprapubic pressure was also originally described in isolation and therefore the sequential use of these movements would be acceptable. An episiotomy is not currently deemed necessary by the RCOG guideline [8] unless internal rotational manoeuvres or delivery of the posterior arm is anticipated.

If simple manoeuvres fail, the options are either internal manoeuvres or turning the women into an all fours position. For internal manoeuvres, vaginal access should be gained posteriorly as the most spacious part of the pelvis is in the sacral hollow. The whole hand should be inserted to perform either internal rotation or delivery of the posterior arm. The eponymous internal rotational manoeuvres, Wood's Screw and Rubin's II can be very confusing, and difficult to execute properly [11]. Mnemonics and eponyms should be avoided [12]. Delivery of the posterior arm will reduce the diameter of the fetal shoulders, however delivery of the posterior arm can be associated with humeral fractures in between 2 and 12% of cases [10].

McRobert's (and/or suprapubic pressure) alone is not as effective as previously thought. In Hong Kong McRobert's alone was only effective in 25.8% of SDs [12]. Furthermore, a recent paper describes an increase in the performance of suprapubic pressure (27.8–60.3%) and internal manoeuvres from 14.5% of shoulder dystocias to 47.8% in association with a 100% reduction in brachial plexus injury and a reduction in the head-body delivery interval[13]. Therefore, earlier recourse to internal manoeuvres may be protective.

If first or second line manoeuvres are unsuccessful consideration should be given to such techniques as cleidotomy, symphysiotomy and the Zavanelli manoeuvre. These are rarely required. A neonatologist should examine the baby after delivery for evidence of brachial plexus or bony injury and paired cord gases should be taken for acid base status. In addition, the operator should prepare for post-partum haemorrhage.

28.3 Clinical Governance Issues

Some of the risk factors associated with shoulder dystocia (SD) are seen in Fig. 28.2. However, it is generally accepted that shoulder dystocia is notoriously difficult to predict antenatally. A previous shoulder dystocia is a risk factor for subsequent shoulder dystocia. A prior history of a birth complicated by shoulder dystocia confers a 6-fold to nearly 30-fold increased risk of shoulder dystocia recurrence in a subsequent vaginal birth, with most reported rates between 12 and 17% [1]. Women should be informed that their birth was complicated by shoulder dystocia and should be counselled about their options for place of birth and risks in a future pregnancy [1].

Table 1. Factors associated with shoulder dystocia

Pre-labour	Intrapartum
Previous shoulder dystocia	Prolonged first stage of labour
Macrosomia >4.5kg	Secondary arrest
Diabetes mellitus	Prolonged second stage of labour
Maternal body mass index >30kg/m^2	Oxytocin augmentation
Induction of labour	Assisted vaginal delivery

Fig. 28.2 Factors associated with shoulder dystocia

The RCOG Guidelines for shoulder dystocia (SD) [1] recommend consideration of elective Caesarean section for two antenatal indications: previous SD, and/or estimated fetal weight (EFW) of more than 4.5 kg in the presence of maternal diabetes or 5 kg without maternal diabetes.

However, delivery by Caesarean section is not without consequence and the risks are presented in the contemporaneous national guidance for delivery by elective caesarean section [14]. It is important to present the risks and benefits, in a Montgomery compliant fashion, for the woman and her family to make the best decision for them.

Another proposed strategy to reduce the incidence of shoulder dystocia would be to consider induction of labour for women with an estimated weight greater than 4 kg at term. This significantly reduced the risk of shoulder dystocia compared with expectant management—relative risk 0.32 [15]. However, the rate of brachial plexus injury was unaffected.

All obstetric and midwifery staff should be trained to deal with a shoulder dystocia. There are important differences between effective and ineffective training for shoulder dystocia: *'practice does not make perfect, if it is the wrong* practice' [9]. For example, fundal pressure is associated with a high rate of brachial plexus injury and rupture of the uterus. It should therefore not be applied during shoulder dystocia [1].

The current RCOG shoulder dystocia guideline [1], recommended: '*Shoulder dystocia training associated with improvements in clinical management and neonatal outcomes was multiprofessional, with manoeuvres demonstrated and practiced on a high fidelity mannequin. Teaching used the RCOG algorithm rather than staff being taught mnemonics (e.g. HELPERR) or eponyms (e.g. Rubin's and Woods' screw)*'. This recommendation appears to be the same today: all staff should be trained locally, annually and provided with the opportunity to practice all the manoeuvres required to release the shoulders using a high-fidelity model. Documentation of shoulder dystocia should be comprehensive and accurate. The RCOG shoulder dystocia guideline includes a pre-formatted sheet for documentation of care provided during shoulder dystocia and this identifies the standard elements that should be recorded (Fig. 28.3).

28.4 Reasons for Litigation

- Failure to recognise the signs suggestive of shoulder dystocia
- Failing to state the problem and summon help
- Failure to call a neonatologist to the delivery
- Difficulty inserting the hand into the sacral hollow
- Confusion over internal rotational manoeuvers, particularly the use of eponyms
- Resorting to excessive traction to release the shoulders
- Using fundal pressure
- Poor documentation particularly with regard to documenting the posterior arm and the head to body delivery interval.
- Failure to anticipate the maternal risks post delivery
- Failure to fully debrief the women and her family

28.5 Avoidance of Litigation

The cases that are more likely to proceed to litigation are those where babies are delivered with evidence of fetal injury including transient and permanent brachial plexus injury, bony fractures and evidence of hypoxic damage due to a delayed interval between delivery of the head and the body. In addition, there are also some litigation cases centred around the psychological trauma and post-traumatic stress suffered by birth attendants.

Not all brachial plexus injuries should be deemed the fault of the accoucheur. However, there is a small (<10%) subset that are related to excessive traction by the accoucheur leading to permanent injuries to the anterior arm after shoulder dystocia. The position regarding posterior injuries remains predominantly the same; if the injury is to the posterior shoulder, the injury is likely to have been caused by maternal propulsion against the sacral promontory before the

SHOULDER DYSTOCIA DOCUMENTATION

Date .....
Time .....
Person completing form ..... Designation .....
Signature .....

Mother's Name _____
Date of birth _____
Hospital Number _____
Consultant _____

Called for help at:		Emergency call via switchboard at:		
Staff present at delivery of head:		Additional staff attending for delivery of shoulders		
Name	Role	Name	Role	Time arrived

Procedures used to assist delivery	By whom	Time	Order	Details	Reason if not performed
McRoberts' position					
Suprapubic pressure				From maternal left / right (circle as appropriate)	
Episiotomy				Enough access / tear present / already performed (circle as appropriate)	
Delivery of posterior arm				Right / left arm (circle as appropriate)	
Internal rotational manoeuvre					
Description of rotation					
Description of traction	Routine axial (as in normal vaginal delivery)	Other -		Reason if not routine axial.	
Other manoeuvres used					

Mode of delivery of head	Spontaneous		Instrumental – vacuum / forceps	
Time of delivery of head		Time of delivery of baby	Head-to-body delivery interval	
Fetal position during dystocia	Head facing maternal left Left fetal shoulder anterior		Head facing maternal right Right fetal shoulder anterior	
Birth weight kg	Apgar	1 min :	5 mins :	10 mins :
Cord gases	Art pH :	Art BE:	Venous pH :	Venous BE :
Explanation to parents	Yes	By	AIMS form completed	Yes

Neonatologist called? Yes Neonatologist arrived: ..... Name: .....
If neonatologist not called or didn't arrive, give reason: .....

Baby assessment after birth (maybe done by M/W):			If yes to any of these questions for review and follow up by Consultant neonatologist
Any sign of arm weakness?	Yes	No	
Any sign of potential bony fracture?	Yes	No	
Baby admitted to Neonatal Intensive Care Unit?	Yes	No	
Assessment by			

Please copy x 2 copies: x1 maternal notes, x 1 attached ti AIMS form.

Fig. 28.3 Shoulder dystocia documentation [1]

fetal head is delivered, rather than excessive and inappropriate traction. However, there is no reliable evidence that a combination of maternal propulsion and diagnostic traction alone causes significant and permanent injury to the anterior shoulder after shoulder dystocia.

It is widely recognised that not all cases of shoulder dystocia are reported. There are several large series that demonstrate that between 44 and 56% of infants born with obstetric brachial plexus injuries, there was no recorded or coded shoulder dystocia [16–18]. Some authors have argued that this reflects a failure of diagnosis and/or documentation, i.e. the shoulder dystocia was not recorded, rather than a different causation. There is also increasing evidence that shoulder dystocia is under recognised [19]. A US group have reported a similar under-reporting [20] and in our own most recent data the reduction of permanent injury from 0.38 per 1000 births to 0 in >17,000 vaginal births has been associated with an increase in the recorded shoulder dystocia rate from 2.04 to 3.24%. In the absence of shoulder dystocia, it is difficult to imagine how the delivery management could be improved to prevent obstetric brachial plexus injuries and therefore the injury is more likely to be due to a function of the labour rather than any failure of the accoucheur.

Both the 2008 clinical template [9] and the recent American College of Obstetricians and Gynaecologists (ACOG) report [21] suggest that posterior brachial plexus injuries are likely to be caused by impaction of the posterior shoulder on the sacral promontory where the uterine forces continue to push the baby down the birth canal, which stretches the fetal brachial plexus. In particular, the head travelling along the curve of Carus could cause the necessary widening of the angle between the shoulder and head to cause the injury. However, it is accepted that anterior arm injuries after shoulder dystocia are more likely to be related to accoucheurs pulling on the head, once again widening the angle between the shoulder and head. This traction is likely to be causative in different ways related to the force employed, its direction and also its nature.

Force in a downward direction appears to be particularly injurious [19] as is force of a 'jerking' nature [22]; both of which are avoidable with reasonable care. Excessive traction definitely increases the risk of injury as does "jerking" or non-axial traction: in simulated shoulder dystocia downward traction increases the stretch of the brachial plexus by 30% [23]. A group in Sweden has published their prospectively collected data of 112 children diagnosed with obstetric brachial plexus palsy after 31,828 vaginal births between 1999 and 2001 (35 per 10,000) [24]. The authors concluded that the persistent injuries were associated with a perceived higher level of downward traction on the head than the transient injuries. In addition, the transient injuries were associated with a perceived higher level of downward traction than used for a control set of uninjured infants. Moreover, permanent brachial plexus injury after shoulder dystocia affecting more than one nerve root is very likely to be related to the actions of the accoucheur at birth and not a function of labour [24].

Where obstetric brachial plexus injury occurs in the absence of shoulder dystocia, a short second stage (<20 min) is more common than in cases with antecedent shoulder dystocia. This suggests that propulsive forces may be responsible for injury in these instances. Poggi *et al.* identified a precipitous second stage is the most prevalent labour abnormality prior to shoulder dystocia complicated by subsequent brachial plexus injury [25].

Shoulder dystocia does have an associated neonatal hypoxic morbidity, but it is rare and appears to be related to the duration of the head to body delivery interval. In a recent series from Hong Kong, the risk of hypoxic ischaemic encephalopathy (HIE) for head to body delivery intervals of less than 5 min was 0.5%, compared with 23.5% for intervals of greater than 5 min ($P < 0.001$) [26]. There was a single infant with a delivery interval of greater than 10 mins who subsequently was diagnosed with HIE grade II who died age 3. Moreover, there was a drop in pH of 0.01 per minute of head to body delivery interval [26]. Training increased the rate of internal manoeuvres and there was an associated reduc-

tion in permanent brachial plexus injury [13]. Moreover, in a recent paper documenting the effects of a decade of shoulder dystocia training, the 75th centile for the head-body delivery interval was reduced from 4 to 3 min. Therefore, training can reduce the head to body delivery interval, but the overall risk of HIE is low before 5 min.

Litigation for shoulder dystocia will never be completely avoided. Cases should focus on the timely calling for help and the use of an accepted algorithm with accurate documentation particularly with regard to the posterior arm and the delay between delivery of the head and the body.

28.6 Case Study

RE v Calderdale and Huddersfield NHS Foundation Trust.

RE (the First Claimant) was born on 22nd April 2011 at 39 weeks' gestation at the Calderdale Birth Centre, a midwifery led unit under the control and management of the Defendant. She weighed 4.7 kg (10 lbs. 6 oz.). A claim was brought by her mother and litigation friend, LE (the Second Claimant), for personal injury arising out of the circumstances of her birth. The Second Claimant together with the Fourth Claimant, DE, who is the Second Claimant's mother and was present at the birth, brought claims for personal injury caused by 'nervous shock'. RE's father, AE, was the Third Claimant but did not pursue his claim.

28.6.1 Background

RE was the Second Claimant's second child. Her first child, a girl, was born on 8th June 2007 at 39 weeks' gestation and weighed 7 lb. 4 oz. (3.288 kg). It was an uneventful pregnancy. When, in August 2010, she became pregnant again, she and the Third Claimant decided that their second baby could be delivered at the Huddersfield Birthing Centre. During the pregnancy, the second claimant was diagnosed with symphysis pubis dysfunction (SPD), for which she attended hospital for physiotherapy. Measurements of the symphysis fundal height showed a consistently increased measurement above the 90th centile throughout the pregnancy. The second claimant was tested for maternal diabetes but blood tests came back as normal. She was referred to the Huddersfield Royal Infirmary where she was seen by an Obstetric Registrar who told her that she was having a big baby. No problems were recorded. Two further antenatal ultrasounds were performed at 30 and 34 weeks showing the estimated fetal weight was just above the 90th centile the second claimant was reassured by the registrar about the size of her baby, who also recorded that no induction of labour was indicated, she should be treated as normal and was referred back to the community midwife. Because of the large size of her baby, the Second Claimant rejected the community midwife's reassurance that there was no reason why she couldn't deliver at the Huddersfield Birthing Centre, and she and the Third Claimant chose to go to the Calderdale Birthing Centre which had an 'alongside' unit should obstetric assistance be required. On the morning of 22nd April 2011, the second claimant had spontaneous rupture of membranes and went into spontaneous labour. At 16:45 difficulty delivering the shoulders was noted and the obstetric registrar was summoned. RE was born at 16.53 h with the assistance of the Obstetric Registrar. RE was pale, floppy and without respiratory or heart rate. Resuscitation was commenced, and a heart rate was noticed after 10 min and a first gasp after 12 min. RE suffered an acute hypoxic brain injury. Both the Second and Fourth Claimants suffered post-traumatic stress disorder.

The Claimants' case was that

(a) RE's delivery should have been achieved earlier than it was;
(b) Specifically, RE's head was born but there was shoulder dystocia which delayed the delivery of her body for longer than was appropriate.

(c) Such delay was a consequence of failings by the midwives and obstetricians in both the planning for the birth and in the delivery.

The Judge found in favour of the Claimant that the delivery of RE had been negligent and that the delay in summoning help was causative of hypoxic brain injury. The Judge also found in favour of the second and fourth claimants who suffered post-traumatic stress disorder (PTSD) as a direct result of witnessing the difficulty delivery of RE.

Key Points: Shoulder Dystocia

- Recognise risk factors present during labour
- Anticipate problems and call for help
- Clearly declare a shoulder dystocia and summon all members of the emergency team including a neonatologist
- Nominate a scribe to document events on a proforma sheet
- Go through he manoeuvres in a logical and timed manner according to the RCOG algorithm
- Document the posterior arm
- Accurately record the head to body delivery interval
- Assess baby at delivery for brachial plexus and bony injury
- Ensure cord gases are taken for fetal acid base status
- Debrief the women and her family and counsel re future deliveries

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29 Vaginal Birth After Caesarean Section, Uterine Rupture

Kara Dent

29.1 Background

With an increasing number of caesarian sections occurring in the United Kingdom (26.2% of deliveries were caesarian sections in 2013–2014) [1], a greater number of women are facing the choice of whether to plan a caesarean section or attempt a vaginal delivery in their next pregnancy. For those women who underwent an uncomplicated caesarean first time and have no complications in their current singleton pregnancy, most will be eligible for a Vaginal Birth after caesarean section (VBAC) [2].

Using English NHS statistics, we know that just over 50% of those women eligible attempt a VBAC and of these, two thirds are successful [2]. However uterine rupture is a rare but serious complications that can occur in these women with maternal and fetal consequences and needs to be considered. Uterine rupture is described as the "full thickness separation of the uterine wall and overlying serosa". UKOSS studies estimate that uterine rupture occurs in 2.1 in a 1000 maternities in women with a previous section [3].

From the 85 cases reported to the NHS Litigation Authority between 2000 and 2010 (which carry a total estimated value of over a million pounds) 19 were linked to a vaginal birth after caesarean section. In just under half of the cases looked at, recognition of possible uterine rupture was delayed, with 55–87% of the cases showing an abnormal fetal heart pattern on the cardiotocograph (CTG) [3].

29.2 Minimum Standards

Planned VBAC may be offered to women with a singleton, cephalic presentation at 37 weeks or beyond who have had a previous lower segment caesarean section. Contraindications include a previous classical caesarean section scar or previous uterine rupture as the latter carries a 5% recurrence rate in future labours. A VBAC is also contraindicated if a vaginal birth is not appropriate in its own right, for example a major placenta praevia irrespective of a previous uterine scar [4]. An epidural is not contra-indicated in labour.

If a pregnancy is complicated by post-dates, twin gestations, fetal macrosomia, antepartum stillbirth and maternal age, the data is not as clear regarding the safety and efficacy in these cases and the RCOG guidelines advise a "cautious approach if VBAC is being considered in such circumstances" [4].

In the case of preterm labours, success rates appear to be similar to a term VBAC but carry a lower risk of uterine rupture [4].

A possible VBAC should be planned antenatally with a senior clinician, before the onset of labour with a documented discussion that outlines the pros and cons of a VBAC compared to an

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elective caesarean section. Ideally this should take place around 36 weeks, before the onset of labour. This discussion may be recorded in the form of a checklist that reflects how the woman was part of the decision-making process and was thereby making informed consent. Whilst a successful VBAC carries the least complications overall for the mother, the risks of uterine rupture (0.5%) and an emergency caesarean section should also be clearly outlined (See Table 29.1 for recognised risks).

For those women who have undergone two previous sections, the RCOG guidance states that they "may be offered VBAC after counselling with a senior obstetrician. This should

Table 29.1 Risks and benefits of opting for VBAC versus ERCS from 39[40] Weeks of gestation

	Planned VBAC	ERCS from 39[40] weeks
Maternal outcomes	• 72–75% chance of successful VBAC. If successful shorter hospital stay and recovery	• Able to plan a known delivery date in select patients. This may however change based on circumstances surrounding maternal and fetal wellbeing in the antenatal period
	• Approximately 0.5% risk of uterine scar rupture. If occurs, associated with maternal morbidity and fetal morbidity/mortality	• Virtually avoids the risk of uterine rupture (actual risk is extremely Low: less than 0.02% • Longer recovery • Reduces the risk of pelvic organ prolapse and urinary incontinence in comparison with number of vaginal births (dose–response effect) at least in the short term[69] • Option for sterilisation if fertility is no longer desired. Evidence suggests that the regret rate is higher and that the failure rate from sterilisation associated with pregnancy may be higher than that from an interval procedure. If sterilisation is to be performed at the same time as a caesarean delivery, counselling and agreement should have been given at least 2 weeks prior to the procedure[70]
	• Increases likelihood of future vaginal birth	• Future pregnancies-likely to require caesarean delivery, increased risk of placenta praevia/accreta and adhesions with successive caesarean deliveries/abdominal surgery
	• Risk of anal sphincter injury in women undergoing VBAC is 5%-and birthweight is the strangest predictor of this. The rate of instrumental delivery is also increased up to 39%?	
	• Risk of maternal death with planned VBAC of 4/100,000 (95%CI 1/100,000 to 16/100,000)?	• Risk of maternal death with ERCS of 13/100,000 (95% CI 4/100,000 to 42/100,000)?
Infant outcomes	• Risk of transient respiratory morbidity of 2–3%	• Risk of transient respiratory morbidity of 4–5% (6% risk if delivery performed at 38 instead of 39 weeks).The risk is reduced with antenatal corticosteroids, but there are concerns about potential long-term adverse effects[72]
	• 10 per 100,000 (0.1%) prospective risk of antepartum stillbirth beyond 39[40] weeks while awaiting spontaneous labour (similar to nulliparous women)	
	• 8 per 100,000 (0.03%) risk of hypoxic ischaemic encephalopathy (HIE)	• <1 per 100,000 (<0.01%) risk of delivery-related perinatal death or HIE
	• 4 per 10,000 (0.04%) risk of delivery-related perinatal death. This is comparable to the risk for nulliparous women in labour	

The estimates of risk for adverse maternal or fetal events in VBAC are based on women receiving; continuous electronic monitoring during their labour

include the risk of uterine rupture and maternal morbidity" [4] A review of the literature in 2009 suggested that the rates of uterine rupture are similar to that of one previous section at 1.36% and comparable maternal morbidity [5].

29.3 Clinical Governance Issues

Uterine rupture is a trigger for a risk investigation locally and requires notification to the risk team, normally by a datix form. Review of the case is for learning and feedback to the department to ensure lessons are learned for the future. Mandatory training for midwives and obstetricians includes regular CTG training which is vital to ensure that abnormalities of the fetal heart during labour are recognised and managed in a timely manner. Many units have adopted a "buddy approach" or "fresh eyes" approach where a second person reviews the CTG regularly through labour [6] in order to improve interpretation of the fetal monitoring.

29.4 Reasons for Litigation

- Failure to recognise rupture/impending rupture
- Failure to recognise an abnormal cardiotocograph (CTG)
- Failure to act on an abnormal CTG in a timely manner
- Inappropriate augmentation of labour/Induction of labour (IOL)
- Failure of senior involvement in the management of labour for a woman requesting a VBAC

29.5 Avoidance of Litigation

29.5.1 Antenatal

There should be detailed discussion and documentation in the notes with a senior obstetrician. This should include the relative risks and benefits of VBAC versus an elective section (see Table 29.2) and follow the approved local guideline of the Trust. Ideally this plan should be made by 36

Table 29.2 RCOG Green-top guideline no 45 [4]

Appendix IV: Birth choices after caesarean delivery pathway			
Likelihood of		Overall	Tick when discussed
Successful VBAC (one previous caesarean delivery, no previous vaginal birth)		3 out of 4 or 72–75%	
Successful VBAC (one previous caesarean delivery, at least one previous vaginal birth)		Almost 9 out of 10 or up to 85–90%	
Unsuccessful VBAC more likely in: Induced labour, no previous vaginal delivery, body mass index (BMI) greater than 30 and previous caesarean for labour dystocia. If all of these factors are present, successful VBAC is achieved in 40% of cases.			
Likelihood of	VBAC	ERCS	
Maternal			
Uterine rupture	5 per 1000/0.5%	< 2 per 10,000/< 0.02%	
Blood transfusion	2 per 100/2%	1 per 100/1%	
Endometritis	No significant difference in risk		
Serious complications in future pregnancies	Not applicable if successful VBAC	Increased likelihood of placenta praevia/morbidly adherent placenta	
Maternal mortality	4 per 100,000/0.004%	13 per 100,000/0.013%	
Fetal/newborn			
Transient respiratory morbidity Antepartum stillbirth beyond 39^{40} weeks while awaiting spontaneous labour Hypoxic Ischaemic Encephalopathy (HIE)	2–3 per 100/2–3% 10 per 10,000/0.1% 8 per 10,000/0.08%	4–6 per 100/4–6% (risk reduced with corticosteroids, but there are concerns about potential long-term adverse effects Not applicable <1 per 10,000/<0.01%)	

weeks into the pregnancy, before the onset of labour with a plan in case labour starts before the scheduled timings. The woman should be made aware that the risk of uterine rupture is of the order of 0.5% (2/1000) in spontaneous labour. There should be awareness by the obstetrician in the decision making of additional risks including increased maternal age and induction of labour. Some of the literature also questions the effect of a raised BMI [3]. Provision of an information leaflet outlining the above information and discussion points should be provided to reiterate the conversation and to indicate the choices being made.

29.5.2 Intrapartum

These labours should take place in a consultant led labour ward with access to an emergency theatre and appropriate equipment. There should be senior input for the management plans in labour with regular obstetric review alongside continuous CTG monitoring in labour. Intravenous access and pre-delivery FBC and Group and Save samples will reduce unnecessary delay in going to theatre for suspected uterine dehiscence or rupture. Whilst an epidural is not contra-indicated in labour, increasing requirement for pain relief should trigger a suspicion of uterine rupture as should a presenting part that ascends, rather than descends on vaginal examinations. Women should be made aware that induction of labour or augmentation of labour in a VBAC situation carries an increased risk (2–3×) of uterine rupture compared to a spontaneous labour and discussed with the woman intrapartum [4].

29.6 Case Study

The claimant's mother opted for VBAC. There was an interval of 16 months between the previous caesarean section and this delivery. Mode of delivery was discussed at 16 weeks with the consultant and a maternal preference for vaginal delivery was noted. The Claimant attended hospital at 41 weeks gestation, having noticed occasional tightenings, but she was not in labour. Prostin E2 3 mg was inserted and IV Syntocinon was commenced 24 hours later with increases in the rate of infusion three times in the next 3 hours up to 36 mL/h. Ultimately a forceps delivery was performed, following a delay in the second stage, in the presence of fetal bradycardia. Blood and mucus needed to be removed from the claimant's trachea before intubation and successful re-establishment of the circulation. A gaping hole was discovered in the lower segment of the uterus when the Claimant's mother was taken to theatre post-delivery, when the placenta did not deliver. The claimant has cerebral palsy. The principal allegations were [1] that in breach of the Trust's own guidelines, medical induction was carried out notwithstanding that these guidelines stipulate that there should be no such induction in women with a previous caesarean section scar and [2] that the Claimant's mother was not advised antenatally, or following her admission to hospital, of the increased risk of uterine rupture associated with induction of labour. Liability was admitted. The Trust's guidelines on use of prostaglandins for induction in a VBAC case were inconsistent with RCOG Guidelines and it was accepted that there had been a failure to con-

Key Points: Vaginal Birth After Caesarean Section, Uterine Rupture

- VBAC is suitable to offer in a singleton uncomplicated pregnancy with cephalic presentation at 37 + 6 weeks with a single previous LSCS
- Antenatal discussion with senior Obstetrician in the antenatal period
- Documented discussion in the notes of VBAC versus elective LSCS
- Labour in a Consultant led unit with access to emergency theatre and equipment
- Ensure senior Obstetric input in the management of VBAC labours
- Be aware of the 2–3× increase in risk of uterine rupture in induced or augmented VBAC labour
- Ensure there are local trust guideline for VBAC delivery which are followed

sult the claimant's mother about the increased risk of uterine rupture with induction of labour in a VBAC case. The claim resolved on the basis of an order for periodic payments with a conventional lump sum value of £6.1 million.

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Sepsis in Pregnancy

30

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30.1 Background

Sepsis is the body's overwhelming and life-threatening response to infection that can lead to tissue damage, organ failure, and death. It is a significant cause of maternal death. Sepsis is defined as infection plus systemic manifestations of infection. Severe sepsis may be defined as sepsis plus sepsis-induced organ dysfunction or tissue hypoperfusion. Septic shock is defined as the persistence of hypoperfusion despite adequate fluid replacement therapy. Severe sepsis occurs in around 1 in 2000 pregnancies with septic shock occurring in around 1 in 10,000 pregnancies. It is an important cause of maternal mortality and morbidity but there are also implications for the fetus. Whilst there is clear evidence that the prompt treatment of maternal infection can improve maternal outcomes the evidence for the improvement of fetal outcomes is more difficult. Litigation in relation to sepsis focuses upon whether the infection could have been prevented, whether it was suspected or identified at an early enough point and whether the treatment support and source control of infection were managed in an appropriate way (Table 30.1).

Table 30.1 Risk factors for maternal sepsis

Obesity
Impaired glucose tolerance or diabetes
Impaired immunity/immunosuppression medication
Anaemia
Vaginal discharge
History of pelvic infection
Amniocentesis or other invasive procedure
Cervical cerclage
Prolonged rupture of membranes
Vaginal trauma, caesarean section, wound haematoma
Retained products of conception
Group A streptococcal infection in close contacts/ family members
Black or minority ethnic group origin

30.2 Minimum Standards

The general principles of infection control are relevant in all aspects of obstetric practice. This should include sepsis source control, source isolation, treatment with appropriate antibiotics according to local and national guidelines and notifying infectious disease agencies for reportable infections. It is particularly important to ensure that there is appropriate hand hygiene. It is important that women are informed of the need to reduce the risk of transmission of infection, particularly with young children when a sore throat may be a sign of Group A Streptococcal infection or when there are outbreaks of parvovirus. Vaccination in the third trimester of pregnancy should be offered for both influenza and whooping cough.

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Antibiotics are required for the following obstetric interventions:

- Caesarean section prior to the skin incision [1]
- Preterm pre-labour rupture of membranes (PPROM)—prophylaxis with erythromycin is given to allow prolongation of the pregnancy [2]. However, additional treatment should be given where there is evidence of sepsis.
- Third and fourth degree tears [3]
- Prolonged rupture of membranes at term, the current recommendation is to give antibiotics after 18 hours of labour.
- Group B streptococcus prevention. Currently pregnant women are not routinely screened or treated if the infection is detected antenatally. Treatment should be given in labour if there is bacteriuria in the current pregnancy, or a previously affected baby. There is a wide variation in practice for where women are found to have a positive swab in the current pregnancy. Current recommendations are that they do not require treatment [4]. Women presenting with ruptured membranes who are positive for GBS should be offered immediate induction.
- Manual removal of placenta
- Retained products of conception

(Currently there is no recommendation for antibiotics following instrumental delivery, however the results of the ANODE trial [5] are awaited).

30.3 Clinical Governance Issues

In most obstetric cases, it is not the treatment that gives rise to litigation, but the failure to recognise sepsis. Clinicians should, therefore, have a low threshold to investigate women who present with non-specific symptoms particularly in women who may be more vulnerable to sepsis such as those with conditions, which make them immunosuppressed (including pregnancy) such as sickle cell disease or connective tissue disorders. This principle applies to both antenatal and postnatal women.

Table 30.2 The sepsis six care bundle

1. Give oxygen to keep saturations greater than 94%
2. Take blood cultures
3. Administer antibiotics within 1 hour
4. Give fluids
5. Measure serum lactate
6. Monitor urine output

There have been campaigns to try and improve the outcomes of sepsis generally but also specifically in pregnancy. There is now a generally recognised package of assessment that should be performed in women who present with potential sepsis [6] (Table 30.2). This should include the taking of blood cultures and the prompt administration of antibiotics. There is good evidence that delay in the administration of antibiotics has a detrimental effect and mortality is increased for each hour delay. Antibiotics should be given within 1 hour of presentation. Fluids should be administered and there should be accurate measurements of basic observations but particularly the urine output. Oxygen should be administered and the serum lactate can give good guidance as to the severity of tissue hypo-perfusion in severe sepsis. Arterial blood gas measurements with lactate are an important aid to identifying the severity of the condition and targeting treatment. Clinicians should liaise closely with microbiologists especially when sepsis is unresponsive to current treatment regimens. This will enable adjustment to more appropriate antimicrobials. The involvement of senior clinicians at an early stage is also imperative.

30.4 Reasons for Litigation

- Failure to recognise sepsis
- Failure to instigate appropriate investigation
- Delayed treatment
- Incomplete treatment
- Failure to consider urgent delivery
- Failure to isolate source of infection
- Failure to involve senior clinicians at an early stage
- Failure to utilise the multidisciplinary team including anaesthetists, intensivists, microbi-

ologists and infectious disease specialists at an early stage
- Delay in recognising failed treatment and instigating additional or alternative antimicrobials
- Failure to transfer to HDU or critical care setting

30.5 Avoidance of Litigation

When women present who are unwell it is important that appropriate observations are performed. The signs of sepsis may not be straightforward such as tachycardia, high or low temperature or tachypnoea. Women may present with non-specific symptoms or fail to respond to treatment; both are suggestive of infection. Another challenge in pregnancy is that the inflammatory markers white cell count (WCC) and c-reactive protein (CRP) are often elevated, particularly around the time of labour and therefore trying to determine a threshold for concern is difficult. It is for that reason that the full clinical picture has to be considered.

Sepsis is a potentially life-threatening condition. If women are unwell they need high dependency or intensive care. It is important that senior clinicians are involved in the management at an early stage. In addition to the administration of antibiotics and fluids it can be necessary to support the blood pressure with vasopressors.

One of the key elements that is often delayed in women with sepsis is source control. In pregnancy, the source of infection is usually uterine, but not always. If the pregnancy is still ongoing then delivery will assist with the treatment of infection from both the maternal and fetal point of view. If there is retained products then this should be dealt with promptly. It may be necessary to perform definitive surgery such as hysterectomy if there is severe sepsis which is not improving with medical management. In other cases, there may be significant wound infection and appropriate drainage or debridement of the wound can be important in controlling the source of sepsis. Other infections such as mastitis or pneumonia can occur in pregnancy and it is important to involve microbiologists to ensure that the antibiotics that have been prescribed are appropriate for this type of infection. The standard infection control measures should be employed; isolate women in a single room, healthcare professionals should wear protective clothing and surgical masks and relatives should be provided with suitable information and relevant personal protection equipment [7, 8]. All of these aspects of clinical care can lead to litigation if the treatment is not provided promptly at an appropriately senior level.

One of the most challenging areas for obstetric practice is the decision making around women who develop a pyrexia in labour. Whilst the general principles above of blood cultures, antibiotics and fluids are important there has to be a clinical decision about the risks and benefits of continuing the pregnancy. This will be based upon the likelihood of a vaginal delivery within a reasonable time frame. It would take into account the gestation, parity and stage of labour together with the progress of labour to that point. It would also be necessary to take into account the nature of any fetal heart rate abnormalities and the response of both the fetal heart rate and the maternal condition to the therapy that would be provided once the treatment has been administered. Whilst delivery by caesarean section will reduce the duration of labour the addition of a surgical procedure can put the woman at a greater risk of morbidity. There is therefore a balance in terms of making that clinical decision. This can be a contentious area in medico legal cases.

Women presenting with spontaneous rupture of membranes can also present a challenge. According to current guidance these women should be offered immediate induction of labour or expectant management up to 24 hours [9]. Unfortunately, due to continuing pressures on many obstetric units it is not always possible to offer either option. Delayed induction with SROM is also likely to increase the risk of sepsis in labour and is another potential area for litigation especially in those women who are known carriers of Group B streptococcus.

30.6 Case Study

A 27-year-old lady in her second pregnancy presented to the obstetric unit at 26 weeks gestation. She complained of a raised temperature with upper respiratory congestion, cough, shivers and chills and feeling generally unwell for the preceding 6 hours. She was assessed as having a mild viral infection and was discharged home and recommended to have oral fluids and paracetamol. The following day she returned to the obstetric unit by ambulance. Maternal observations showed the patient had a temperature of 38.6 degrees Celsius, she was flushed and tachycardic with a pulse of 120 beats per minute and blood pressure of 80/40 mmHg. On examination of the chest there were no added sounds. A diagnosis of severe sepsis was made. Over the next 12 hours the patient's clinical condition deteriorated despite antibiotic therapy and aggressive fluid resuscitation and she required ventilation and admission to the intensive care unit. Viral swabs taken confirmed H1N1(swine flu). The patient required urgent delivery by emergency caesarean section for deteriorating maternal condition. The baby subsequently died at 6 months post-natal. The Mother continued to have a very stormy course on the intensive care unit and subsequently died 6 weeks later. The post mortem confirmed multi-organ failure secondary to H1NI. The husband subsequently brought a claim against the trust regarding the failure to recognise a case of viral illness at a time when there was a world-wide pandemic of swine flu. The case was won based on the medical team's failure to assess the patient and attribute her symptoms to influenza and a failure to inform and administer Tamiflu.

Key Points: Sepsis

- Every unit should have agreed protocols for antibiotic prophylaxis in agreement with national guidelines
- Prompt identification of those women particularly at risk
- Low threshold for investigation and treatment
- Use of sepsis care bundles
- Use of modified early warning scores
- Early involvement of multidisciplinary team to include obstetric anaesthetists, microbiologists, infectious diseases and critical care specialists
- Early recourse to HDU or ICU setting

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Twins

31

Mark D. Kilby and Peter J. Thomson

31.1 Background

Twins of all types, are associated with increased maternal and perinatal morbidity and mortality [1]. Over the last 20 years, the incidence of 'twining' has increased significantly, presently being 1 in 60 pregnancies in the UK [1]. This increase is associated with three main factors:

1. The increased use of subfertility treatment: particularly with the use of agents that induce supraovulation and in-vitro fertilization. To an extent, these risks have been mitigated by careful control of induced-ovulation and a policy of single embryo transfer. However, internationally and indeed in the United Kingdom; these 'safe guards' have been used with varying success (RCOG Scientific Advisory Paper, 2017 [2]).
2. Deferment of pregnancy until a later maternal age. Again, over the last 25 years, the median age of pregnant women has increased. All multiple pregnancies are more common in women over the age of 35 years.
3. Movement of people around the world. There is some evidence that multiple pregnancy, especially dizygous twining, is more common in certain African races (i.e. Nigerian delta). Immigration and free movement of peoples has increased the risk of twining by these means in the United Kingdom, also.

These factors have led to an increase in the prevalence of multiple pregnancy in general and twins, in particular over time. Although not specifically related to the management of multiple pregnancy *per se*, the reduction of risk of a multiple pregnancy related to subfertility treatment is an important pre-pregnancy discussion point. The use of supraovulation therapies and the reduction of number of embryos transferred after in-vitro fertilisation (two single or at most two) are important and have medicolegal consequences for the infertility practitioner. Even the number of days of embryo culture and morula 'hatching' may influence the risk of monochorionic pregnancies with the inherent pregnancy related risks. These discussions should take place with a couple before embarking upon infertility treatment and should be prospectively and carefully documented.

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31.2 Minimum Standards

The majority of twins are identified at the dating ultrasound scan, usually performed after 9 weeks of gestation. The ultrasound scan will check fetal number and viability. The number of fetuses are counted and the number of amniotic sacs and placentae associated with each fetus. In twins the fetus with the largest crown rump length (CRL) is used to date the pregnancy and calculate the expected date of delivery. The most important aspect of the first trimester scan is to assess chorionicity as this will dictate the management pathway for the entire pregnancy. It is mandatory that chorionicity is established and documented and that an electronic copy of the ultrasound images is stored. If the chorionicity is uncertain then referral to a more experienced centre is required. Once stratification of risk by chorionicity has been performed, the intervals of antenatal care are dictated by the ultrasound scan timings (Fig. 31.1).

At a gestation of between 11 + 0 and 13 + 6 weeks gestation (CRL from 45 to 84 mm) women with twin pregnancies are also offered first trimester combined screening for the detection of trisomy 21, 18 and 13. The conversation regarding the detection rates of these chromosomal anomalies using this screening test and the false positives should be documented [3]. A documented conversation should take place relating to the complexity of high risk results in twins, the effects of chorionicity on management and the potential of discordant fetal results. For those women presenting after this gestation a second trimester biochemical test is also available, but the detection rates are lower and this should be fully discussed. Finally, with the advent of non-invasive prenatal testing (NIPT) this presents a further screening option for women with a twin pregnancy although the pros and cons should be clearly discussed and documented. Currently this option is only available in the private sector or within the confines of on-going research trials.

The objective evidence on which to base the timings of ultrasound scan examinations is poor. However, recent data appears to confirm the expert opinion set out in the professional national (and international) clinical guidelines [4]. For monochorionic twins, the ultrasound scan

Schedule of specialist antenatal clinic appointments

Type of pregnancy (uncomplicated)	Minimum contacts with core multidisciplinary team	Timing of appointments PLUS scans	Additional appointments WITHOUT scans
Monochorionic diamniotic twins	9 (including 2 with specialist obstetrician)	Approximately 11 weeks 0 days to 13 weeks 6 days* and 16, 18, 20, 22, 24, 28, 32 and 34 weeks	
Dichorionic twins	8 (including 2 with specialist obstetrician)	Approximately 11 weeks 0 days to 13 weeks 6 days* and 20, 24, 28, 32 and 36 weeks	16 and 34 weeks

* When crown–rump length measures from 45 mm to 84 mm

Fig. 31.1 Multiple pregnancy: antenatal care for twin and triplet pregnancies (CG129)

examinations should start from 16 weeks of gestation and be repeated at 2 weekly intervals throughout the pregnancy. At each scan, fetal biometry should be measured (and the estimated fetal weight recorded). In addition, the maximum vertical pool of amniotic fluid in each sac should be recorded. For dichorionic twins, after the first trimester ultrasound scan, a 20-week anomaly scan is recommended and then ultrasound assessments at four weekly intervals. The ultrasound surveillance in monochorionic twins is for selective growth restriction (15% of monochorionic twins), twin to twin transfusions syndrome (10% of monochorionic twins) and rarer complications of spontaneous single twin demise (<5%) and twin anaemia polycythaemia sequence (TAPS (1–2%). In dichorionic twins, ultrasound screening is predominantly for selective growth restriction (10% of pregnancies).

The majority of twins will deliver prematurely, either spontaneously or because of a pregnancy-related complication (circa 60%). In those undelivered (and without complication) national guidelines recommends delivery of monochorionic twins by 36 weeks and dichorionic twins by 37 weeks of pregnancy [5–7]. If this recommendation is not taken up by patients, then close fetal surveillance is required. Among monochorionic twins, this approach must be balanced against a 1.5% risk of late in-utero death.

31.3 Clinical Governance Issues

At the first trimester ultrasound examination, there should be the assignment of the spatial nomenclature of the babies to the maternal uterus (for example, upper and lower, or left and right) in twin pregnancies. This should be documented in the antenatal notes to ensure consistency throughout pregnancy.

Clinical governance issues should be focused around both maternal and fetal complications. For the mother advice should be given in relation to diet and general health. There is an increased risk of fetal anaemia and full blood count estimations should be assessed regularly. Screening for gestational diabetes should be performed according to accepted risk factors. Baseline maternal characteristics should be recorded, particularly blood pressure and urinalysis. Even in normotensive women, the risk of developing pre-eclampsia is increased by four times the background rate. For that reason, prophylactic aspirin should be recommended (75 mg daily).

Fetal anomalies may be identified at any point in the pregnancy. A fetal anomaly may be identified (in one or both fetuses) in up to 27% (95% confidence interval 15.0–42.8) of cases [8]. If these are detected in the first trimester it is probable that these are major anomalies such as anencephaly, body stalk anomalies or large nuchal translucencies. Concordance of structural defects (both fetuses being affected) is rare (10% in dichorionic and 20% in monochorionic twin pregnancies). Selective growth restriction (sGR) complicates between 10 and 15% of all twin pregnancies. It is more common in monochorionic twins (depending upon the definition). Currently, the diagnosis is made using ultrasound fetal biometry where there is a difference in estimated fetal weight of greater than 20% (there has recently been a change in definition within the UK, based upon the findings of the Irish study [9]). Previous guidelines [5] use the definition of a difference in estimated fetal weight of >25%. Customised growth charts for twins are being evaluated and show signs of early promise [10]. In both dichorionic and monochorionic twins with SGR there should be consideration of possible underlying aetiologies including aneuploidy, fetal anomaly and fetal infection. In monochorionic twins, the type and prognosis of sGR is staged by the fetal umbilical artery Doppler velocity waveform [11]. For severe sGR with absent or reversed umbilical artery Dopplers there is a risk of single or double twin demise in up to 20% with at least 90% of babies decompensating and requiring intervention; this is usually early delivery before 32 weeks (there is a 10% risk of neurological injury in the larger twin). Before 26 weeks where delivery has inherent risks of long-term morbidity, consideration of selective fetal reduction should be discussed with a tertiary centre.

Twin to twin transfusion syndrome complicates 10–15% of all monochorionic twin pregnan-

cies and presents in the majority of cases prior to 26 weeks (98%) (most commonly between 17 and 22 weeks). There may be an overlap with the ultrasound diagnosis of sGR (~60% of the "donors" having sGR) but the diagnostic ultrasound finding is discordance in liquor volume in the amniotic sacs of the twins; the donor having a maximum vertical pool (MVP) of <2 cms and the recipient having a MVP of at least 8 cm (before 20 weeks) and >10 cm after 20 weeks. Such an ultrasound finding alone should prompt discussion with a fetal medicine centre and referral for assessment and treatment. Further, assessment by detail ultrasound can further stage severity of the disease using intracardiac and fetoplacental arterial and venous Doppler velocimetry but they do not alter the diagnosis or the requirement for assessment in a tertiary centre. The optimal treatment between 16–26 weeks is fetoscopic laser ablation. Informed, written consent should be taken and the couple informed specifically about fetal loss rates (~10–15% double loss and 30–40% single fetal demise), amniorhexis (~5%) and risk of handicap in survivors (5% each fetus). After 26 weeks, treatment should be customised to the pregnancy and may include the option of delivery. Delivery of post-treatment fetuses (as with all complicated monochorionic twin pregnancies) should be achieved before 36 weeks gestation.

The increased perinatal morbidity and mortality for twins is also present during delivery, with a higher risk of hypoxic ischaemic encephalopathy than in singleton pregnancies. The commonest cause of litigation is the misinterpretation of cardiotocographs where both twins are not monitored separately.

31.4 Reasons for Litigation

31.4.1 Antenatal

- Failure to document the risks of twin pregnancy antenatally
- Failure to correctly assess chorionicity in the first trimester
- Failure to seek a second opinion in cases where chorionicity is uncertain
- Failure to treat as highest risk if chorionicity remains uncertain
- Failure to highlight the pitfalls of aneuploidy screening in twins
- Failure to discuss the issue of fetuses discordant for aneuploidy or structural abnormality
- Failure to refer to a tertiary unit when there is discrepant fetal growth
- Failure to discuss options and timing of delivery
- Failure to discuss risk of caesarean section for the second twin

31.4.2 Intrapartum

- Monitoring the same twin's fetal heart rate twice
- Failure to stabilise the lie of the second twin
- Failure to determine presentation
- Failure to involve a senior clinician with appropriate skills to deliver the second twin
- Failure to anticipate post-partum haemorrhage

31.5 Avoidance of Litigation

Once a diagnosis of a twin pregnancy is made all possible attempts should be made to determine chorionicity at the earliest opportunity. Referral to a tertiary centre may be required. Based on chorionicity a discussion should occur regarding the risks of screening in twins as well as the reduced performance of available screening tests. This should include a discussion of the management of babies discordant for fetal abnormality. Any invasive test should be conducted in a tertiary centre to allow accurate identification of any fetus potentially requiring a selective reduction procedure.

Patients with twins should be aware of the risks of preterm delivery and be made aware of the potential signs and symptoms, having a low threshold to attend for assessment. Monochorionic twins should be assessed by ultrasound every 2 weeks looking for the presence of TTTS and SGR. Any concerns should

prompt early referral to a specialist centre for intervention. Dichorionic twins should be assessed every 4 weeks looking for SGR. A discussion should occur antenatally regarding mode of delivery and the risks and benefits of vaginal versus abdominal delivery. This should also include caesarean section for the second twin. Monochorionic twins should be offered delivery from 36 weeks and dichorionic twins from 37 weeks. Mothers declining induction should have increased monitoring.

Vaginal delivery of twins should be conducted in the presence of a senior clinician with the skills for ultrasound and to conduct any potential manoeuvres for delivery of the second twin, including external cephalic version, internal podalic version, vaginal breech delivery and breech extraction. These technical skills are only required to be achieved by Obstetricians in the UK during the Advanced Labour Ward ATSM, in the latter part of their training. Both babies should have continuous electronic fetal monitoring. If this is not possible then consideration to caesarean section should be discussed. There is no absolute time interval between delivery of the first and second twin as long as CTG monitoring is normal. Following delivery there should be anticipation of postpartum haemorrhage.

31.6 Case Study

A 35-year-old multiparous women, with known monochorionic diamniotic twins, presented for a mid-trimester scan at 20 weeks gestation. The ultrasound demonstrated features suggestive of twin to twin transfusion syndrome with Fetus A having polyhydramnios (deepest vertical pool of 11 cm) and fetus B, severe oligohydramnios (<1 cm). The patient was referred to a tertiary centre for assessment and treatment. Within 24 hours fetoscopic laser ablation was performed (a selective sequential method) and both babies were viable. The consent form clearly noted that the chance of at least one survivor was 85% and the risk of neurologic morbidity was ~5% for each fetus. The babies were delivered by emergency caesarean section at 31 weeks after premature, pre-labour ruptured membranes and a course of maternal betamethasone.

The 'ex-recipient' on neonatal cranial ultrasound had localised atrophy of the right frontal cerebral cortex. Further investigation by MRI confirmed focal reparative polymicrogyria.

The parents alleged that once the treatment for TTTS was complete there was no further risk to the babies in terms of handicap (other than the risks of prematurity). Because of clearly documented consent, the case was successfully defended.

Key Points: Twins

- Early assessment of chorionicity
- Documented discussion regarding screening in twins
- Documented discussion regarding twins discordant for fetal abnormality
- Highlight the risks of pre-term delivery
- Referral to a tertiary centre for twins discordant for fetal abnormality
- Adherence to national guidelines regarding ultrasound surveillance
- Low threshold for fetal medicine opinion where TTTS or SGR suspected
- Discuss timing and mode of delivery
- Senior clinician present for vaginal delivery
- Anticipate post-partum complications

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Vaginal Breech Delivery

32

Simon Grant and Emma Ferriman

32.1 Background

Breech presentation complicates 3–4% of pregnancies at term. The incidence of breech presentation in the preterm pregnancy is higher. Associations with breech presentation include uterine anomalies, congenital malformations in the fetus and polyhydramnios. Breech presentation is higher in nulliiparous patients and has a significant recurrence risk [1]. Following the publication of the Term Breech Trial (TBT) in 2000 [2] there was a significant reduction in the number of breech babies being delivered vaginally and this has consequently led to a loss of the skills required to conduct a successful vaginal breech birth. The trial was the subject of considerable criticism particularly with regard to case selection and intrapartum management. For example, in 31% of cases there was no antenatal ultrasound assessment, in 31.9% there was no senior obstetrician present to conduct the delivery and in 13% of cases no obstetrician was present at all [3]. Due to the limited success of external cephalic version (ECV) (50% success rate) [4] and failure to diagnose breech presentation in up to 25% of cases, vaginal breech birth will continue. In addition, maternal choice is also becoming a significant factor especially when women consider the impact of caesarean section on their future fertility. In the NHS Resolution review for litigation surrounding cerebral palsy claims there were six claims related to breech presentation; four at term and two at 34 weeks gestation. In all six cases, delivery occurred out of hours and five were cases of undiagnosed breech in labour. Five were delivered by a specialist registrar without a consultant present. In all six cases, there was an attempt at vaginal delivery, but three were ultimately delivered by caesarean section [5].

32.2 Minimum Standards

Women presenting with a breech presentation after 37 weeks gestation should be offered an ECV by a trained practitioner. In those women who either decline ECV, or where ECV is contraindicated or where ECV is unsuccessful they should be counselled regarding vaginal breech birth or elective caesarean section after 39 weeks gestation. Elective caesarean section has a small reduction in perinatal mortality compared to vaginal breech birth and this is based on the avoidance of stillbirth occurring after 39 weeks, the avoidance of intrapartum risks and the avoidance

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of the direct risks of vaginal breech birth itself. Overall the perinatal mortality rate for elective caesarean section after 39 weeks is 0.5/1000 compared to vaginal breech birth of 2.0/1000. The chance of a successful breech delivery is improved with appropriate case selection. Contraindications will include a hyperextended neck, an estimated fetal weight (EFW) of greater than 3.8 kgs, an EFW less than the 10th centile, footling breech presentation and any evidence of fetal compromise detected antenatally [1].

Women attending for planned vaginal breech delivery should be delivered in a unit where there is immediate access to caesarean section as up to 45% of women will experience labour complications [1]. Induction of labour is not appropriate. In addition, augmentation of labour is also controversial, but there may be a place to improve contraction frequency for women with epidural anaesthesia. There is limited evidence regarding monitoring in labour, but continuous electronic fetal monitoring (cEFM) may lead to improved neonatal outcomes [6]. For women declining cEFM intermittent auscultation should be performed as for cephalic presentation with conversion to continuous monitoring if there are concerns regarding fetal compromise.

The first stage of the delivery should be conducted as for a vaginal cephalic birth. Amniotomy should be restricted to specific clinical indications to reduce the risk of cord compression. Slow progress in labour should generally be managed by caesarean section although there may be a place for oxytocin in women with an epidural and reduced contraction frequency. (This opinion is controversial). The second stage may be managed with a passive hour to allow descent of the breech within the pelvis. If the breech is not visible within 2 hours a caesarean section should be performed as active pushing is not recommended if the breech is not visible. A skilled operator should be present at delivery with the appropriate skills for vaginal delivery including a "hands off" technique as fetal traction is more likely to result in a hyper extended neck. Assisted breech delivery is required if there is an interval of greater than 5 min between delivery of the buttocks and the head or greater than 3 min between delivery to the umbilicus and the head. Women should be warned that babies delivered vaginally in a breech presentation are more likely to have low Apgar scores at delivery and a neonatal team should be present to ensure prompt resuscitation.

There is limited good quality guidance for the preterm breech baby. For those women presenting in spontaneous preterm labour a routine approach of caesarean section is not recommended. The decision for mode of delivery should be taken according to the stage of labour, the type of breech presentation, the wellbeing of the fetus and the availability of a skilled operator. In up to 14% of preterm vaginal breech deliveries the head will become entrapped in an incompletely dilated cervix; in this scenario, lateral cervical incisions may be required to deliver the after-coming head. For breech presentation at the limits of viability (22–25 + 6 weeks gestation) caesarean section is not usually recommended and for those women where delivery is indicated due to either fetal or maternal compromise vaginal breech delivery is not appropriate.

In a twin pregnancy where the first twin is breech the standard practice is for elective caesarean section. For twin pregnancies presenting in labour where the first twin is breech a decision should be made regarding mode of delivery based on the stage of labour, the type of breech presentation, the wellbeing of the baby and the presence of a skilled operator to conduct the delivery. Breech presentation in the second twin occurs in about 40% of twins. Following the results of the Twin Birth study the trial concluded there was no difference in outcome for the second twin presenting in a non-cephalic presentation [7]. The two-year follow up for these babies also showed that a policy of planned caesarean section conferred no benefit in terms of long-term neurodevelopmental sequelae [8].

32.3 Clinical Governance Issues

Women with a diagnosed breech presentation at term should be managed according to a locally agreed protocol. This may include managing women in a specialist breech clinic with access

to detailed ultrasonography to establish estimated fetal weight, liquor and Dopplers as markers for fetal wellbeing, placental site, the type of breech presentation and the attitude of the fetal head. In addition, access to a clinician and midwife who can document any antenatal risk factors and to accurately and impartially discuss ECV, vaginal breech birth and elective caesarean section. For those women electing to attempt vaginal breech delivery there should be appropriate case selection with evidence of both fetal and maternal wellbeing. The use of an antenatal checklist may be of use to ensure all pre-requisites have been discussed and documented.

Delivery should occur within a unit with immediate access to caesarean section and with the presence of an experienced clinician trained in vaginal breech birth. When deliveries occur out of hours the experienced clinician should be present on site. Continuous electronic fetal monitoring should be discussed taking into account both the woman's wishes and the small amount of evidence suggesting improved neonatal outcomes with continuous monitoring.

Following the TBT vaginal breech delivery became less common and subsequently the number of practitioners with the relevant skills and experience in vaginal breech birth declined. The introduction of simulation training has been shown to improve the conduct of vaginal breech birth and to improve perinatal outcomes [9, 10]. Approved courses teaching vaginal breech delivery include PROMPT (Practical Obstetric multiprofessional training) and MOET (managing obstetric emergencies and trauma). These courses aim to teach senior clinicians and midwives the essential skills for successful vaginal breech delivery.

Women with an undiagnosed breech presentation presenting in spontaneous labour (either term or preterm) should also be managed according to an agreed local protocol with assessment of maternal and fetal risk factors, assessment of the stage of labour, the type of vaginal breech and an accurate assessment of current fetal wellbeing. The presence of a skilled operator will also be mandatory in these cases. Where labour is progressing rapidly there has to be a balance of risk, as attempting caesarean section when the breech is very low in the maternal pelvis is more likely to be associated with an increase in both neonatal and maternal morbidity.

32.4 Reasons for Litigation

- Failure to assess relevant antenatal risk factors
- Failure to perform a detailed ultrasound as part of the assessment for vaginal breech delivery
- Poor documentation of pros and cons of planned vaginal delivery versus planned caesarean section
- Failure to discuss the risks of caesarean section in labour
- Delayed diagnosis of breech presentation in labour
- Inadequate fetal monitoring in labour
- Failure to resort to caesarean section in cases where there is either slow progress in labour or evidence of fetal compromise
- Lack of senior obstetric personnel to perform a vaginal breech delivery
- Failure to document higher risks of low Apgar scores and cord gases at delivery
- Traumatic delivery resulting in soft tissue damage, visceral damage, long bone fracture and brachial plexus injury
- Failure to obtain prompt neonatal resuscitation

32.5 Avoidance of Litigation

The avoidance of litigation will be focused in the main around three areas:

1. Strict selection criteria

Women presenting at term with a breech presentation should be counselled based on their antenatal risk factors. For example, a woman with a previous caesarean section may opt for a repeat operation. In addition, the baby needs to

be properly assessed with an accurate EFW estimation (a fetal weight greater than 3.8 kgs may be associated with a greater risk of dystocia), the type of breech presentation (flexed, extended or footling), the attitude of the fetal head and general wellbeing of the fetus. There should be a fully documented discussion surrounding all possible options including ECV. Antenatal checklists are helpful to reduce the risk of omissions.

2. Adherence to an intrapartum protocol

A local protocol for the management of vaginal breech delivery should be constructed with adherence to the guidance when women present in labour. Women should be delivered by caesarean section if there is evidence of poor progress in labour or signs of fetal compromise.

3. An experienced obstetrician in attendance

The presence of a skilled practitioner to facilitate the delivery is mandatory. The prime reasons for litigation in the NHS resolution data review was the lack of a senior obstetrician present at delivery.

Finally, parents should be counselled regarding the risks of babies being born with low Apgar scores, and poor cord gases and should be warned regarding fetal soft tissue and bony injuries. A suitably experienced neonatologist should also be present at delivery to ensure rapid and effective neonatal resuscitation.

32.6 Case Study

Mrs. G was a 32-year-old lady in her second pregnancy with a history of one previous miscarriage. She conceived via ICSI and so was booked for consultant-led care. The pregnancy was uneventful until 27 + 4/40, when she presented with decreased fetal movements, but ultrasound scan and CTG were both normal. At 28 + 3/40, Mrs. Godfrey presented to the hospital again, on this occasion with a five-day history of antepartum haemorrhage and although this was initially thought to be secondary to a cervical ectropion, examination subsequently showed her cervix to be effaced, 2 cm dilated, with bulging membranes. She progressed rapidly to full dilatation over the next 3 hours and was diagnosed with a breech presentation after spontaneous rupture of the membranes at an examination carried out because of fetal bradycardia. Initially, after assessment by the obstetric registrar, pushing was encouraged, to aim for vaginal delivery with consideration of a breech extraction. Subsequently, the registrar found it difficult to reach any part of the baby to make this manoeuvre possible and arranged transfer to theatre for category I caesarean section. On arrival in theatre, Mrs. G had progressed, with the breech on the perineum and an assisted breech delivery was performed, with the assistance of the consultant obstetrician. Unfortunately, the baby was born in very poor condition, requiring extensive resuscitation and transfer to the neonatal intensive care unit (NICU). Care was withdrawn at 8 days of age. The Claimant alleged breach of duty based on the fact that the sudden bradycardia was likely to have been due to a cord prolapse in that it occurred following spontaneous rupture of membranes, the baby was in a breech presentation, had a high presenting part and was preterm. Furthermore, given the above there was no management plan for the delivery and there was a significant delay between the diagnosis of full dilatation with fetal bradycardia and eventual delivery of the baby in theatre. The claim was settled as the Defendants agreed that Mrs. G should have been transferred to theatre for category 1 caesarean section immediately after the bradycardia when it became apparent that the breech was high and not imminently deliverable. In addition, criticism also arose because there was a lack of immediate senior supervision for the junior registrar and no manoeuvres were employed to reduce cord compression as should occur with a cord prolapse.

Key Points: Vaginal Breech Delivery

- Antenatal assessment of fetal and maternal wellbeing
- Antenatal checklist for women considering vaginal breech delivery
- Provide an ECV service to facilitate cephalic presentation
- Ultrasound assessment for suitability of vaginal breech delivery
- Protocol for the management of vaginal breech at term
- Protocol for the management of undiagnosed breech in labour (term or preterm)
- Accurate monitoring to assess fetal wellbeing in labour
- Prompt recourse to caesarean section if poor progress in labour or concerns regarding fetal wellbeing
- Availability of facilities for emergency caesarean section
- Ensure simulation training of senior obstetricians and midwives to conduct a vaginal breech delivery
- Presence of a skilled obstetrician present for vaginal breech delivery
- Presence of a neonatal team for resuscitation at delivery

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Maternal Collapse in Pregnancy

33

Peter Brunskill and Emma Ferriman

33.1 Background

Maternal collapse is defined by the RCOG as 'an acute' event involving cardiorespiratory systems and/or the brain, resulting in a reduced or absent conscious level (and potentially death), at any stage in pregnancy and up to 6 weeks after delivery [1]. Maternal collapse in pregnancy and in the immediate post-partum period is a potentially life-threatening event with a wide range of possible causes. The maternal outcome primarily depends on prompt and effective resuscitation with the mother as the priority. Maternal mortality data is accurately collected via the MMBRACE-UK reporting system; Saving lives, improving mother's care, but data on maternal morbidity and collapse is not routinely collected. 8.5/100,000 women died during pregnancy and up to 6 weeks following delivery in the 2012–2014 report. The 10th Scottish Confidential audit of severe maternal morbidity (SCASMM) produced a morbidity rate of 7.3/1000 births [2]. Maternal morbidity data is further complicated as not all cases of maternal morbidity are preceded by maternal collapse. In reality, this therefore means that the true incidence of maternal collapse lies somewhere between the two figures. In the SCASMM data major obstetric haemorrhage (MOH) remained the commonest cause of maternal morbidity, responsible for over 80% of cases.

33.2 Minimum Standards

Not all causes of maternal collapse can be predicted, although there may be risk factors making severe maternal morbidity more likely. For women with significant medical conditions these women should be cared for by a multidisciplinary team and their management should include a plan for delivery, whether elective or as an emergency. In these high-risk patients, there may be signs and symptoms that precede the acute collapse. A recurring theme in the CEMACH, CEMACE and MMBRACE reports is substandard care where signs and symptoms were present and not acted upon. The 2003–2005 CEMACH report recommended the introduction of an Obstetric Early Warning Score used for all obstetric patients requiring regular observation including those patients being cared for in a non-obstetric setting [3]. The Early Warning Score (EWS) is modified to account for the normal physiological changes occurring as an adaptation to pregnancy (modified early warning score (MEWS)).

Some possible causes of maternal collapse are documented in Table 33.1. These causes may be

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Table 33.1 Causes of maternal collapse in pregnancy

System	Cause
Neurological	Eclampsia Post epileptic seizure Intracranial haemorrhage
Cardiac	Aortic dissection Arrhythmias Myocardial infarction Cardiomyopathy
Chest	Pulmonary embolism Amniotic fluid embolism
Haemorrhage	Massive obstetric haemorrhage Splenic artery rupture Hepatic rupture
Drugs	Magnesium sulphate Local anaesthetic Illicit drugs
Metabolic	Hypoglycaemia Diabetic ketoacidosis
Others	Sepsis Anaphylaxis Maternal trauma including road traffic accidents and domestic violence Vasovagal response

Table 33.2 Reversible causes of maternal collapse

Reversible cause	Cause in pregnancy
4Hs	
Hypovolaemia	Haemorrhage (concealed or revealed) Dense spinal block Septic shock Neurogenic shock
Hypoxia	Pregnant patients become hypoxic more quickly Cardiac events Large vessel aneurysms
Hypo/hyperkalaemia	No increased likelihood
Hypothermia	No increased likelihood
4Ts	
Thromboembolism	Amniotic fluid embolus Pulmonary embolus Air embolus Myocardial infarction
Toxicity	Local anaesthetic Magnesium
Tension pneumothorax	Trauma or suicide attempt
Tamponade (cardiac)	Trauma or suicide attempt
Eclampsia/ pre-eclampsia	Intracranial haemorrhage

pregnancy related or as a direct result of pre-existing maternal disease. (Many of these causes are discussed in the relevant chapters in the obstetric section of this book). Amniotic fluid embolus (AFE) remains a clinical challenge and the management is supportive rather than therapeutic. Management should involve senior clinicians at an early stage with active resuscitation, inotropic support and correction of coagulation defects. When considering a collapsed pregnant patient there should be a structured and systematic consideration to the possible causes.

Collapse in a hospital environment may be amenable to treatment if a reversible cause is identified. The resuscitation council summarise these causes as the 4Hs and the 4Ts, but eclampsia and pre-eclampsia should also be added for pregnant patients as documented in Table 33.2 [4].

The treatment of a maternal collapse should be based on effective and aggressive resuscitation. The physiological adaptions of pregnancy make resuscitation more challenging and it is imperative that obstetric, midwifery, anaesthetic and emergency medicine staff are familiar with the normal physiology of pregnancy. For example, pregnant patients become hypoxic more quickly and are more difficult to ventilate and the cardiovascular changes in pregnancy heighten the effects of blood loss. The pregnant uterus compresses the inferior vena cava and the aorta form 20 weeks gestation reducing cardiac output by up to 40%. This aortocaval compression will be relieved using left lateral tilt or manual uterine displacement. For the anaesthetist intubation is more difficult due to pregnancy weight gain, laryngeal oedema and the enlarged breasts making airway access more difficult. There are also the increased risks of aspiration due to relaxation of the gastro-oesophageal sphincter and delayed gastric emptying. In pregnant patients, the increased circulating blood volume means that large volumes of blood may be lost rapidly. In healthy pregnant women blood loss is well tolerated and these patients may lose up to 35% of their circulating blood volume before becoming symptomatic.

The collapsed pregnant patient should be managed according to the A, B, C, D, E structured approach [5]. In women in cardiac arrest prompt initiation of chest compressions should

occur with ventilation ideally via a secured airway with a cuffed endotracheal tube. Early recourse to delivery of the fetus to aid resuscitation should occur in all pregnant patients at gestations of greater than 20 weeks. Haemorrhage remains the commonest cause of maternal collapse and in these women there should be a high index of suspicion and an awareness that the typical signs and symptoms of shock will occur late.

33.3 Clinical Governance Issues

All pregnant women should be continually assessed for the presence of risk factors for severe morbidity in pregnancy. This is particularly relevant for women at risk of massive obstetric haemorrhage and eclampsia. For those women with significant risk factors a comprehensive delivery plan should be documented in the maternity records and the woman's handheld maternity notes. This plan should include arrangements for both planned and unplanned delivery and postnatal management. Management plans should be made within the realms of a multidisciplinary team including obstetricians, anaesthetists, neonatologists, intensivists and haematologists (where indicated). Obstetric care bundles may assist in planning for women with placenta praevia and accreta [6]. The use of Modified Early Warning Scores (MEWS) should be employed for women requiring intensive monitoring or women at risk of severe morbidity.

All cases of severe maternal morbidity and maternal collapse should be reviewed by the risk management team to ensure effective treatment as per local and national guidance. All maternal deaths should be reported to MMBRACE UK.

All staff caring for pregnant patients should be aware of the normal physiological adaptations of pregnancy that make resuscitation more difficult and be prepared to facilitate early delivery of the baby to aid resuscitation in women of greater than 20 weeks gestation. Staff should attend annual training for cardiopulmonary resuscitation (CPR). In addition, simulation training in small groups also enhances more effective management. Senior obstetric trainees may benefit from attending national courses such as MOET (management of obstetric emergencies and trauma) or ALSO (advanced life support in obstetrics).

33.4 Reasons for Litigation

- Failure to appreciate risk factors for severe maternal disease
- Lack of antenatal planning for pregnant women with pre-existing disease
- Lack of involvement of a multidisciplinary team to facilitate planning
- Late recognition of the critically ill patient
- Failure to escalate to senior clinicians
- Late involvement of the multidisciplinary team
- Inadequate resuscitation
- Failure to empty the uterus early to aid effective cardio-pulmonary resuscitation.

33.5 Avoidance of Litigation

For pregnant women with risk factors for severe disease or with significant pre-existing maternal disease these women should be managed antenatally using a multi-disciplinary approach by senior clinicians. They should be managed according to an agreed and documented management plan with a named clinician responsible who may be contacted in the event of an emergency or out of hours admission. There should be a fully documented record of the relevant risk factors and the possible risks to mother and baby. Delivery options should also be discussed and documented antenatally. Unscheduled admissions should prompt early involvement of senior clinicians from the relevant specialties. All women should have effective monitoring with the minimum standard of twelve hourly in a hospital setting [7].

For women who collapse acutely in whom the episode is unexpected or unpredictable they should be managed according to the UK Resuscitation Council guidelines: basic life support (BLS), adult advanced life support (ALS) and automated external defibrillation (AED) algorithms [8, 9] (Fig. 33.1). All clinicians and

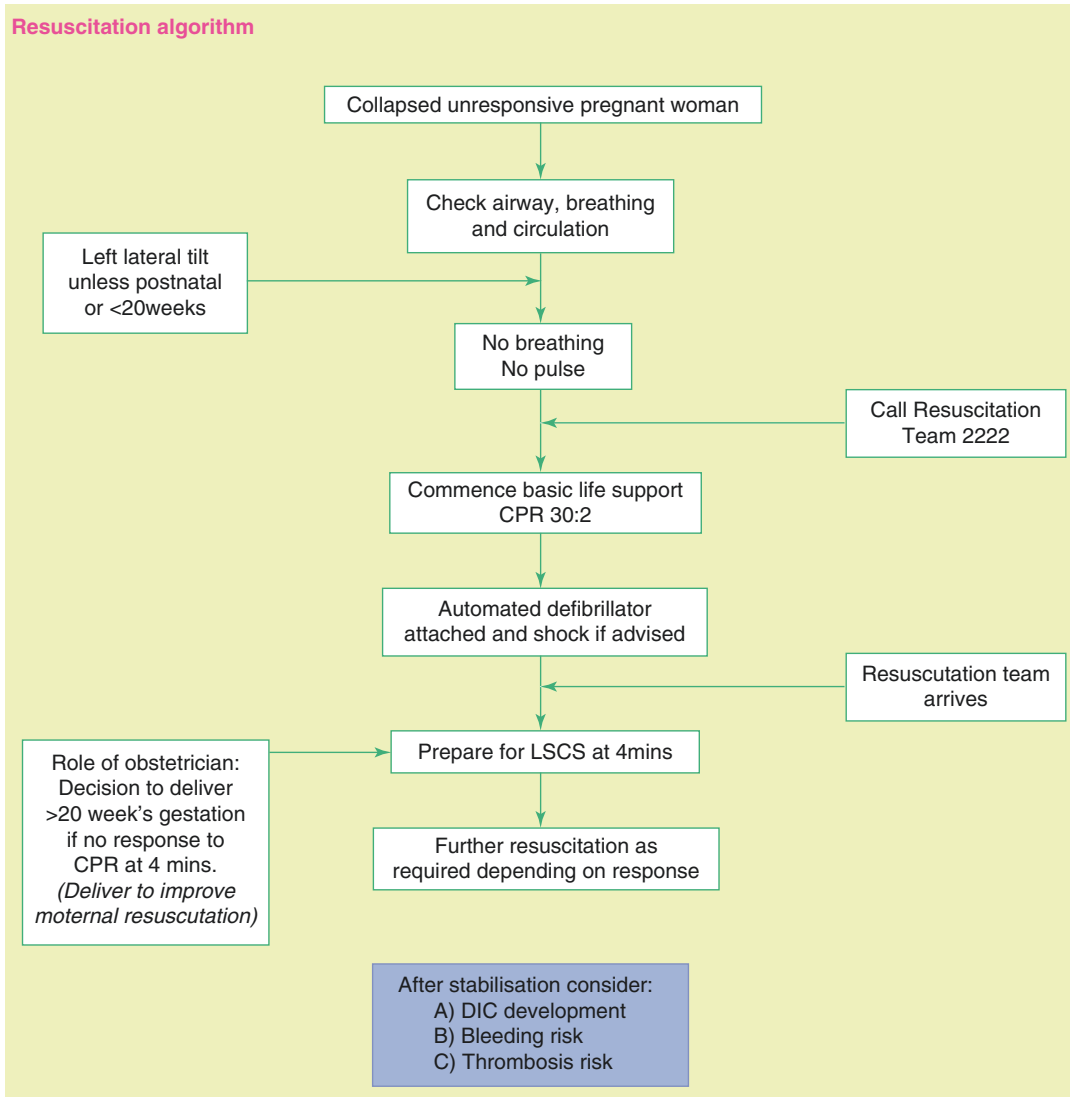

Fig. 33.1 Resuscitation algorithm for the pregnant patient

practitioners should be familiar with the particular challenges of cardiopulmonary resuscitation in pregnant women and should be familiar with possible causes of maternal collapse. Particular emphasis should be paid to treatment of the reversible causes that may make resuscitation successful. All staff should have documented evidence of annual CPR training via the risk management pathway of the department. In addition, attendance at small group simulation training will enhance the functioning of the team in a resuscitation scenario.

Contemporaneous documentation of the acute event is mandatory, but not always well-executed making legal claims difficult to defend. The use of a scribe with a scribe sheet especially with regard to major obstetric haemorrhage will enhance documentation. For women and families involved in an acute maternal collapse scenario a debrief by a senior clinician will help to address

any concerns regarding diagnosis and treatment with follow up of traumatic events in obstetric debrief clinics. Maternal collapse requiring resuscitation should be assessed by the risk management process. Issues with poor practice may then be addressed through a supportive learning environment for staff and direct feedback to patients and their families provided.

33.6 Case Study

M v P 2011 (Maher v Pennine Acute Trust).

Mrs. D was a Jehovah's Witness, who declined both blood and blood products throughout her pregnancy and had signed an advanced directive. She was delivered by caesarean section but deteriorated over the subsequent 3 hours due to haemorrhage from a rupture in the posterior wall of the uterus. Mrs. D was eventually returned to theatre but despite surgical control of the haemorrhage died 2 days later from multi organ failure.

The Claimant argued that the Defendants had failed to recognise the signs of haemorrhage—tachycardia, pallor, poor urine output and the relatively late sign of falling blood pressure. The Defendants agreed that Mrs. D's post-operative management had been below an acceptable standard—the Defendant's expert described it in Court as 'woeful'. The Defendants however argued that the delay in return to theatre made no difference to the outcome.

In his assessment of the case the Judge considered when death from overwhelming blood loss without replacement would have become inevitable. He concluded that, if Mrs. D had been returned to theatre at an appropriate time, she would on balance have survived without the transfusion of blood products.

The Defendants also argued that even at the later time of surgery, Mrs. D would not have died if she had received blood and blood products, and that her refusal therefore 'broke the chain of causation'. The Judge however concluded that Mrs. D's refusal of blood products was reasonable, based on her religious convictions and that the Defendants were aware of her views and had protocols in place to deal with them. As the Defendants were responsible for a period of time in failing to mitigate the blood loss and knew during that period that Mrs. D would not accept a blood transfusion, the Judge found in favour of the Claimant whose family was awarded £375,000.

This case highlights the importance of early recognition of the signs and symptoms occurring prior to a maternal collapse. In particular, that a fall in blood pressure is a late feature of major obstetric haemorrhage in a previously healthy pregnant patient. Had the signs of major haemorrhage been identified at an earlier stage, the Claimant would have received earlier surgical intervention thereby arresting the ongoing bleeding. This in turn would have resulted in a reduced blood loss that could have been managed according to the local protocol for women with major haemorrhage declining blood and blood products.

Key Points: Maternal Collapse in Pregnancy

- Identify any antenatal risk factors
- Mange patients with pre-existing disease in a specialist clinic as part of a multidisciplinary approach
- Document a management plan for delivery and the postnatal period for high-risk patients
- Ensure adequate monitoring of patients with a MEWS chart and escalate accordingly
- Involve senior clinicians early
- Ensure all staff are trained in CPR in pregnant patients
- There should be early recourse to emptying the uterus in women beyond 20 weeks gestation to aid effective resuscitation

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34 Postpartum Haemorrhage and Retained Products of Conception Postnatal

Stephen O. Porter

34.1 Background

Obstetric haemorhage is the fourth most common cause of direct maternal death in the United Kingdom, accounting for 21 deaths per 100,000 maternities (MBRACE 2013–2015) [1] a concerning increase of 7 deaths from the previous triennium [2]. Between 1994 and 2012, postpartum haemorrhage accounted for between 30 and 80% of deaths attributable to obstetric haemorrhage [2]. It is however, widely acknowledged that this small mortality rate forms the tip of a much larger morbidity ice-berg. In addressing maternal mortality and morbidity, Bewley et al. estimated that the associated morbidity rate is up to one hundred times higher [3]. Based on this assertion, the morbidity rate associated with postpartum haemorrhage in the 2012–2014 triennium may have been as high as 1040 per 100,000 maternities.

Although morbidity following postpartum haemorrhage is not necessarily due to clinical negligence, claims for clinical negligence are likely to arise in the setting of morbidity (Fig. 34.1).

A 10-year review of NHSLA claims identified 111 claims for postpartum haemorrhage. Eighty-two of the cases involved retained products, twenty-five involved haemorrhage and in four cases no central theme was identified. The total value of the claims identified was £3 million [4].

34.2 Minimum Standards

Primary postpartum haemorrhage (PPH) is defined as the loss of 500 mL or more of blood from the genital tract within 24 hours of the birth of a baby. Minimum clinical standards relate to the prediction or prevention of haemorrhage, recognition of loss and appropriate treatment.

1. Prediction/Prevention: Some of the risk factors for postpartum haemorrhage are listed in the Fig. 34.2. Once identified these should be documented and used to form a clear plan of care.
2. Recognition: Visual estimation of blood loss following delivery is unreliable and typically overestimates loss at small volumes and underestimates loss at larger volumes [5, 6]. Symptoms of haemorrhage often precede signs. These include unexplained anxiety, a feeling of being cold or breathlessness. It is therefore vital that healthcare workers pay particular attention to these symptoms in women at risk of postpartum haemorrhage. The use of MEWS/MEOWS (Modified Early Obstetric Warning Scores) charts should be employed to record the observations of all high-risk patients.

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3. Treatment: In the event of significant primary postpartum haemorrhage, the patient should be resuscitated in accordance with established national and or local guidelines. Blood loss should be accurately recorded, and all swabs weighed to ensure accuracy. Thereafter management should be directed at the cause of bleeding. It is vital that the clinician in charge appoints a scribe whose job it is to document the personnel present and the nature and timing of any interventions. If possible, the scribe should also note the timing of conversations with the patient and relatives particularly in relation to the consent for procedures. It is also vital that the clinician, at the conclusion of the case, records the events in chronological order.

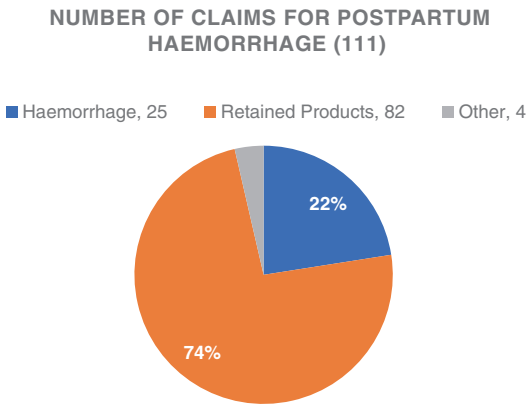

Fig. 34.1 Number of claims for postpartum haemorrhage 2000–2010 [4]

Secondary postpartum haemorrhage, defined as excessive vaginal bleeding from 24 hours up to 6 weeks postpartum, remains a complex condition to manage and treat. The amount of blood loss is not defined. Furthermore, normal postpartum loss may continue beyond 6 weeks in 25% of women [7], especially if breast-feeding, and the first period may be particularly heavy. These diagnostic uncertainties give rise to a lack of consensus on how best to manage secondary postpartum haemorrhage. Indeed, a Cochrane review of the management of secondary postpar-

Risk factor	The four Ts	OR (95% CI)
Multiple pregnancy	Tone	3.30 (1.00–10.60)[16] 4.70 (2.40–9.10)[24]
Previous PPH	Tone	3.60 (1.20–10.20)[16]
Pre-eclampsia	Thrombin	5.00 (3.00–8.50)[16] 2.20 (1.30–3.70)[11]
Fetal macrosomia	Tone	2.11 (1.62–2.76)[20] 2.40 (1.90–2.90)[24]
Failure to progress in second stage	Tone	3.40 (2.40–4.70)[23] 1.90 (1.20–2.90)[11]
Prolonged third stage of labour	Tone	7.60 (4.20–13.50)[16] 2.61 (1.83–3.72)[20]
Retained placenta	Tissue	7.83 (3.78–16.22)[20] 3.50 (2.10–5.80)[23] 6.00 (3.50–10.40)[24]
Placenta accreta	Tissue	3.30 (1.70–6.40)[23]
Episiotomy	Trauma	4.70 (2.60–8.40)[25] 2.18 (1.68–2.76)[20] 1.70 (1.20–2.50)[24]
Perineal laceration	Trauma	1.40 (1.04–1.87)[20] 2.40 (2.00–2.80)[23] 1.70 (1.10–2.50)[24]
General anaesthesia	Tone	2.90 (1.90–4.50)[11]

Fig. 34.2 Risk factors for postpartum haemorrhage [15]

tum haemorrhage concluded that there was no evidence from randomised controlled trials to demonstrate the efficacy of treatments for secondary postpartum haemorrhage [8]. The most common cause of secondary post-partum haemorrhage is sub-involution of the uterus, either due to infection, retained placental tissue or both.

Investigations will include baseline blood tests such as a full blood count, C reactive protein, group and save, coagulation studies and a serum bHCG. Vaginal swabs and wound swabs should be undertaken. In stable patients, a transvaginal ultrasound scan should be performed although its interpretation may be difficult.

In the presence of significant haemorrhage, resuscitation following local guidelines should be commenced prior to establishing a cause. In the presence of mild or moderate bleeding, or once the patient has been stabilised, broad spectrum antibiotics should form the part of the management of all patients with secondary post-partum haemorrhage [9]. If a conservative approach is adopted it is good practice to ensure the patient has easy access to medical review should her symptoms worsen.

Uterine evacuation and or hysteroscopy in women with secondary postpartum haemorrhage are not without complications and should be undertaken by a senior clinician. Uterine perforation may occur in 1.5% of cases [10] and a recent review showed that intra-uterine adhesions were present in 21.5% of women with a history of postpartum curettage [11]. Furthermore, there may be morbidity associated with a second procedure due to the incomplete evacuation of retained tissue or the need for a hysterectomy. It is therefore imperative that that the woman is *fully informed* of these risks and that this is carefully documented in the case notes.

Although pelvic ultrasound is often performed in women with secondary postpartum haemorrhage, the role of ultrasound in determining whether there are retained products, and whether surgical evacuation is needed, is not clear. In a study by Edwards et al. [12], in which women with normal postpartum loss were scanned, an echogenic mass within the endometrial cavity was found in 51% of women on day seven, 21% on day fourteen and 6% on day twenty one. They hypothesised that either 'an echogenic mass does not always represent retained products of conception, or that products of conception are commonly retained and are therefore of little clinical significance in many cases'. In another study, the authors concluded that in women with postpartum bleeding in the week following delivery, the presence of an echogenic mass and a uterine antero-posterior (AP) diameter greater than the 90th centile (approximately 25 mm) indicated the presence of retained products of conception [13]. Although the study did not address ultrasonic findings beyond the first postpartum week, similar findings later in the puerperium are likely to have a greater association with retained placental tissue. In the presence of on-going troublesome bleeding and equivocal scan findings, surgical evacuation of the uterus may be beneficial as was demonstrated in a study in which all 72 women undergoing a uterine evacuation for secondary postpartum haemorrhage stopped bleeding despite only 36% having proven histological evidence of retained tissue [14].

The indications for uterine evacuation or hysteroscopy in secondary postpartum haemorrhage are:

(a) Significant uterine bleeding irrespective of, or in the absence of positive scan findings
(b) Troublesome uterine bleeding with an echogenic mass and a uterine AP diameter of greater than 25 mm
(c) Persistent loss that has not responded to antibiotics, irrespective of scan findings.

34.3 Clinical Governance Issues

The Royal College of Obstetricians & Gynaecologists (RCOG) and the World Health Organisation (WHO) are two of several organisations that that have produced robust evidence-based guidelines for the management of postpartum haemorrhage [15, 16]. These form the basis of assessing the minimum standard of

care owed to patients. Guidelines by definition are not mandatory. However, departure from accepted practice may help a claimant who is seeking to prove negligence.

Organisations as well as individuals owe a duty of care to patients. In *Bull v Devon AHA* [17], Mrs. Bull had brought an action against Devon Health Authority on behalf of her severely handicapped son, one of twins, who had been injured as a result of a delay in the registrar's arrival while she was in labour. The system for summoning an obstetrician urgently had broken down and there was a delay of over an hour before the registrar arrived. The Court of Appeal held that the system had failed to provide an acceptable level of care. In *Wilsher v Essex Area Health Authority* [18], a baby sustained a hypoxic brain injury because a junior doctor inserted an umbilical catheter into the vein instead of the artery even though he checked with the registrar, who made the same error. The Court of Appeal held that the standard of care should not be lower for inexperienced doctors.

These cases suggest that an organisation can be held directly responsible, and not just vicariously through the actions of its employees, for the standard of care provided for its patients. In relation to postpartum haemorrhage it is therefore important that trusts have up to date guidelines and that all staff involved in the management of post-partum haemorrhage are trained to so. This can be evidenced by documented regular skills and drills, mandatory training and by ensuring that the induction of all new doctors includes training in the management of postpartum haemorrhage in accordance with local practice.

All cases where blood loss is in excess of 1500 mls, requiring theatre readmission, hysterectomy or intensive care admission should be reported by the appropriate risk management pathway. Accurate documentation remains essential and this may be aided by the use of preformatted proforma sheets. Where there is blood loss in excess of 1500 mls clinicians should active the major obstetric haemorrhage (MOH) protocol to endure urgent arrival of blood and blood products and senior personnel over a wide range of specialties.

34.4 Reasons for Litigation

The reasons for litigation following postpartum haemorrhage relate to:

- Delayed diagnosis
- Under estimation of blood loss
- Failure to initiate active resuscitation with blood and blood products
- Delayed investigation of continued postpartum bleeding
- Failure to offer ultrasound examination of the post-partum uterus
- Failure to consider both conservative and surgical management
- Delayed evacuation of retained placental tissue
- Failure to follow hospital guidelines
- Inadequate pre-operative counselling regarding the risks of complications for women requiring surgical management
- Complications arising during a surgical procedure (uterine perforation, ureteric injury) or following a procedure (e.g. Asherman's syndrome)

34.5 Avoidance of Litigation

Hospital Trusts need to ensure that easy to access, up-to-date, evidence-based guidelines are available within maternity departments. All staff working with women at risk of haemorrhage should be adequately trained. There should be evidence of regular skills and drills training involving all relevant staff. Trusts should ensure that there are clear operational policies dealing with logistics and infrastructure, including the provision of appropriate equipment, theatre space, medication, and directions on major incident procedures.

The key to avoiding complaints, litigation and significant morbidity in post-partum haemorrhage is:

- Prediction/Prevention
- Recognition
- Action

Women at high risk of post-partum haemorrhage should be identified early. They should be assessed for risk factors antenatally, during labour and in the immediate post-partum period. Any risks identified should be clearly documented along with a plan of care. This should include as a minimum, active management of the third stage of labour and any other measures specific to the type and severity of haemorrhage thought to be most likely. Recognition of significant postpartum haemorrhage may not be obvious if there is low level persistent bleeding. Regular clinical assessments including the use of and correct interpretation of MEWS/MEOWS charts is essential to avoid missing the 'slow bleeder'. The initial management of postpartum haemorrhage is uncontroversial and is widely available in a number of national and international guidelines [15, 16]. It is therefore essential that the practitioner adheres to these guidelines unless there is a very good reason not to do so. An adverse outcome following widely accepted practice is easier to defend than one which arises after deviation from standard practice. It is good practice to ensure that every decision for a post-partum hysterectomy is discussed with at least one other senior clinician.

In the UK, the most common source of litigation in relation to postpartum haemorrhage involves the management of persistent bleeding with retained products [4]. Before undertaking uterine evacuation at any time in the puerperium, it is essential that the clinician carefully counsels the patient about the risk of perforation, return to theatre, hysterectomy and subsequent intra uterine adhesions. Surgical evacuation with antibiotic cover should be offered to women with secondary post-partum bleeding/loss and scan findings of a thickened endometrium (over 25 mm) and an echogenic mass. In the authors unit, endometrial measurements with echogenic masses are not reported. All women with an echogenic mass in the uterine cavity of 3 cm or more are offered surgical evacuation. Surgical evacuation should also be offered to women with negative scan findings with persistent loss that has not responded to conservative management. If a conservative approach with the use of antibiotics is adopted or indeed chosen by the woman, the clinician must ensure that the patient is reviewed either in the community or in a Gynaecology Assessment and Treatment Unit (GATU). This approach allows the clinician to reassess the patient and be proactive in adopting surgical management should conservative measures fail.

Communication is vital, and the clinician must arrange timely follow-up, preferably, in a quiet setting, in order to debrief the woman and her partner and address any concerns they may have.

When a woman initiates a claim after a postpartum haemorrhage, a court will determine negligence based on:

- What was said or not—Montgomery [19]
- What was done or not—Bolam [20], England, Wales & NI; Hunter [21], Scotland
- Whether harm occurred as a direct result

The standard for valid consent is high. When proposing a treatment, with its attendant risks and benefits, a clinician must consider whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or whether he is or should reasonably be aware that the particular patient would be likely to attach significance to it." It is therefore vital that when undertaking a placenta accreta caesarean section or transferring a woman bleeding heavily to theatre, that the clinician explains clearly and calmly that hysterectomy is a potential outcome. This is particularly important in women of low parity in whom fertility may be an important consideration. It is also vital to communicate this calmly and sensitively to her partner.

If the clinician's actions are not *"in accordance with a practice accepted as proper by a responsible body*", (Bolam) or those *"which no doctor of ordinary skill in that field would have taken if acting with ordinary care"*, (Hunter), then they have breached their duty of care to the

patient. Breach of duty may be an act of omission or commission. If harm follows as a direct result the clinician will be found to have been negligent. The standard likely to be employed is that set by national evidence-based guidelines.

The importance of clear, comprehensive, contemporaneous documentation cannot be overemphasized. Illegible, incomplete documentation may create an impression of a *laissez-faire* approach to the care of the patient. Furthermore, as the limitation period is currently 3 years the clinician may have no direct recollection of the patient and so will be entirely reliant upon his documentation.

34.6 Case Study

Mrs. H, a 23-year-old professional photographer in her first pregnancy, was pregnant with twins. The pregnancy progressed without any complication, until week 36 when she went into preterm labour. Mr. L was the obstetrician on duty. As the first twin was a breech presentation, an emergency caesarean section was performed under spinal anaesthetic and both twins were delivered in good condition.

Soon after the procedure, whilst still in the recovery room, Mrs. H began bleeding steadily vaginally and became hypotensive. She was resuscitated with intravenous fluids. Mr. L administered oxytocin with little *effect*, *followed by insertion of misoprostol per rectum*.

He did not follow hospital protocol for postpartum haemorrhage which advised the administration of ergometrine and carboprost if the bleeding continued despite the use of oxytocin. As the bleeding continued, Mr. L decided to take Mrs. H to theatre for an examination under general anaesthesia to identify the source of bleeding. In the meantime, resuscitation continued with blood products.

During laparotomy, the uterus was found to be atonic, but there was no rupture or evidence of any retained products of conception. Unfortunately, Mrs. H's condition deteriorated, and she began to develop disseminated intravascular coagulation. Mr. L reported this to the patient's husband, informing him that "there were no options" other than removing the uterus.

It was impossible to gain informed consent from the patient as a consequence of her clinical condition at that time. Mr. L proceeded to perform a hysterectomy. Mrs. H made a satisfactory recovery from her surgery but made a claim against Mr. L for his management.

Experts were critical of Mr. L, as he had failed to follow the hospital guidelines on the management of postpartum haemorrhage and secondly by not considering alternative surgical options such as internal iliac artery ligation or ligation of the uterine and ovarian arteries.

Furthermore, Mr. L had not documented why he had not considered less radical intervention before resorting to a hysterectomy in such a young woman in her first pregnancy. The case was settled out of court for a moderate sum.

In this case, reported in the January 2013 edition of the MPS journal [22], one could argue (as the author would) that Mr. L quickly concluded that the cause of the bleeding was surgical and therefore, returned the patient to theatre for an EUA. Deviation from the hospital guideline which in this case may have been appropriate at the time, was not documented. There was also no consultation with a consultant colleague. The issue of consent in these cases is fraught with difficulty but needs to be obtained in as sensitive and compassionate manner as possible. It is not clear whether the Obstetrician considered and discounted internal iliac or uterine artery ligation—it was not documented.

Documentation is crucial, particularly if treatment departs from local or national guidelines. It is also good practice to gain the support of a colleague when performing a post-partum emergency hysterectomy.

The importance of post-partum debriefing (which may be several appointments with the woman and her partner) is vital.

Key Points: Postpartum Haemorrhage and RPOC Postnatal

- Identify women at high risk for postpartum haemorrhage and document management plan.
- Ensure that delivery suites have the personnel, equipment and infrastructure to manage postpartum haemorrhage
- Adhere to guidelines for major primary postpartum haemorrhage unless there is a logical reason not to do so.
- Ensure consent for surgical procedures is thorough and valid
- Ensure that documentation is contemporaneous and meticulous
- If secondary postpartum haemorrhage is managed conservatively, ensure that follow-up arrangements are made with the woman
- Ensure that the woman and her partner are offered at least one opportunity to be debriefed following a postpartum haemorrhage in a quiet interruption free environment.

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Perineal Trauma and Episiotomy

35

Dharmesh S. Kapoor and Abdul H. Sultan

35.1 Background

All clinicians should be trained in accurately diagnosing and classifying perineal trauma. Per rectal examination should be an integral part of post-partum perineal evaluation to exclude a third or fourth degree tear. Competency based assessments should be mandatory for all clinicians performing perineal repairs. Episiotomy should be considered for operative vaginal delivery and when clinically indicated in normal deliveries. A 60 degree angled mediolateral episiotomy at crowning is the recommended technique.

Perineal trauma affects 80% of pregnant women with nearly 50% requiring suturing. The term is inclusive of injuries in the anterior and posterior perineal compartments. Anterior trauma includes injuries to the urethra, clitoris, and periurethral region. In addition, labial tears can occur.

In the UK, perineal trauma was the fourth highest reason for obstetric medico-legal claims in obstetrics over a ten-year period accounting for 8.7% of claims [1]. Thirty one million pounds were paid out for 441 claims made for perineal trauma.

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Posterior perineal tears have been reclassified by Sultan (Fig. 35.1) [2–4] in which third and fourth degree tears are collectively referred to as OASIs (Obstetric Anal Sphincter Injuries). These are dealt with in the chapter on OASI.

Rectal button-hole tears are outside this classification, but can also occur and predispose women to rectovaginal fistula.

35.1.1 First Degree Perineal Tears

These are diagnosed when only the perineal skin is disrupted. While traditional midwifery practice has been to leave them unsutured, it is recommended to suture 1st degree tears when there is bleeding, or when the tear is extensive. NICE [3] recommends, "Advise the woman that in the case of first-degree trauma, the wound should be sutured in order to improve healing, unless the skin edges are well opposed".

35.1.2 Second Degree Perineal Tears

These are diagnosed when the skin and perineal muscles are disrupted. Studies have shown that leaving 2nd degree tears unsutured can lead to gaping wounds [3].

NICE advises the following:

"Advise the woman that in the case of second-degree trauma, the muscle should be sutured in order to improve healing.

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https://doi.org/10.1007/978-3-319-78683-4_35

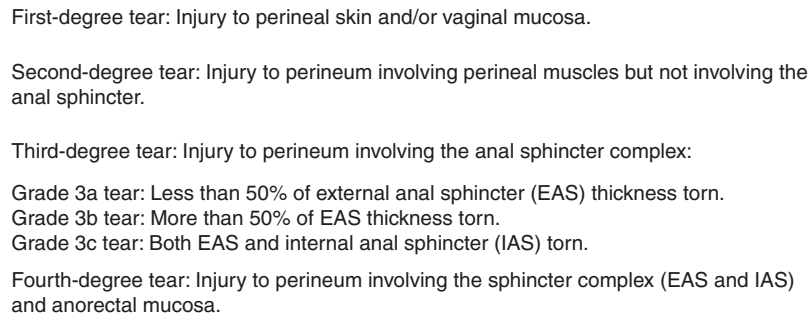

Fig. 35.1 The Sultan classification of perineal trauma [2–4]

If the skin is opposed after suturing of the muscle in second-degree trauma, there is no need to suture it."

The Royal College of Midwives also cautions against leaving such trauma unsutured [4].

35.1.3 Episiotomy

An episiotomy is an incision performed to enlarge the vaginal outlet to facilitate delivery of the baby. Only mediolateral episiotomies are performed in the UK [3, 4] and Europe (some also perform lateral episiotomies) while median (midline) episiotomies are prevalent in the USA.

Previously the concept of mediolateral episiotomy was one that was angled away from the midline, and consequentially, the anal sphincter muscle complex. However, there were no universally agreed definitions. Various authors recommended episiotomies at 40–60 degrees and the technique recommended to cut from the posterior fourchette towards the ischial tuberosity of the woman in the lithotomy position [3, 4].

Recently, it has become known that an episiotomy cut at 40 degrees results in a sutured angle of 22 degrees, and episiotomies cut at 60 degrees resulted in sutured angles of 45 degrees [5–8]. It was also found that the suture angle of the episiotomy at 45 degrees resulted in a 20-fold OASIs reduction compared to a sutured episiotomy angle of 25 degrees [9, 10]. The RCOG guidance recommends a 60 degree angled episiotomy at the time of crowning and stresses the difference between the incision angle and the sutured episiotomy angle. The guidance also asserts that sutured episiotomy angles of 40–60 degrees are more important that the incision angles of 45–60 degrees [3].

35.2 Minimum Standards and Clinical Governance Issues

The explicit aim of an episiotomy is believed to be to prevent OASIs that may occur otherwise. Common indications for episiotomy include suspected fetal distress, to prevent severe perineal tears when they are deemed imminent, a rigid/inelastic perineum, prolonged second stage and when there is need to enlarge the vaginal opening during operative vaginal deliveries.

A key question arises about which patient subgroups are at high risk for OASIs, and where an episiotomy may logically be expected to be beneficial in reducing the risk of OASIs.

The RCOG [3], NICE [4] and the NHS Litigation Authority report [1] acknowledge the literature showing a protective effect for mediolateral episiotomies in operative vaginal deliveries.

NICE states, "Perform an episiotomy if there is a clinical need, such as instrumental birth or suspected fetal compromise".

The RCOG Green-Top Guideline states, "there is evidence that a mediolateral episiotomy should be performed with instrumental deliveries as it appears to have a protective effect on OASIs."

Whilst there are other high risk groups identified for OASIs such as Asian ethnicity, nulliparity, shoulder dystocia, occipito-posterior position and birth weight > 4 kg, there are no large

randomised studies showing that a prophylactic episiotomy is beneficial in reducing OASIs. There are no validated scoring systems that individualise the risk for a patient either.

35.2.1 Perineal Repair Techniques

It is recommended both by the RCOG [3] and RCM [11] that a rectal examination should be performed before and after suturing the perineal tear or episiotomy.

NICE [3] recommends the following:

- If the skin does require suturing, use a continuous subcuticular technique.
- Undertake perineal repair using a continuous non-locked suturing technique for the vaginal wall and muscle layer.
- Use an absorbable synthetic suture material to suture the perineum.
- Offer rectal non-steroidal anti-inflammatory drugs routinely after perineal repair of first- and second-degree trauma provided these drugs are not contra-indicated.

The RCM [4] also endorses that the continuous suturing method of suturing vagina, perineum and skin with an absorbable Polygalactin suture is preferred to suturing the muscles with interrupted stitches and skin with transcutaneous stitches.

35.2.2 Training and Good Practice

All doctors and midwives who care for women during labour and delivery can repair perineal birth trauma, provided that in addition to having attended training sessions in assessment and repair they have been certified to be competent.

NICE recommends, "All relevant healthcare professionals should attend training in perineal/genital assessment and repair, and ensure that they maintain these skills [4]."

Although specialist registrars are required to complete OSATS (Objective Structured Assessment of Technical Skills) as a measure of competence in repairing perineal trauma, this should become mandatory for all obstetricians and midwives.

35.3 Reasons for Litigation

Within a secondary review conducted by the National Health Service Litigation Authority, the important reasons for litigation included

- Grade and experience of the accoucheur who sutured the laceration and conducted the follow-up
- Failure to consider a caesarean section
- Failure to perform or extend the episiotomy
- Failure to diagnose the true extent and classification of the injury including
- Failure to perform a proper rectal examination
- Inadequacy of the repair, or failure to repair in the first instance were also reported as allegations.

Failure to diagnose or classify the tear accurately was claimed in 59% of deliveries performed by midwives, and 66% of deliveries performed by doctors. In both groups, 87% of the claims were confirmed as OASIS that had been under classified as first or second degree tears.

35.4 Avoidance of Litigation

The above data highlights the importance of hospitals providing time and resources to staff for attending training courses in perineal trauma detection and repair [1].

The RCOG [3] and NICE [4] state that all women having a vaginal delivery are at risk for OASI, and that a digital rectal examination prior to commencing repair should be performed to assess the damage.

The RCOG also specifies that an appropriately trained clinician or a trainee under supervision should repair OASI [3], and it would be reasonable to assume that the same principles should apply for other grades of perineal trauma.

Systematic assessment of genital trauma should include [2–4]:

- Further explanation of what the healthcare professional plans to do and why
- Confirmation by the woman that effective local or regional analgesia is in place
- Visual assessment of the extent of perineal trauma to include the structures involved, the apex of the injury and assessment of bleeding
- A rectal examination to assess whether there has been any damage to the external or internal anal sphincter if there is any suspicion that the perineal muscles are damaged.

The woman should usually be in the lithotomy position to allow adequate visual assessment of the degree of the trauma and for the repair itself. This position should only be maintained for as long as is necessary for the systematic assessment and repair. The systematic assessment and its results should be fully documented, preferably pictorially.

The RCOG [3] states that failure to diagnose OASIS may be considered substandard care and be regarded as negligent. The NHSLA report [1] endorses the RCOG point of view. It goes further to state that all women should be advised to attend a post-natal check at 6–8 weeks after delivery and should be asked about their stitches and perineum. Women should be advised to report symptoms of faecal incontinence.

The average settlement time by NHSLA is 4.3 years from the incident, but 8.5 years for more complex cases. Hence, it is important to consider this while planning financial reserve allocations for future liabilities. The erstwhile CNST maternity standards included perineal trauma courses for all levels of certification.

NICE (2015) [4] guidance did not revise the original section (2007) [4] concerned with episiotomy and therefore continues to mention an episiotomy incision angle of 45–60 degrees. However there is now evidence that cutting episiotomies at 45 degree angles resulted in sutured episiotomy angles of 22 degrees, that puts women at a 20 times higher OASI risk, than if the sutured episiotomy angle was around 45 degrees.

Medico-legally, the RCOG guidance would be considered more reflective of current practice and therefore adherence to the NICE guidance and not the RCOG guideline would not exonerate a practitioner if OASIs occurred [12].

In 2013, the High Court awarded £1.6 million in damages to a woman where breach of duty of care included failure to perform an episiotomy adequately angled away from the anal sphincters. Therefore, it is vital to appreciate that a mediolateral episiotomy sutured angle needs to be more than 30 degrees away from the midline to prevent OASIs. The episiotomy also needs to be of adequate length and depth to prevent additional tearing. In accordance with NHSLA and RCOG recommendations, a pictorial representation/photograph of the sutured episiotomy scar would be regarded as good practice in contentious cases.

It is in the normal deliveries that the role of episiotomy remains debated. A large English cohort of more than 1.2 million births and a systematic review have both found mediolateral episiotomy to be protective in first normal vaginal births, reducing OASIs by 67% [13, 14].

The recent revision of episiotomy in the Cochrane review [2017] [15] has been retitled ‘selective versus routine episiotomy’. Ironically, the ranges in both selective (mean = 32%, range = 8–59%) and routine (mean = 83%, range = 51–100%) groups overlapped, and there was heterogeneity in trial criteria for selective episiotomies. However, they did report reduced OASIs with selective episiotomies. It should be borne in mind that none of the studies included in this review measured the angle of the episiotomy. It has been shown that very few episiotomies achieve a suture angle of 40 degrees [16]. If episiotomies were being given inaccurately, there would be more OASIs expected in the routine episiotomy group.

While such data are important in assessing the overall benefit of a procedure, it is the application of this knowledge to the individual patient that is relevant from the medico-legal standpoint. The decision to perform an episiotomy or not is based on the accoucheur’s clinical experience and judgement and quite often it is a last minute decision. While most clinicians would consider an

episiotomy if it can expedite delivery in fetal distress, it is the other indications where there are subjective differences in perception. For example, if there has been a prolonged second stage with the head at the perineum for a length of time, a rigid perineum could be the cause. An episiotomy might be considered in such a situation.

The dilemma arises when the perineum begins to tear. The accoucheur has to judge whether it will result in a small first/second degree tear, or extend to an OASI. The decision cannot be criticised in retrospect, as routine episiotomy in normal deliveries is not recommended by RCOG/NICE. It would, however, be worthwhile considering other proven and recommended interventions such as manual perineal protection and warm perineal compresses. Failure to employ (and document) any measures to reduce OASIs could be viewed with concern.

Under English law, the testimony of the expert witness will remain paramount in informing the Court. However, any clinician who has failed to adhere to national guidelines and does not have a reasonable explanation for his/her actions will be inviting the court to uphold the allegations of negligence [12]. Hence it is recommended that clinicians consider episiotomy during operative vaginal delivery, and perform episiotomies at 60 degrees away from the midline when clinically indicated.

35.5 Case Study

A patient's delivery was being managed by a senior registrar, under the supervision of the consultant obstetrician. It was completed using Keilland's forceps after three tractions. The medical records were detailed. A second degree tear was sutured and a first degree tear was also noted. No third degree tear was noted nor an extension to the episiotomy. This was said to be a straightforward delivery.

The claimant developed disabling faecal incontinence as a result of a third degree tear. She was unable to work. Her claim was valued in the region of £500,000.

An endo-anal ultrasound scan confirmed that the tear in the external anal sphincter was not present at the anal verge and was "occult". This confirmed the findings of the specialist registrar and the tear was not clinically detectable.

With good quality notes and independent radiology, the claim was withdrawn and the Trust's legal costs met. "However, since the publication by Andrews et al. [17], for all intents and purposes, occult injuries of the external sphincter do not exist and therefore such cases would no longer be defensible.

Key Points: Perineal Trauma and Episiotomy

- Perineal trauma is the fourth highest reason for medicolegal claims in obstetrics.
- It can lead to long-term problems of sexual dysfunction and dyspareunia even without OASIS.
- Episiotomies that are too acute (less than 30 degrees suture angle) or too wide (more than 60 degrees suture angle) have higher incidence of OASIS
- Perineal trauma should be appropriately classified. A drawing or pictorial representation is desirable.
- Trusts should provide adequate training in detection and repair of perineal trauma.
- Per rectal examination must be performed before and after suturing
- Episiotomy must be performed at 60 degree angle to the midline at crowning.
- Episiotomy should be considered in operative vaginal deliveries especially forceps.

Conflicts of Interest DS Kapoor is a co-inventor of the EPISCISSORS-60 episiotomy scissors. He is a shareholder of MEDINVENT LTD, the company that owns the commercial rights to the scissors.

AH Sultan-none.

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Part IV

General Gynaecology

Swati Jha and Janesh Gupta

Abdominal Hysterectomy

36

Thomas Keith Cunningham and Kevin Phillips

36.1 Background

Hysterectomy is one of the most common surgical procedures for managing benign gynaecological disease such as, abnormal uterine bleeding, fibroid uterus, and prolapse, with reportedly 30% of women in the US by the age of 60 undergoing the procedure [1]. Up until the 1990s the vast majority of hysterectomies were performed either vaginally or abdominally and this may have varied from region to region depending on the training undertaken. The advances in laparoscopic surgery have allowed hysterectomies to be performed totally laparoscopically or laparoscopically assisted with the uterus being removed vaginally. Gynae-oncologists now offer laparoscopic hysterectomies for certain stages of endometrial cancer (NICE IPG 356) [2].

36.2 Minimum Standards and Clinical Governance Issues

NICE have recently issued guidance that hysterectomy should not be performed as a first line treatment for heavy menstrual bleeding (HMB). Hysterectomy should only be considered when other medical treatments have failed (NICE CG44) [3]. This includes a trial of levonorgestrel-releasing intrauterine system, for at least 12 months, transexamic acid or non-steroidal anti-inflammatory drugs (NSAIDs) or combined oral contraceptive pills or norestesterone daily from days 5 to 25 of the menstrual cycle in women with no or small <3 cm fibroids. For those women with fibroids greater than 3 cm GnRH analogues can be offered. Use of Ulipristal acetate will depend on the guidance issued following review, as it was temporarily stopped in February 2018.

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Endometrial ablation can be offered when medical management has failed to control the women's symptoms and the bleeding is still having an effect on their quality of life and fertility is not an issue, or as a first line if the women is fully counselled of the risks and benefits of the procedure.

Women can undergo numerous medical and less invasive surgical procedures that can be performed in the outpatient department rather than undergoing major abdominal surgery. At this point hysterectomy should only be considered when:

- The above treatments have failed or are unsuccessful
- The women wishes amenorrhea
- The women no longer wishes to retain her uterus and thus her fertility
- A fully informed women requests it

Hysterectomies are thus being offered less frequently as a result of the introduction of these uterus-preserving treatments. This has a direct effect on the skills of the gynaecological surgeons of the future. Thus not all gynecologists will be able to perform a hysterectomy independently. In fact the RCOG offer Advanced Training Skills Modules (ATSM) titled Benign abdominal surgery: open and laparoscopic, to develop skills to perform routine gynaecological procedures and the advanced laparoscopic ATSM to train for more advanced laparoscopic surgery including laparoscopic myomectomies and total laparoscopic hysterectomies. This demonstrates that modern training is also adapting to the change in practice and only those gynaecologists trained to a specific level will be allowed to perform these procedures independently.

Women considering a hysterectomy must be informed of the risks and benefits of surgical and medical management of their condition whether that is due to HMB, pressure symptoms secondary to fibroids, or pain associated with adenomyosis. Previous medical and surgical history, comorbidities, previous management of their condition, and the women's preference must be taken into consideration. The patient must be made aware of the various surgical techniques, which include:

- Total abdominal hysterectomy
- Vaginal hysterectomy
- Laparoscopically assisted vaginal hysterectomy
- Total laparoscopic hysterectomy

Selecting what type of hysterectomy to perform will be based on a number of factors, these include the surgical proficiency of the surgeon, the woman's characteristics (previous surgery, BMI, parity) and clinical evidence. These are all important factors when consenting a patient for surgery as these will directly effect the risks of surgery and the short/long-term morbidity of the woman.

NICE states the surgeon must assess each patient individually and consider several factors including:

- Uterine size
- Presence and size of uterine fibroids
- Mobility and descent of the uterus
- Size and shape of the vagina
- History of previous surgery
- Presence of any other gynaecological conditions or disease

The woman must also be made aware why certain surgical approaches are not appropriate for them and if the woman chooses an option not available at that unit they must be offered referral to an appropriately trained surgeon.

36.3 Reasons for Litigation

The reasons for litigation following a hysterectomy are related to

- Preoperative counselling and choices provided
- Preoperative investigation
- Consent and discussion of complications
- Training of the surgeon
- Complications arising during or after the surgery and failing to recognise and deal with them at the time of surgery
- Negligently causing or contributing to known risks of the surgery, including bladder, ureteric, bowel, vaginal vault granulation and post operative infections
- Unnecessary or improper surgery

36.4 Avoidance of Litigation

As with any consultation, the patient must have undergone the necessary preoperative assessment and the appropriate investigations arranged such as an USS or MRI for fibroid uterus or endometrial biopsy to exclude pathology. At this point the patient can be counselled and offered medical and/or surgical treatments for their condition, but the consequences and risks of having no treatment must also be explained (RCOG CGA6) [4]. If surgery is required the surgeon should discuss the options available, with an explanation of the risks and complications and supply a patient information sheet and offer the patient thinking time if they require it.

NICE recommend that all surgeons undertaking hysterectomy should demonstrate competence in both their consultation and technical skills during training and in subsequent practice (NICE CG44) [3]. Those surgeons undertaking training should be assessed by trainers through a structured process as per the RCOG ATSM process or alternative systems in place. Makinen et al. [5] prospectively reported on the surgical learning curve of 10,110 hysterectomies for benign disease (5875 abdominal, 1801 vaginal and 2434 laparoscopic). The surgeons experience significantly correlated inversely with the occurrence of urinary tract injuries in laparoscopic hysterectomy and bowel injuries in vaginal hysterectomy. Makinen et al. [6] then published a ten year follow up and noted that the overall complication rates fell significantly for laparoscopic hysterectomy over the 10 year period demonstrating the benefits of surgical experience.

To reduce complications follow appropriate structured surgical technique including safe port entry at laparoscopy. Women must be counselled regarding the risks of the laparoscopic entry technique [7] (RCOG Green-top No.49) [8]. These include injury to the bowel, urinary tract and major vessels. The difficulty in that bowel injury may not be immediately recognised and patients usually present after discharge from hospital. Following open or laparoscopic entry the importance of good exposure of the operative field, including full examination of the pelvis and associated structures should be undertaken to plan the surgical approach.

The most common cause of litigation following a hysterectomy is a ureteric injury and the failure to recognise these injuries frequently results in a successful claim [9]. Ureteric injury remains a major concern regarding laparoscopic hysterectomy. A large meta-analysis of 47 studies by Aarts et al. [1] was underpowered to detect any clinically significant increase in bladder and ureter injuries as separate entities for a laparoscopic approach to total abdominal hysterectomy, however when these two entities were pooled they detected a significant increase in urinary tract injuries for laparoscopic injury versus abdominal hysterectomy.

The most common sites of ureteric injury are [10].

- Lateral to the uterine vessels
- Uterovesicle junction adjacent to the cardinal ligaments
- The base of the infundibulopelvic ligaments as the ureters cross the pelvic brim at the ovarian fossa
- At the level of the uterosacral ligament

The appropriate use of urology if required for assistance in visualising ureters or inserting ureteric

stents in those women with complex anatomy for example distorted by fibroids, adhesions or endometriosis. With caesarean section rates on the rise, this can increase the risk of both bladder and bowel injuries at hysterectomy by any approach as the bladder is adherent to the uterus and also the risk of bowel adhesions.

Damage to the bowel is another common visceral injury associated with hysterectomy. Aarts et al. [1] found bowel injury more likely to occur in abdominal hysterectomy. The risk of adhesion related-bowel obstruction was investigated by Al-Sunaidi and Tulandi [11] in 326 women admitted for small bowel obstruction. Once malignancy was excluded, of the 135 remaining cases 50.4% were related to gynaecological surgery, most commonly total abdominal surgery with no cases following laparoscopic hysterectomy.

It would now be routine for patients to receive prophylactic antibiotics following a hysterectomy, irrespective of the route. A recent Cochrane review [12] shows a significant reduction of postoperative infections with antibiotic use. There is no clear consensus on dose regimen or route though it would be usual to give intravenous broad spectrum coverage intraoperatively.

All patients must be counselled and risk assessed regarding VTE prevention. Appropriate measures taken to reduce an intraoperative VTE, for example intermittent pneumatic compression devices. If complications arise it is necessary to reassess the VTE status of the patient postoperatively. Barber et al. [13] studied VTE events on a database of 44,167 subjects undergoing hysterectomy for benign disease. 12,733 underwent total abdominal hysterectomy, 22,559 underwent laparoscopic hysterectomy and 8857 underwent vaginal hysterectomy. Women who underwent a total abdominal hysterectomy had a 3-fold increase in the risk of VTE compared to minimally invasive surgery (laparoscopic and vaginal). This increase persisted even after for controlling for BMI, smoking, age, diabetes and hypertension. However prolonged operating times with laparoscopic surgery can increase the risk of VTE with decreased venous return associated with pneumoperitoneum [14].

Laparoscopic procedures rely on the use of electrocautery which result in a large proportion of both ureteric and bowel injuries. It is imperative that throughout both laparoscopic and abdominal surgery always visualise the electro-cautery device and to remember that the tip of the instrument may remain hot even after the power has been turned off after use. These injuries are often not detected at the time of surgery and usually the patient will represent with abdominal pain.

36.5 Case Study

In the case of Hooper vs. Young [1995] C.L.Y. 1717, the claimant underwent a routine abdominal hysterectomy and had a left ureteric injury. it was felt that unintended kinking of the ureter was caused by the proximity of a suture, and was negligent.

In the court of appeal (Hooper vs. Young [1998] Lloyds Rep Med 61), this judgement of negligence was reversed based on evidence given by experts. The claimant and defendant experts unanimously agreed that if a ureter was obstructed during a hysterectomy by an encircling suture or the application of a clamp, then substandard surgery had been performed. However, if the ureter had been kinked by a suture, then liability was at issue. They concluded that the ureteric kinking arose by a non-negligent cause. The four methods by which the ureter might be damaged are a misplaced encircling stitch, a misplaced clamp, kinking of the ureter by a stitch placed near the suture and use of diathermy.

The Appeal Court Judges accepted the evidence of the patient's urologist that he had found **a** lot of fibrosis around the ureter that could not have been predicted. This judgement demonstrates that each case must be considered on its own merits and there may be a non-negligent explanation for ureteric damage if it is probable that the mechanism of ureteric damage is kinking and not direct trauma.

Key Points: Abdominal Hysterectomy

- Patients must be assessed and all forms of medical treatment must be discussed and offered to the patient.
- Thorough preoperative counselling and patient choice.
- The procedure whether open or laparoscopic must be undertaken by an appropriately trained surgeon who is aware of the surgical risks and complications.
- Good surgical technique will allow prompt recognition of complications and their management.
- Safe laparoscopic entry technique and exclude visceral injury after primary trocar insertion.
- Have in insight to know when necessary to convert laparoscopic procedure to open procedure in the event of complications.
- Appropriate follow up of patients.

Those patients that present with delayed complications are managed appropriately with necessary clinical governance procedures undertaken.

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37 Diagnostic and Operative Laparoscopy

Andrew Baxter

37.1 Background

Laparoscopic complications are one of the main sources of medical litigation in the UK, with incidents of visceral injury from 'blind' insertion of the primary trocar making up a large share of claims. It worth bearing in mind that the threshold for litigation can be low in diagnostic procedures, as women generally are suffering from benign conditions and the decision for surgery can therefore be based on a delicate balance of quality of life and risk. 'Minimal access' surgery also suggests small incisions with a fast recovery, leaving patient expectations to be high.

37.2 Minimal Standards and Clinical Governance Issues

37.2.1 Pre-operative Counseling

As with any procedure the decision to opt for surgery should only be taken after a comprehensive discussion of the risks and benefits of the operation, allowing the patient to weigh up such risks against their symptoms. The consent process should be carried out in accordance with the judgment in the case of Montgomery v Lanarkshire Health Board, which consolidated the pre-existing GMC guidance on consent: "*Consent: Patients and Doctors Making Decisions Together*", 2008. It is now mandated to discuss and to document all conservative, medical and surgical options available to the patient. If surgery is chosen, the pros and cons of laparoscopic versus open surgery should be discussed.

It is important to clarify and document any potential limitations to the operative part of the planned procedure. The patient themselves may place restrictions on the type of surgery undertaken, but the clinician should make it clear where their limits lie and whether, depending on the surgical findings, a further laparoscopy might be required under a more specialist surgeon.

Specific risks of a diagnostic laparoscopy are detailed in the RCOG Green top guideline No.49: *"preventing entry-related gynaecological laparoscopic injuries"* [1]. The quoted incidences of laparoscopic complication rates vary considerably between reports and the experience of the surgeon. They also increase significantly in obese patients and those with other pathologies. The RCOG Consent advice on diagnostic laparoscopy states that women should be informed of the following risks:

- Serious risks (injury to bowel, bladder or major blood vessel requiring immediate laparotomy): 2 in 1000 cases

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- Failure to gain entry to abdominal cavity
- Death in 3–8 women in every 100,000
- Blood transfusion

The frequent more minor risks are bruising, infection, dehiscence of the port sites and shoulder-tip pain. Women should also be informed that they may require a laparotomy, blood transfusion or repair of visceral damage.

Women undergoing a diagnostic laparoscopy should be advised that the chance of negative laparoscopy is up 50%. This may be reassuring or useful in planning future treatment, but it is important to set realistic expectations on the outcome of surgery.

It is good practice to record all written patient information leaflets given to the patient pre-operatively.

37.2.2 Surgical Training

It is essential that any surgeon undertaking a laparoscopy has received the requisite training or is adequately supervised, is familiar with the equipment and has suitable assistance. Independent performance of a diagnostic laparoscopy should be within the remit of any trainee in obstetrics in gynaecology who has completed RCOG core training. Operative laparoscopy would generally require, as a minimum, completion of the RCOG advanced training module in benign gynaecology, or equivalent.

37.2.3 Operative Technique

37.2.3.1 Primary Port Insertion

Gynaecologists have tended to prefer the closed Veress needle technique for primary port insertion, although increasingly direct access optical ports are being used. General surgeons have generally favoured the open Hasson technique. There is no strong evidence to indicate which method is safest, but whichever technique is used the surgeon should use a proven one that they find most successful and comfortable [2].

37.2.3.2 Site of Primary Port

In most cases the ideal location for the primary port is at the base of the umbilicus, where the abdominal wall is thinnest and the abdominal layers tend to be closely attached. However, when the chances of intra-abdominal adhesions are increased, insertion in the left upper quadrant, or Palmer's point, is advised. In women with a midline scar the incidence of adhesions underneath may be up to 50%; in such cases it is inappropriate to insert a primary port in the umbilicus.

37.2.3.3 Gas Pressure

If a closed technique is used the gas pressure should be increased to 20–25 mmHg before insertion of the primary port to reduce the risk of major vascular injury by the trocar.

37.2.3.4 Secondary Port Insertion

This should be performed under direct vision ensuring that the inferior epigastric vessels are avoided. In most patients this artery with its veins are readily visible on the underside of the abdominal wall. However, in obese patient identification may not be so easy. As these vessels are in most cases located 6 cm or less from the midline, inserting secondary ports in a perpendicular fashion lateral to that distance will generally avoid this vascular injury. A surgeon should have a clear plan for the management of an injury to the inferior epigastric vessels. Options for treatment are suturing with a port-closure device or large curved needle, tamponade with a urinary catheter balloon or direct suturing after extension of the abdominal wall incision.

37.2.3.5 Port-closure

A port-site hernia can occur in any location and with any size trocar. However, the risk only becomes significant with secondary ports larger than 8 mm and the sheath of all secondary ports >8 mm should be sutured. Umbilical primary port

sites often do not require closure of the sheath, although each case should be assessed individually. However, in very slim patients, consideration should be given to closure of the sheath of all ports.

37.2.3.6 Post-operative Care

Any patient who has undergone laparoscopic surgery should improve steadily in the days following surgery. Patients should be informed therefore to contact the hospital directly if they develop increasing abdominal pain, a pyrexia or become systemically unwell. Any patient presenting in the post-operative phase with the above features should be assumed to have a visceral injury until proven otherwise. The white cell count and C-reactive protein levels should be monitored and if there is any concern over a perforation, a CT scan should be performed. Clearly if bowel or vascular damage has occurred a laparotomy should be undertaken, but in more borderline cases a diagnostic laparoscopy can be performed.

37.3 Reasons for Litigation

Litigation may arise from the following

- Failure to warn of the risks including laparotomy and visceral injury
- Failure to adhere to the Guidance of prevention on entry related injuries
- Intra-operative visceral damage (bowel, bladder or blood vessels)
- Failure to diagnose visceral damage at the time of surgery
- Failure to close ports adequately

37.4 Avoidance of Litigation

Pre-operative counseling should be thorough and comprehensive allowing the patient time to consider all treatment options and whether the risks of surgery are justified in relation to the potential benefits.

A surgeon should ensure that they are adequately trained for the procedures they are undertaking.

The surgeon should rigidly adhere to the same criteria for diagnostic laparoscopy in both private and NHS practices. A lack of indication for surgery could leave a surgeon open to litigation should a recognized complication arise in an otherwise competently performed procedure.

The primary port should be inserted in a standard technique. If a complication should arise in a case when a non-standard technique is used, the onus would be on the surgeon to demonstrate that their method was based on sound surgical concepts.

Secondary ports should be inserted under direct vision. Visceral injury during this part of the procedure would be hard to defend.

Close the rectus sheath in all port sites greater than 8 mm.

A high index of suspicion should be maintained for any patient presenting with potential signs of visceral or vascular damage. Appropriate investigations should be undertaken early and if necessary repeatedly. Should a complication occur, an appropriate specialist colleague should be asked to attend promptly; a substandard repair of any trauma would only compound the potential adverse outcome and in turn, the risk of a successful litigation.

Any complication should be discussed fully and frankly with the patient at the time and then again in clinic a few weeks later.

A surgeon should maintain a prospective record of their surgical practice along with their complication rate.

37.5 Case Study

Greenall v ST Helens & Knowsley Hospitals NHS Trust (2009)

During a diagnostic laparoscopy the claimant suffered a vascular injury to her aorta with the formation of a large haematoma. It was identified during surgery when her blood pressure fell significantly and as a result an emergency laparotomy was performed. A vascular surgeon was called

from a neighbouring hospital and they detected a perforation on the right side of the claimant's aorta, above the right common iliac artery. This was caused by a failure to insufflate the abdomen sufficiently during the laparoscopy. The perforation was subsequently closed. The claimant spent several weeks in hospital and suffered extreme pain and immobility during the recovery. She required assistance in her day to day activities and suffered occlusion of her right common iliac needing several angioplasties.

Liability was admitted by the Trust and an out of court settlement for £40,000 made.

Learning points include the need to adhere to basic principles during abdominal entry for a laparoscopy. Mere detection of an injury is not a guarantee against litigation if adequate precautions to prevent it from happening have not been taken.

Key Points: Diagnostic and Operative Laparoscopy

- Fully informed consent in line with Montgomery and the GMC
- A clinician should not attempt procedures without adequate training
- Primary and secondary ports should be inserted using sound, proven techniques
- A high index of suspicion for visceral injury should be maintained should a patient become unwell post-operatively

Clear and thorough note-keeping on pre-operative discussions, the procedure itself, as well as a prospective log of operation numbers and any complications will facilitate the defence of any claim.

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38 Diagnostic and Operative Hysteroscopy

Ertan Saridogan

38.1 Background

Modern hysteroscopy for the diagnosis and treatment of intrauterine disorders has been an integral part of clinical practice since the second part of the twentieth century after the development of cold light fiberoptics. With the development of hysteroscopic resectoscopes, minihysteroscopes, endometrial ablation techniques and hysteroscopic morcellators, it has been possible to treat many gynaecological conditions arising from the uterine cavity in an ambulatory or outpatient setting. There are now a wide range of indications for diagnostic and operative hysteroscopy (Table 38.1). Diagnostic and therapeutic hysteroscopic procedures may be carried out in the outpatient setting or in operating theatres under anaesthesia or sedation.

38.2 Minimum Standards and Clinical Governance Issues

The Royal College of Obstetricians and Gynaecologists (RCOG) and the British Society for Gynaecological Endoscopy (BSGE) provided best practice guidelines for outpatient hysteroscopy [1]. The BSGE, in association with the European Society for Gynaecological Endoscopy (ESGE) published guidelines on the management of fluid distension media for operative hysteroscopy [2]. The National Institute for Health and Care Excellence (NICE) has guidelines on the management of women with heavy menstrual bleeding [3] and evidence based recommendations on hysteroscopic metroplasty [4, 5], sterilisation [6] and morcellation [7].

Initial assessment of the patient should include a history and clinical examination if appropriate. Alternatives to hysteroscopy for diagnosis and treatment should be considered. Alternatives to diagnostic hysteroscopy include pelvic ultrasound examination with or without endometrial biopsy and saline instillation sonography, but quite often these are used together as complementary investigations. Alternatives of operative hysteroscopy depend on the indication but may include no treatment, medical/hormonal treatment, Mirena IUS, abdominal (laparoscopic or open) myomectomy, hysterectomy, uterine artery embolisation and laparoscopic sterilisation as well as other hormonal and non-hormonal contraceptives. The views of the patient and her background clinical circumstances (comorbidities) should be taken into account and a method that is likely to deliver her expectations with an acceptable safety profile should be agreed upon. If the patient chooses a method that is not available in the unit to which they have presented,

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Table 38.1 Indications for diagnostic and operative hysteroscopy

Diagnostic hysteroscopy	Operative hysteroscopy
Abnormal uterine bleeding • Heavy and irregular periods • Postmenopausal bleeding • Intermenstrual bleeding • Hypomenorrrhoea	Endometrial/ Endocervical polyps Submucosal fibroids Endometrial ablation/ resection Metroplasty for mullerian anomalies
Infertility • Filling defects in the uterine cavity (polyp, submucosal fibroid, intrauterine adhesions) • Abnormal (thin or thick) endometrium	Intrauterine adhesions Hysteroscopic sterilisation for contraception or occlusion of hydrosalpinges Persistent retained products of conception
Congenital uterine anomalies	

they should be given the option of being referred to another unit where the method is available.

The clinician who carries out the procedure should have appropriate training or should be under supervision of an accredited person. In the United Kingdom training structure, diagnostic hysteroscopy and endometrial polyp removal are covered in the core curriculum, however surgeons carrying out operative hysteroscopic procedures should have received specialised training for the relevant procedure such as the 'Advanced Training Skills Module Benign Gynaecological Surgery: Hysteroscopy'. Gynaecologists who completed their training prior to 2007 had a different accreditation structure. There are also accreditation programmes for outpatient hysteroscopy for nurses and general practitioners.

38.3 Reasons for Litigation

Litigation related to diagnostic hysteroscopy is less common, however the clinicians should be aware that there is a campaign against outpatient hysteroscopy due to pain or lack of pain control. Litigation related to operative hysteroscopy is however more likely for a number of reasons:

- Preoperative assessment and counselling
- Consent and discussion of complications
- Recognition of complications
- Management of complications

Complications can be grouped as intraoperative, early or late postoperative events. Intraoperative complications of diagnostic hysteroscopy include cervical laceration, uterine perforation, bleeding and failed procedure. As long as they are managed appropriately, these complications are unlikely to cause severe morbidity.

Intraoperative complications following operative hysteroscopy include cervical laceration, uterine perforation, bleeding, visceral injury and fluid overload. Some of these complications can be severe and may lead to severe morbidity and even mortality, especially when there is bowel perforation. Infection is an early postoperative complication and intrauterine adhesion formation which may lead to hypo- or amenorrhoea and infertility as a late postoperative complication.

38.4 Avoidance of Litigation

Preoperative counselling and consent process should not only cover the possible success and failure rates of the procedure, but also include a detailed description of possible complications. The procedure should be expected to meet the patient's expectations and the patient should be involved in the decision making process, having been informed of the alternatives. Provision of patient information leaflets would be useful.

Clinicians performing the procedure should have appropriate training and/or accreditation as explained earlier and an adequate annual case load.

Measures should be taken to reduce risk of complications. Risk factors which increase risk of complications should be identified. For example, presence of intrauterine adhesions, history of previous caesarean section (particularly those with scar defect or niche) and extreme anteversion or retroversion with reduced mobility would increase risk of uterine perforation. Determining the position of the uterus before dilatation of the cervix, use of ultrasound guidance and preoperative cervical priming may help reduce the risk of perforation during cervical dilatation. Fluid overload is more likely to develop in the presence of

large uterine cavity, low mean arterial pressure, high distension medium pressure and during procedures that require deep myometrial penetration. The intrauterine pressure should be kept as low as possible to maintain adequate distension of the cavity to reduce the risk of fluid overload. Hypotonic media that is used for monopolar resection systems such as glycine are more likely to cause electrolyte imbalance and its subsequent complications, hence consideration should be given to bipolar resection systems and isotonic distension media. Fluid input and output should be monitored throughout the operative hysteroscopy procedures and the procedure should be terminated when the recommended fluid deficit is reached. Fluid balance should be recorded in the operation records and it is advisable to use a separate fluid monitoring sheet. Preoperative antibiotic prophylaxis should be given to women who have higher risk of infection, for example to those with tubal disease or hydrosalpinx.

A very important aspect of avoiding litigation is recognition and appropriate management of complications when they occur. Perforation site may be directly visible or intraperitoneal structures may be seen, confirming perforation. It should be suspected when there is sudden loss of cavity distension or unexplained inability to distend the cavity. Midline and fundal perforations, particularly with blunt instruments, are unlikely to cause excessive bleeding or injuries to other structures. Cervical and lateral wall perforations, particularly with large and sharp instruments can cause troublesome bleeding and retroperitoneal haematomas. Perforations during activation of the electrode of the resectoscope can cause sharp or thermal injury to other viscera and blood vessels. In this situation, the procedure should be terminated and consideration should be given to a laparoscopy or laparotomy. If expectant management is chosen, the patient should be admitted for observation for possible intraabdominal bleeding or visceral injury. The patient should be advised to report signs of delayed visceral injury such as worsening abdominal pain, fever, feeling unwell, nausea and vomiting when she is discharged home.

When fluid overload is diagnosed the procedure should be terminated, a urinary catheter should be inserted, strict fluid input-output monitoring and measurement of serum electrolytes should be implemented.

38.5 Case Study

A 37 year-old woman with a history of infertility was found to have a ‘filling defect’ in the uterine cavity during fertility investigations and she was referred to a gynaecologist for further investigation and treatment. After an initial consultation a hysteroscopy and resection procedure was performed. At surgery the gynaecologist was unsure whether the filling defect was due to a submucosal fibroid or intrauterine adhesions, this area was resected. The gynaecologist noted abdominal distension at the end of the procedure and suspected that the uterus might have been perforated. A laparoscopy was performed and a small fundal perforation was found. Three litres of glycine solution was aspirated from the peritoneal cavity and the perforation site was cauterised for haemostasis. No other visceral injury was detected. The patient was kept in overnight for observations. Her postoperative serum electrolyte analysis showed a sodium level of 125 mmol/L. She remained stable overnight and was discharged home the following morning with no further follow up arrangements.

The medicolegal expert was critical of the following points:

- The gynaecologist was not able to differentiate between a submucosal fibroid and intrauterine adhesions,
- Uterine perforation was not recognised during the procedure until abdominal distension was noticed,
- No fluid balance monitoring was carried out or recorded during the hysteroscopy procedure,
- There was no evidence of fluid input-output monitoring postoperatively,

- The sodium levels were not checked again before discharge,
- There was no follow up arrangement or evidence of the patient being asked to report signs of delayed visceral injury.

The case was settled for a moderate sum.

Key Points: Diagnostic and Operative Hysteroscopy

- Appropriate preoperative assessment and counselling should include a discussion to establish the views of the patient and her comorbidities. A method that is likely to deliver the patient's expectations with an acceptable safety profile should be agreed upon.
- The procedure should be performed by an accredited/trained surgeon.
- Risk factors for complications should be determined preoperatively and measures should be taken to reduce risks.
- Complications should be recognised when they occur and should be managed appropriately.
- Good documentation of the procedure, monitoring of fluid balance and management of complications is of paramount importance.

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Endometriosis

39

Alfred Cutner

39.1 Background

Endometriosis is a condition where endometrial type tissue lies outside the uterus. This can be asymptomatic but may cause fertility issues, painful periods, pain on intercourse, pain opening bowels and bladder pain. Progression may result in chronic pain that is outside the menstrual cycle. Endometriosis affecting the adnexa may result in loss of tubal function and hydrosalpinges and it may also reduce ovarian reserve. Where the endometriosis affects the ovary, it may result in an abdominal mass and the patient can present due to pressure symptoms. Progression of severe disease may result in haematuria, rectal bleeding and occasionally bowel obstruction. On rare occasions, patients may develop a loss of renal function. This is normally a silent loss and is not preceded by renal angle tenderness.

Endometriosis is often classified according to the revised American fertility scoring system (AFS). However, this largely relates to fertility and does not correlate with the other pain symptoms. Surgically endometriosis is better classified as:

- Superficial where there are peritoneal patches
- Adnexal disease involving the tubes and ovaries
- Deep infiltrative disease
- Non-pelvic disease

Deep infiltrative disease can be anterior and invade the bladder. Where it is on the side wall it may result in ureteric involvement. Posterior disease involves the uterosacral ligaments and may cause pain on intercourse. Where the rectovaginal septum is involved then there may be pain opening the bowels and rarely bowel obstruction. Deep disease may extend laterally and involve the ureters. Endometriosis may be found at distant sites to the pelvis. Typical areas are the appendix and the diaphragm. The latter may result in cyclical shoulder pain.

Endometriosis classically presents in nulliparous women in their 30s. However, it should not be discounted in women who have had children especially if there was a degree of subfertility. In addition, it may be found in adolescents and hence the possibility should not be disregarded.

39.2 Minimum Standards and Clinical Governance Issues

Treatment for endometriosis related symptoms may be reassurance or simple pain relief where the symptoms are mild. Medical treatment consists of hormone manipulation. This may be the combined contraceptive pill (normally taken continuously

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for at least 3 months without a break) or progestogen therapy. It may take the form of high dose progesterone for 6 months, the mini-pill or the Mirena contraceptive device. Danazol and other drugs in this class are now rarely used. The alternative option is down regulation with LHRH analogues to make the woman menopausal. Use of this without add-back hormone replacement therapy is licensed to a maximum of 6 months.

Surgical treatment is normally carried out laparoscopically and can entail ablation or excision of lesions and releasing adhesions in severe disease and excising nodules of disease. Under-treatment will result in early recurrence. Over-treatment will increase the possibility of complications and may in the case of the ovaries, reduce the ovarian reserve. Where the tubes are found to be blocked and dilated this will have a negative effect on IVF outcomes and they may require removal as part of the surgical treatment.

Excision of rectovaginal disease where there is extensive dissection required, may result in post-operative voiding difficulties. This can be short term or long term. Monitoring of bladder function post-operatively is essential to prevent bladder over distension with its sequelae. Shaving of the bowel rather than bowel resection is preferred as a low bowel resection has the risk of developing anterior resection syndrome and swapping pain for severe bowel dysfunction.

The overall risks of excision of recto-vaginal disease is of the order of 10% and major risks include a secondary leak from the bowel, development of a fistula, bowel injury, ureteric injury and developing a ureteric stricture. All patients need to be made aware that the pain may remain and endometriosis may recur. Apart from these risks all the other risks of laparoscopic surgery are as in general laparoscopic surgery but the risk of laparotomy or vascular injury are increased as are the risks of thromboembolism due to the extent of surgery that may be required.

Endometriosis may be associated with adenomyosis and some patients will opt for hysterectomy. In this situation, the ovaries need to be discussed as well as the requirement to excise endometriosis at the same time.

39.3 Reasons for Litigation

Litigation will normally result following one of the list below:

- Complications of long-term LHRH analogues (used off license)
- Silent loss of a kidney due to delayed treatment
- Suffering pain long-term without treatment being offered
- Loss of ovarian reserve from surgery
- Inadequate treatment resulting in progression and a complication of subsequent surgery
- Lack of appropriate treatment due to non-expert care
- Intra-operative damage to a ureter or the bowel
- Undiagnosed ureteric or bowel injury
- Development of ureteric stricture
- Development of bowel leak or fistula
- Inappropriate treatment for the patient's current requirements

39.4 Avoidance of Litigation

When a patient with symptoms of endometriosis presents it is important that they are seen by a gynaecologist with an interest in the care of women with this condition. This is part of the organisation of services as laid out in the recent NICE guidance on the management of endometriosis [1]. An ultrasound should be carried out and it is recommended that this should be a vaginal scan (unless contra-indicated). An MRI may be considered as an alternative. A trial of medical treatment would be advised except where the patient presents with fertility issues or where on examination and/or investigations suggest severe disease. Long-term medical treatment or reassurance without referral to a specialist centre will result in a patient suffering from pain and can be a cause of complaint. Such care is not normally

the main indication for litigation but often an aggravating factor in any claim.

Lack of an examination and appropriate investigations in women with severe disease may result in long-term medical treatment. By the time the patient presents to a specialist centre, she may have lost renal function in one kidney. In women with a large rectovaginal nodule, a renal scan should be done as a screen to exclude ureteric involvement. Severe disease requiring extensive surgery due to long-term lack of appreciation of the condition can be another cause of litigation.

Women with severe disease require referral to a specialist centre with a multidisciplinary set-up for the surgical care of these women. All the options must be clearly documented. Patients require treatment by appropriate surgeons with the correct level of expertise and careful postoperative observation. This is highlighted in the recent NICE guidance on endometriosis and is integral within British Society for Gynaecological endoscopy (BSGE) endometriosis centres criteria [1]. Pre-operative counselling and investigations needs to exclude absolute indications for surgery such as ureteric or bowel stricture. Assuming this is not the case, it is important to determine whether fertility or pain is the primary indication. Removal of recto-vaginal disease in a relatively asymptomatic woman who requires IVF would be breach of duty. Litigation would result if there was a complication or loss of ovarian function from the surgery carried out.

Where excision surgery is to be considered, two stage surgery should be contemplated to enable full counselling about the pros and cons of radical excision and the risks of any surgery to be performed. It also enables the use of pre-operative down regulation to reduce vascularity and the size of the lesions. Where surgery results in an inadvertent bowel or ureter injury but carried out by a surgeon without specific expertise, this may give rise to litigation. The requirements for multidisciplinary surgery in centres of excellence for severe cases is identified by the BSGE and the recent NICE guideline. Joint surgery with a colorectal surgeon where there is significant bowel involvement will reduce the risk of litigation where a complication arises. The possibility of requiring an elective ileostomy or colostomy must be fully discussed. The issue of bowel preparation remains contentious but local guidelines should be adopted.

Specific areas that result in litigation are delayed recognition of a ureteric injury or a delayed bowel leak or fistula. Use of ureteric stents would reduce the chance of missing a ureteric injury but failure to use them would not be considered a breach of duty. At the end of any procedure requiring excision of recto-vaginal endometriosis, a sigmoidoscopy should be carried out to perform an air test and document bowel integrity. In the past gynaecologists used a 50 ml syringe but this is not adequate to test for a leak. Energy sources used to cut out tissue may result in heat spread and typically the patient will present at 5 to 10 days due to a avascular necrosis. If a patient becomes unwell after major endometriosis surgery it is mandatory to perform a CT to exclude a leak and it is advisable to enlist the help of a colorectal colleague to exclude a bowel cause. Delayed recognition will lead to severe morbidity and indeed mortality and delay in diagnosis is a common cause for litigation.

The digital recording of an operation will identify appropriate technique and may prevent litigation when it can be demonstrated that the bowel or ureter injury was not due to poor surgical technique. However, it must be appreciated that retrospective viewing of an operation may also incriminate a surgeon and demonstrate a breach of duty. Without a digital record, the surgical report would be relied upon and also the demonstration of the surgeon having the required experience. Post-operative care must include a measurement of bladder residual after the catheter is removed to ensure that the patient will not develop over-distension resulting in long term voiding problems.

39.5 Case Study

[2013] EWHC 4744 (QB)

The claimant underwent a laparoscopic excision of a rectovaginal nodule in 2009. Monopolar

scissors were used for the excision via an operating laparoscope. The claimant was discharged the following day. She re-presented 6 days later in severe pain. She had a laparotomy to repair a 2 cm hole in the rectum and a loop colostomy was carried out.

The whole operation had been recorded. The claim was that the rectal probe was not used appropriately and that diathermy had been applied directly to the bowel wall. These were both rejected. It was accepted that the injury occurred due to delayed necrosis due to heat caused by diathermy at the time of the initial operation. It was accepted that there is no standard as to how a rectal probe should be used and the direct application of diathermy to the bowel wall was not proven. In addition, the court determined that inadvertent heat damage to the tissue is a recognised complication of this type of surgery.

This case demonstrates that injury can occur during surgery for severe endometriosis and is a recognised complication and does not necessarily indicate a breach of duty.

Key Points: Endometriosis

- Do not delay referral for symptoms that fail to respond to medical treatment
- Refer to an appropriate unit
- Severe disease should be operated on in an appropriate multidisciplinary set up
- Operate according to patients current clinical requirements and fully discuss all the implications of extensive surgery
- Check for renal obstruction in severe disease
- Discuss ovarian reserve at time of surgery
- Treat endometriosis at the time of hysterectomy
- Do not delay investigating post-operate patients who become unwell

Reference

1. NICE guideline [NG73]: Endometriosis: diagnosis and management 2017.

Ectopic Pregnancy and Miscarriage

40

Andrew Farkas

40.1 Background

An ectopic pregnancy is the occurrence of a pregnancy in a location other than the body of the uterus, usually in the fallopian tube. The incidence of ectopic pregnancy is around 11 per 1000 pregnancies. It usually presents at between 6 and 8 weeks gestation, usually with vaginal bleeding and lower abdominal pain but sometimes as an acute abdomen with haemoperitoneum following rupture of the fallopian tube.

Risk factors for ectopic pregnancy include a history of pelvic infection, pelvic surgery and, in particular, tubal surgery and IVF. It remains an important cause of maternal death, with six maternal deaths reported between 2006 and 2008 [1]. It is important to avoid delay in the diagnosis of an ectopic pregnancy to minimise the risk of rupture. Medical management with methotrexate has to some extent replaced surgical management by removal of the fallopian tube (salpingectomy), so altering patients' expectations of diagnosis and treatment. Although most known cases are treated medically or surgically, spontaneous resolution may also occur.

Miscarriage occurs in 10–20% of clinical pregnancies. A miscarriage may be associated not only with significant physical morbidity such as haemorrhage and sepsis, but also with psychological sequelae.

40.2 Minimal Standards and Clinical Governance Issues

The National Institute of Clinical excellence (NICE) guidance highlights the importance of an early pregnancy assessment service (EPAS) [2]. It should be a dedicated service provided by healthcare professionals competent in diagnosing and caring for women with pain and/or bleeding in early pregnancy. It should offer ultrasound and assessment of serum human chorionic gonadotrophin (hCG) levels. hCG is the hormone measured when performing a pregnancy test. Systems should be in place to enable women referred to their local EPAS to attend within 24 h if the clinical situation warrants it.

The combination of a positive pregnancy test, vaginal bleeding and abdominal pain should raise the suspicion of an ectopic pregnancy. A ruptured ectopic pregnancy should be treated as an acute surgical emergency.

The diagnosis of either a miscarriage or an ectopic pregnancy is usually made on the basis of investigations rather than clinical findings. Pelvic examination is not usually performed in the setting of an EPAS. Key to diagnosis is the use of transvaginal ultrasound scanning (TVS). Ultrasound scan-

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ning is increasingly used to identify an ectopic pregnancy as well as an intrauterine gestation and transvaginal scanning is the tool of choice. A tubal ectopic is diagnosed by the identification of an adnexal mass that moves separate to the ovary. There is no specific endometrial appearance of an ectopic. The presence of fluid inside the uterus can give the appearances of a pseudosac and should be distinguished from an early intrauterine pregnancy. The presence of free fluid in the abdomen is a common finding, but not diagnostic of an ectopic. When present in excessive amounts it may suggest a rupture. The Royal College of Obstetricians and Gynaecologists (RCOG) have identified ultrasound criteria for the diagnosis of cervical, cornual/interstitial, abdominal, heterotopic and caesarean scar pregnancy [1]. An intrauterine pregnancy is diagnosed on the basis of the size of the gestational sac and the crown rump length (CRL) of the fetal pole. To make the diagnosis of a viable intrauterine pregnancy, the gestation sac should be ≥25 mm with a CRL ≥ 7 mm.

The absence of an intrauterine pregnancy in conjunction with hCG estimations often leads to the diagnosis of an ectopic pregnancy. hCG is produced by the rapidly proliferating trophoblastic tissue in early pregnancy. The discriminatory zone is the hCG level at which it is assumed all viable intrauterine pregnancies will be visualised by transvaginal ultrasound. This level is usually 1000–1500 iu/L, depending on local guidelines. An increase in serum hCG concentration > 63% from the baseline level after 48 h suggests the likelihood of a developing intrauterine pregnancy, although the possibility of an ectopic pregnancy still cannot be excluded.

NICE recommends that methotrexate should be the first line management for women who are able to return for follow-up and who have:

- No significant pain
- An unruptured ectopic pregnancy with a mass smaller than 35 mm with no visible heartbeat
- A serum hCG between 1500 and 5000 iu/L (below 5000 iu/L is the usual cut off used in practice)
- No intrauterine pregnancy (as confirmed on ultrasound scan)

Important contraindications to methotrexate include haemodynamic instability, presence of an intrauterine pregnancy, breast-feeding, and abnormal liver function.

It is not always possible to make a firm diagnosis of either a viable intrauterine pregnancy or ectopic pregnancy, leading to the term 'pregnancy of unknown location (PUL)'. Expectant management is an option for PUL in clinically stable women and those with an ultrasound diagnosis of ectopic pregnancy and a decreasing hCG, initially <1500iu/L.

40.3 Reasons for Litigation

The main reasons for litigation in cases of ectopic pregnancy are related to delay in making the diagnosis, leading to:

- Failure to diagnose the ectopic
- Failure to counsel regarding the various treatments
- Rupture of the ectopic pregnancy
- Laparotomy
- Salpingectomy
- Complications related to the surgical treatment
- Loss of opportunity for medical treatment with methotrexate
- Inadequate monitoring in cases managed conservative
- Loss and perceived loss of fertility

Reasons for litigation in respect of miscarriage include:

- The failure to make the diagnosis of miscarriage accurately on ultrasound scanning
- Failure to offer various options for treatment
- Complications of surgical management of miscarriage, including haemorrhage and uterine perforation
- Retained products of conception

40.4 Avoidance of Litigation

The diagnosis of pregnancy should be considered in all women of reproductive age. Menstrual age cannot be relied upon to exclude a preg-

nancy. A urine pregnancy test is extremely sensitive and will usually give a positive result (hCG 20 iu/L) the day after the menstrual period was expected.

Women should be offered a range of management options for a confirmed miscarriage. These include expectant management, which is recommended by NICE as a first line management, medical management and surgical management.

In cases of suspected miscarriage, particularly when symptoms have included pain as well as bleeding, it must be ensured that a urine pregnancy test is negative two weeks following presentation. When undertaking abortions at early gestations adequate precautions need to be taken to avoid missing an ectopic pregnancy. This is discussed in more detail in the chapter on abortion.

Patients should be informed that methotrexate is recommended as first line management in women with a small unruptured ectopic pregnancy. It is not always effective and subsequent surgical treatment may be required. There is also a small risk of rupture.

Methotrexate should never be given at the first visit unless the diagnosis of an ectopic pregnancy is absolutely clear and a viable intrauterine pregnancy has been excluded.

Although 90% of ectopic pregnancies are tubal, the possibility of an ectopic pregnancy in another location should be considered. These include the ovary, interstitial (uterine) portion of the fallopian tube (Cornual ectopic), caesarean section scar and abdominal pregnancies.

The majority of tubal ectopic pregnancies are managed surgically. Laparoscopy is preferable to laparotomy in terms of speed of recovery, although there is no difference in terms of subsequent successful pregnancy benefits between laparoscopy and laparotomy. The RCOG guidance [1] states that in the absence of a history of sub-fertility or tubal pathology, women should be advised that there is no difference in the rate of fertility, the risk of future tubal ectopic pregnancy or tubal patency rates between the different methods of management.

Women with a previous history of sub-fertility should be advised that treatment of their tubal ectopic pregnancy with expectant or medical management is associated with improved reproductive outcomes compared with radical surgery, i.e. salpingectomy. In this group, conservative surgery (salpingotomy) is associated with a higher rate of subsequent intrauterine pregnancy than salpingectomy [3].

Clinicians undertaking ultrasound for the diagnosis of early pregnancy problems must have received appropriate training. There should be departmental protocols in place to identify which structures are to be examined and what measurements need to be taken. The written report from the scan is an important legal document and should be issued in all cases. Surgical management of ectopic pregnancy requires appropriate training. In particular, laparoscopic surgery requires appropriate equipment and trained theatre and surgical staff.

40.5 Case Studies

Although it is often possible to demonstrate breach of duty in respect of the management of ectopic pregnancy, very few cases come before the courts. This is because such claims are usually of relatively low value and causation is either not present or limited. The cases described below illustrate some of the issues which may arise in litigation.

Case 1

Mrs. AB was aged 31 when she presented to the EPAS with a history of vaginal bleeding. She was discharged three days later following a fall in hCG levels from 240 to 120 iu/L. Further follow-up was not arranged. She presented four weeks later with abdominal pain and vaginal bleeding. An ectopic pregnancy was identified. She underwent laparoscopic salpingectomy. The claim was settled on the basis of the failure to adhere to the unit protocol of checking that a urine pregnancy test became negative two weeks following initial discharge.

Case 2

Mrs. CD had a history of anxiety and depression. She attended the EPAS with a history of abdominal pain and vaginal bleeding. hCG was 4200 iu/L. Ultrasound scan showed the absence of an intrauterine gestation. She was reviewed two days later, when the hCG had risen to

7300 iu/L. Continued monitoring was advised. She presented a further three days later with a ruptured ectopic pregnancy and a laparotomy and salpingo-oophorectomy was required.

It is likely that earlier intervention would still have required a salpingo-oophorectomy. However, a laparoscopic approach would have been possible. Psychological stress would have been reduced.

Key Points : Ectopic Pregnancy and Miscarriage

- Suspect a pregnancy in all women of reproductive age
- Confirm an intrauterine pregnancy by ultrasound
- Methotrexate is first line management in a small, unruptured ectopic pregnancy in a clinically stable patient
- A laparoscopic approach is preferable to open surgery for ectopic pregnancy
- There is no difference in fertility rate following different treatments for ectopic pregnancy in women with no previous history of sub-fertility

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Ovarian Surgery

41

Swati Jha and Ian Currie

41.1 Background

The ovaries lie within the ovarian fossa, which is bound by important structures such as the external iliac, obliterated umbilical artery and the ureter. At birth a female has approximately one to two million eggs but only 300–400 of these will ever mature and be released for purposes of fertilisation. From puberty till the menopause the ovaries produce a range of hormones including oestrogen and progesterone. They also produce other hormones including testosterone and androstenedione in lesser amounts. In post-reproductive life, however the female hormone production from the ovary terminates as this is linked to the menstrual cycle. Thus, the androgens that are produced take on a greater siginificance as they are converted to oestrogen elsewhere.

Ovarian surgery may be performed as part of

1. Infertility treatment (ovarian drilling)
2. Removal of part of ovary (benign conditions)
3. Removal of total ovary with:
   Cyst (benign or malignant)
   Another procedure (hysterectomy)
   Prevention of ovarian cancer

Surgery on the ovary for whatever reason requires specific counselling due to the pivotal importance of these organs on a womans reproductive capability, whether this be for infertility treatment such as ovarian drilling, or the removal of ovarian cyst/ovary for endometriosis.

An oophorectomy may be performed either alone or in combination with another procedure usually a hysterectomy or a salpingectomy. Oophorectomy is performed in a range of medical conditions including ovarian tumours benign and cancerous, endometriosis, ovarian torsion, ovarian/tubo-ovarian abscess and pelvic inflammatory disease. It may also performed prophylactically in women with a family or personal history of breast or ovarian cancer who are at a higher than average risk. Ovarian surgery can be performed through one of several routes including the open abdominal or laparoscopic route. The specific complications of laparoscopic surgery will not be discussed in this chapter as they are discussed elsewhere.

41.2 Minimum Standards and Clinical Governance Issues

As with any surgical procedure adequate preoperative counselling is imperative and should be in line with the GMC guidance and Montgomery ruling on consent. In particular, the options a woman has to consider must be understood by

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her and its impact on reproduction must be clearly documented. Special considerations that may arise might include when someone is considering oophorectomy whilst still being nulliparous or a women who specifically states that they never want children. Careful counselling, documentation of their reflection and understanding as well as second opinion are all best practice points to consider. It is not appropriate to think that a clinician is protected from breach of duty just because information is given to the patient and received. Recognition of the impact of ovarian function, or rather the lack of, is given high priority by the courts.

When surgery may impact on ovarian reserve this needs to be discussed with the patient. Clear concise bullet points in the medical notes are always helpful in later scrutiny of a woman's decision making process.

Ovarian drilling is sometimes offered to women with polycystic ovarian disease to induce mono-ovulatory cycles when they have failed initial medical treatment. As well as documentation of complications it is also important that not only is the correct treatment suggested but that it sits correctly in the treatment algorithm for the condition being treated. Over zealous and prompt recourse to surgery may be criticized thereafter, particularly if it is within private practice. For example, ovarian drilling should not be offered as a first line treatment as there is no evidence of superiority over more conservative treatments [1, 2]. When it is performed monopolar electrocautery (diathermy) or laser can be used giving comparable results. Normally, three to eight diathermy punctures are performed in each ovary using 600–800 J energy for each puncture, and this leads to further normal ovulation in 74% of the cases in the next 3–6 months. However, patients should be informed about the risk of reduction in ovarian reserve and premature ovarian failure when undergoing this procedure though the impact of this is not substantiated in meta-analysis [3]. Harming ovarian function in a patient who is trying to conceive very often leads to litigation.

When women who have not completed childbearing require a unilateral oophorectomy they need to be informed that this may affect their ovarian reserve and this has a link to reduced IVF capacity, even though pregnancy rates were found to be the same as women with both ovaries [4]. Clear explanation of why the clinician is resorting to oophorectomy rather than possible cystectomy needs to be documented. This is particularly true when there is torsion or a large benign tumor on one ovary which will necessitate the removal of the entire ovary. Ovarian torsion deserves a special mention in that practice has been moving to more conservative intraoperative treatment with attempts being made to salvage the ovary. Clear operative notes are essential giving reasons as to the course of action taken.

Several benign tumours of the ovary can also be bilateral. In women presenting with such tumours when childbearing is not complete, a cystectomy should be performed in preference to an oophorectomy where possible. As this cannot always be predicted in advance, especially when the tumor is large, patients should be warned of the risk of developing the tumor on the contralateral ovary. Approximate recurrence risks should be given preoperatively with further clarification once histology is received. Dermoids are the commonest benign tumor of the reproductive age group and are bilateral 20% of the time. Even if a contralateral dermoid is not present at the time of surgery there is a 25% risk of developing another dermoid on the opposite side. This figure may lead to an older patient opting for bilateral oophorectomy. Benign serous cystadenomas and mucinous cystadenomas can also be bilateral in up to 25 and 10% respectively.

Ultrasound confirmation of whether an ovarian tumor is benign or malignant can be difficult and where there is doubt patients should be adequately warned of this as a cystectomy in this scenario with a subsequent diagnosis of malignancy may warrant further surgery.

Where malignancy is suspected referral to an oncologist should be considered and usual cancer pathways should be followed. The clinician should be aware of the available grading systems for suspected malignancy as they are a useful adjunct to conservative management. When a patient is expressing a desire to avoid surgery and

have conservative management, the clinician should document as to whether he/she is in agreement with this.

In women undergoing a prophylactic oophorectomy without an underlying risk factor at the time of a hysterectomy, the benefits of removal and prevention of ovarian cancer has to be weighed up against the risks of removal and a full discussion with the patient regarding this should take place. In premenopausal women this includes the sudden onset of menopausal symptoms and the possible need for HRT. Studies have shown that compared with ovarian conservation, bilateral oophorectomy at the time of hysterectomy for benign disease is associated with a decreased risk of breast and ovarian cancer but an increased risk of all-cause mortality, fatal and nonfatal coronary heart disease, and lung cancer. In no analysis or age group was oophorectomy associated with increased survival [5].

In women with familial cancer syndromes such as hereditary breast and ovarian cancer syndrome (BRCA1 and BRCA2) and Lynch syndrome due to an increased risk of developing ovarian cancer, prophylactic removal of their ovaries and fallopian tubes at age 35–40 years after childbearing is complete is commonly recommended. Risk reducing salpingo-oophorectomy (RRSO) has been shown to significantly impact on woman's psychological and sexual well-being, with women wishing they had received more information about this prior to undergoing surgery [6]. The most commonly reported sexual symptoms experienced are vaginal dryness and reduced libido. Preoperative counselling should include discussion of these sequelae and the limitations of menopausal hormone therapy in managing symptoms of surgical menopause. Linking with genetic counsellors, oncologists are a useful addition to the decision making process.

During surgery complications can arise usually related to distorted anatomy, and the early involvement of a colorectal or urological surgeon is advised. When an oophorectomy was planned for benign indications but risks causing injury to adjacent viscera, it is not substandard to leave an ovarian remnant behind, but the patient needs to be informed of this in the postoperative period. Adequate care to positively identifying and thereby avoiding injury to the ureters should be taken in this scenario due to its close proximity to the ovary. The usual precautions as discussed in the chapter on Laparotomy and Laparoscopy should be taken. Failure to recognise and discuss when surgery may not be straightforward and routine is frequently met with regret for the clinician as the complication is seen in the light of a low risk procedure. Potential bowel adhesions from diseases such as endometriosis or infection, distortion of anatomy from pathology or previous surgery must not be overlooked or understated. A patient may have chosen a more conservative approach in hindsight.

41.3 Reasons for Litigation

- Failure to counsel women of the reproductive impact of reduced ovarian reserve when operating on/removing an ovary.
- Failure to inform women of the risk of developing a tumor on the remaining ovary when performing a unilateral oophorectomy.
- Failure to warn of menopausal symptoms following bilateral oophorectomy.
- Failure to warn of advantages of retaining the ovaries (cardio-protection/libido).
- Removal of the wrong ovary.
- Removal without consent.
- Incorrect diagnosis (Diagnosis of a benign tumor being made instead of a malignancy, a fibroma can mimic a fibroid).
- Failure to adequately refer to an oncologist where malignancy is suspected.
- Persistence of an ovarian remnant.
- Visceral injury occurring during removal.

41.4 Avoidance of Litigation

As discussed, adequate informed consent and a detailed discussion of the advantages and disadvantages of an oophorectomy or a cystectomy depending on the indication for surgery should take place. Giving time to make appropriate

decisions is always helpful as well as documentation in medical notes regarding the level of understanding, citing specific examples is useful.

At surgery, precautions should be taken in entering the abdomen to gain access to the ovaries irrespective of the route of entry. These are discussed in detail in the chapter on laparotomy and laparoscopy. Where bowel adhesions are anticipated in advance of the surgery, a bowel surgeon should be available especially when an oophorectomy is being performed for known endometriosis. When advanced stage disease is already suspected consideration should have taken place preoperatively with respect to tertiary centre referral. When bowel involvement is considered to be significant preoperative referral and discussion with a bowel surgeon should be considered. It is inappropriate to be suddenly calling for a general surgeon suddenly when the clinical picture suggested high risk of bowel involvement. When there are concerns about visceral injury, the decision to proceed to a laparotomy should be made to rule this out particularly when there are intra-abdominal adhesions.

When performing ovarian drilling the settings should be documented in the operative notes and greater than 7–8 holes should be discouraged [7].

When operating on women with benign tumours, wherever possible a cystectomy should be performed especially when this can be bilateral, however if an oophorectomy is required the reasons for this should be documented. When there is doubt about the nature of the tumour and conservative treatment is agreed on, the patient should be warned of the need for further surgery if the tumour is subsequently found to be malignant on histology. The risks of spillage should also be discussed in this context of uncertainty.

Occasionally an oophorectomy is required due to surgical difficulty where it was not anticipated. This is usually when performing a difficult hysterectomy and every attempt should be made to conserve one ovary if the patient has not consented to an oophorectomy. Clear documentation of the reasons for the unplanned oophorectomy should be made and this should be discussed with the patient immediately postoperatively.

When there is difficulty removing the ovary in its entirety, the reasons for this should be clearly documented in the notes and explained to the patient. This is especially true in cases of endometriosis, tumours and when removing residual ovaries because of adhesions. When an oophorectomy is being performed for benign indications it is not substandard care to fail to remove it if the risks associated with removal outweigh the risk of injury to adjacent viscera including the bowel and urinary tract. In these situations the reasons for incomplete excision should be documented and explained to the patient. This can sometimes be difficult to confirm and it is worth checking the histology to establish if complete removal has been achieved.

41.5 Case Study

Case 1. Ms. G's ultrasound scan demonstrated a mass on her left ovary and the consultant, recommended laparoscopy to investigate this mass to rule out malignancy and remove it if necessary. Ms. G was peri-menopausal and had a history of endometriosis and adhesions which had been noted during a laparoscopy a few years earlier. During laparoscopy multiple bowel adhesions were noted completing encasing the ovary and to the anterior abdominal wall. Diathermy was used to dissect the ovary which was found to be healthy. The operative notes stated "the possibility of a thermal injury and leak remains". Unfortunately there was a bowel perforation which presented a few days after surgery requiring several further surgeries. The perforation had occurred to the ileum at the ovarian adhesion site.

An allegation of negligence was made on the grounds that had a laparotomy been performed the risk of bowel perforation would have been reduced and would have been more likely to be detected at the time of surgery. The expert gynaecologist supported this view saying that 'the manipulations required to free dense adhesions through the laparoscope are difficult, and the risk of thermal injury to the bowel in these circumstances is high. The patient would have been

better served by abandoning the laparoscopic attempts to free the adhesions and proceeding to open laparotomy, where the adhesions could have been dealt with much more easily and safely.' An out of court settlement was made.

Learning points include early conversion to open surgery when the view is obscured, there is uncontrolled bleeding, the equipment isn't adequate for the job in hand (or fails), or the operation is taking too long. The reasons for doing so should then be fully documented.

Case 2. Mrs. SD underwent a TAH and BSO for severe grade 4 endometriosis. The theatre notes at the time document clearly that the procedure was difficult and access to the ovaries limited by multiple bowel adhesions. The patient made an uneventful recovery and as she was premenopausal was commenced on HRT. She presented with non-specific symptoms of bloating and gastrointestinal symptoms for several years and was treated for IBS as her uterus and ovaries had been removed. After 2 years of treatment an ultrasound scan demonstrated a mass in the left adnexae. When she was referred back to her gynaecologist, the histology from the initial specimen was reviewed and this stated that the left ovary had not been identified at the time of histology. She underwent further surgery for this and a borderline ovarian tumor was confirmed. It was alleged that it had been negligent to leave behind an ovarian remnant and this led to the development of the borderline tumor. The expert stated that leaving behind an ovarian remnant was not negligent but failing to inform the patient of this was and led to a delay in the diagnosis. An out of court settlement was made. Learning points include cross checking the histology where anatomy is distorted.

Key Points: Ovarian Surgery

- Women in the reproductive age group undergoing ovarian surgery should be adequately counselled of the risks of reduced ovarian reserve.
- Women undergoing a prophylactic oophorectomy (for underlying BRCA and ovarian cancer risk or at the time of routine hysterectomy) should be informed of the pros and cons of ovarian removal.
- Adequate counselling of the operative risks depending on the route of surgery.
- Involvement of other specialists when a complication is identified.
- Low threshold for Conversion to a laparotomy when complications arise/in the presence of adhesions.
- In difficult cases, check histology confirms complete removal of ovaries so that the patient can be informed of the possibility of an ovarian remnant.

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Laparotomy

42

James Campbell

42.1 Background

The Oxford English Dictionary defines Laparotomy as a surgical incision into the abdominal cavity for diagnosis or in preparation for major surgery. A laparotomy may be exploratory and diagnostic or targeted and therapeutic. A diagnostic laparotomy may of course become a therapeutic procedure. A laparotomy may also be performed after a diagnostic laparoscopy or following a complication at laparoscopic surgery.

With more procedures being carried out using laparoscopic surgical techniques and the increasing use of good diagnostic imaging, the need for diagnostic laparotomy has reduced. However it is still an important surgery for acute life threatening gynaecological conditions (e.g. collapsed unstable patient with haemoperitoneum, pelvic trauma, peritonitis) and where a laparoscopic approach would be too hazardous or contra-indicated for anaesthetic reasons or lack of operator experience.

Elective laparotomy would be considered for patients with significant pelvic adhesions from chronic infection, advanced endometriosis, cancer and complex mixed pathologies involving the bowel, renal tract and retroperitoneum. Scheduled surgical care permits involvement of colleagues with appropriate experience.

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42.2 Minimum Standards and Clinical Governance Issues

The Royal College of Surgeons (RCS) have issued guidance for emergency and elective surgical care and surgical standards for unscheduled surgical care [1]. The GMC have issued guidelines on good standards of medical and surgical practice [2].

A detailed clinical history, examination and targeted investigations should be performed. Information from the patient's relatives and GP should be sought if the patient is unable to communicate and lacks capacity. Dementia assessment for elderly patients should be considered. An appropriate translator for non-English speakers should be sought. Ideally this should not be a relative. Pre-operative imaging (ultrasound, MRI, CT) can be extremely helpful when assessing the patient's condition and surgical approach to treatment. There may be no time to complete these investigations in an emergency situation. A differential diagnosis should be made and a plan for what might be anticipated in theatre.

Expectant and medical management options and interventional radiology might be considered before thoughts are given to surgery. The type of surgery, laparotomy versus laparoscopy, and scheduling acute versus elective should be considered. Peri-operative care is important to optimise the chance of having a successful surgical

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episode and uncomplicated recovery. Enhanced recovery programmes have been introduced for gynaecological operations [3, 4].

An anaesthetic opinion when a patient has complex co-morbidities is valuable. Operations are carried out under general and regional anaesthesia with some anaesthetists choosing a combined approach. Advice from a Multi-Disciplinary team may be sought before the procedure. Surgical colleagues may be called upon for advice and help in undifferentiated cases and in anticipation of an exploratory laparotomy.

Only gynaecologists who have received appropriate training in open surgical procedures should undertake a laparotomy. They must be competent in opening and closing the abdominal wall and recognising pelvic anatomy particularly the structures on the pelvic sidewall. A senior colleague should supervise a gynaecologist with less experience and be involved with the care of the patient where the risk of complication and mortality is high. Gynaecologists should be encouraged to keep a record of their cases and outcomes for audit and clinical governance meetings.

Patients requiring a therapeutic laparotomy (e.g. multiple myomectomy, open abdominal hysterectomy) should be informed of the benefits and risks of surgery and the alternatives available (e.g. radiological intervention and pharmacology therapies) and a surgical approach should consider the patient's likely pathology, medical and surgical history, co-morbidities and treatment preferences. The patient is entitled to choose which treatment to undergo.

Surgical advice depends on the suspected condition, the nature of the treatment and the concerns of the patient.

The gynaecologist should make sure a patient knows the material risks of the operation and alternatives and the risks associated with those alternatives.

Consent is usually signed in advance of the surgery and confirmed on admission. Valid consent from conscious patients in emergency situations is challenging and the doctor's duty of care is to ensure decisions taken about her management are in her best interests [5].

Consent should include a discussion about the diagnosis, aims of surgery, alternative procedures and surgical complications, their management, success and prognosis and the clinicians involved. The possibility of pregnancy and fertility status should be appreciated. A preoperative pregnancy test would be recommended. The patient may be unaware of pregnancy and enquiries should be made about the last menstrual period, menstrual cycle and contraception. The impact of delaying surgery on the patient's health should be considered and the sequelae from laparotomy. Caution is advised when dealing with cancer patients; some may not want to know the seriousness of their condition.

Patients should be made aware of the different types of surgical incision. The three main approaches are:

- Pfannenstiel incision
- Midline incision
- Paramedian incision

Midline incisions may extend above the umbilicus and the incision may skirt around the umbilicus or pass through it. The choice of incision and surgical approach should be explained and the patient's wishes considered. Some patients may object to having a midline incision for cosmetic reasons. Some may have abdominal scars already and prefer the gynaecologist to operate through the same scar.

A "mini-laparotomy" may be performed to help remove an ovarian cyst or fibroid or apply sterilisation clips.

Patients having elective surgery will have a pre-operative assessment usually by a nurse practitioner [3]. The patient's pre-operative condition should be optimised (e.g. anaemia should be corrected, periods postponed, fibroids reduced in size, weight loss if obese, stop smoking, tightening glycaemic control, treat hypertension and chest conditions, MRSA negative, bridging therapy for anticoagulants). Local guidelines should be followed. Pre-operative preparation of the bowel using enemas and laxatives is thought to be unnecessary for many cases. If bowel surgery is anticipated information about de-functioning

and stomas ought to be given by a surgeon and stoma practitioner. Allergy to latex and iodine should be noted and theatre informed. The emergency patient should also have their pre-operative condition optimised. This may involve a period of fasting, intravenous fluid replacement, antibiotics, correction of anaemia and clotting and electrolyte and glucose imbalance and normalising blood pressure and urine output. Thromboembolism (VTE) risk assessment should be performed taking into account the current and future risk of haemorrhage. An anaesthetic opinion prior to surgery should be sought and consideration given to the postoperative care bundle which might include high dependency care. This is important with unplanned emergency returns to theatre.

Patients declining recommended treatment should be offered a second opinion.

A number of specialists may be required in theatre particularly when the diagnosis is uncertain or complex pathology involving the bowel and renal tract is predicted. Good team working is essential and communication with pathology services including haematology and transfusion.

The WHO surgical safety checklist must be completed before starting the operation and the use of the checklist should be entered into the clinical notes or electronic record.

Gynaecologists should ensure their operative notes are clear and accurate, comprehensive and contemporaneous and follow the standards expected for good surgical practice [1]. Handover to colleagues should be appropriate and any important information mentioned in the theatre case debrief. Pain management should be highlighted and plans for any immediate drain and catheter care.

Communication with patients and relatives following surgery is important. The GP should receive a summary of the surgical episode. Advice about enhanced recovery and VTE prophylaxis should be mentioned. Patients should receive feedback about the operation and be offered an appropriate follow up appointment. Discharge advice should include information about accessing care if there were to be a complication. Risk of ectopic pregnancy should be mentioned in appropriate cases.

42.3 Reasons for Litigation

The reasons for litigation following a laparotomy are related to:

- Consent, advice and discussion of complications.
- Competency of surgeon/failure to consult colleagues.
- Intra-operative and post-operative complications—immediate and delayed/failure to recognise complications and inappropriate management.
- Pre-procedure investigation and care.
- Post-surgical care and recovery.
- Surgical complications associated with laparotomy include—haemorrhage, return to theatre, urine retention, bladder/ureteric/bowel/vessel and nerve injuries, post-operative ileus, Ogilvie syndrome, sepsis, abdominal wall collection (haematoma, abscess, seroma, infection), necrotising fasciitis, dehiscence, incisional/ventral hernia, adhesive intestinal obstruction, enterocutaneous fistula, sterility, adhesions.

Patients may also complain of altered sensation around the scar, hypertrophic and unsightly scars, a bulge/roll of loose skin above the Pfannenstiel incision, awareness of suture material/knots below the skin.

Complications can arise with drains, suprapubic catheters, stomas.

NHS England Patient Safety Domain published a revised never events policy and framework on 27/3/15. Serious incidents still occur in the operating theatre environment. “Never Events” meet all the following criteria—are preventable, have the potential to cause serious patient harm or death, have occurred in the past and occurrence of the Never Event is easily recognised and clearly defined.

Relevant to laparotomy were:

- Wrong site surgery—an operation performed on the wrong patient or wrong site.
- Retained foreign object post-procedure.
- Unintentional transfusion of ABO incompatible blood components.
- Misplaced nasogastric tube in the respiratory tract.

42.4 Avoidance of Litigation

There should be in-depth pre-operative planning with realistic and appropriate surgical aims. The reason for performing an exploratory laparotomy should be discussed and the fact that a therapeutic procedure may be performed under the same anaesthetic. Patient's wishes should be considered, particularly her desire for fertility and ovarian and cervical conservation. Laparotomy should be mentioned as a possible additional surgery to patients having a laparoscopic procedure, either diagnostic or therapeutic. Conversion to a laparotomy might be required to deal with more extensive pathology than was anticipated or a surgical complication or as part of the planned treatment (e.g. to remove a solid ovarian tumour). Elective laparotomy may be carried out under a regional or general anaesthetic. Patients should attend for a pre-operative assessment screen and appropriate patient information sources should have been disclosed and the explanation for surgical treatment with clear aims, risks, complications, benefits and alternative treatments documented. The concept of enhanced recovery should be mentioned [3, 4].

Consent for a laparotomy should be valid and the provision of information is essential. A signature on the consent form is not proof of valid consent. In the case of written consent make sure you record discussions within the patient's health record and confirm the patient still wishes to go ahead with surgery answering any further questions where necessary. Adequate time for reflection should be given. A copy of the consent form should be given to the patient. Any changes to the consent form thereafter should be initialled and dated by both the patient and the doctor [5].

The choice of incision should be discussed. A final decision may not be made until after a pelvic examination in theatre. This should be made clear to the patient.

The gynaecologist should be competent performing the procedure and be carrying out this surgery on a regular basis. Senior support should be considered and opinions sought from other specialities if additional non-gynaecological surgery is thought likely. Gynaecological oncologists are trained and able to operate on and with the adjacent viscera. Case selection and delegation is important. In an emergency situation, the gynaecologist might have no alternative but to perform an unfamiliar operative procedure if there is no other option to ensure the patient's best interests and safety. There may not be a more experienced colleague available to help. Accurate note keeping describing the episode is especially important.

In emergency cases, there should be prompt attendance and timeliness of surgery. Team working is essential when dealing with undifferentiated emergency patients in the casualty department. Appropriate delegation of surgical cases is important and a senior doctor should review admissions at high risk of complications and mortality.

An anaesthetic review prior to theatre should have taken place. The choice of anaesthetic and use of local nerve blocks for postoperative analgesia should be discussed. The use of rectal analgesia should be mentioned and any objections recorded in the notes.

The WHO Surgical Safety Checklist must be completed before the start of the operation.

An indwelling urinary catheter should be inserted to empty the bladder and reduce the chance of injury when opening the lower peritoneum. Antiseptic solution should be applied to the vaginal tissues and pooling avoided. A nasogastric tube might be required to decompress the stomach if there are anaesthetic concerns about aspiration or as part of the management of bowel obstruction. The patient may be positioned supine or in a flat "Lloyd-Davies" position to improve access to the deeper pelvis when rectal surgery might be anticipated. Positioning and support is important to reduce the likelihood of compression injuries to the common peroneal nerves from stirrups and straining of the lower back. The arms are either placed by each side or abducted at right angles to the body avoiding hyperextension. The diathermy plate should be applied properly to a dry surface. Any superficial bruises should be noted. The operating table should allow for intraoperative radiology should that be required.

A laparotomy is undertaken either through a low transverse incision or midline incision in most cases.

An infra-umbilical midline incision is usually performed. The initial size of incision will be dependent on the anticipated diagnosis and the incision can always be extended if required. A scalpel or cutting diathermy is used to incise the skin and cut through the subcutaneous fat. The rectus abdominis muscles are split in the midline taking care not to disturb the inferior epigastric vessels. The preperitoneal fat is divided and the peritoneum identified. The peritoneal layer is breached with digital dissection or opened with scissors. The peritoneum is grasped with two forceps and opened after checking for the presence of bowel and omentum. A second laparotomy may be more challenging because of scarring and adhesions to the abdominal wall. Care must be taken to avoid electro-cautery injuries to the skin and inadvertent contact with bowel and bladder when cauterising vessels or cutting tissues.

Care must be taken not to damage the bowel and omentum if they are adherent to the anterior abdominal wall. It is prudent to explore the margins of the incision digitally before carefully positioning a retractor so as not to trap loops of small bowel and omentum before stretching the wound. Care should be taken to avoid muscle tears and bleeding. Compression of the lateral pelvic vessels and nerves should be avoided by the use of appropriately sized blades. Care must be taken in very thin patients.

New non-metallic retractors are less likely to cause these problems (e.g. Alexis wound retractor).

An initial systematic exploration of the peritoneal cavity is performed and a plan formulated. The patient is placed in a Trendelenburg position with adequate support to stop sliding and the bowel and its mesentery lifted and packed out of the pelvis. Packing is done carefully to avoid tears in the mesentery. An adhesiolysis might be required and mobilisation of the sigmoid colon to improve exposure.

Haemoperitoneum can be associated with rupture of a physiological and pathological ovarian cyst, ectopic pregnancy, trauma, retrograde menstruation and non-gynaecological causes. Bleeding after surgery can occur with the use of non-steroidal anti-inflammatory drugs and low molecular weight heparin. Careful inspection of the pelvis is required to identify the source of bleeding and appropriate action taken. Pressure is applied to the source. Good exposure is obtained before controlling measures are put in place. Soft tissue clamps can be applied initially. Insertion of sutures and ligatures in a blind fashion should be avoided if at all possible. On occasion damage to adjacent structures from efforts made to stop bleeding can happen. Circumstances will dictate what action is acceptable and the surgical misadventure can be understandable.

Multiple sources of arterial and venous bleeding in the pelvis can be a difficult challenge and hot compression packs left in the pelvis for a few minutes can be helpful. Haemostatic agents can also be used and intravenous tranexamic acid.

If bowel pathology is diagnosed—a perforation and spillage of contents, obstruction, volvulus, torsion, infarction, tumour, inflammation (appendicitis, diverticulitis), dense adhesions, burn—a bowel surgeon must be requested. Thermal spread from electrosurgical devices should be appreciated.

The management of chronic pelvic inflammatory disease, tubo-ovarian abscesses, advanced endometriosis and malignancy should be done with the help and advice of experienced colleagues. A urologist should be asked to help if ureterolysis or stenting of a ureter or bladder repair is required.

Laparotomy should be adequately covered with prophylactic antibiotics. Co-amoxiclav should be avoided in penicillin sensitive patients.

At the conclusion of the operation, all packs and swabs should be removed. The scrub practitioner completes a count of instruments, needles and swabs before the peritoneum is closed and again before the skin is closed. There should be no count discrepancy. Information about swabs and instruments (e.g. ureteric stents) intentionally retained after the procedure has finished should be clearly recorded in the patient's notes with a plan for removal at a later date.

Different techniques may be used to close the incision. A single layer mass closure is popular for vertical incisions. Closing the wound in layers can also be considered and is the method of choice for Pfannenstiel incisions. A continuous suture using an absorbable suture material or delayed absorbable suture material is usually used. There is a difference in opinion as to whether closure of the peritoneum is necessary or not. It is important to ensure that the bowel and omentum are not caught when suturing the sheath and peritoneum. Care must be taken at the lower limit of the mid-line incision not to catch the bladder. The skin is closed using clips or a delayed subcutaneous absorbable suture or non-absorbable interrupted sutures. Local anaesthetic may be injected into and around the wound or given via catheters. This is unnecessary with an epidural anaesthetic. The placement of a drain in the rectus sheath or pelvis is dependent on the circumstances. A drain might be placed to reduce the risk of haematoma or abscess formation. Careful insertion is required to avoid injuries to abdominal wall vessels and intraperitoneal contents. Drain entrapment can be a problem if it is brought out of the Pfannenstiel incision and inadvertently caught in the rectus sheath closure. It is wise to check the drain slides before closing the skin and anchoring the drain to the skin. Appropriate wound dressings should be used. A note should be made of any loss in the drain and urine volume and colour. Frank blood with no urine in the catheter should alert to the risk of bladder injury and re-exploration of the pelvis.

Good communication with the relatives is encouraged if there are intraoperative complications and the surgery is difficult and not going to plan. A message from theatre to the ward staff and relatives can be helpful.

The operation should be recorded and any pathology specimens labelled correctly. A case debrief should occur with all staff. The operative notes must be clear and preferably typed and accompany the patient to the ward. Abbreviations open to misinterpretation should be avoided. Notes of the laparotomy should include—date and time, names of the gynaecology team and anaesthetist, operation performed, incision and operative diagnosis and findings, complications and extra procedures required, specimens removed, details of closure technique and anticipated blood loss, postoperative care instructions and signature.

A formal handover of the patient should occur.

Postoperatively, patients should receive appropriate fluid and nutritional support and pain relief [4]. VTE prophylaxis should be considered. Physiotherapy support and advice about wound care should be given. Bladder care guidelines should be followed and help to address constipation. Enhanced recovery programme should be encouraged. Patients should be told the diagnosis and treatment undertaken. If a complication occurred an explanation should be offered and apologies and careful follow up. Patients should be offered a post-operative review usually 6–8 weeks after discharge, but this is not always necessary.

Audits should be performed looking at the outcomes of surgical treatment and complications related to elective and emergency laparotomy and any readmissions within 30 days.

42.5 Case Study

A 47-year-old woman underwent a laparotomy for a cholecystectomy. She was referred to a physician eight years later for abdominal pain and hepatic enlargement. Antibiotics failed to resolve symptoms and a diagnosis of hepatic carcinoma was made but as the patient remained well was revised to a chronic hepatic abscess. Chest X-rays showed elevation of the right hemi-diaphragm, pleural reaction at the right costophrenic angle and elevation and thickening of the horizontal

fissure. An opacity below the right hemi-diaphragm was overlooked. Over the next 12 years until approximately 20 years after the cholecystectomy the patient received ongoing regular treatment from the specialist and her GP. At 68 years of age she consulted a new doctor about her continuing abdominal pain and discomfort. Barium meal demonstrated two calcified masses and an enlarged liver which were confirmed on a CT scan. At laparotomy two large abscesses in the subphrenic space above the liver were found. In one of these abscesses besides pus, a large surgical swab was found with calcification of the wall. Following this the patient made an uncomplicated recovery and liability for the retained swab was admitted by the hospital. The patient received £27,000 in compensation.

Gossypiboma or textiloma is referred to as a surgical gauze or towel inadvertently retained inside the body following surgery. Though this is a rare medical error it is completely preventable and in the doctrine of *res ipsa loquitur* will always be viewed as surgical negligence. Learning points include

- Surgical counts before during and at the end of surgery are an essential error minimisation technique, but are not infallible.
- Symptoms may not present initially, and complications may present after a great delay sometimes even decades.
- Presentation may be with infection, abscess or adhesion formation with consequent obstruction, as well as fistula formation and migration.
- Suspicion of retention of surgical materials warrants the use of plain radiographs to detect intact radio-opaque materials in the first instance but inevitably result in further surgery for removal.

Key Points: Laparotomy

- Adequate perioperative care and counselling, valid consent and material risks discussed and patient choice.
- Procedure performed by competent gynaecologist following standards for surgical care.
- Good surgical technique, timely control of haemorrhage and involvement of surgeons for non-gynaecological pathology.
- Appropriate use of WHO surgery safety checklist.
- Appropriate use of antibiotics and VTE prophylaxis.
- Appropriate operation note.
- Adequate follow up of patients.
- Immediate and delayed complications should be appropriately managed and recorded.

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Urological Injuries

43

Christopher R. Chapple

43.1 Background

Urinary tract injury is reported in approximately 1% of women who undergo pelvic surgery [1].

The urinary tract is at risk of injury particularly during laparoscopic gynecological surgery, either due to the entry process (for example, during suprapubic port insertion) or as a consequence of its close relationship with the operative field (for example, during hysterectomy). In more complex situations, the bladder can also be at risk because of its direct involvement in the disease process (for example, utero-vesical endometriotic nodules). The reported incidence varies greatly. Injury rates range from 0.02 to 8.3% [2]. This places bladder injury at the top of the list of viscera which can be damaged in the context of laparoscopic pelvic surgery [3]. Dissection of the bladder from the cervix, the introduction of the Veress needle/trocar are common incidences when injury may occur to the urinary tract. Certain procedures such as laparoscopic assisted vaginal hysterectomy appear to be associated with a higher frequency of bladder injury compared with other procedures [4]. Ureteric proximity to the female genital tract also puts it at risk of injuries during pelvic surgery. Most published studies quote a range or ureteric injury rates of laparoscopic gynecological surgery from <1 to 2% [3]. However, there is a significant range in the literature, with rates being as low as 0.06% and as high as 21% [5, 6]. It is estimated that approximately 250,000 women undergo laparoscopic surgery in the UK each year; the majority are without problems, but it can be assumed that approximately 250 serious complications occur every year.

Observing the ureter for peristalsis is often used to identify the ureter, but it is not a valid test for ureteral integrity. In a prospective study in which women undergoing total abdominal hysterectomy were evaluated with intraoperative cystoscopy, peristalsis was present in five of six women with ureteral injury [7]. Full evaluation of a ureter may require further dissection of the ureter, if the ureter has not been fully isolated. Whether to perform this ureteral dissection initially or defer dissection and evaluate the urinary tract integrity at a later time during surgery (e.g., with cystoscopy) is based upon the surgeon's preference and skills.

As a general rule, symptoms coincide with the location and type of injury. A combination of obstruction or the sequelae of a laceration in the urinary tract may present with a combination of signs and symptoms. It is also important to realise that more than one area may be involved and a

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classical example is where a vesicovaginal fistula is identified but there is no imaging of the upper tracts and a concomitant ureterovaginal fistula is missed. Whilst a ureteral or bladder defect with leakage of urine into the peritoneal cavity will present with abdominal pain and as a consequence of obstruction to the upper tract, also with flank pain, the clinical symptoms may be misleading. If there are any atypical signs then imaging of the upper tracts initially with ultrasound is essential. Certainly on some occasions cases of complete ureteric obstruction may present with minimal symptoms and signs other than of mild sepsis or non-specific discomfort.

43.2 Minimum Standards and Clinical Governance Issues

The best management is prevention with clear delineation of anatomy to identify important structures such as the ureters, bladder and urethra. Whether it is open or laparoscopic, the surgeon should be experienced, not only in appropriate anatomical dissection but also management of adhesions. Particular account should be taken of any previous abdominal scar and adhesions relating to the urinary tract suspected when mobilizing tissues to gain access to the gynecological organs. If a surgeon is not fully experienced in a new technique then they should be adequately trained and/or supervised. Surgeons should be familiar with the equipment, instrumentation and energy sources that are being used. Surgeons undertaking any surgery should ensure that the nursing staff and surgical assistants are appropriately trained for the roles that they will undertake during the procedure.

Full informed consent is essential, and should outline all of the major complications and minor complications. It is important that women should be aware of the risks of significant morbidity and mortality association with any surgical procedure. Issues of consent have been outlined in previous chapters.

43.2.1 Intraoperative

When there is a finding suggestive of injury, intraoperative evaluation is essential. If a defect can be seen grossly after a laceration or transection to a ureter or the bladder, then an appropriately skilled individual should be called to the operating theatre. If injury is suspected (a telltale indication of this being the presence of haematuria) then a cystoscopy is mandatory. If a ureteric injury is suspected, then this can be clearly delineated by a cystoscopy and passage of a guide wire, with or without an appropriate ureteric catheter passed up the ureter which is thought to be potentially affected.

If there is a direct injury to the bladder (cystotomy) then direct closure to this can be carried out as long as it is not close to the ureter. If this is suspected then a cystoscopy and insertion of a guide wire or stent is appropriate, potentially involving a urological surgeon to assist.

If a clamp is identified in close proximity to the ureter, or a suture or staple, then a ureteric injury should always be excluded by passage of a guide wire and/or stent up the ureter.

Bladder injuries are more likely to be diagnosed during visual inspection than ureteric injuries. In a prospective study of 839 women who underwent hysterectomy, visual inspection detected 9/24 bladder injuries (38%) versus 1/15 ureteric injuries (7%) [8].

The use of intravesical or intravenous dye to colour the urine can be advised. The intravesical dye which is commonly used is methylene blue and intravenously carmine 2.5 mL of 0.8% solution, which can be administered by the anesthetist. It is not recommended that methylene blue should be given intravenously because a cumulative dose greater than 7 mg/kg can result in methemoglobinemia in susceptible individuals. If a urologist is called to the scene, then they can also use other techniques such as ureteroscopy to inspect a ureter.

43.2.2 Postoperative

Postoperative recognition of injury is a significant precursor to litigation. In a series of 20 urinary tract injuries in women after pelvic surgery,

the main time to diagnose this was 5.6 days (range 0–14 days) [9].

Precursor symptoms are:

- Unilateral or bilateral flank pain
- Haematuria
- Oliguria
- Anuria
- Abdominal pain or distension
- Nausea with or without vomiting
- Ileus
- Fever

The manifestations of fistulation of the urinary tract are very variable in nature and may take from days to weeks to present. If pathology is suspected, then a thorough clinical examination is essential. Routine biochemistry and a full blood count, and examination of any drained fluid can also be helpful in identifying the presence of urine. Standard imaging of the upper tracts whether by intravenous urography, CT scanning or MRI are mandatory, optimally after discussion with a radiological colleague to identify the best modality. In particular a cystogram is useful along with a subsequent cystoscopy.

If ureteric injury is suspected, then in addition cystoscopy and insertion of a ureteral stent can be considered. If complete obstruction of the ureter is felt to be the case, then insertion of a nephrostomy tube as an emergency is appropriate, with the antegrade passage of a stent performed by a radiologist.

If any injury is identified within the first 2–3 weeks whether it is a bladder injury with a fistula for instance or a ureteric injury and a stent cannot be passed, then early intervention can certainly be contemplated and conducted by an experienced surgeon who is familiar with all of the techniques available, as this will obviate the need for a prolonged period of management, because beyond 3 weeks, most reconstructive surgeons who deal with urinary tract injury will advise leaving tissues to heal for a period of 3 months.

A common discussion in medico legal circles relates to whether ureteric injury has occurred as a consequence of a thermal injury, a clamp, or a suture. It is usually not possible to differentiate between these in the context of a delayed onset of manifestation of the injury. Likewise, discussions relating to complete or partial damage to the ureter rely heavily on surmise.

43.3 Reasons for Litigation

- Inadequate preoperative discussion and counselling, and failure to document adequate consent.
- Lack of surgical experience.
- Poor surgical technique, usually resulting from lack of training or inadequate senior supervision.
- Inappropriate surgical approaches, such as laparoscopic approaches in a heavily scarred abdomen, or failure to convert from laparoscopy to open surgery.
- Failure to adequately examine the abdomen at the time of suspected injury and/or failure to call upon a senior colleague in the same specialty or an alternative specialty such as urology.
- Difficulty managing peri-operative bleeding, leading to inappropriate placement of clamps and sutures, with potential occlusion of structures such as the ureter or injuries to the blood supply to the ureter or bladder.
- Inappropriate early management of a patient with suspected complications.
- Failure to recognize the likelihood of a urinary tract injury and to evaluate appropriately, for example in a patient with incontinence of urine occurring de novo after hysterectomy, the failure to recognize the potential for there being a fistula; an alternative scenario would be failure to investigate a non-specific symptom such as flank pain or persistent pyrexia with subsequent recognition of a ureteric injury.

43.4 Avoiding Litigation

1. Careful preoperative preparation and consent; taking a careful history of previous surgical intervention; informing the patient about any potential complications and how these would be managed; devoting time to counsel the

patient and answering any questions that they may have; discussing all alternatives to the proposed treatment strategy; documenting all potential complications relating to both morbidity and mortality.
2. Careful surgical technique and recognition of situations where a urinary tract injury may have occurred. Calling on a senior colleague or colleague from another specialty such as a urologist, to reassess the situation should be considered.
3. Appropriate recognition, investigation and early management of any urinary tract injury. It is important that the patient should be fully informed of what may have occurred, how this will be evaluated and dealt with. Failure to involve the patient in the process and explain to them exactly what is going on is more likely to lead on to litigation.
4. Early intervention, whenever an injury is suspected, may allow early resolution of the problem. Litigations is more likely to occur if the patient has to live with the complication for some months prior to final resolution of the problem.
5. Preventing unnecessary deterioration in renal tract function, for example early intervention will prevent loss of renal function if there is a ureteric obstruction. Appropriate use of antibiotics and management of infection are also essential to prevent unnecessary damage to the urinary tract.
6. When there is an unsuspected lesion such as urethral diverticulum during prolapse or sling surgery a urologist/urogynaecologist should be involved in the management of this situation. If this is not managed optimally then a complication and subsequent litigation are more likely to occur.

43.5 Case Study

43.5.1 Case Study #1: Laparoscopic Surgery

A 34-year-old woman underwent a laparoscopic sacrocolpopexy. The surgeon felt the procedure was uneventful, but marked haematuria was noted by the assistant at the end of the procedure. No action was taken. The haematuria persisted on the ward for 48 h and then settled. The catheter was removed after 72 h. Three weeks later, the patient contacted the clinician's secretary to state that she was experiencing marked frequency and urgency, and had been diagnosed as having a urinary tract infection. She was advised antibiotic therapy. She re-contacted the department two weeks later (five weeks postoperatively) to say that she had a persistent urinary tract infection and persistent symptoms. She was advised that she would be seen in clinic as previously arranged, and was seen at seven weeks postoperatively. She was reviewed by the Staff Grade doctor in the department, who reassured her that such a situation was not uncommon, and she was advised that she would be seen in a further three months. Her symptoms persisted and she was referred to a urologist who carried out a cystoscopy and identified the presence of polypropylene mesh which had been used for the sacrocolpopexy, lying at the dome of the bladder.

Comment: The presence of marked haematuria was a strong indication for carrying out a cystoscopy at the end of the procedure. It is likely that this would have demonstrated an abrasion at the dome of the bladder and early intervention would have saved the subsequent course of events. When this lady presented with persistent symptoms for the second time, then certainly earlier investigation would have been appropriate, either when she called the department on the second occasion or when she was seen in clinic.

43.5.2 Case Study #2: Obstetric Surgery

A 44-year-old lady who had a previous normal vaginal delivery underwent an emergency caesarean section following which she was troubled by persistent abdominal discomfort. A week after the surgery, having been discharged after 48 h, she got in contact to say that she had a purulent discharge per vaginum which was intermittent in nature, and passage of the discharge relieved her discomfort. The discharge was not continuous and at times it was clear in nature. She was reassured and told that this should settle. When she re-presented for review at a post-natal visit at one month, the symptoms were persisting and on examination there

was noted to be a clear discharge in the vagina, but the history was that the discharge was not continuous. She was reassured. Her symptoms persisted and six weeks later her general practitioner wrote to the department stating that she was still experiencing intermittent discharge and abdominal discomfort, which was usually relieved by the discharge. A cystoscopy was arranged which showed no intravesical abnormality. No imaging of the upper tracts was carried out and it was not until four months later following this that she was referred to the urology department where imaging of the upper tracts was performed and a ureterouterine fistula was identified.

Comment: Early imaging of the upper tracts may well have identified this as contrast would have been seen passing into the uterine cavity.

43.5.3 Case Study #3: Radical Surgery

A 44-year old lady underwent a radical hysterectomy for an early stage endometrial cancer. She noticed when she returned home that she was experiencing persistent urinary discharge per vaginam. She contacted her gynecologist who told her that it was very common to get some urinary leakage after radical surgery such as this for up to 18 months. Her symptoms persisted and she was using 8–10 pads per day. Her general practitioner referred her back to the hospital at a month and she was again reassured. Eventually at three months following surgery a locum surgeon in the department who was reviewing her arranged for her to have a cystogram, which showed the presence of a vesico-vaginal fistula. This was noted to be small, approximately 4 mm in diameter according to the imaging, and she was told that this might well heal. Her symptoms persisted and she contacted her local Citizens Advice Bureau who suggested she contact the hospital complaints group. A review of her case led on to her being referred to another centre where tertiary work was carried out. Imaging of her upper tract showed the presence of both a vesicovaginal and ureterovaginal fistula.

Comment: The case demonstrates a failure to act on the patients symptoms, a subsequent failure to investigate or counsel her adequately and a failure to arrange a timely specialist referral.

Key Points: Urological Injuries

- Counsel and consent patients, and document it appropriately.
- Document the potential for injury of the urinary tract, whether it be ureter, bladder or urethra.
- Early intraoperative discovery of an injury and seeking advice of either a senior colleague or urologist may well allow for early resolution of the problem and avoid subsequent litigation.
- In cases where there is significant bleeding then careful reappraisal of the situation either peroperatively or postoperatively, and appropriate imaging are essential. If any possibility of urinary tract injury may have occurred, then document this to allow potential early intervention as necessary.
- Whenever in doubt, utilize cystoscopy to exclude an intravesical injury. If a ureteric injury is thought to even be possible, then coupled with a cystoscopy, passage of a guide wire or ureteric catheter up the ureter is an easy way of excluding pathology. Appropriate use of dye as noted above can identify urinary tract leakage.
- Having a low index of suspicion for the possibility of a urinary tract injury having occurred with and arranging an ultrasound of the upper tracts, will usually identify the possibility of obstruction to a kidney or show the presence of a fluid collection, which may then prompt further investigation.
- The presence of incontinence occurring de novo should always lead on to early investigation.

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Bowel Injury

44

Janesh K. Gupta and Tariq Ismail

44.1 Background

As of 2009, 20% of 600,000 hysterectomies performed in the United States were done laparoscopically [1] and approximately 250,000 women undergo laparoscopic surgery in the UK each year. The advantages of laparoscopy over laparotomy have been well established and include less post-operative pain, shorter hospital stays and reduced blood loss [2, 3].

Laparoscopic related complications involving the bowel usually occur during initial abdominal access, trocar placement, dissection of adhesions or the use of electrosurgery. Complications are more litigious when it is associated with gynaecological laparoscopic surgery rather than by laparotomy.

A recent meta-analysis [4] indicated that there were 604 bowel injuries reported following 474,063 gynaecological laparoscopies, giving an incidence of 1:769. Bowel injury rate varied from 1:3333 for sterilisation to 1:256 for hysterectomy. The small bowel was the most frequently injured (47%). Fifty-five percent of bowel injuries occurred during Veress needle or trocar placement. Most bowel injuries were recognised intra-operatively (no deaths) but when injury was unrecognised at the time of surgery and when the diagnosis was delayed (41% of cases), this resulted in a mortality rate of 1 in 31. Eighty percent of bowel injuries were managed by laparotomy.

Bowel injury can also occur from other gynaecological procedures such as dilatation and curettage (D&C), open abdominal hysterectomy and hysteroscopic procedures. The incidence of bowel injuries is 1:333 in hysterectomy [5]. Usually the sigmoid colon and rectum is at risk in women with a history of endometriosis, malignancy, pelvic inflammatory disease or diverticulitis.

For the purposes of this chapter we shall discuss pertinent issues between gynaecological laparoscopy and bowel injury and also cover methods to identify the mechanism of injury depending on the timescales of presentation in the post-operative period.

44.2 Minimal Standards and Clinical Governance Issues

44.2.1 Open Laparotomy

See chapter on laparotomy.

44.2.2 Safe Laparoscopic Entry

In gynaecological practice, the closed method for port entry is commonly used, using a Veress

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needle. Initially blind trocar insertion of the primary port through the umbilicus is followed by direct vision insertion of lateral trocars. The direct trocar entry has also been used in gynaecological practice. There is evidence to suggest that this technique is associated with a lower risk of vascular injury and failed entry compared to closed entry techniques [6].

Alternative entry techniques should be used such as Palmer's Point or open Hasson for patients with previous abdominal surgery, obesity, extremely thin patients and those with known abdominal adhesions.

The open Hasson technique may be considered an alternative to the closed technique. Although it is associated with a reduced rate of failed abdominal injury, there is no significant difference in the risk of vascular or visceral injury rates [6].

44.3 Reasons for Litigation

- Failure to adequately select patients.
- Failure to adhere to the principles of safe laparoscopic entry as recommended by National Bodies (see below).
- Failure to detect bowel injury at the time of surgery.
- Failure to detect bowel injury in the early postoperative period.
- Failure to convert to a laparotomy when bowel injury suspected.
- Failure to call a bowel surgeon when bowel injury suspected/occurs.
- Attempting repair of bowel injury in the absence of adequate case load as a gynaecologist.

44.4 Avoidance of Litigation

44.4.1 Open Laparotomy

See chapter on laparotomy.

44.4.2 Laparoscopic Surgery

There are several national and international specialist Society guidelines that can be summarised as specific steps for safe laparoscopic entry [6–9].

1. Patient should be lying flat with an empty bladder.
2. Veress needle should be checked for spring and gas patency. This should be indicated on the insufflator as 0 mm Hg pressure and a flow rate of between 1.7 and 2.3 L/min, depending upon the calibre of the Veress needle. This can only be checked after allowing the insufflator to run for at least 20 s.
3. A 10 mm vertical intra-umbilical incision starting in the umbilical pit, extending caudally.
4. Insertion of Veress needle at the level of the deep umbilical pit 90° to the skin in a controlled manner and not inserting the needle more than 20 mm. The Veress needle should not be excessively moved after insertion to avoid any injury to be extended to become a large complex tear.
5. Initial intra-abdominal pressure should be negative. During insufflation a pressure of <8 mm Hg pressure with a high flow rate indicates correct Veress placement.
6. The insufflator should be set to 25 mm Hg pressure which allows maximum safe distance between abdominal wall and underlying abdominal contents. This abdominal pressure also achieves a tympanic splinting effect of the abdominal wall and does not compromise inferior vena caval compression.
7. Insertion of trocars should not be uncontrolled. Primary trocar insertion should be in a controlled two-handed screwing manner, vertically at 90° to the skin. Further advancement should not be beyond the tip of the trocar through the abdominal wall.
8. Initial 360° laparoscopic check for intra-abdominal visceral or vascular injury should be performed.

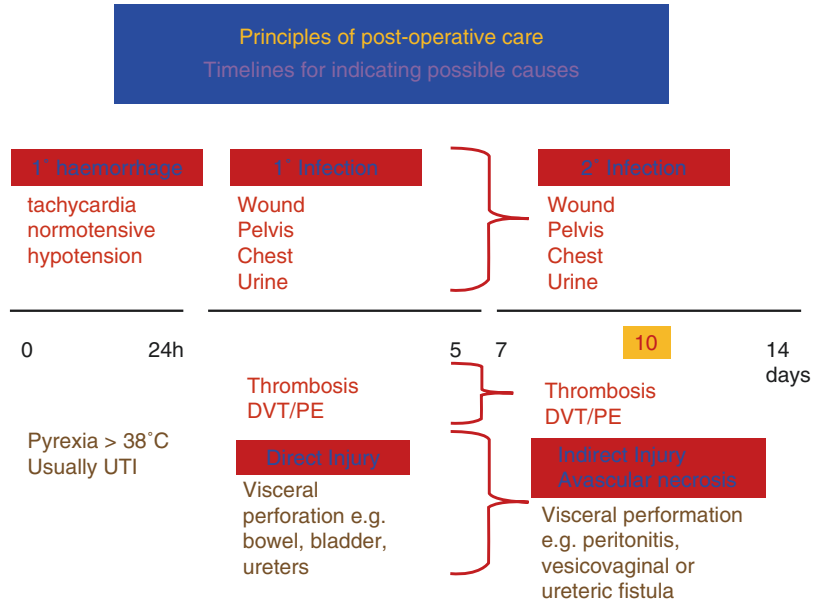

Fig. 44.1 Timeline for post-operative complications

9. Insertion of secondary trocars under direct vision should be in a two-handed controlled manner at 90° to the skin, avoiding inferior epigastric vessels. Following the insertion of trocars, the intra-abdominal pressure should be reduced to a working pressure of between 12 and 15 mmHg pressure.

Concise, clear and comprehensive documentation of the surgical technique is important following the principles for safe laparoscopic entry. Recognition of intra-abdominal injury and resorting to laparotomy reduces the risks of litigation. Laparoscopic repair should not be performed without first seeking help and involving trained surgeons. In the systematic review only 8% of injuries were managed laparoscopically [4]. It is believed that Veress needles injuries can be observed expectantly but only six cases in 46 years of literature have followed this approach [4]. Patients returning with atypical symptoms should be investigated thoroughly for intra-abdominal injury to avoid a delay in diagnosis, which is a common reason for morbidity, mortality and litigation. Principles for post-operative care should be followed [10], which can indicate a mechanism of injury, and are summarised in Fig. 44.1.

44.5 Case Study

A 32-year-old woman with a BMI of 24 was requesting laparoscopic sterilisation procedure after completing her family with three normal vaginal deliveries. She had no previous abdominal surgery. A 3-L carbon dioxide insufflation was carried out through a two port procedure and a Filshie clip sterilisation of the fallopian tubes was carried out. Three days later she was admitted with pain and abdominal distension. Laparotomy confirmed rectal injury requiring a Hartman's procedure.

In an uncomplicated case, if there had been good surgical techniques, the likelihood of laparoscopically related bowel injury is highly unlikely. If there are no alternative pausible non negligent explanations for a complication, then the defendant is likely to be liable and follows the principles of *res ipsa loquitir* ("the thing

speaks for itself") [11]. Although the defendant's view point is that a bowel injury is a recognised complication of laparoscopy, the occurrence is therefore not proof of negligence *per se*. However, if there are no risk factors and the surgeon follows safe laparoscopic entry techniques, as detailed above, then the risk of injury is highly improbable.

Key Points: Bowel Injury

- The overall incidence of bowel injury in gynaecological laparoscopies is 1:769 but increases with surgical complexity.
- Laparoscopic hysterectomy bowel injury rate is 1:256.
- Delayed diagnosis is associated with mortality rate of 1:31.
- Following ten surgical steps can aid safe laparoscopic entry.
- Alternative methods for entry include open Hasson and direct trocar entry.

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Vascular Injury

45

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45.1 Background

A survey of all hospitals in Sweden undertaking gynaecological surgery and a review of the literature found that the frequency per 10,000 operations were: 0.93 after laparoscopy, 0.76 after laparotomy, and 0.33 after major vaginal surgery [1]. It seems counter-intuitive that laparoscopic procedures, which are often diagnostic, are associated with a higher risk of vascular injury than open procedures, and is explained by the fact that the majority of laparoscopic injuries are entry-related. Another reason is that retroperitoneal vascular injuries are more easily missed. A large section of this chapter therefore deals with entry-related laparoscopic injuries.

In the Swedish survey, laparoscopic injuries affected the iliac arteries more often and most were simply treated by arterial suture without complications. Injuries during laparotomy were most frequently venous and accompanied by more severe bleeding. In one case the external iliac vein was ligated, with immediate postoperative swelling, and in another case the external iliac artery was ligated, after which the patient developed postoperative ischemia.

Similar rates of vascular injury have been reported from Finland where 256 complications were reported to the National Patient Insurance Association following 70,607 laparoscopic procedures [2]. The rate of major vascular complications was 0.1/1000. In the Netherlands, the results of a prospective multi-centre study of 72 hospitals found 145 complications from 25,764 laparoscopies [3]. There were two fatalities and 84 women required a laparotomy to deal with the complications. There were 27 cases of vascular injury (1.05/1000), and 57% of the injuries were attributed to laparoscopic entry. Women with a previous laparotomy were also found to be at particular risk.

45.2 Minimum Standards and Clinical Governance Issues

The RCOG 'Standards for Gynaecology Care' [4] states that "*Valid consent must be taken prior to any operative procedure*" and that "*Gynaecologists who perform elective surgery should be able to demonstrate their competency at the procedures they perform. This will be by continuous personal audit of the number of different procedures and log of outcomes, any complications, readmissions, return to theatre and complaints. This information is required for consultant appraisal*".

Documentation of vascular injury as a possible complication on the consent form is no defence if the procedure is performed

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incompetently or the vascular injury poorly managed. If the procedure has a particularly high risk of vascular injury, then the surgeon also needs to ensure that adequate vascular cover, or assistance, is in place.

The Standards also state that "*There must be a locally agreed protocol for the thromboprophylaxis and antibiotic prophylaxis to women undergoing surgery.*"

This protocol needs to follow NICE Guidance [5] in terms of timing, dosage and duration, depending on the risk factors. A particular problem with pelvic surgery is that DVT may commence in the iliac veins, rather than in the leg veins. Therefore, duplex ultrasonography to exclude DVT must include the iliac veins, and if not visualised, an MR venogram should be considered [6].

No surgeon should undertake a new procedure without adequate training and supervision. This applies to consultants as well as trainees. Surgeons also need to ensure an adequate procedure-specific caseload to maintain their competence. All surgeons should be able to provide patients with details of their caseload and complication rates. These standards should also apply to trainees who perform procedures unsupervised. Such trainees must be able to demonstrate their experience from a logbook and competence from workplace-based assessments, and a procedure should ideally be signed off as an 'Entrustable Professional Activity' by their Educational Supervisor, as now recommended by the GMC.

The Standards also state that "*If surgery is being performed in a satellite unit, there must be a defined pathway for the anaesthetist and surgeon to call for additional help of a colleague and a transfer pathway to the nearest emergency gynaecological inpatient hospital. In the event of a complication and where relevant, facilities to convert to abdominal surgery must be available. A rapid access ambulance and transfer team must be available if a higher level of care is required postoperatively. Wherever the surgery is being conducted, there must be a clear pathway to call for assistance from a general, gastrointestinal, vascular or urological surgeon if complications occur*".

The RCOG Green Top Guideline number 49 on 'Preventing entry-related gynaecological laparoscopic injuries' states [7]:

> "*Women must be informed of the risks and potential complications associated with laparoscopy. This should include discussion of the risks of the entry technique used: specifically, injury to the bowel, urinary tract and major blood vessels, and later complications associated with the entry ports: specifically, hernia formation. Surgeons must be aware of the increased risks in women who are obese or significantly underweight and in those with previous midline abdominal incisions, peritonitis or inflammatory bowel disease. These factors should be included in patient counselling where appropriate*".

During Laparoscopic surgery an intra-abdominal pressure of 20–25 mmHg should be used for gas insufflation before inserting the primary trocar. It is necessary to achieve a pressure of 20–25 mmHg before inserting the trocar, as this results in increased splinting and allows the trocar to be more easily inserted through the layers of the abdominal wall. The increased size of the 'gas bubble' and this splinting effect has been shown to be associated with a lower risk of major vessel injury. If a constant force of 3 kg is applied to the abdominal wall at the umbilicus to an abdominal cavity insufflated to a pressure of 10 mmHg, the depth under the 'indented' umbilicus is only 0.6 cm. When the same force is applied to an abdomen distended to 25 mmHg, the depth increases to 5.6 cm (range 4–8 cm). The mean volume of CO_2 required to reach this pressure was 6 L [8]. No adverse effect on circulation or respiratory function was observed as long as the patient is lying flat, but In the Trendeleburg position, it is advisable to reduce the distension pressure to 12–15 mmHg once the insertion of the trocars is complete. This reduces the risk of lower limb venous/arterial insufficiency and makes ventilation easier.

The primary trocar should be inserted in a controlled manner at 90° to the skin, through the incision at the thinnest part of the abdominal wall, in the base of the umbilicus. Insertion should be stopped immediately the trocar is inside the abdominal cavity. Once the laparoscope has been introduced through the primary cannula, it should be rotated through 360° to

check visually for any adherent bowel or bowel/vascular damage.

Secondary ports must be inserted under direct vision perpendicular to the skin, while maintaining the pneumoperitoneum at 20–25 mmHg. During insertion of secondary ports, the inferior epigastric vessels should be visualized laparoscopically to ensure the entry point is away from the vessels.

Secondary ports must be removed under direct vision to ensure that any haemorrhage can be observed and treated, if present. Before placing the lateral ports, it is essential that the inferior epigastric vessels are visualised from within the peritoneal cavity by the laparoscope and that the entry point of the port is away from these vessels. The inferior epigastric arteries and veins can be visualised just lateral to the lateral umbilical ligaments (the obliterated hypogastric arteries) in all but the most obese patient. In the woman who is obese, the incision should be made well lateral to the edge of the rectus sheath, taking care to avoid injury to the vessels on the pelvic side wall.

Many vascular injuries to arteries and veins are relatively minor, and many will stop with the application of sustained pressure for 5 min or so. This is preferable to repeated attempts at electrocoagulation, as this is likely to make any vascular injury worse. If the area continues to ooze, then further compression should be applied after application of an absorbable haemostat or thrombin sealant. Once the bleeding has stopped, the area should be re-inspected prior to closure to ensure that it remains dry.

Continued bleeding from a minor 'unimportant' vessel such as the epigastric artery is best dealt with by over-sewing the area with 2/0 Vicryl or similar.

If a small hole can be easily identified in an 'important' vessel such as the iliac artery or vein, then it is reasonable for a gynaecologist with experience of dealing with such a complication, to attempt repair with a 4/0 or 5/0 Prolene suture. This requires a good assistant to keep the area clear of blood with well-directed suction. The sutures should be placed in line with the longitudinal axis of the vessel to reduce the risk of narrowing. Any narrowing of the iliac vein or artery risks peri-operative thrombosis, and a vascular opinion should be obtained before closure (see case report 2).

If the hole is large, or the gynaecologist/ assistant inexperienced, then pressure should be reapplied and help from a vascular surgeon requested. If there is no vascular available onsite, then help should be summoned from the nearest major vascular unit. The commonest cause of adverse sequalae from vascular injury is due to a failure to ask for help at an early stage.

45.3 Reasons for Litigation

The commonest reasons for litigation following arterial injury relate to:

1. Inadequate preoperative discussion/documentation of complications prior to obtaining consent.
2. Lack of appropriate thromboprophylaxis or failure to diagnose postoperative DVT.
3. Poor surgical technique, lack of training and inadequate senior supervision.
4. Inadequate facilities to convert to laparotomy or delay in transfer of a patient with a significant vascular injury to a major vascular centre for treatment.
5. Failure to document/investigate peripheral arterial disease and/or absent femoral pulses prior to surgery.
6. Poor surgical technique, particularly regarding laparoscopic entry procedures.
7. Failure to recognise, or take seriously, peri-operative bleeding, leg swelling or ischaemia.
8. Inadequate treatment of a vascular complication and/or failing to ask for help from a vascular surgeon.

45.4 Avoiding Litigation

45.4.1 Preoperative Preparation and Consent

All patients undergoing gynaecological surgery should be asked about a history of deep venous thrombosis (DVT) and peripheral arterial disease (PAD). A history of DVT is important as it will

influence the thromboprophylaxis regime. A history of PAD is important because leg ischaemia due to aortoiliac arterial disease may be made worse by open pelvic or vaginal surgery, and the presence of PAD increases the Waterlow score regarding the prevention of pressure sores [9].

45.4.2 Avoiding Entry-Related Vascular Injuries

The most effective way to reduce complications of laparoscopic entry is to optimise insertion of the primary trocar and cannula, although there is controversy as to the safest technique for achieving this. Gynaecologists have tended to favour the closed or 'Veress' needle entry technique, whereby the abdominal cavity is insufflated with carbon dioxide gas before introduction of the primary trocar and cannula. The Royal College of Surgeons of England recommends that the open or 'Hasson' approach be used in all circumstances. This latter method uses a small incision to enter the peritoneal cavity under direct vision. The two techniques are well described in an article published by the Society of Obstetricians and Gynaecologist of Canada [10].

A meta-analysis of systematic review and two randomized trials found a higher risk of bowel injury associated with open access but the risk of vascular injury was too small for any difference to be observed [11]. The use of a direct trocar entry technique appeared to have some benefit in prevention of vascular injury though the quality of data was poor [11]. Therefore, what really matters is strict adherence to an accepted technique (see case report 1).

45.4.3 Managing Vascular Injuries

Minor vascular injuries should be dealt with by application of pressure or over sewing of vessels. Electrocoagulation should be used with caution and repeated electrocautery avoided to prevent worsening of the vascular injury. Once major vascular injury has been identified, assistance from a vascular surgeon should be sought early on to prevent deterioration in the patient's condition.

Postoperatively, if there has been a vascular injury during surgery, then both legs should be checked for foot pulses, sensation, movement, pain and swelling. Foot pulses should be equal—if they are weaker on the affected side then arrange for urgent Doppler studies and notify the vascular surgeon immediately. Any loss of sensation or power represents a vascular surgical emergency, especially if foot pulses are weak or absent. Swelling of the leg may indicate occlusion of the iliac vein, or a compartment syndrome due to reperfusion injury after a prolonged laparoscopic procedure, especially if painful. In summary, any postoperative limb symptoms must be taken seriously.

45.5 Case Study

45.5.1 Case Study 1 (Laparoscopic Surgery)

A woman with four children underwent day-case laparoscopic sterilisation after being counselled about the alternatives. Consent included the risk of bleeding, blood transfusion, repair of any damage and laparotomy, and was obtained by the locum consultant surgeon. A Veress needle was used to create the pneumoperitonem. After application of clips to both fallopian tubes, significant bleeding was noted from the retroperitoneum. A laparotomy was performed to allow pressure to be applied to the area of bleeding and the on-call vascular surgeon summoned. The vascular surgeon arrived without delay and repaired a small laceration in the left common iliac vein without much difficulty. She made an uneventful recovery, although a blood transfusion was required (estimated blood loss 2000 mL).

The situation was explained to the patient and her family by the surgeon before her discharge, and at a subsequent meeting with the Clinical Director. Despite adequate consent regarding the risk of such a complication and the lack of any adverse complications, apart from the laparotomy

scar, the patient successfully sued. The damages were not large but the costs were high, because the case went to court. In court, it was not possible for the experts to determine whether the injury had been caused by the Veress needle or trocar, but the case was lost because the surgeon admitted that the Veress needle had been inserted too far after hearing the double-click and that insufficient CO_2 had been insufflated to ensure sufficient intra-abdominal pressure before insertion of the primary trocar.

45.5.2 Case Report 2 (Open Surgery)

A senior consultant oncological gynaecologist performed a radical hysterectomy with pelvic and iliac lymphadenectomy for invasive cervical carcinoma. During the procedure, the right external iliac vein was torn during the extraperitoneal dissection of the pelvic lymph nodes. Before the vein could be repaired, it was necessary for the surgeon to mobilise and sling the external iliac artery to allow adequate access to the vein, so that it could be clamped above and below the tear before it was repaired with a 2/0 absorbable suture. On completion of the repair, the repaired segment was narrowed, but it did not seem to be occluded. The iliac artery was also narrowed, which the surgeon attributed to arterial spasm caused by mobilization of the artery.

In recovery, the surgeon noted that the right leg pulses were weaker than the left and therefore contacted the on-call Vascular Surgeon. The Vascular Surgeon measured the Doppler Ankle Brachial Pressure Index, which was only 0.6 (normal greater than 1.0). A subsequent duplex ultrasound scan reported occlusion of both the right external iliac artery and vein. Attempted arterial embolectomy via the femoral artery in the groin failed to restore inflow and therefore a femoro-femoral crossover graft was performed. Therapeutic anticoagulation was instigated to prevent extension of the DVT, but this resulted in pelvic bleeding which required a second laparotomy and further blood transfusion.

Despite a patent bypass graft, the claimant was left with a post-thrombotic limb due to persistent occlusion of the iliac vein and a femoral nerve injury cause by the bypass graft surgery. The case was settled for a large sum on the basis that although very experienced, the consultant gynaecologist had undertaken an inappropriate and inadequate vascular repair. On the balance of probability, calling for help from a Vascular Surgeon, would have resulted in successful repair of the iliac vein (and artery), thus avoiding the crossover graft, femoral nerve injury, second laparotomy and post-thrombotic syndrome.

Key Points: Vascular Injury

- Laparoscopic procedures have a higher risk of vascular injury than open gynaecological surgery, mainly due to entry-related injuries to the iliac or inferior epigastric vessels.
- Documentation of vascular injury on a consent form is no defence if the procedure has been performed incompetently, or the injury poorly managed.
- Documentation of a history of a previous DVT or PAD, and further investigation/management if present, is vital before any major gynaecological procedure.
- Failure of adequate thromboprophylaxis, or investigation of postoperative leg swelling, is indefensible.
- Creation of a pneumoperitoneum and trochar insertion/removal must be by an approved technique.
- Units without on-site 24-h vascular cover must ensure that adequate arrangement are in place, in case vascular injury occurs.
- If a vascular injury cannot be simply treated, then apply pressure and call for advice/help from the nearest on-call vascular surgeon.

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Part V

Urogynaecology

Swati Jha

Vaginal Repair and Concurrent Prolapse and Continence Surgery

46

Philip Toozs-Hobson

46.1 Background

With an aging population the prevalence of pelvic organ prolapse and urinary incontinence is increasing and with it the need for corrective surgery. Advances in anaesthetic techniques and the wider adoption of spinal anaesthetics mean that more patients may potentially be offered surgery. The complexity of surgery is also increasing as patients have higher demands, are more likely to have had previous pelvic surgery (including Caesarean section) and have more co-morbidities. Identifying women who would be suitable for concurrent prolapse and continence surgery is imperative to reducing morbidity and dissatisfaction with the procedure.

46.2 Minimum Standards and Clinical Governance Issues

Incontinence surgery and prolapse surgery should only be carried out by surgeons who practice this regularly and should have either subspecialty training or advanced training skills module (ATSM) in Urogynaecology if UK trained. The RCOG, BSUG and NICE recommendation is that surgeons should collect their data and in the UK that would equate to using the BSUG database [1] or equivalent. One such equivalent is the IUGA database [2] yet both of these are voluntary and not funded or supported as mandatory; as such both lack strength in that cases may not be sequential. However the BSUG database now has over 115,000 registered cases and some data is being extracted to inform on a large dataset.

In accordance with the principles of Montgomery all risks, benefits and alternatives for pelvic surgery should be discussed. In terms of recent evidence for treatment of prolapse, the POPPY study has outlined the role of Physiotherapy as a primary treatment [3] and should now be discussed as an option prior to further management. However prolapse surgery is more complex in terms of the options and to a degree surgeons leaning as to what is advised. Emphasis, from as "little as possible" surgery to the "best objective result" maximum can be patient or surgeon driven. Some surgeons will be keen to emphasize on "level 1 support" and favour vault procedures wherever possible, in some circumstances as the basis of any other repair, to reduce the risk of further surgery; others will look to repair the defect on its own to reduce the risk of complications. Data supporting either approach are lacking. Identifying patients with pain conditions (including dyspareunia) pre operatively may be particularly important in predicating outcomes and providing realistic

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expectations of what to expect postoperatively. In the author's practice the use of the ePAQ questionnaire [4] has been extremely helpful in identifying patients with significant pain problems pre-operatively and suggesting that pain was pre-existing.

When considering concurrent prolapse and incontinence surgery, appropriate investigation to identify voiding dysfunction, post void residuals, urgency symptoms with underlying detrusor over-activity should be undertaken preoperatively. This will usually be by urodynamic investigations. Though urodynamics has not been shown to alter outcomes following continence surgery alone [5], most urogynaecologists would not perform concurrent surgery without it. It is also likely, in the current environment where tape and mesh surgery has been an area of medicolegal interest, that the process of Urodynamics and reporting is likely to come under increasing medicolegal scrutiny.

Increasingly consent is becoming a longer event, starting with imparting information, allowing patients to reflect, potentially reviewing cases in a MDT, giving an "appropriate" patient information leaflet, ideally discussing surgeon specific outcomes/complications. Risks should include general risks such bleeding, infection, DVT and PE. There should then be more specific risks such as visceral injury, scarring, pain, dyspareunia, recurrence and failure to achieve satisfactory result. When performing concurrent surgery it is important to give patients the option of having the two procedures separately and for patients choosing to have them done together highlighting

- Increased risk of voiding dysfunction.
- Difficulty identifying which of the two operations has caused a complication particularly in relation to voiding problems.
- Increased overall complications when performing both surgeries together.
- Potential resolution of incontinence symptoms with prolapse surgery alone thereby negating the need for continence surgery.

In England the new NHSE leaflets on prolapse [6] and tape surgery should be used, which require the patients to give written acknowledgement separate to consent of their active participation in understanding the risks and benefits [7].

With the later in mind, best practice would be to identify the patient's most bothersome symptoms before proceeding to surgery. It is useful to list patient related outcome measures, e.g. what would you like to be able to do after the surgery? This must be both realistic and specific. These can be used as the basis of the anticipated benefits of surgery.

Alternatives to surgery must include physiotherapy, pessaries and the range of operations which may be considered, acknowledging when and where this may require referral to another unit/clinician. Where suggesting multiple procedures (including continence procedures) the increased risk of side effects (e.g. pain or voiding difficulties) should be mentioned.

If an injury does occur then one should involve colleagues early and make sure that the patient has early recourse to review and details of how to be seen. An apology should be given, which is not an admission of negligence and an offer to be seen by a colleague made.

Complications should be handled in accordance with the trust governance procedures and recorded on their database (as national figures are only right if the data included inclusive).

Audits should be undertaken for monitoring outcomes of surgical treatment and complications related to surgery. This can be achieved by submitting their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG) and international Urogynaecology association (IUGA).

46.3 Reasons for Litigation

The reasons for litigation following vaginal surgery and concurrent prolapse and incontinence surgery are related to:

- Preoperative counselling/ choices provided.
- Failure to offer a two stage procedure.
- Failure to highlight added risks of concurrent surgery.
- Preoperative investigation.
- Consent and discussion of complications.

- Training of surgeon.
- Complications during/arising from the procedure especially visceral injury and problems with intercourse.
- Failure to involve a urologist or bowel surgeon when a complication has arisen.
- Failure to adequately manage/comply with guidelines for high residuals following removal of the catheter.
- Failure to follow-up.

46.4 Avoidance of Litigation

Appropriate preoperative assessment and counselling of the patient followed by adequate investigation and the offer of conservative and/or medical treatment should form the basis of management of all patients presenting with prolapse. When performing concurrent prolapse and continence surgery urodynamic investigations would be considered good practice. The use of validated questionnaires and PROM's ensure that the surgeon is addressing the relevant problems for the patient. If the prolapse is part of a larger issue then the express objectives of prophylaxis should be outlined. If surgery is needed, patients should be given the range of options and alternatives, appropriate patient information leaflets and an explanation of the risk and complications. Sources include NHS leaflets, the BSUG and the IUGA websites. One suggestion has been that patients should request surgery rather than consent, the emphasis being they chose when they are adequately informed and certainly allowing a period of reflection, documenting patient questions are important. Writing directly to the patient covering the above points copying to the GP also ensures that adequate discussion has taken place.

Clinicians performing the procedures should have adequate training and an adequate case load. Where clinicians are unable to offer patient's the procedure of their choice they should be referred elsewhere.

The procedure should be undertaken with due diligence to avoidance of bladder, ureter, urethral and bowel injury as well as vaginal mucosa in the sulci. Attention to adequate positioning of the patient should be made during surgery. Complications during surgery are not themselves a reflection of negligence and where they are recognised and repaired immediately the impact of any injury is often minimised. If there is any concern about visceral injury then a cystoscopy should be considered and advice from appropriate colleagues sought. If performed the presence of ureteric jets should be noted. The application of instillagel over the bladder base is a simple and quick way which may aid visualisation of the ureteric jets now that intravenous methylene blue has been discouraged. Intravenous diuretics can be administered and where the skills are available ureteric catheterisation performed. Ureteric catheterisation is quoted as having a 1% risk of ureteric injury; this figure is based on a large series of operative ureteric procedures including stone removal. Some would advise the availability of imaging if ureteric catheterisation is to be considered, but this remains contentious and the use of an image intensifier has not been shown to reduce this risk. Likewise a rectal examination can be performed if there are concerns about a rectal injury.

Early involvement of an Urologist or a Colorectal Surgeon should be considered when a complication has been identified to allow optimal management of the complication. Attention and confirmation of haemostasis with an estimated blood loss is mandatory. The use of vasoconstriction agents during surgery generally will reduce loss, but confirming haemostasis is important as these agents may wear off, clot may be dislodged or other agents (NSAID's or anticoagulants) may subsequently lead to bleeding.

Post operatively the patients should be reviewed and an assessment of post-void residuals made. This is especially vital if concurrent surgery has been performed. If symptoms are disproportionate to the surgery then serious consideration to a complication should be documented. In particular pain is associated with a haematoma, haematuria with a bladder injury and rectal bleeding with a rectal injury. Early recognition prevents further unnecessary interventions (e.g. blood transfusion or further pain) and early return to theatre, or active decision to manage conservatively should be documented.

46.5 Case Study

Mrs. SD had long standing problems with stress urinary incontinence. At 52 she presented with prolapse symptoms both of the anterior and posterior vaginal wall. She was consented for a vaginal wall repair and was adequately counselled of all the risks of this surgery. She was offered the option of a concurrent procedure for her urinary incontinence but given very little information on what this would entail and was referred for Urodynamics preceding her surgery. The Urodynamics was performed by another clinician as the treating clinician was not trained to undertake the tests. A diagnosis of urodynamic stress incontinence was made. The clinician performing the UDS identified that the patient had no understanding of what the continence component of the surgery would involve and advised the treating clinician to discuss this with the patient prior to proceeding to concurrent surgery for both prolapse and incontinence. This discussion did not take place and the patient was not given the choice of having a two stage procedure. She went on to develop voiding problems and it was felt this was related to the repair hence nothing was done in the immediate postoperative period. The patient accepted this but returned a year later with ongoing problems. The midurethral sling had started to extrude into the vagina and was cut to alleviate her voiding problems. The claimant alleged that there had been a breach in failing to adequately consent her for a synthetic sling and its inherent risks, failure to offer her a two stage procedure and warn her of the increased risk of voiding problems with concurrent surgery. She also alleged that had she been informed there was a small possibility that her incontinence may improve after surgery she would not have opted to have the two performed together. An out of court settlement was made.

The case highlights the importance of treating the patients main presenting complaint, adequately consenting patients undergoing concurrent surgery as well as giving them the option of undergoing a two stage procedure.

Key Points: Vaginal Repair and Concurrent Prolapse and Continence Surgery

- Adequate assessment and offer of conservative treatment. Appropriate investigation where indicated. Adequate preoperative counselling [PILs] and patient choice.
- Use standardised instruments e.g. QoL questionnaires and PROM's pre operatively.
- Procedure undertaken by adequately trained surgeons who audit and monitor outcomes and complications.
- Good surgical technique with prompt recognition of complications and their management.
- If there is concern perform a check cystoscopy/rectal examination during procedure.
- Record estimated blood loss.
- Appropriate use of antibiotics.
- Recognise (and document) where the patients post-operative course is different to what would normally be expected.
- Adequate follow up of patients.

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Midurethral Synthetic Slings

47

Swati Jha

47.1 Background

Midurethral slings have revolutionised the management of stress urinary incontinence and has replaced Colposuspension as the leading surgical procedure for this condition. With 17 year data available, they are well established in routine clinical care [1]. When obtaining consent and performing these procedures it is important to bear in mind some of the problems which have been described and are unique to synthetic slings.

47.2 Minimum Standards and Clinical Governance Issues

The National Institute of Clinical Excellence (NICE) have issued guidance when performing mid-urethral slings [2]. Assessment of symptoms with a detailed history should be undertaken. Quality of life questionnaires and frequency volume charts can be useful aids in initial patient assessment. Patients should be offered conservative treatment as one of the options for the management of urinary incontinence before surgery. Conservative treatments should be commenced before invasive investigations. This includes lifestyle interventions such as weight reduction [those with a BMI > 30] and reduction of Caffeine intake. Pelvic floor muscle exercises and behavioural therapy in the form of bladder retraining should be offered to all patients. Conservative treatment may also include a trial of anticholinergics which are usually used in the treatment of OAB.

Investigation in the form of urodynamics should be considered in those who have symptoms of overactive bladder, previous surgery or voiding dysfunction. In a select group of women where the diagnosis is of pure Stress urinary incontinence (SUI) based on a detailed clinical history, 3 day diary, office investigations such as uroflowmetry and examination, Urodynamics may not be necessary.

Consideration of the child-bearing wishes should be made when counselling women considering surgery. Surgery should ideally be delayed till childbearing is complete or patients should be informed of the risks of recurrence if they pursue further pregnancies.

Duloxetine should not be offered routinely but may be offered as second-line therapy if women prefer pharmacological to surgical treatment or are not suitable for surgical treatment. If duloxetine is prescribed, women should be counselled about its adverse effects.

Surgery for SUI should be undertaken only by surgeons who have received appropriate training

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in the management of urinary incontinence and associated disorders or who work within an MDT with this training, and who regularly carry out this surgery. Only surgeons who carry out a sufficient case load to maintain their skills should undertake this surgery. An annual workload of at least 20 cases is recommended. Surgeons should maintain an audit of their outcomes.

Patients considering surgery for stress urinary incontinence should be informed of the benefits and risks of surgical and non-surgical options and should be reviewed at an MDT to consider the woman's preference, past management, comorbidities and treatment options. Patient Decision Aids (PDA) may assist the consent process allowing patients to identify their own values and compare the various procedures before deciding which procedure is most appropriate for them.

When offering surgery patients should be made aware of the various surgical approaches which include:

- Synthetic mid-urethral tape
- Open colposuspension
- Autologous rectus fascial sling
- Urethral Bulking agents

If the patient chooses an option not available in the unit to which they have presented, they should be offered referral to an alternative surgeon/unit.

When using synthetic slings, devices for which there is current high quality evidence of efficacy and safety should be used. Some criteria that these devices should fulfil include:

- Use of a device that surgeons have been trained to use.
- Use a device manufactured from type 1 macroporous polypropylene tape.
- Consider using a tape coloured for high visibility, for ease of insertion and revision.

When women are offered a procedure involving the obturator approach, they need to be informed of the lack of long term outcome data.

The Scottish Independent review of the use, safety and efficacy of transvaginal mesh implants in the treatment of stress urinary incontinence and pelvic organ prolapse in women [3] went a stage further and recommended that when surgery involving polypropylene or other synthetic mesh tape is contemplated, a retropubic approach is recommended.

In October 2016 NICE published interventional procedures guidance on single-incision short sling mesh insertion for SUI in women (IPG566) [4]. This stated that, given the current evidence, the procedure should not be used unless there are special arrangements in place for clinical governance, consent and audit or research.

Patients should be offered a follow up appointment within 6 months to exclude extrusion/erosion.

47.3 Reasons for Litigation

The reasons for litigation following a mid-urethral synthetic sling are related to:

- Preoperative counselling/choices provided.
- Preoperative investigation.
- Consent and discussion of complications.
- Training of surgeon.
- Complications during/arising from the procedure.
- [Bladder, urethral, ureteric, nerve, rectal or blood vessel injury, fistula formation, voiding dysfunction and self-catheterisation, retropubic haematoma, groin pain for trans-obturator tapes, need for a laparotomy, sexual dysfunction, failure, recurrence].
- Failure to follow-up.
- Mesh Erosion/Extrusion.

47.4 Avoidance of Litigation

Appropriate preoperative assessment and counselling of the patient followed by adequate investigation and the offer of conservative and/or medical treatment should form the basis of management of all patients presenting with urinary incontinence. If surgery is needed, patients should

be given the range of options and alternatives, adequate patient information leaflets and an explanation of the risk and complications.

Clinicians performing the procedures should have adequate training and an adequate case load [NICE have historically recommended 20 cases per annum]. Where clinicians are unable to offer patient's the procedure of their choice they should be referred elsewhere. If an Obturator tape is offered, the lack of long term data, increased risk of groin pain and problems associated with complete removal of the tape should be discussed. In should also be born in mind that the Scottish Independent review made a recommendation for a retropubic tape in preference to an obturator so going forwards this should be the preferred synthetic sling of choice.

The procedure should be undertaken with due diligence to avoidance of bladder, ureter, urethral and bowel injury as well as vaginal mucosa in the sulci. Attention to adequate positioning of the patient should be made during surgery. This should be the lithotomy position [avoiding more than 70° flexion] for retropubic tapes and hyper flexed position of the hips over the abdomen for trans-obturator tapes.

For retropubic midurethral slings, adequate retropubic and suburethral infiltration followed by dissection should be undertaken. Three incisions are made, two 1 cm wide incision at the upper rim of the pubic bone, each 2–4 cm lateral to the midline and a vaginal midline incision approximately 1.5 cm wide starting 0.5 cm from the urethral meatus. Careful blunt paraurethral dissection between the vaginal mucosa and pubocervical fascia in undertaken. The tape is passed starting at the suburethral incision along the dissected paraurethral space and emerging at the skin incision.

Trans-obturator tapes requires dissection more laterally and skin incisions are in the groins with the position depending on the device being used.

Cystoscopy should be undertaken in all cases of both retropubic and trans-obturator synthetic tapes. This should be with a 70° scope to avoid missing a bladder injury near the dome for retropubic tapes and in the inferolateral position [five and seven o clock position] with trans-obturator tapes. If bladder injury is noted the needle is removed and the tape reinserted. Recognition of excessive bleeding and attention to tape adjustment free of tension is necessary. The procedure should be adequately covered with antibiotic prophylaxis.

Postoperatively all patients should have post-void residuals checked on two occasions before discharge to ensure they are voiding normally. This should be checked in accordance with local guidelines. In patients who fail to void at all within 24 h, consideration should be given to loosening of the tape, and this can be undertaken up-to 7 days after the procedure. For patients where residuals remain high this should be observed closely to ensure this is improving. Provided patients are voiding in excess of 50% of their bladder volume this usually resolves over the next few days. Postoperatively all patients should be offered a follow-up appointment in outpatients at 3 to 6 months to rule out mesh extrusion.

Patients presenting at a later date with problems such as voiding dysfunction or problems of mesh extrusion or erosion should be referred to centres where there is a sufficient caseload and dealt with by clinicians who have experience of dealing with these complications. All complications of erosion/extrusion related with the mesh should be reported to the MHRA. Patients who present with recurrence of stress urinary incontinence should also be managed in centres which have the expertise to offer different treatment options and are recognised centres commissioned for purposes of recurrent incontinence.

Audits should be undertaken for monitoring outcomes of surgical treatment and complications related to surgery. This can be achieved by submitting their outcomes to national registries such as those held by the British Society of Urogynaecology (BSUG), British Association of Urological Surgeons Section of Female and Reconstructive Urology (BAUS-SFRU) or the International Urogynaecology Association (IUGA).

47.5 Case Study

McGinty v Pipe [2012] EWHC 506 (QB) (QBD): M (Claimant), a 46 year old underwent a TVT operation in July 2006. During surgery, the main artery in her left leg was damaged, leading to serious injury and permanent disability. P (Defendant) admitted liability. M had previously been fit and active but discomfort, restricted mobility and fatigue were now a part of her daily life. She was left with scarring and suffered a moderately severe depressive illness.

M sought damages for pain, suffering and loss of amenity, past and future loss of earnings, past and future care costs, and the cost of orthotics, upgrades to holidays as a result of her needing more leg room on flights, travel including an automatic car, increased heating, DIY and gardening, therapies and housing adaptations.

The court assessed damages as a result of a surgeon's admitted negligence during surgery. The total award of damages was the sum of £365,260.

For pain, suffering and loss of amenity (PSLA): M was awarded £52,500.

Special damages included £6000 for past loss of earnings; £51,375 for two-and-a-half years' net loss of her pre-accident earning potential; £101,154 for care and seven hours of paid assistance per week for the rest of her life; £31,360 for upgrades and priority boarding during travel; M was also awarded costs of DIY and gardening, increased heating, travel and the provision of an automatic car, therapies including podiatry and ultrasound tests, and housing adaptations.

Key Points: Midurethral Synthetic Slings

- Adequate assessment and offer of conservative treatment. Appropriate investigation where indicated. Adequate preoperative counselling [PILs] and patient choice.
- Procedure undertaken by adequately trained surgeons who audit and monitor outcomes and complications.
- Good surgical technique with prompt recognition of complications and their management. Adequate positioning and check cystoscopy of patients during procedure. Appropriate use of antibiotics.
- Post-void residuals checked before discharge and high residuals adequately dealt with.
- Adequate follow up of patients.
- Patients presenting with delayed complications should be adequately managed and reported.

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Colposuspension and Autologous Fascial Sling

48

Andrew Farkas

48.1 Background

Colposuspension is a surgical procedure to treat stress urinary incontinence (SUI). Through a suprapubic transverse incision, the paravaginal fascia is attached to the ipsilateral iliopectineal ligament of the pubic bone. The procedure may also be performed laparoscopically. An autologous fascial sling involves the use of the patient's own fascial tissue, usually from the anterior abdominal wall but sometimes from the thigh, to form a sling supporting the urethra.

Until the early 2000s, colposuspension was regarded as a gold standard surgical treatment for SUI. TVT and other synthetic mid-urethral tape procedures became increasingly popular because they could be performed as day case procedures with low immediate surgical morbidity. In recent years, concern about mesh complications has led to a re-evaluation of alternatives to synthetic mid-urethral tapes, including colposuspension and fascial slings.

Sling surgery carries a slightly higher risk of voiding dysfunction than colposuspension, though these problems are usually short or medium term. Other than in certain specific circumstances the choice between these two procedures generally rests with surgical preference and training. Colposuspension tends to be favoured by gynaecologists and fascial slings by urologists, but there is overlap.

48.2 Minimum Standards and Clinical Governance Issues

NICE guidance [1] highlighted the importance of assessment of symptoms with a detailed history, quality of life (QoL) questionnaires and frequency volume charts. Conservative measures are considered in the chapter on synthetic mid-urethral slings.

Surgery should only be considered following the failure of conservative measures, particularly pelvic floor physiotherapy. In recent years, practice has moved from undertaking urodynamic investigations in all cases of planned surgery. They should still be performed in cases other than pure SUI, which include patients with symptoms of overactive bladder such as frequency, urgency, and urge incontinence, previous surgery and voiding dysfunction. Urodynamics should however be considered in all cases of recurrent incontinence following failed surgery.

Patients considering surgery for stress urinary incontinence should be informed of the benefits and risks of surgical and non-surgical options. They should be reviewed at an MDT meeting to

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consider patient preference, past management, comorbidities and treatment options. Surgical options include:

- Urethral bulking agents
- Synthetic mid urethral tapes
- Open/laparoscopic colposuspension
- Autologous fascial sling

Women should be given comprehensive information about planned procedures. Examples include patient information leaflets on colposuspension or autologous fascial slings produced by the British Society of Urogynaecology [2] and the British Association of Urological Surgeons [3] which are available from their website. Decision making and the consent process may be facilitated by the use of shared decision making tools.

There are issues around the number of procedures performed by an individual surgeon. It is recommended that only surgeons who carry out a sufficient case load to maintain their skills should undertake surgery for urinary incontinence in women. An annual workload of at least 20 cases of each primary procedure for SUI is recommended [1]. With increasing use of conservative measures and a wider variety of surgical procedures, it may not be possible to meet this standard.

Surgeons who undertake incontinence surgery should maintain careful audit data so that their outcomes contribute to the national registries such as those held by BSUG and BAUS Section for Female Reconstructive Urology (BAUS–SFRU).

48.3 Reasons for Litigation

The main reasons for litigation in cases of colposuspension and fascial sling include:

- Lack of conservative management before proceeding with surgery.
- Failure to counsel women about the various alternatives and warn of risks and complications.
- Operating for inappropriate indications, i.e. overactive bladder.
- Operative complications:
  - Bleeding
  - Bladder injury
  - Failure to identify suture material within the bladder
  - Ureteric injury
- Longer term problems:
  - Urinary voiding problems
  - Prolapse, particularly of the posterior vaginal compartment
  - Recurrent stress incontinence
  - Stitch complications when using permanent suture i.e. stitch migration into the bladder or stone formation

48.4 Avoidance of Litigation

There should be adequate evidence of stress incontinence and its effect on a woman's quality of life. This evidence may be adduced from the clinical history, examination findings and urodynamic investigations.

Women should be offered conservative management in the first instance, particularly pelvic floor physiotherapy [1]. Some women refuse pelvic floor physiotherapy and in others the extent of SUI is so severe that proceeding directly to surgery is reasonable. A range of surgical alternatives should be discussed with the patient and appropriately documented in the medical records. Preferably, decision making should be made taking account of patient choice and within the context of an MDT discussion.

Surgery should be performed by an adequately trained surgeon who undertakes a reasonable number of procedures for urinary incontinence.

As a routine, colposuspension should be performed as an open procedure. Only an experienced laparoscopic surgeon working in the MDT with expertise in the assessment and treatment of urinary incontinence should perform the procedure laparoscopically [4].

It is important when obtaining patient consent for a colposuspension or fascial sling to explain the likelihood of success, which is around 70% at 10 years [4], and potential complications. In particular, are the risks of urinary tract trauma, urinary voiding problems and symptoms of overactive bladder. Such an explanation is considerably assisted by evidence of the patient having being supplied with a patient information leaflet.

Operative complications may arise. The bladder may be injured when reflecting it medially, particularly in cases of previous surgery. This does not represent substandard technique. The ureter may be kinked following dissection and elevation of the paravaginal fascia. In the author's opinion, kinking does not represent a breach of duty whereas encirclement of the ureter by a suture is substandard.

At open surgery, the use of an absorbable suture such as PDS or vicryl is preferred, although some surgeons do use non-absorbable suture material. It is, however, more common practice to use a non-absorbable suture at laparoscopic colposuspension. Practice varies in respect of intra-operative cystoscopy. Many gynaecologists do not undertake routine intra-operative cystoscopy at colposuspension but this should be considered if there are any concerns with urinary tract injury. Stone formation in the bladder may occur around the suture, whether it was originally in the bladder or eroded into the bladder at a later date. Such a complication is highly unlikely when absorbable sutures are used.

Voiding problems occur frequently, particularly in the short term, following these procedures. Post-void residuals should be checked, usually using a portable ultrasound machine on the ward. There should be a low index of suspicion for urinary voiding problems following such surgery. Although these problems are usually short-term, it is crucial that they are managed appropriately with catheter drainage. This may be with a suprapubic or urethral catheter or through intermittent self-catheterisation (ISC).

SUI is associated with weakness of the pelvic floor and urogenital prolapse. Prolapse, particularly of the posterior vaginal compartment, may occur following colposuspension. The failure of the procedure may lead patients to consider litigation. However, success is not guaranteed and recurrent SUI is a recognised complication. For avoidance of legal action it is important that patients are prewarned of these problems including failure, recurrence and development of prolapse in the long term.

48.5 Case Study

Haughey v Newry and Mourne Health and Social Care Trust

Court of Appeal (Northern Ireland)

Reported 2013

H had undergone an operation for urinary incontinence [colposuspension]. The surgeon used sutures to elevate the neck of the bladder. Afterwards she complained of severe back ache, and a second operation was necessary to remove the suture on one side, as one of the ureters had kinked. The judge accepted the evidence of the surgeons who had been involved in the first and second operations that the stitches had not been inserted in the wrong place and that elevation of the bladder might have resulted in kinking of the ureter through lack of elasticity following an earlier hysterectomy.

The appeal was dismissed.

Key Points: Colposuspension and Autologous Fascial Sling

- Both colposuspension and autologous fascial slings are appropriate alternatives to a synthetic mesh sling.
- Adequate counselling and discussion of the procedure, alternatives, risks and complications.
- Preoperatively:
  - Appropriate assessment of symptoms and bladder function.
  - Adequate conservative measures have been tried.
  - Appropriate counselling and patient information given.
- Operatively:
  - The procedure is performed by an appropriately trained surgeon.
  - Absorbable suture material is used for open colposuspension.
  - Adequate precautions are taken to ensure the bladder has not been breached, particularly if non-absorbable sutures are used.
- Postoperatively:
  - There is awareness of the risk of urinary voiding problems.
  - Assessment of voiding function so that these are adequately dealt with.

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Vaginal Mesh Surgery

49

Mark Slack

49.1 Background

Vaginal surgery involving the use of mesh either for the management of stress urinary incontinence (SUI) or pelvic organ prolapse (POP) has gained much prominence and attracted an enormous amount of attention regarding potential litigation in recent years. This chapter deals with the use of vaginal mesh for POP.

The use of mesh first came to prominence in the late 1990s with the introduction of the Tension Free Vaginal Tape (TVT®) which was marketed for the management of Stress Urinary Incontinence (SUI). The TVT was subject to extensive scientific evaluation, and was compared against the standard of treatment (the Burch colposuspension) in the context of a large randomized controlled trial [1]. Two year data from this trial has been presented showing the TVT to be as effective as the colposuspension, and to be associated with a low complication rate [2]. The introduction of TVT as treatment for SUI was followed by a wave of very similar alternative procedures for SUI, as well as the introduction of multiple operations for the treatment of POP. Alongside the use of mesh in SUI procedures, transvaginal operations for prolapse using mesh were also developed and promoted by device companies as an improvement over standard procedures. Unfortunately, many of these procedures were introduced and promoted without any supporting data or documentation.

In 2008, following an escalation in complications reported to the Manufacturer and User Facility Device Experience (MAUDE) Database, the US Food and Drug Administration (FDA) issued a notification to warn the public about possible negative outcomes from vaginal mesh surgery. These included vaginal mesh erosion (exposure, extrusion or protrusion), pain (including painful sexual intercourse known as dyspareunia), infection, urinary problems, bleeding, and organ perforation. There were also reports of recurrent prolapse, neuro-muscular problems, vaginal scarring/shrinkage and emotional problems. Many of the Medical Device Reports (MDRs) cited the need for additional intervention, including medical or surgical treatment and hospitalization.

In the UK there are still a number of operations carried out that utilise mesh for both the treatment of urinary incontinence and POP. Despite calls by patient groups and politicians for these to be banned the official position remains that many are safe and should continue to be used. Both the Scottish Government group and the English Mesh Oversight Group Report concluded that mesh midurethral slings are equally effective as colposuspension but that the use of transvaginal mesh

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for POP should not be used for primary repair and should only be considered in complex cases in particular after failed primary surgery [3, 4]. Following publication of the results of the PROSPECT study [5], in December 2017 NICE issued guidance on the use of vaginal mesh for anterior and posterior vaginal wall prolapse (NICE IPG 599) [6] which recommends that these devices only be used in a research setting. This was due to the absence of evidence of long term efficiency. The PROSPECT trial demonstrated that the augmentation of a vaginal repair with mesh or graft material did not improve women's outcomes in terms of effectiveness, quality of life, adverse effects, or any other outcome in the short term, but more than one in ten women had a mesh complication. Increasing recognition of complications has resulted in a significant decline is use of vaginal mesh for POP in recent years.

49.2 Minimum Standards and Clinical Governance Issues

Appropriate selection of patients remains the cornerstone of correct practice when considering these procedures as treatment options. It is also essential that patients have been informed of all the available options including conservative and surgical approaches. Ideally all patients should have had a trial of conservative therapy ahead of surgery.

When surgery is agreed it is important to ensure that the patients have been informed of all the surgical options available and had the opportunity to discuss these with the surgeon. It must be demonstrated that the patient has had the opportunity to reflect on the advice and been given an opportunity to make their own decision. The consent process must be meticulous, and involve clear evidence of dialogue between the patient and her doctor. Risks specific to the use of the vaginal mesh operation must be discussed alongside risks that are relevant to that specific patient, in line with the Montgomery standard of consent. An up to date consent form must be completed which gives a clear indication that the pros and cons of the operation have been discussed.

The surgeon and hospital must be able to produce evidence that systems are in place to monitor the outcome of these operations. Ideally outcomes should be added to an external database such as the BSUG database or included in the hospitals regular audit of complications and outcomes. Adverse outcomes related to the mesh should always be reported to the MHRA. Surgeons must be able to demonstrate they have a sufficient case load.

The surgeon must be able to demonstrate that they are practising according to the accepted standards of care and that they follow an evidence-based approach. This is a rapidly evolving field, and surgeons have a personal responsibility to ensure their own practice is in line with current professional standards of care. Only implants with an appropriate CE mark or FDA clearance should be used. Any products without such approval should only be used with the appropriate ethics approval or in the context of a clinical trial.

All cases being considered for surgery must be discussed in an MDT.

49.3 Reasons for Litigation

Potential reasons for litigation include:

- Inadequate counselling.
- Failure to offer conservative therapy ahead of surgery.
- Failure to make the patient aware of all the options, risks of the specific procedure and complications including the need for further surgery.
- Poor documentation of the process of counselling and the decision making process.
- Inadequate patient information leaflets.
- Failure to audit practice.
- Suboptimal surgical outcomes.

49.4 Avoidance of Litigation

Any surgeon using vaginal mesh based products needs to be aware of the controversy surrounding these operations and to keep up to date with the national and specialist guidelines on the subject. They also have a responsibility to ensure that their patients are also aware of the issues and are fully advised of the alternatives, their risks and benefits, and potential outcomes as well as limited evidence of added efficiency compared to native tissue repair.

49.4.1 Current Understanding

A number of publications exploring the controversies surrounding mesh have been produced by health bodies in recent months. The first was the Scientific Committee on Emerging and newly identified Health Risks (SCENIHR) opinion on the safety of surgical meshes used in urogynecological surgery [7]. In addition there have been reports by NHS England [4], the Scottish Government [3] and the Cochrane group [8]. There have also been other authoritative publications on the same subject in the peer reviewed literature [9, 10].

The conclusion of all these bodies is that mesh procedures for anterior and posterior compartment prolapse cannot be recommended for primary repair.

Given the very high failure rate of primary prolapse surgery it is conceivable that surgeons may want to consider transvaginal mesh augmentation for a select group of failed surgery patients who are likely to experience suboptimal native tissue repair and who have a contraindication to abdominal surgery. Normally the next step for failed primary surgery would be consideration of an abdominal (open, laparoscopic or robotic) sacrocolpopexy with a concomitant anterior and posterior repair or a transvaginal sacrospinous colpopexy with simultaneous natural tissue repair. Some patients may have a contraindication to abdominal surgery or have a vaginal length too short for a sacrospinous fixation. In this very small group of patients consideration can be given to a mesh based transvaginal operation. This should only be considered in situations where very strict governance and guidelines are in place. Ideally this would only be done in specialist centres by surgeons considered to be reconstructive experts with significant experience in repeat surgery.

There will also likely to be developments in mesh technology delivering new and improved mesh designs. As the failure rates for primary vaginal surgery continues to be high surgeons, in an attempt to improve outcomes, will try these new technologies. In the light of the current controversy it would seem prudent that any new technologies are introduced under trial circumstances with the necessary ethical framework and under Good Practice Guidelines (GCP) conditions.

It remains to be said that patients presenting with anterior and posterior repair, in the absence of any apical defect, are increasingly uncommon. Surgeons seeing this group of patients must be properly trained and dealing with an appropriate case load. They should have evidence of good training and be able to show evidence of robust governance.

Surgeons undertaking this work should ensure meticulous documentation of the discussions at consultation and be able to demonstrate that they have given the patient the necessary information on the available options both surgical and non-surgical. The outcomes of surgical cases should be captured on an appropriate database such as the British Society of Urogynaecology (BSUG) database. Their unit must have an audit process that allows scrutiny of the surgical results. The surgeon must also be able to produce evidence of ongoing professional development.

Finally, any patients being offered surgery must be informed of all the options available including those of doing nothing and those not offered in the local hospital. The hospital needs to be willing to refer patients to centres that can undertake the surgery that the patient chooses.

49.5 Case Study

Mrs. A, a 60 year old patient, was referred to hospital with a history of incontinence and vulval soreness. A diagnosis of Lichen Sclerosus was made by the Gynaecology Vulva clinic. She had previously undergone a hysterectomy for menorrhagia. She was then referred to general gynaecology for an opinion on her bladder and the physical finding of a rectocele. At that clinic she was noted to be complaining of symptoms of overactive bladder (OAB) and a small rectocele was diagnosed. Urodynamics were organised which demonstrated marked detrusor over activity. She was started on anticholinergics. She had no response to two different anticholinergic medications and was then offered a transvaginal mesh repair by Mr. B. He suggested that this would reduce the vulval irritation, correct the bladder symptoms and reduce the bulge. She was warned that this could be complicated by "*haemorrhage, infection, injury to rectum and a 1–3% risk of mesh erosion*". A month later she underwent a CE marked transvaginal mesh kit (For

posterior and apical prolapse) repair by Mr. B. Postoperatively the patient continued to complain of problems with OAB. She also developed vaginal bleeding and was noted to have a mesh extrusion. The mesh was excised under anaesthetic. As her symptoms were worsening her GP referred her to another gynaecologist in the same hospital. A further mesh extrusion was noted and the patient then referred to a tertiary referral hospital for further management. Despite excision of the mesh the patient continues to suffer with severe OAB and is continuously troubled by the symptoms of Lichen Sclerosus. As a result of this case Mr. B was referred to the Medical Director. It transpired that the trust had banned all vaginal mesh procedures following the FDA warning of 2008. The trust had agreed that any patients being considered for a mesh procedure should be referred to the adjacent teaching hospital for an opinion. The Medical Director was of the opinion that Mr. B had acted outside of his area of expertise and had operated outside of the governance framework that the trust had mandated. The Medical Director was also concerned that the patient had had major surgery for prolapse when in fact her dominant symptoms were due to Lichen Sclerosus and OAB. Disciplinary procedures were started against Mr. B who subsequently resigned from the trust. He was also referred to the General Medical Council (GMC) for unprofessional behaviour. The trust made an undisclosed out of court settlement to the patient.

Key Points: Vaginal Mesh Surgery

- Adequate assessment and offer of conservative treatment. Appropriate investigation where indicated. Adequate preoperative counselling [PILs] and patient choice.
- Procedure only to be undertaken undertaken by adequately trained surgeons who audit and monitor outcomes and complications.
- Procedure only to be undertaken as a secondary procedure when it is judged that a repeat natural tissue repair is contraindicated and where there is no value in resorting to an abdominal procedure.
- Procedure only to be undertaken after discussion in a formal MDT.
- Cystoscopy of patients at end of procedure to ensure good ureteric function.
- Adequate follow up of patients.
- Patients presenting with delayed complications should be adequately managed and reported.

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Vaginal Hysterectomy

50

Swati Jha and Linda Cardozo

50.1 Background

Pelvic floor disorders are common in women of all ages with a 12% lifetime risk of needing prolapse or continence surgery between the ages of 20 and 80 [1]. A vaginal hysterectomy and pelvic floor repair remains the commonest operation performed for uterine prolapse [2] in the UK. The vaginal route has been shown to be the safest and most cost-effective for hysterectomy, and even in the absence of prolapse is the first-line approach whenever possible as demonstrated by a Cochrane review [3].

In women with prolapse there are relative contraindications and caution should be exercised in the following situations when considering a vaginal hysterectomy:

- Enlarged uterus (greater than 16–18 week size).
- Immobile uterus.
- Adnexal disease eg severe endometriosis or adhesions.
- Clinical indication for salpingo-oopherectomy i.e. need for concurrent abdominal procedures, which can often be overcome using a laparoscopically assisted approach.

The procedure can be performed under regional or general anaesthetic, and is usually suitable even for women with comorbidities and in the frail elderly.

50.2 Minimum Standards and Clinical Governance Issues

Surgeons appropriately trained in pelvic floor procedures should undertake this surgery. They should have an adequate case load, and should audit the outcomes of their surgery and complications. This can be done through the use of National databases such as the British Society of Urogynaecology (BSUG) database.

Adequate alternatives including doing nothing where the prolapse is above the introitus (vaginal opening), Pelvic floor exercise therapy and the use of vaginal pessaries should be discussed. The surgical alternatives including uterine conserving options should be discussed and where facilities for performing these are not available the patient should be given the option of referral to another unit able to offer alternatives.

It is routine practice to give patients prophylactic antibiotics within 1 h of commencing surgery,

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usually given intraoperatively. Thromboprophylaxis is also routine and it is good practice to introduce an indwelling catheter.

The patient is placed in the lithotomy position and may need head down tilt to allow adequate exposure. The buttocks should be positioned over the end of the table. Stirrups or leg supports which protect the vulnerable neurologic, vascular and bony points of the lower extremities should be used e.g. (Allen Stirrups) and hyperflexion of the thighs avoided as this can cause femoral neuropathy. If using Candy cane stirrups adequate padding should be used at potential pressure points.

Once anaesthetised an examination is performed to assess the degree of prolapse the size of the uterus and any undetected adnexal pathology. Some surgeons prefer an indwelling catheter from the start, others insert one at the end of the surgery preferring to empty the bladder with an in/out catheter or not at all when starting the procedure.

Some surgeons use vasoconstrictor agents with or without local anaesthetic injected into the cervical, paracervical and sub epithelial tissues to identify tissue planes and reduce bleeding but these are not mandatory. The vaginal incision is aimed at opening the peritoneum both anteriorly and posteriorly. This is achieved by circumscribing the cervix followed by a combination of sharp and blunt dissection. The advantage of opening the peritoneum anteriorly before clamping the uterosacral ligaments is that the ureters are deflected when the bladder is mobilised upwards from the operative field. If however this is not feasible then after opening the posterior cul de sac to access the peritoneal cavity, the uterosacral are identified and clamped perpendicular to the uterine axis incorporating the lower portion of the cardinal ligaments. When clamping the uterine vessels, the anterior and posterior leaves of the visceral peritoneum should be included. The final pedicle incorporating the round ligaments and fallopian tubes, once clamped and cut will usually allow delivery of the specimen. Where the uterus is enlarged, more than three pedicles may be required and a variety of methods needed to deliver the specimen including uterine bisection, morcellation and intramyometrial coring.

Before closure of the peritoneal cavity the pedicles are checked to secure complete haemostasis. To prevent enterocele formation and subsequent vaginal vault prolapse, either a McCalls Culdoplasty (obliterating the cul-de-sac, plicating the uterosacral-cardinal complex, and elevating any redundant posterior vaginal apex) or a Moschcowitz repair (closing the cul-de-sac and bringing the uterosacral-cardinal complex together in the midline) is recommended. The vaginal epithelium is reapproximated vertically or horizontally with either continuous or interrupted sutures. If the sutured vaginal vault descends into the introitus during closure a sacrospinous ligament fixation can be undertaken.

If a concurrent vaginal repair is to be performed, this can be completed before or more commonly after the hysterectomy.

50.3 Reasons for Litigation

The common reasons for litigation following a vaginal hysterectomy are:

- Wrong diagnosis and/or unnecessary or improper procedure.
- Failure to adequately counsel and consent the patient.
- Failure to offer alternatives.
- Visceral injury
  - Ureteric
  - Bladder
  - Bowel
- Bleeding.
- Shortening of the vagina.
- Sexual dysfunction.
- Negligently causing or contributing to any of the above risks.
- Failing to get the patient's permission before performing new procedures, except in emergency situations.

Surgery for pelvic organ prolapse (POP) addresses bother related to quality of life. As POP is rarely dangerous, it is necessary to establish what the patients expectation are from outcomes from surgery. Whereas surgery addresses the bulge it does not necessarily improve urinary or bowel problems and is unlikely to improve sexual function. It may even exacerbate stress urinary incontinence (occult incontinence) and the patients must be forewarned of this. It is important to avoid performing prophylactic surgery concurrently such as a mid-urethral sling or posterior repair. Patient satisfaction has been shown to be directly linked to the patient's self-described preoperative goals and dissatisfaction to unpreparedness for surgery, perception of routine postoperative events as complications (eg. need for a Foleys catheter after the initial post-operative period) and development of new symptoms.

50.4 Avoidance of Litigation

Once a diagnosis of uterine prolapse has been made it is important to emphasise to patients that this is not usually a dangerous condition hence surgery can usually be timed to suit patient convenience rather than being urgent surgery. Alternatives to surgery as well as the various surgical options should be discussed including their risks and benefits. Success of individual procedures should be discussed. The possible complications associated with each operation should be explained and patient's expectations from surgery explored.

Surgery should be undertaken by surgeons with appropriate training and adequate case load. Where the expertise is not available for the procedure of choice the patient should be referred to another specialist with appropriate expertise.

Visceral injury may be caused by surgical dissection, injury during clamping of pedicles or thermal injury from cautery, however, irrespective of the mechanism of injury it is axiomatic that these injuries be diagnosed with certainty intraoperatively. Failure to diagnose a visceral injury is a common cause of litigation. Resorting to a cystoscopy if there is suspicion of urinary tract injury is advisable. The actual repair of a cystotomy depends on the size and location of the injury as well as the expertise of the surgeon. Where a bowel injury is suspected, this must be ruled out with certainty and will sometimes require additional surgery (Laparoscopy/laparotomy). Early involvement of the urologist or colorectal surgeon is advisable in the case of a visceral injury.

An important function of the vagina is for sexual intercourse. Therefore if there is a good anatomical repair but the patient suffers postoperative dyspareunia there can be significant dissatisfaction following the surgery. Although the risk of this is not great after vaginal hysterectomy and native tissue repair, it is important to identify pre-existing or predisposition to pain such as fibromyalgia, pre-existing dyspareunia, chronic pain syndrome or bladder pain syndrome. Pain can be caused due to the creation of vaginal constriction rings, vaginal shortening due to excision of excess vaginal mucosa, nerve entrapment, plication of the levator muscles or from fibrosis scarring or inflammation. During excision of vaginal epithelium digital assessment should be performed to avoid excessive trimming of skin. Urogenital atrophy in postmenopausal women should be identified and treated with low dose local oestrogen therapy as this may contribute to postoperative dyspareunia.

Where a complication occurs intraoperatively a detailed explanation including the consequences of the complication if any should be made to the patient postoperatively.

For the majority of women vaginal hysterectomy with or without pelvic floor repair is a safe and straightforward procedure with good outcomes. However, as with any surgery complications can occur due to unexpected findings at the time of surgery, poor surgical technique or just bad luck. In order to avoid litigation every effort must be made to correct any problems which do occur

promptly and efficiently using clinicians with the appropriate skills. Apologies to the patient and her relatives and an explanation of what went wrong will help to avoid later complaints.

50.5 Case Study

Mrs. T, a 36-year-old mother of two young children, attended as an inpatient for an elective vaginal hysterectomy and repair of prolapse. She was fit and well. The procedure was complicated by a significant bleed and in recovery she was noted to be pale and agitated, complaining of abdominal pain. She returned to the ward just under an hour after surgery, but nursing staff called the anaesthetic registrar, an hour later as she had become unwell, pale and hypotensive with a borderline bradycardia (BP 100/60 mmHg, pulse 52 bpm). She was prescribed 40% oxygen and 500 mL of colloid fluid over an hour. An attempt to take venous blood failed and it was noted that the patient's vital signs were unchanged but her veins were collapsed.

Mrs. T was given one unit of whole blood over the next hour and a further unit of blood was to be transfused over the following four hours. Although she was reviewed several times and persistent hypotension noted no action was taken.

Two hours after the blood transfusion had been started, Mrs. T had a BP of 95/55 mmHg and a heart rate of 52 bpm. A urinary output of 100 mL since surgery was recorded. It was finally decided to return Mrs. T to the recovery room to put her on a monitor and insert a CVP line. Before this could be done, however, the patient collapsed and stopped breathing. A vaginal examination revealed no haematoma or other abnormality, and a chest X-ray was reported as normal. Fresh frozen plasma was instituted but during the transfusion Mrs. T had a fit, developed bradycardia and cardiac arrest. She did not respond to attempts to resuscitate her.

At autopsy, the cause of death was given as 'haemorrhagic shock due to an intra-abdominal haemorrhage from pelvic operative site following hysterectomy and vaginal repair for uterine prolapse.'

Significant intra-abdominal bleeding must be the number one differential diagnosis of sustained postoperative hypotension, in the absence of other differential diagnoses such as sepsis, anaphylaxis and myocardial depression. Sustained clinical indicators of hypovolaemia must not be ignored in a postoperative patient.

Key Points: Vaginal Hysterectomy

- Appropriate explanation to the patient of the various treatment options including doing nothing and other conservative options such as pelvic floor physiotherapy and the use of vaginal pessaries.
- Exploration of the patients problems in the various domains of pelvic floor function including urinary, bowel and sexual function in addition to vaginal prolapse symptoms.
- Adequate counselling regarding the risks and benefits of surgery.
- Surgery undertaken by appropriately trained surgeons with adequate case load.
- Good surgical technique.
- Post-operative explanation of procedures undertaken.
- Identification of visceral injury and its management.

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Laparoscopic Prolapse Surgery

51

Simon Jackson

51.1 Background

Our ever ageing population has meant that pelvic organ prolapse has become a common problem, with an overall 19% lifetime operation risk [1]. The traditional vaginal surgical approach of managing prolapse has a reoperation rate ranging between 17 and 29% [2–4]. Over the last decade there has been an increase in the amount of synthetic mesh being used in order to try and prevent this recurrence. A wide range of laparoscopic procedures have been described in the literature but by far the most commonly performed procedures are laparoscopic sacrohysteropexy and laparoscopic sacrocolpopexy. Both have evidence to support their safe use [5, 6] It is important to consider some of the problems specific to this type of surgery.

The use of prosthetic mesh materials was introduced to augment inherent tissue weakness, reduce prolapse recurrence rates and maintain normal vaginal function. Both biological and synthetic mesh grafts are available but it is the polypropylene implant in the form of transvaginal mesh kits which have been scrutinised by media coverage in the past few years. Mesh kits such as Prolift®, Apogee®, Avaulta® and Perigee® appeared to have good objective success rates, but significant morbidity associated with these has meant that they have been abandoned by many urogynaecologists. There have been thousands of transvaginal mesh lawsuits filed against medical device companies and many of these have now been recalled or withdrawn from the market.

Repairing weak native tissue has a high risk of failure; there is consequently a continued need for mesh implant in selected cases. The problems encountered with transvaginal mesh implant have necessitated a move towards abdominal implant surgery. Type 1 macroporous polypropylene abdominal mesh implants have been used successfully over the last 10–15 years for both laparoscopic sacrohysteropexy and laparoscopic sacrocolpopexy [7]. Vaginal mesh erosion rates are significantly lower than with transvaginal mesh kits.

51.2 Minimum Standards and Clinical Governance Issues

Urogenital prolapse assessment should include a detailed account of clinical symptomatology. Asymptomatic or non-bothersome prolapse, frequently detected coincidentally during gynaecological examination, does not require treatment. There are no specific investigations required for urogenital prolapse. Urodynamics are not necessary as part of prolapse assessment.

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Management of prolapse should be individualised in order to relieve prolapse symptoms, restore function and improve quality of life. A systematic approach to management include the following as a minimum:

1. Is treatment necessary?
2. What conservative measures can be used?
3. What are the surgical options—vaginal surgery versus a laparoscopic abdominal approach?
4. What are the advantages and disadvantages of each?

A common cause of litigation is the omission of this discussion [8].

Lifestyle changes such as weight loss, directed pelvic floor muscle training, and the reduction of heavy weight lifting should be part of the recommendation to all patients. Conservative treatment options such as ring pessaries may be considered in the very frail and elderly, in those whose families are incomplete or those who wish to avoid surgical intervention.

There is no available guidance to direct clinicians as to the best surgical approach. Many factors have an impact when deciding which approach is ideal for each individual patient.

In women who have not completed their families, surgery should preferably be recommended once accouchement is complete. Women who have not completed their families and who opt for sacrohysteropexy should be informed that delivery will need to be by caesarean section if the hysteropexy technique involves the mesh completely encircling the cervix. Data in relation to pregnancy is minimal.

If considering laparoscopic surgery, patients must be suitable for general anaesthetic, pneumoperitoneum and Trendelenburg positioning.

When counselling women for prolapse surgery it is important to offer all the appropriate surgical and non-surgical options available, to discuss the benefits and risks of each procedure, provide the appropriate patient information leaflets and finally obtain informed consent.

The law on informed consent has changed following the ruling in the case Montgomery vs Lanarkshire Health Board. It is now necessary for doctors to ensure that patients are aware of any risks involved in a proposed treatment and that patients are given all the alternative options that they would reasonably wish to consider. The previous 'Bolam test' has been superseded by Montgomery in issues of consent. The General medical Council is clear about providing patient-centred care when taking consent [9]. Patients should be counselled in depth and should be provided with all the necessary information, aided by the use of patient information leaflets to allow them to make an informed decision. Despite being an onerous task, concise evidence that this has been adhered to should be documented.

With respect to laparoscopic urogynaecology The National Institute of Health and Clinical Excellence (NICE) provide guidance for both sacrocolpopexy and hysteropexy, and have recently being updated (NICE IPG 583 and 584) [5, 6]. NICE supports this type of apical prolapse surgery on the understanding that surgeons are adequately trained, work within multi-disciplinary teams and appropriate consent has been taken. Audit and compliance with clinical governance is also mandated. Opinions with regards to the use of mesh in urogynaecology have also been published by the RCOG and various European societies including the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

The risks documented on the consent form and explanation to the patient should include general risks of surgery (infection, haemorrhage, thrombosis, anaesthetic risks) but also the more specific risks associated with these procedures, which are:

- Visceral damage (bladder, bowel, ureter, vessels, nerves)
- Pain/neurological damage
- Prolapse recurrence
- Mesh extrusion/erosion
- Infection in or around mesh (Discitis, vaginal infection)
- Bladder and bowel dysfunction
- Sexual dysfunction

Laparoscopic surgical treatment of prolapse should be performed by surgeons who have had training and experience in the field and who are part of a multidisciplinary team. An adequate surgical workload of each procedure in a year should be necessary in order to maintain the appropriate

skills, although there is no recommended number. Referral to an appropriate surgeon should be made if the patient chooses a procedure which cannot be offered locally.

At present UK training in these procedures are only mandated within the RCOG accredited Urogynaecology subspecialty training program. The Urogynaecology and Vaginal Surgery Advanced Training Skills Module (ATSM) does not train surgeons to perform this surgery but is available as an optional training module.

It may be necessary to develop a certification system for gynaecologists who wish to offer these procedures but who have completed their training prior to the onset of ATSM/Subspecialty training. Consultants with a special interest in Urogynaecology who would like to learn to perform these procedures may be able to affiliate themselves with experts in the field to attend regular training sessions.

As with all surgical procedures it is good practice to maintain a log of surgical cases and audit the results of these and any associated complications. All data relating to these procedures should be captured in the national British Society of Urogynaecology (BSUG) database.

51.3 Reasons for Litigation

- ***Counselling***
  - Inadequate preoperative counselling and not providing all available choices.
  - Failure to follow appropriate national & international guidance.
- ***Consent***
  - for Sacrocolpopexy clinicians should ensure patients understand there is a risk of vaginal vault prolapse happening again and of serious mesh complications including mesh erosion into the vagina and neighbouring viscera which would require further surgery.
  - for Sacrohysteropexy patients should be informed of the risk of recurrence of uterine prolapse and potentially serious complications including erosion into the bladder and the need for further surgery.

In all cases clear written patient information leaflets should be given and the use of the NICE information for the public is recommended.

- ***Substandard surgery***
  - Inadequate surgical training.
  - Complications during/arising from the procedure (injury to bladder, bowel, ureters blood vessels, nerves, fistula formation, sexual dysfunction, bowel obstruction, vaginal discharge, prolapse recurrence, back pain, osteomyelitis, need for laparotomy).
  - Mesh and polyester suture complications (erosion/shrinkage/rejection).
- ***Failure to recognise complications*** and manage them proactively.

51.4 Avoidance of Litigation

Laparoscopic entry associated injuries and failure to recognise these are a major cause of litigation [10]. Various entry techniques and technologies have been introduced over the years to try and eliminate this risk, but there is no evidence to support one single technique over another.

1. Appropriate knowledge of anatomy and the technology in use is the cornerstone to safe access.
2. Palmer's point entry may be more appropriate in those with midline incisions.
3. On entry it is important to have good optics at all times.
4. Skilled assistants with knowledge of the procedure are vital; this surgery cannot be safely performed by an individual operator.
5. A 360° survey should be made initially and bowel injury should be excluded especially in the area where the first trocar is inserted. Following this it is necessary to identify the anatomical landmarks and also anatomical anomalies (e.g. Adhesions, endometriosis, pelvic kidneys, abnormally low bifurcation of the aorta and vena cava on the sacrum etc.)
6. Ensure the bladder is empty and secondary ports are placed above the bladder dome in order to avoid inadvertent bladder injury.
7. Injury to the inferior epigastric vessels can be avoided by lateral port placement. Identifying the vessels by trans illumination is good practice but where this is not possible, knowledge of the pelvic anatomical landmarks is essential.

8. The mesh is anchored to the sacral promontory either by sutures or titanium fixation devices. Knowledge of the sacral promontory and the surrounding landmarks is crucial. Inability to clearly visualise the anterior longitudinal ligament due to low vascular bifurcation or adipose deposition is an indication to abandon the procedure.
9. When using electro surgery the whole of the active part of the instrument should be kept in view to avoid injury to surrounding structures. The tips of electrosurgical instruments remain hot after use and should not be used to subsequently manipulate organs.

It is important not to operate outside your comfort zone and to have a backup plan in place should the original procedure not be possible. New consultants are most vulnerable and should always be prepared to approach senior more experienced colleagues for help.

The type of mesh chosen for laparoscopic prolapse surgery varies depending on whether mesh is applied directly to the vagina/vault or around the uterus. It is important to use implants which have characteristics to ensure both compliance and strength. Various techniques have been described for each:

Hysteropexy: the mesh may be sutured to the posterior aspect of the uterus, or may be transfixed around the cervix.

Sacrocolpopexy: the extent of dissection is dependent on the type of prolapse, vaginal compliance and length. Where the mesh is applied to the vagina is dependent on which compartment requires support.

Often, with sacrocolpopexy, the vault is scarred from previous surgery. Inadvertent injury to the bladder or opening the vagina may occur.

If cystotomy occurs this may be repaired by a suitably experienced Urogynaecologist. If this experience is not available a Urological colleague must be called. Once the bladder has been repaired it would be the authors practice to complete surgery, proceeding with mesh implant. However, intravesical mesh erosion risk will be increased and this practice may be criticised by some medicolegal experts.

If the vagina is inadvertently opened it must be repaired before proceeding with mesh implant. If possible it is best to keep the implant away from the site of vaginal incision as subsequent erosion rates at this site will be elevated, presumably to a level seen with transvaginal mesh implant.

If bowel is inadvertently opened a surgeon must be called to effect repair. Mesh implant must be abandoned as the surgical field is no longer sterile.

Non-dissolvable polyester sutures (e.g. Ethibond, Ethicon Inc., Somerville, NJ, USA or Prolene) may be used to secure the mesh to the posterior or anterior aspect of the uterus during a sacrohysteropexy and has been used to suture the vagina/vaginal vault during a sacrocolpopexy, though most clinicians would use a dissolvable (polydioxanone or PDS) suture when attaching mesh to the vagina. Late complications can arise from non-dissolvable sutures including erosion, chronic granulomas, and chronic infection leading to abnormal vaginal discharge and pain. When suturing to the vagina, dissolvable alternatives must be considered to avoid long-term complications.

Previously it was not thought necessary to peritonealise abdominal mesh [11] but we now know exposed mesh leads to subsequent complications such as bowel adhesions and bowel obstruction. The entire length of the mesh must be peritonealised. Care must be taken when peritonealising along the pelvic side wall, to identify the ureter so as not to include this in peritonealisation or cause kinking.

Patients having laparoscopic surgery should be fit for earlier discharge compared to patients having laparotomy. Patients not making an appropriate recovery should be monitored closely and any deterioration in their condition should trigger timely and appropriate management. If there is any suspicion of sepsis from bowel or urinary tract injury prompt investigation (Imaging or diagnostic laparoscopy as appropriate) is mandatory.

Discitis from sacral promontory fixation is extremely rare but the neurological sequelae can be devastating. If there is any suspicion of discitis prompt investigation by MRI is essential. All mesh complications should be reported to the MHRA.

Mortality from sepsis is extremely high and any suspicion of this must be managed proactively (e.g. CT scan, MRI, repeat laparoscopy etc.)

51.5 Case Study

A 50 year old underwent a laparoscopic sacrohysteropexy in 2012. The mesh was completely peritonealised and the procedure was documented as uncomplicated. Sixteen months after her procedure she developed small bowel obstruction secondary to bowel torsion around non-peritonised exposed abdominal mesh. 15 cm of gangrenous bowel was resected.

It is probable the suture used for peritonealisation came undone during the post-operative period, the patient claimed negligent surgery.

The claimant's medical expert did not consider surgery was performed negligently; sutures can come undone and there is published literature to support non peritonealisation of abdominal mesh.

However, the clinician had not discussed conservative and alternative surgical options. There was no documented discussion that hysteropexy was a new procedure and alternative options such as vaginal hysterectomy were available. There was no evidence that mesh implant, and potential complications, were discussed. Counselling did not comply with Montgomery 2015 and the hysteropexy national guidelines (NICE) were not followed.

Consequently the patient was able to claim causation; had she been aware of mesh risk, she stated she would have chosen vaginal hysterectomy, and all subsequent mesh complications would have been avoided.

The case succeeded, not because of substandard surgery, but because of substandard counselling and consent.

Key Points: Laparoscopic Prolapse Surgery

- Patients have the right to know all treatment options (Montgomery 2015).
- All risks must be discussed when mesh implant surgery is being offered.
- Only surgeons with appropriate training should perform laparoscopic Urogynaecology, and they must audit outcomes and report complications (BSUG and MHRA).
- Surgeons who do not recognise their limitations and fail to abandon surgery or call for assistance are at high risk of litigation. New consultants are particularly vulnerable.
- Any post-surgery complications must be managed proactively. Always assume the worst case scenario!

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Acute Urinary Retention

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52.1 Background

Acute urinary retention is a common consequence of gynaecological surgery, regional anaesthesia and childbirth. When unrecognised it can result in acute prolonged bladder overdistension leading to irreversible bladder damage with long-term voiding dysfunction. Prevention, early recognition and timely intervention are essential to prevent significant life-long lower urinary tract symptoms and litigation.

52.2 Minimum Standards and Clinical Governance Issues

Acute bladder overdistension occurs when the bladder is filled to greater than 120% of normal bladder capacity [1], which is typically greater than 400–600 mL. At the time of writing there are no published National Guidelines specifically dedicated to the prevention and management of acute urinary retention in Obstetrics and Gynaecology.

NICE guidance on intrapartum [2] and postnatal care [3] advises that the frequency of passing urine should be documented during the first and second stage of labour, and that voiding should be documented within six hours of delivery. A urinary catheter should be inserted for 24 h after repair of perineal trauma to prevent urinary retention. If urine has not been passed within 6 h after the birth, efforts to assist urination should be advised, such as taking a warm bath or shower. When these measures are not successful, urgent action to evaluate bladder volume and catheterisation is advised.

Most units will have local guidelines on bladder care after gynaecological surgery, regional anaesthesia and childbirth. Guidelines should cover the prevention, recognition and management of acute urinary retention. However these patients often require a highly individualised approach. Therefore guidelines must be supplemented by robust training programs for medical, nursing and midwifery staff, together with 24-h access to clinical expertise should problems arise. Junior staff must be encouraged to ask for advice if there is any uncertainty in decision-making.

52.3 Reasons for Litigation

Potential reasons for litigation include:

- Failure to implement routine post-operative / delivery bladder monitoring.
- Failure to consider acute urinary retention as a cause of bladder symptoms.

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- Failure to place an indwelling catheter after an episode of acute urinary retention.
- Early removal of catheter after an episode of prolonged bladder over distension, with inadequate assessment of ongoing voiding function.

Patients with persistent voiding dysfunction require prompt referral to specialist urogynaecology or urology services for further investigations and longer-term management.

52.4 Avoidance of Litigation

All healthcare professionals caring for women at risk of acute urinary retention should be aware of the importance of prevention, recognition and urgent treatment of this condition.

52.4.1 Risk Factors and Prevention

All women undergoing gynaecological surgery, or after childbirth, should be considered to be at risk for acute urinary retention, even in the absence of specific risk factors. The operating surgeon, obstetrician or midwife should document clear bladder care instructions in the patient's medical records, and ensure that this is clearly communicated to the nursing staff caring for them.

Women without an indwelling catheter must be monitored carefully to ensure that they pass an adequate volume of urine within 4–6 h of surgery or delivery, and that this is documented clearly in the medical records. Ideally the volume of urine passed should be also be measured and recorded. If there is any suspicion of retention, the woman requires further evaluation with a post-void bladder scan or intermittent clean catheterisation. An indwelling catheter should be placed if there is a significant post-void residual volume of urine within the bladder (400 mL or more), to prevent overdistension injury.

Women with significant risk factors for acute urinary retention should have a prophylactic indwelling catheter placed into their bladder, left on free-drainage. Significant risk factors include age over 50 years, regional anaesthesia, prolonged surgery (greater than two hours), incontinence or radical pelvic surgery, prolonged labour, perineal pain, and vaginal packing.

52.4.2 Trial Without Catheter

The indwelling catheter should be removed as early as possible to minimise the risk of urinary tract infection. However, the timing of removal must be balanced against the presence of risk factors, and clinical judgement is required to evaluate the appropriate timing for each individual case.

Clear protocols should be in place for trial without catheter, including how to access expertise if problems arise. A typical protocol will involve removing the catheter and instructing the patient to wait to pass urine until she either has a strong urge to void, or until four hours have passed, whichever is sooner. She is given clear instructions to void into a measuring collection device and to inform the nursing staff when she had done so. The residual volume of urine in the bladder is recorded immediately (within 15 min), either by bladder ultrasound scanning, or by clean catheterisation. Definitions of success vary, but it is usually defined by a post-void residual volume of less than 100 mL, or the ability to void greater than two thirds of the total bladder volume (which is the sum of the voided and residual volume). This should be carried out successively twice. The trial is deemed successful if they pass the second trial, and there is no need for further intervention or assessment. Patients who are completely unable to void, or who fail the first test with a large residual volume (typically 400 mL or more), should be re-catheterised immediately. All patients who fail the second test will require re-catheterisation.

Women who fail their trial without catheter can be managed with either an indwelling bladder catheter, or clean intermittent self-catheterisation. A repeat trial without catheter

should be planned on an individual basis and exacerbating factors, such as analgesics or constipation, should be addressed where possible. The patient can be discharged from hospital for outpatient management unless there are additional medical or social issues that necessitate inpatient care.

Clean intermittent self catheterisation (CISC) is preferred over indwelling catheterisation for women who can master the technique, as it is associated with fewer complications and lower rates of infection. Women should be advised to continue catheterisation until their post void residual volumes are consistently less than one third of the total voided volume. Women who are unable to manage intermittent catheterisation should have a follow-up trial without catheter.

52.4.3 Acute Urinary Retention

The implementation of regular post-operative or post-delivery bladder monitoring should prevent acute bladder overdistension. However, acute urinary retention is a medical emergency and timely recognition and management is essential to prevent long term bladder damage. Bladder overdistension results in reduced bladder blood flow from high intra-vesicular pressure, with progressive bladder wall ischaemia, and associated nerve and muscle damage. An indwelling catheter must be inserted immediately to drain the bladder. Recovery will depend on the degree of damage the bladder has sustained during the episode of overdistension. Larger volumes, especially if greater than 1000 mL, and prolonged duration, are associated with an increased risk of long-term bladder damage. Whenever an indwelling catheter is placed for acute retention of urine, the total volume of urine in the catheter must be measured and documented clearly at 30 min post-catheterisation. Premature measurement will result in a potential under-estimate the total volume of urine within the bladder, as there will have been insufficient time for the retained urine to drain. Conversely, delaying the measurement will result in an overestimate of retained urine. Accurate documentation of volumes and measurements are essential in case of future litigation.

When retention presents with a total inability to void, abdominal pain and a painful palpable bladder, recognition is simple and usually leads to prompt intervention. However, clinicians must have a high index of suspicion for patients with more subtle clinical presentations. Retention may be relatively silent, without significant abdominal discomfort, particularly with the use of regional anaesthesia and analgesics. Focusing on the voided volume alone may miss retention. Other signs may include increasing frequency of micturition, with diminishing voided volumes and incontinent episodes of overflow. The elderly may present with acute delirium. When retention is suspected, bladder volume should be assessed urgently with bladder scanning or catheterization.

If the volume exceeds 400 mL, the catheter should be left in place, especially for women with prolonged and large volume urinary retention. Recovery of bladder function will depend on whether irreversible damage has occurred. Women should be followed up to ensure that voiding returns to normal, or referred to specialist services if there is any evidence of persistent voiding dysfunction.

52.5 Case Study

Post-Partum Urinary Retention [4]

Mrs. A was transferred to the postnatal ward after the birth of her baby. She had not yet passed urine, and began to experience low back pain. The midwife advised her to practice pelvic floor exercises. Mrs. A was struggling to pass urine and experienced two episodes of urinary incontinence. A catheter was placed and removed 24 h later. On removal of the catheter she again failed to pass urine and was re-catheterised. The physiotherapist advised her to use a flip-flow valve to retrain her bladder, and she was discharged home. She returned 10 days later to have the catheter removed. Post-voiding residual volumes were not measured, and she was discharged.

She continued to have ongoing problems, and a month later she was unable to pass urine. She was left with permanent neurological damage to her bladder. Mrs. A was awarded £42,500 in an out-of-court settlement for the failure to identify and manage her urinary retention following the birth of her baby.

Key Points: Acute Urinary Retention

- In the absence of National Guidelines, local units should establish clear protocols for the prevention and management of acute urinary retention in women undergoing gynaecological surgery, childbirth and regional anaesthesia.
- Guidelines should be supplemented by adequate training for doctors, nurses and midwives, and 24-h access to clinical expertise for advice.
- Fastidious attention to detail and documentation of voided and residual volumes should be standard practice for all women at risk of acute urinary retention.
- A high index of suspicion is essential to detect urinary retention in women with minimal or atypical symptoms.
- Acute urinary retention should be treated as a medical emergency with swift intervention to reduce the risk of bladder overdistension injury and long-term voiding dysfunction.
- Whenever an indwelling catheter is placed for acute retention of urine, the total volume of urine in the catheter must be clearly documented at 30 min.
- Women who experience acute bladder overdistension should be referred to specialist services for ongoing assessment and management.

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Obstetric Anal Sphincter Injury [OASI]

53

Swati Jha and Abdul Sultan

53.1 Background

The incidence of OASI varies but in the UK it is reported to occur in 2.9% of women undergoing vaginal delivery (6% during first vaginal delivery) [1] and is a serious maternal complication following childbirth. The classification of different types of OASI is given in the chapter on Perineal Trauma. Unfortunately not all risk factors for OASI are modifiable and therefore not entirely preventable. It is now established that if a sphincter defect is seen on anal ultrasound in woman after the first delivery, the most likely reason is that OASI was missed at delivery [2].

53.2 Minimum Standards and Clinical Governance Issues

Following a vaginal delivery all women should undergo a meticulous vaginal and rectal examination by the trained accoucheur (as described in the Chapter on Perineal Trauma). Failure to do so risks missing an OASI. Even in women who have an intact perineum there may be a button hole tear between the rectum and vagina which may be missed without a rectal examination. Failure to recognise these buttonhole tears can be associated with a rectovaginal fistula. OASI cannot be excluded without a proper rectal examination. The technique of examination and accurate classification has been described [3].

If there is doubt about the grade of the external sphincter tear it is advisable to classify it to a higher degree Eg. 3b instead of 3a [4]. Although it is good practice to suture the tear soon after it has occurred, a delay for reasons such as lack of surgical expertise or theatre capacity does not appear to affect functional outcomes [5].

The patient should be informed of the tear and its potential implications for future bowel function as well as future pregnancies. Repair of these tears should be undertaken after proper consent in the operating theatre with good lighting, under aseptic conditions with adequate anaesthesia and assistants. Intra-operative intravenous antibiotics should be commenced and in keeping with the local protocol the antibiotics can be continued orally. Stool softening agents such as Lactulose should be prescribed post-operatively to ensure a loose consistency of the stools to avoid constipation and bowel impaction.

All obstetricians undertaking OASI repair should be adequately trained in the repair of OASI. Formal training in anal sphincter repair techniques is recommended as an essential

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component of obstetric training by attending formal hands-on workshops and undergoing Objective Structured Assessment of Technical Skill (OSATS). Obstetricians should also familiarise themselves with their local departmental guidelines on the management of these tears.

All patients who suffer an OASI should be adequately followed up by an Obstetrician/Gynaecologist or specialist nurse/midwife with expertise in this area, and women with ongoing problems or symptoms of incontinence or pain should be appropriately investigated. Where facilities are available this should be in a designated Perineal Trauma clinic.

Women who suffer an OASI, may do so after a prolonged labour and/or traumatic delivery and patients often associate the two. General dissatisfaction with the way their labour was managed accounts for the reason why many seek compensation and this can be avoided by communicating with patients and allowing them an opportunity to go through events leading up to the OASI. This can be in the setting of a "Birth Afterthoughts Clinic" or a debrief with a senior clinician who can address any unresolved issues.

Most Obstetric units will have guidance in place for the management of OASI, and clinicians should familiarise themselves with local guidelines. Where such guidance does not exist the RCOG [4] and the ACOG [6] have issued guidance which should be followed.

Identification of risk factors antenatally is not usually an indication for elective caesarean section. For the prevention of OASI, it is advisable to perform an episiotomy when performing a forceps delivery and with a Ventouse where appropriate [4, 7]. Where an episiotomy is indicated, the mediolateral technique is used in the UK ensuring a 60 degree angle at perineal distension (See Chapter on Perineal trauma and episiotomy).

When describing OASI, the RCOG recognised international classification should be used [3, 4]. The internal anal sphincter [IAS], external anal sphincter [EAS] and anorectal mucosa should be identified and their integrity commented on. Repair should be performed in the operating theatre with few exceptions and patients adequately anaesthetised with either a regional block or general anaesthesia. Repair of individual components of the IAS and EAS should be with either monofilament sutures such as Poydiaxonone [PDS] 3–0 or Polyglactin [Vicryl] 2–0. The IAS should be repaired using end-to-end interrupted mattress sutures. The EAS should be repaired using the same technique but an overlap technique can be used only if there is full thickness EAS tear or greater. A Cochrane review demonstrated no difference in outcomes between an end-to-end and an overlap repair although it identified that compared to an end-to-end repair an overlap repair is associated with a lower incidence of urgency symptoms and a lower anal incontinence score [8]. The procedure should be adequately covered with antibiotics which should be commenced intra-operatively and continued post-operatively depending on local protocols. Post-operative laxatives should be used to prevent wound dehiscence. Women should be offered physiotherapy as it may be beneficial.

All women should be offered postoperative follow up and referred on where they have ongoing problems. If facilities are available, follow-up of women with OASIs should be in a dedicated perineal clinic with access to endoanal ultrasonography and anal manometry as this can aid decision making regarding future delivery [4].

A small number of women may require referral to a colorectal surgeon for consideration of secondary sphincter repair. It is important to recognise that concordance of digital examination and endoanal scan when assessing the anal sphincter is poor.

Women who have suffered an OASI in a previous pregnancy should be counselled regarding the mode of delivery by a senior obstetrician and this should be clearly documented in the notes. Women should be informed that following future pregnancies there is a risk of worsening of symptoms with subsequent vaginal delivery. They should therefore be given the choice of a vaginal delivery or a caesarean section, and adequately counselled of the risks of a caesarean delivery too. In a future vaginal delivery there is no proven role for prophylactic episiotomy unless clinically indicated. If the woman is symptomatic or shows

abnormal anorectal manometric or endoanal ultrasonographic features, she should be counselled regarding the option of elective caesarean birth.

Units should undertake rolling audits of the incidence of OASI to ensure these are comparable to National standards and local/National guidelines are being adhered to.

53.3 Reasons for Litigation

The reasons for litigation following OASI include

- Failure to diagnose an OASI or a rectal mucosal tear [single most common reason for successful litigation].
- Failure to perform a proper rectal examination before and after the repair of a perineal laceration or episiotomy.
- Delay in suturing.
- Non performance of episiotomy where clinically indicated.
- Lack of communication regarding the diagnosis and implications of the tear.
- Formation of a fistula.
- Failure to repair in theatres.
- Failure to cover with antibiotics and laxatives.
- Faecal incontinence.
- Inadequate training of the surgeon.
- No follow up.
- Pain following repair and scar tissue formation causing dyspareunia.

53.4 Avoidance of Litigation

Appropriate management of the second stage requires adherence to guidelines to prevent OASI where possible with interventions such as episiotomy. It is not routine to offer elective caesarean to women who suffer OASI as risk factors are difficult to predict until after the incident. All clinicians managing women in labour should be trained in the identification of OASI and where there is doubt, a senior review should be sought. Accurate identification and classification is the first step to prevention of litigation.

Once diagnosed, suturing should be undertaken in theatres with appropriate lighting and adequate anaesthesia. Aseptic techniques should be adopted with antibiotic prophylaxis, use of appropriate sutures, appropriate techniques and assistants. Antibiotics should be used to cover the patients intra-operatively and post-operatively (depending of local protocols) together with stool softeners.

All obstetricians undertaking repair of OASI should be adequately trained or supervised to do so.

All patients who suffer an OASI should be followed up after delivery and assessed for outcomes following the repair. Patients who are symptomatic or have evidence of deficiency of the anal sphincter should be refereed for anal ultrasound and manometry. They may need referral to either a Urogynaecologist or a colorectal surgeon for further management if they have ongoing faecal urgency or incontinence.

In future pregnancies, all women should have a choice regarding the mode of delivery and advised in favour of a caesarean section if they are symptomatic or have a defect in the anal sphincter on anal endosonography. Recommended criteria have been published [4]. They should also be informed of the risk of deterioration in anal sphincter function following a vaginal delivery.

In keeping with the principles of good clinical practice the anatomical structures involved, method of repair and suture materials used should be clearly documented and the woman informed of the nature of the injury.

53.5 Case Study

53.5.1 Davison vs. Leitch 2013; EWHC 3092; QB

Mrs. Sarah Davison delivered her first child on the 7th December 2008 whilst under the care of the defendant. During the course of her delivery both her external and internal anal sphincter were damaged but no proper examination was carried out and there was no clear documentation of the severity of tear which remained undetected.

There was no treatment with antibiotics and the discharge letter stated that a small midline episiotomy had been performed which had been repaired with Vicryl.

Due to ongoing problems she was reviewed by the colorectal surgeon who following investigation with endoanal sonography identified unequivocal evidence of a structural internal and external sphincter defect and an associated functional deficit. Despite surgery she was left with significant ongoing symptoms with obvious impact on her mental as well as physical health.

The High court Judge identified the breach of duty which included failure to comply with National Guidelines [4, 7], failure to perform an episiotomy which was adequately angled away from the anal sphincter, a failure to diagnose the injury, inadequate postoperative care and a failure to inform the patient and her GP about the condition.

Mrs. Davison was 32 at the time of her delivery and had a highly successful banking career in the City. The issues at trial related largely to quantum consequent on the injury suffered during childbirth. She was awarded £1.6 million in damages.

Key Points: OASI

- Adequate identification of the grade of tear.
- Appropriate explanation to the patient. Debrief of the delivery and the factors contributing to the tear as well as its implications for future bowel function and pregnancies.
- Repair in theatres with adequate lighting, good surgical technique with use of appropriate sutures under appropriate anaesthesia and antibiotic cover.
- Repair undertaken by adequately trained surgeons.
- Adequate follow up of patients to identify adverse outcomes and complications.
- Patients presenting with a fistula should be managed by a colorectal surgeon and will probably need a defunctioning colostomy.
- Mode of delivery in future pregnancies is based on patient choice, symptoms and endoanal ultrasound and manometry [where available].

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Part VI

Infertility, Subfertility and the Menopause

Swati Jha and Raj Mathur

54 Fertility Testing and Treatment Decisions

Ying Cheong and Rachel Broadley

54.1 Background

For many people, the wish to have a family is a natural desire and the prospect of childlessness can bring significant heartache.

The definition of subfertility by NICE is the "inability to conceive after 1 year of unprotected vaginal sexual intercourse, in the absence of any known cause of infertility" (NICE 2013).

However, fertility is not a binary state. In addition to clinical knowledge and acumen, the management of people experiencing subfertility requires careful dialogue to reassure and manage expectations. In the context of shared decision-making, clear and comprehensive information pertinent to the individual's circumstance is enormously helpful to avoid misunderstanding that could lead to complaint or litigation.

54.2 Minimum Standards and Clinical Governance Issues

To guide practice, NICE has recommended minimum standards relating to fertility investigations:

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Male

- Semen analysis (SA)—WHO reference values

Semen volume: ≥1.5 mL
pH: ≥7.2
Sperm concentration: ≥15 million spermatozoa per mL
Total sperm number: ≥39 million spermatozoa per ejaculate
Total motility (percentage of progressive motility and non-progressive motility): ≥40% motile or ≥32% with progressive motility
Vitality: ≥58% live spermatozoa
Sperm morphology (percentage of normal forms): ≥4%

- Sperm antibody screening (not recommended).
- Repeat SA if first test is abnormal (3 month gap between tests recommended).

Female

- Post coital test not recommended.
- Ovarian reserve testing

Use age as an initial indicator
Total antral follicle (AFC) ≤4 = low response; >16 = high response
Anti-Müllerian hormone (AMH) ≤5.4 pmol/L = low response; ≥25.0 = pmol/L high response
Follicle-stimulating hormone (FSH) >8.9 IU/L = low response; <4 IU/L = a high response

- Luteal phase progesterone for ovulation status.
- Prolactin, thyroid function test, endometrial biopsy should not be routinely performed.

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- Women without history of fertility-related comorbidities should be offered tubal assessment, with the remained being offered a laparoscopy and dye test.
- Rubella, chlamydia status should be determined.

54.3 Reasons for Litigation

1. Missed or misinterpretation of investigations.
2. Delay in investigations and diagnosis.
3. Miscommunication of investigation results and diagnosis.
4. Miscommunication pre- and post-operatively.

54.4 Avoidance of Litigation

The NICE definition of subfertility as failure to conceive after 12 months offers a valid starting point for investigations relating to fertility. However, in cases where there is a known condition affecting fertility (e.g., endometriosis) or factors in the history point to an obvious potential cause (e.g., irregular menstrual cycles, previous testicular surgery), investigation should commence without delay. Delaying investigation and/or referral in such situations may be negligent, and may lead to a reduction in the chance of conception owing to passage of time.

Up to one third of couples who undergo fertility investigation will have 'normal' investigation outcomes. This diagnosis is termed unexplained subfertility. After investigation or the inability to conceive, to be informed that 'nothing wrong can be found' can be distressing and difficult to comprehend. It is also challenging for a clinician not to be able to provide an adequate answer for the disappointed patient who is desperate to conceive. This clinical conundrum has, over the years, led the fertility industry to offer a large panel of tests, some quite expensive, but without a sufficient evidence-base for improving outcomes. Patients are in a position of vulnerability and will frequently defer to the specialist's recommendations. Even with transparent discussion as to the lack of scientific evidence, a clinician could leave themselves open to complaints, litigation and accusations of negligence by recommending such courses of investigation outside of the clinical trial arena [1].

It is the clinician's duty to ensure that all investigations are accurately interpreted. Notwithstanding the impact on the patient, an error in the interpretation leading to potential or actual harm, could bring question as to the clinician's ability to practice and could indeed be deemed a breach in the clinician's duty of care or medical negligence.

Many fertility clinics are now privately owned. It is not uncommon for patients to visit several fertility centres and undergomultiple investigations at each. It is the clinician's responsibility to ensure that they have access to previous test results. If the results of a critical investigation are not available to the treating clinician, they may need to be repeated, or reports requested from elsewhere. If the investigation results are abnormal, it is the responsibility of the current managing clinician to initiate further investigations and/or intervention prior to commencing fertility treatment.

If the patient requires further advice from another specialty (e.g. genetics, haematological advice for anti-coagulation) it is the clinician's duty to ensure that the patient seeks this advice prior to the commencement of treatment. Failing to do so, resulting in actual or potential harm to the patient could be deemed negligent.

For a multitude of reasons, there may be significant delays in initiating appropriate investigations and reaching a diagnosis. Much of the frustration patients experience is further fuelled by the inconsistent guidance on the age limit acceptable for IVF funding set by national guidelines e.g. NICE and commissioners e.g. Clinical Commissioning Groups (CCGs) in the UK. Be it organisational, administrative or clinically related, a significant delay in the patient's treatment pathway ultimately can impact on fertility prognosis, and the cost associated with potential negligence claim.

Clarity is key to the avoidance of complaints and litigation. Taking the time to ensure understanding and encouraging questions to avoid

ambiguity and misinterpretation is enormously valuable.

Informed consent is mandatory and must be carefully documented and supplemented by written patient information provided in a timely manner before an intervention. Fundamentally, performing an operation without a patient's explicit consent (applying the principles of the Mental Capacity Act where relevant) could leave a clinician open to criminal charges as well as jeopardizing medical registration.

If, during the course of a procedure, it was necessary to deviate from the pre-operative plan to avoid serious patient harm, a full discussion must be held with the patient (after full recovery from sedation/anaesthesia) and carefully documented. The clinician should note they should only perform the least invasive intervention to prevent serious harm or death. Any further management should be completed at a later stage after detailed discussion with the patient. In addition, the Duty of Candour is a statutory obligation on all healthcare providers.

54.5 Case Study

The claimant had a history of ruptured appendicitis in her teens. At age 38, she was referred the fertility specialist for a 2 year history of subfertility. Prior to her referral, she had a laparoscopy in another hospital, by a different surgeon, which revealed a large left hydrosalpinx that was drained. She did not qualify for NHS funded IVF cycle, and was referred to Mr. X privately for IVF treatment. During the consultation, the significance of hydrosalpinx removal was not clarified, and the claimant subsequently underwent two cycles of self-funded fresh IVF cycles and one frozen embryo transfer with no success.

The claimant sought a second opinion elsewhere, underwent a laparoscopic right salpingectomy and since had a successful IVF pregnancy at age 40.

It was alleged that Mr. X's failed to provide the correct advice prior to the IVF treatment, and as such, his standard of care fell below what was expected of a reasonable clinician in the same field. As a result, the claimant suffered multiple cycles of failed IVF.

The case was settled out of court, for an undisclosed moderate amount.

Key Points: Fertility Testing and Treatment Decisions

- Specialist multidisciplinary teams should manage patients with subfertility requiring treatment at the tertiary level; initial investigations are performed as per NICE Guidance in the community and secondary care where appropriate.
- Discussions, investigations and management must be tailored to the patient's individual circumstances and be guided by up-to-date evidence-based practice.
- Taking the time to understand and realistically manage expectations of patients with subfertility, right from the initial appointment, is crucial for patient satisfaction, even in the absence of ultimately achieving a pregnancy.
- Clear communication of investigations results, their implications on the individual patient's fertility; seek to ensure clear understanding and supplement with written information wherever possible.
- Explain the implications and impact of treatment (surgical or medical) on fertility prior to embarking on treatment.
- Audit and monitor appointment referral to treatment time; unnecessary delays can have major implications for treatment prognosis and availability of funding.

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Assisted Conception

55

Raj Mathur

55.1 Background

It is estimated that one in six couples who try for a baby will fail to conceive despite 12 months of regular sexual intercourse. Couples without an obvious cause of subfertility retain a reasonable likelihood of conception in the second 12 months of trying, but thereafter the likelihood of spontaneous conception is low. Treatment of subfertility may involve measures directed to a detectable cause, such as ovulation induction in anovulatory women with polycystic ovary syndrome or surgery for endometriosis. However, if these measures do not succeed, or if no cause is obvious, then assisted conception is an important option to allow couples to attain parenthood [1].

Assisted conception refers to techniques where gametes (eggs or sperm) and/or embryos are manipulated outside the body. Broadly speaking, these are Intra-Uterine Insemination (IUI), In-vitro Fertilization (IVF) and Intra-cytoplasmic Sperm Injection (ICSI). Additional measures may include the use of donor gametes or embryos and genetic screening of gametes or embryos prior to therapeutic use. Over 60,000 cycles of assisted conception are performed annually in the UK.

Certain specific features of assisted conception practice in the UK are relevant to understanding medicolegal risk management in this area. Many clinics are entirely privately-owned and most provide treatment to both state-funded and privately-funded patients. In a competitive market, advertising and social media are used to enhance provider profiles. Patients often compare 'success rates' between clinics. Whilst the Human Fertilisation and Embryology Authority (HFEA) provides validated and complete figures on its public website, this data is usually at least a year or more out of date (because of the length of time from treatment to birth). As a result, patients may rely on figures from clinic websites, which are published prior to full validation and may not reflect accurately the likelihood of a successful outcome.

The field of assisted conception is dynamic and female fertility specifically is highly age-dependent. Hence, there is a temptation to bring into clinical practice techniques that may not have completed the usual process of scientific testing and randomised evaluation. When the patient is considering paying for treatment that has a scant evidence base, the need to counsel the patient appropriately and maintain adequate documentation is obvious.

A further significant feature of UK practice is that assisted conception clinics are often

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free-standing enterprises not linked to an acute hospital. Hence, patients who develop complications of treatment may require further management in centres other than the clinic that carried out their fertility treatment.

55.2 Minimum Standards and Clinical Governance Issues

Assisted conception is probably the most closely regulated branch of medicine in the UK, falling under the purview of the Human Fertilisation and Embryology Act 1990, amended in 2008. All UK clinics are subject to regulation by the HFEA, an 'arms-length' government body. The HFEA licenses and inspects clinics, sets standards for clinical practice and research and provides authoritative information to patients and public. The HFEA publishes a Code of Practice, which is an invaluable resource for staff working in assisted conception. Every clinic is mandated to have a Person Responsible (PR), who "should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the centre's work to be able to supervise its activities properly", besides possessing integrity, and managerial authority and capability. It is not mandatory that the person should be a clinician. The PR carries significant legal responsibilities for the work of the clinic, although they are not expected to be able to personally provide every aspect of care. Broadly speaking, the PR must ensure that the functioning of the clinic at all times is compliant with the regulations of the HFEA.

The Code of Practice lays out specific standards on patient investigation and information to be provided prior to treatment. Further standards cover procuring, processing, storage, import and export of gametes, screening and compensation for donors, egg sharing arrangements, surrogacy, traceability and premises and facilities. Clinics are inspected against these standards and a serious breach of standards may result in a clinic losing, or suffering restrictions to, its license to provide assisted conception treatment.

Although the HFEA defines standards, the regulator has steered clear of writing detailed clinical guidelines, preferring instead to work in collaboration with the National Institute of Health and Clinical Excellence (NICE), the Royal College of Obstetricians and Gynaecologists (RCOG) and specialist professional bodies such as the British Fertility Society (BFS) and Association of Clinical Embryologists (ACE).

55.3 Reasons for Litigation

- Inadequate evaluation of the couple/individual prior to starting assisted conception, 'missing' a potentially significant finding in history or investigation—for instance uterine septum or submucous fibroid.
- Delayed provision of assisted conception leading to reduced likelihood of success due to increased female age.
- Advising couples to have assisted conception when a less invasive option would have provided a reasonable likelihood of success, e.g. ovulation induction, lifestyle modification.
- Inadequate counselling prior to treatment about the risks and implications of treatment.
- Failure to complete valid consent forms for legal parenthood prior to start of donor gamete treatment.
- Complications of treatment—Ovarian Hyperstimulation Syndrome where available preventative measures were not advised, severe pelvic infection following egg collection.
- Complications relating to adjuvant treatment for which the evidence base is poor, e.g. immunosuppressive treatment for recurrent implantation failure.
- Laboratory error resulting in 'mis-match' of gametes or embryos and use of 'wrong' gametes or embryos in treatment.

55.4 Avoidance of Litigation

The PR of an assisted conception clinic must discharge his duties in accordance with the HFEA Code of Practice. The duties of a PR are so broad as to seem daunting, particularly in an NHS setting where management may not be aware of the implications of a breach of the Code. It is important for the PR in NHS clinics to have adequate time in their job plan, along with the confidence of senior management and the ability to raise concerns when issues arise. In private clinics, the PR must be conscious of the potential conflict between their statutory role in ensuring compliance with regulation, and commercial imperatives. 'Success' rates advertised to the public should be presented according to HFEA guidelines, ensuring accuracy and completeness.

Clinical practice that is in keeping with the Code is likely to be sufficient for the purpose of avoiding regulatory sanction and certain types of litigation. For instance, following the specific provisions in regard to consent for legal parenthood may pre-empt the possibility of litigation in cases of donor gamete treatment where the relationship breaks down following successful treatment.

However, the Code is not sufficiently comprehensive as to provide a defence against several types of patient complaints and litigation. Clinicians must follow the principles of good medical practice, be familiar with the evidence base and ensure adequate patient counselling and documentation to minimise the risk of litigation. Specific clinical guidance from the RCOG, BFS and other professional bodies covers most aspects of clinical practice in assisted conception. UK clinicians who base their practice on such guidance could legitimately claim to deliver care at a reasonable level of competence. Where practice diverges from guidelines, for instance in reproductive immune testing and treatment, patients should be clearly informed that this is the case and be made aware of the risks and potential benefits of treatment. In the example of reproductive immunology, professional body guidance is clear that tests and treatments aimed at uterine or blood 'natural killer' cells are not supported by the evidence base as it currently stands. Nonetheless, several clinics and competent clinicians prescribe these in their practice. In order to defend against litigation in the event of a complication from such treatment, one possible argument could be that there is a divergence of opinion amongst experts and basic science studies indicate a role for immunologic modification in reproductive success. Demonstrating thorough and adequately-documented patient counselling would be helpful.

Clinicians practicing in assisted conception often receive patients who have had their initial investigations, and even treatment, elsewhere. In such a situation, it is important to have first-hand communication from the referring clinician about the results of investigations, operative findings and treatment provided. In the absence of clear information, it is reasonable to advise further investigation. For instance, if it is not clear whether a submucous fibroid or uterine septum has been resected completely, a hysteroscopy should be offered before assisted conception is started.

OHSS is recognised to be the most significant short-term complication of assisted conception [2]. The BFS has published guidelines on the prevention of OHSS and every clinic should include prevention of OHSS within its protocols [3]. In the prevention of litigation, it is important to document adequate patient counseling and the use of preventative measures such as GnRH antagonist protocol, agonist trigger or cryopreservation of all embryos depending on the clinical situation.

The management of OHSS presents specific risks where the clinic and the acute hospital are separate [4]. Good communication and joint protocols between the clinic and the acute hospital are recommended. The HFEA requires clinics to report all cases of severe or critical OHSS who are admitted to hospital and this requires efficient communication and adherence to agreed classification schemes. In the UK, the classification system used by the RCOG and accepted by the HFEA should be used.

The BFS [3] and RCOG [2] have both published guidance on management of OHSS, and

clinics should ensure that their protocols are current and available to staff at all times. There are problems both with under- and over-diagnosis of OHSS, as affected women are often assessed as emergencies by junior staff with little experience of assisted conception. In the author's experience, non-specialist clinicians are sometimes quick to label women presenting with abdominal pain after fertility treatment as suffering from OHSS. This carries the risk of missing serious pathology, occasionally with tragic consequences (see Case 2). It should be kept in mind that severe abdominal pain, pyrexia and peritonism are not features of OHSS and an alternative diagnosis should be sought if these are noted, or if features of severe OHSS such as ascites and haemoconcentration are absent. Diagnoses that have been wrongly attributed to OHSS include Group B Strep pelvic sepsis following IUI, ovarian torsion and appendicitis.

Clinicians should keep in mind that infective complications following egg retrieval, although uncommon, are more often seen in women with endometriosis or pelvic inflammatory disease. If pelvic sepsis occurs, it is a reasonable defence to say that an endometrioma had to be traversed in order to access follicles that were otherwise inaccessible. Provision of prophylactic antibiotics in such cases would also constitute a reasonable precaution, even though there are no trials on the benefit of this measure and severe infection can still occur in cases of endometriosis despite antibiotic administration at egg retrieval. Importantly, if a patient presents with significant abdominal pain at embryo transfer, she should be assessed clinically rather than automatically proceeding to transfer. In a number of cases, patients were likely ill at the time of transfer but this was not take seriously by clinicians focused on the task at hand.

55.5 Case Study

Case 1

SL was known to suffer from severe endometriosis and had been trying to conceive for several years before being referred for IVF. Ovarian stimulation with FSH in a long protocol down-regulated cycle resulted in a good ovarian response. At egg collection, a large endometrioma was found to lie between the puncture site and a number of ovarian follicles. The endometrioma was drained and follicles aspirated. Antibiotics were not provided. When SL presented for embryo transfer she was in pain and felt unwell with tachycardia. Further assessment was not carried out and embryo transfer was performed. Later that day, SL presented as an emergency with pelvic infection. Over a period of several weeks, she had severe pelvic sepsis, culminating in laparotomy and unilateral salpingo-oophorectomy. The patient alleged that antibiotics should have been provided at egg collection and the embryo transfer should not have been carried out without a full evaluation of her severe symptoms, which were not to be expected three days after egg collection. A significant out of court settlement was agreed.

Case 2

KH presented to the Emergency Department the day after IUI, having undergone monofollicular ovulation induction, with severe pain and tachycardia. The hospital did not have an on-site gynaecology service and she was discharged with analgesia. She re-presented 3 days later on a Friday afternoon with severe pain, pyrexia and abdominal tenderness and was sent by blue-light ambulance to the gynaecology unit of a neighbouring hospital. Here she was diagnosed with severe OHSS (despite having had only one pre-ovulatory follicle) and started on the 'OHSS protocol'. She remained unwell with severe pain requiring morphine, tachycardia and raised white cell count. Some 72 h after admission, she collapsed and a diagnosis of septicaemic shock became apparent. Sadly, despite intensive care, she passed away a few days later. Her survivors alleged that the diagnosis of pelvic infection was missed and a misdiagnosis of OHSS made which led to her not receiving antibiotics for several days, by which time it was too late for survival. A substantial settlement was agreed.

Key Points: Assisted Conception

- Assisted conception in the UK is subject to statutory regulation by the HFEA, which publishes a Code of Practice. Adherence to the Code is likely to be sufficient to avoid regulatory penalties, but may not be sufficient to prevent litigation.
- Individuals and couples considering assisted conception should be fully informed and consented, including consents for legal parenthood, prior to starting treatment.
- Assessment should be carried out before treatment to rule out any correctable potentially significant abnormalities.
- OHSSS should be recognised as an important and often unpredictable complication for which explicit patient information is necessary. Preventative measures should be provided in high risk cases.
- Clinics should maintain good communication and shared protocols for managing OHSS with acute hospitals in their catchment area, guarding against both under- and over-diagnosis of OHSS.
- Women presenting with significant abdominal pain at embryo transfer should be assessed fully prior to deciding whether to proceed with transfer.

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Gamete Donation and Surrogacy

56

Sharon Pettle and Hannah Markham

56.1 Background

The medico-legal landscape is broad and complex. This chapter will focus on the implications of incorrect management of the consent process in third party reproduction, comment on surrogacy, and on the use of foreign clinics. Thinking prospectively is a measure of prudent professional conduct for clinicians, enhances the treatment of the patients and demonstrates care for the children created.

56.2 Minimum Standards and Clinical Governance Issues

The creation, storage and implantation of human embryos is controlled by the Human Fertilisation and Embryology Act 1990, amended by the complex provisions of Part 1 of the Human Fertilisation and Embryology Act 2008. The question of who is, or are, the parent(s) in law of a child created using donated gametes is covered in Part 2, s33-47 of the 2008 Act. All UK clinics are subject to regulation by the Human Fertilisation and Embryology Authority [HFEA].

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Clinic staff must be aware of the full statutory provisions and guidance, and the strict rules governing consent forms which must be signed before treatment begins. They must be familiar with documents and able to inform prospective parents of these matters and their importance. Directions given by the HFEA, in accordance with its' statutory powers, have at all times required that consent required under sections 37(1) and 44(1) "must" be recorded on specified forms. From April 3rd 2017 new consent documents will apply to married couples and those in civil-partnerships. Forms WP and PP [critical sections relating to birth registration are summarised below] will continue for unmarried heterosexual couples and non-civil partnered same sex couples. This change will mean that staff must be particularly vigilant as to which forms are used and if a couple change status during the treatment process, new forms will need to be completed.

56.2.1 Form WP: 'Your Consent to Your Partner Being the Legal Parent'

The first two sections provide the names and birth dates of the woman receiving treatment and her partner. The third entitled 'Your consent' requires that the patient consents to their named partner being the legal parent of any child resulting from the treatment. The patient signs that they have been given information about the

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options set out in the form and have had an opportunity to have counselling, and that they understand the implications of giving consent, and the consequences of withdrawing it.

56.2.2 Form PP: 'Your Consent to Being the Legal Parent'

This requires two names and birth dates [identical to the above]. The section entitled 'Your consent' requires that the person signing consents to being the legal parent of any child born as a result of his/her partner's treatment. The next critical section for the purposes of birth registration is a declaration that, before completing the form, s/he was given information about the options and an opportunity to have counselling, and is aware of the implications and consequences of giving, or withdrawing, consent.

56.2.3 Registration of Births

The Registrar General issues instructions and guidance to General Register Office staff [1]. One chapter covers the registration of births following assisted conception. At present the relevant paragraphs are B2A.1(iii), 2 and 3.

Para B2A.1: "The Human Fertilisation and Embryology Act 2008 provides the following parenthood definitions regarding who is the father or second female parent (i.e. the mother's female partner) of a child born to a woman as a result of the placing in her of an embryo or of sperm and eggs or her artificial insemination.

And later ….

(iii): where a woman received fertility treatment from a licensed person in the United Kingdom and no husband is to be regarded as the father … or no spouse or civil partner is to be regarded as the second female parent …, the man with whom the mother has a parenthood agreement (see B2A.2) is regarded as the father".

In this context:

2: The **Parenthood agreement** means where the mother has given to the clinic written notice stating that she consents to her male partner being regarded as the father and the partner has given written notice consenting to being regarded as the father, or where the mother has given to the clinic written notice stating that she consents to her female partner being regarded as the second female parent and the partner has given written notice consenting to being regarded as the second female parent, and that such consent has not been withdrawn.

The Handbook clarifies in the following paragraph that:

3: It is not necessary routinely to see copies of the consent notices in order to confirm that the necessary consent had been given and/or that treatment was carried out by a licensed person/clinic in the United Kingdom. However, if there is doubt as to the accuracy of information given by an informant in these respects or there is any conflict between the parents as to the facts, copies of their consent notices should be requested in order to establish the correct parenthood before registering. Copies of consent notices should be readily available from informants if needed as UK clinics automatically give copies to their patients at the time of giving consent."

The accuracy of record keeping is absolute. Whether clinics have followed the correct practice and procedure has been scrutinised in cases placed before The President of the Family Division of England and Wales commonly known as the '*alphabet'* cases, in which several parents lost their rights to register their child as their lawful child due to procedural errors at the clinic. The Handbook requires updating following the lead judgment of The President known as Re A [2].

56.2.4 If an Error Occurs

If an error occurs or is found by any member of clinic staff, the Person Responsible and/or Clinical Director should be contacted as a matter of urgency. If necessary, legal advice should be

sought as to the appropriate action[s] to take. Patients should be informed about this and efforts made to rectify this and/or to manage the consequences.

56.2.5 Surrogacy

Surrogacy arrangements are defined in s54 of the 2008 Act which sets out the law regarding parental orders. Hearings in the Family Courts have argued the 'parental' rights of intending parents, and those of the woman the law regards as the legal mother. Existing surrogacy legislation was debated in the House of Lords [3] and is under review including the rights of single people as the President of the Family Division declared that the current HFEA provisions in relation to single people are incompatible with Human Rights Law and Adoption legislation. The Department of Health is developing best practice guidelines for surrogates, professionals and intended parents but these have not yet been published.

Family Judges repeatedly identify difficulties arising when there is a breakdown in the relationship between a surrogate and commissioning parents but the law currently gives no guidance to those involved, save for reference to the Children Act 1989.

Psychological assessment of commissioning parents, potential surrogates and of the relationship between them is rarely undertaken and regulations do not promote counselling in these circumstances. Currently the HFEA does not suggest any special preparation is required when using surrogacy and it should be noted that 'implications counselling' for those using donated gametes is still only optional.

56.3 Reasons for Litigation

- Failure of clinics to adhere to the statutory guidance within the HFEA.
- Failure of clinics to provide correct advice and direction in the signing of and completion of the forms prior to the commencement of the treatment.
- Lack of understanding of consent.
- Errors in record keeping.
- Lack of counselling for couples prior to treatment.

56.4 Avoidance of Litigation

It is a possibility that recommendations to use a foreign clinic could result in such claims. Arrangements between clinics [more or less formalized] are known to exist and travelling abroad is suggested for cost reasons; greater accessibility of donated gametes [particularly eggs and embryos]; and for donor anonymity. There are potential pitfalls as many prospective parents assume that the regulations are identical in a clinic linked with one in UK, and do not fully understand the ramifications of treatment abroad. They express surprise at proposed multiple embryo transfer, the paucity of non-identifying information about donors, do not appreciate that donors are not registered through the HFEA and do not have the option to re-register as identifiable. Donor gametes may be suggested with little time for consideration and no counselling being offered. Furthermore, the consent documentation outlined above is not in place raising the potential for difficulties at birth registration. Some parents feel unprepared, and struggle to help their children deal with anonymity when other children of a similar age have more information and express their feelings about meeting donors in the future [4].

Reviews of research exploring the impact fertility treatment conclude that many couples experience a negative impact on their partnership, emotional distress, depression and high stress levels [5, 6]. Issues of blame may exacerbate the distress [7] and in lower/middle income countries and some cultures, infertility increases the risk of domestic violence [8]. H*owever well people present in the consulting room, patients represent* a

potentially vulnerable group whose capacity to think through the ramifications and implications may be compromised.

It may be advisable for a UK clinic recommending a linked clinic abroad to offer or provide counselling, and/or to provide written details of the differences, and likely expectations and outcomes if this option is pursued, so that prospective parents are fully informed. Clinics need to help patients understand the wider issues involved and have executed their duty of care to people who are psychologically vulnerable.

Additionally:

- Clinics can ameliorate reasons for litigation through internal training from either external or internal lawyers specialist in this area.
- Creation of a role within the clinic of a person trained in record keeping and understanding of the current law and any subsequent changes, who is responsible for helping the Person Responsible disseminate information and audit relevant processes.
- Regular audits of record keeping and consent will also identify any potential pitfalls. These are required by the HFEA as part of its inspection regime for clinics.
- Recommendation to the prospective parents to access counselling and or legal advice prior to treatment in cases of surrogacy or where the legal parenthood of any resulting children is unclear. An example would be the use of donor embryos by a single woman.

56.5 Case Study

In 2013 a Judgement Justice Cobb—AB v CD and the Z Fertility Clinic [2013] EWHC 1418 (Fam), [2013] 2 FLR 1357 named serious shortcomings in a clinic due to failure to adhere to the regulations: including the way forms were completed, signed, and whether counselling had been offered. This led to a mother who had been declared one of the child's two legal parents, losing her right to legal parentage. This has dramatic consequences for the mother and the child. Subsequently, an audit required by the HFEA revealed that 51 clinics (46%) discovered "*anomalies*" in their records relating to consent forms: being absent; incorrectly completed (unsigned, incomplete, completed by the wrong person or having missing pages); or, completed/dated after the treatment had begun; and in many instances, there was no evidence that an offer of counselling had been made. Over 75 legal cases were identified in which legal parenthood had been affected by the failure to follow procedures. Adherence is essential as this allows intended parents [male or female] to be parents **in law** and register their child as their legitimate and lawful child. The HFEA 2017-2020 Strategy [9] cites as Objective 1 in 'fewer non-compliances and incidents in clinics'.

The subsequent run of the aforementioned 'alphabet cases' heard by the President of the Family Division highlighted the failings of a number of clinics and necessitated some careful review of the formulation of the consent forms to preserve parenthood for a number of parents. It also led to several claims against the clinics who met the cost of the litigation and settled claims out of court.

Some Judgements are in the public domain albeit in anonymized form: one concerned a surrogate who had such resentment towards the biological commissioning parents that she refused consent to the making of a parental order yet she agreed that the children should be brought up by them [10]. The outcome was to adjourn the application making a Child Arrangement Orders which gave them Parental Responsibility. In another case where no agency was involved [11], the behavior of parties during the pregnancy [a homosexual couple and the surrogate] was considered relevant in deciding with whom the child should reside and who was best placed to meet the child's emotional needs.

Key Points: Gamete Donation and Surrogacy

- Adherence to the statutory guidance in the HFEA as laid out in the Code of Practice.
- Ongoing training and understanding of the laws relating to consent and parenthood within the HFEA.
- Ensuring forms WP & PP are the correct up to date versions.
- Training and understanding of record keeping and form filling prior to treatment.
- Provision of adequate support to prospective parents prior to treatment via counselling and access to legal advice if required.

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Termination of Pregnancy (Abortion)

57

Swati Jha and Lesley Regan

57.1 Background

Abortion is the spontaneous or induced termination of pregnancy. For the purposes of this chapter, abortion is used to refer to induced termination of pregnancy. Abortion in England, Scotland and Wales is regulated by the *Abortion Act 1967* [1]. However, the *Scotland Act 2016* [2] now allows the Scottish Parliament to legislate on abortion law. The *Abortion Act 1967* has never extended to Northern Ireland, where abortion continues to be regulated by provisions in criminal law and is illegal other than in very specific circumstances [3]. All abortions other than those performed as an emergency require approval by two registered medical practitioners and must be performed in facilities registered for this purpose. Ninety-eight per cent of abortions were funded by the NHS. Of these, over two thirds (68%) took place in the independent sector under NHS contract, as was the case in 2015 (68%) [4]. Abortions over 24 weeks can only take place in an NHS hospital [1].

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Since 2012 the average number of abortions performed in the UK has remained relatively constant at 185,000 per annum. In 2016 [4], abortion rates for women between 15 and 44 years of age were 16.0 per 1000 and the under 16 year rate was 1.7 per 1000. The abortion rate was highest for women at the age of 22. Most abortions are carried out at under 13 weeks (92%). Of the abortions performed in 2016, 2% were performed because of the risk of the child being born with serious handicap (Criteria E of the TOP act).

In a legal setting where sterile facilities are available, abortion is a safe procedure for which major complications and mortality are rare at all gestations. However, when performed in an unsafe environment abortion can lead to chronic disability.

Various methods are used to terminate a pregnancy and depends on the gestation and individual preferences. These include medical and surgical approaches. Medical abortions accounted for 62% of the total abortions in 2016. This is higher than in 2015 (55%) and more than double the proportion in 2006 (30%).

57.2 Minimum Standards and Clinical Governance Issues

Women requesting an abortion should be given written, objective, evidence-guided information to allow them to make an informed choice and

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decision-making support about their pregnancy options [5]. Women should be informed of the methods of abortion available and the characteristics of both methods. The complications, sequelea of abortion and the risks of the medical versus the surgical method should be highlighted. The need for severe bleeding requiring transfusion (1 in 1000 rising to 4 in 1000 when gestation is >20 weeks), risk of uterine perforation and cervical trauma should be mentioned. When a serious complication arises the need for further treatment (laparoscopy, laparotomy blood transfusion and hysterectomy) should also be discussed.

Abortion on grounds relating to the physical or mental health of the woman or of any existing children can be performed within the law at gestations up to 24 weeks. At all gestations up to this limit, abortion can be performed using either surgical or medical methods; however, different abortion techniques are appropriate at different gestations. It should be highlighted that a particular method may be more suitable for some women. In severely obese women, women with uterine malformations, previous cervical surgery or in women wishing to avoid surgical intervention the medical approach may be more appropriate. Where there are constraints of time or when medical methods are contraindicated the surgical method may be more suitable. Women opting for medical abortions should also be informed that this mimics a miscarriage and can take more time to complete the abortion and be somewhat more unpredictable with more clinic visits required. Whereas surgical abortions, although quicker, requires uterine instrumentation and carries a small risk of uterine or cervical injury. The procedure for the abortion should be described and the patient informed of symptoms likely to be experienced. Pain management options should also be discussed. The time likely to be taken and the postoperative follow up including contraceptive advice should be discussed. The emotional impact of an abortion should also be discussed.

Women should be informed that there is a small risk of failure to end the pregnancy (2/100 procedures) and a risk of further intervention after the initial treatment (<2% in surgical and 5% with medical). This may be a surgical intervention following a medical or re-evacuation following a surgical management.

Women should be reassured that there is no association between abortion and subsequent ectopic pregnancy, placenta praevia, infertility, breast cancer or psychological problems. They should have a pre-procedure blood test including assessment of Rhesus status and haemoglobin levels. It is also good practice to investigate for STI but this should not delay the abortion. Alternatively antibiotic prophylaxis should be given. Before a woman is discharged, future contraception should have been discussed with each woman and contraceptive supplies should have been offered.

For pregnancy less than 14 weeks a surgical or medical abortion is a feasible option. Surgical methods involve the use of vacuum aspiration using either a suction cannula or forceps if required. Oxytoxics are not recommended. Where abortion is undertaken at less than 7 weeks it is good practice to inspect the aspirated tissue to confirm completeness of products.

For medical abortion, mifepristone when used in conjunction with misoprostol is most effective.

Regimens include

- Upto 63 days: mifepristone 200 mg followed 24–48 h later by misoprostol 800 μg.
- From 64 days to 14 weeks: mifepristone 200 mg followed 24–48 h later by misoprostol 800 μg, followed by misoprostol 400 μg every 3 h until abortion occurs.

Where mifepristone is not available, misoprostol 800 μg, followed by misoprostol 400 μg every 3 h until abortion occurs.

For pregnancy greater than 14 weeks, surgical abortion can be undertaken using either a large bore cannula for vacuum aspiration or by dilatation and evacuation.

Cervical preparation should be considered before surgical abortion and both mifepristone and misoprostol are both suitable options. Where possible women's contraceptive options should be provided as part of the package of care for their abortion.

Prompt identification of features of sepsis is essential to prevent morbidity and mortality. Features of infection include:

- Raised temperature
- Guarding and rebound on abdominal examination
- Localised/generalised abdominal or uterine tenderness
- Foul smelling discharge or pus
- Hypotension
- Tachycardia
- Increased respiratory rate

57.3 Reasons for Litigation

Most cases of litigation are settled out of court and reasons for litigation include:

- Ongoing pregnancy/failed abortion
- Incomplete abortion or substantial retained products
- Infection
- Infertility
- Perforation of uterus/bowel
- Undiagnosed ectopic
- Cervical, uterine or bladder lacerations
- Sexual problems
- Emotional trauma

57.4 Avoidance of Litigation

Consenting women for an abortion should take into account eligibility in relation to the *Abortion Act 1967*. An ultrasound scan is now routinely performed to establish the gestational age of the pregnancy. In very early pregnancy a pseudo sac may be seen when there is actually an ectopic pregnancy. Where a definite intrauterine sac is not seen, the active exclusion of an ectopic is necessary. Another risk in very early abortions is the possibility that only decidual endometrium has been aspirated rather than the actual gestational sac, hence adequate safeguards are imperative to ensure the abortion is complete and include visual inspection of the products removed.

All women undergoing an abortion should be appropriately counselled about their choices, and the options available to them. Patient information leaflets should be provided, and complications discussed. Special consideration is required in cases where:

- Patients lack mental capacity.
- The abortion is biased by gender selection.
- Objections to the termination are raised by the patient's partner or family.
- The patient is under 16 years of age. The Gillick criteria are applied in cases where a parent is not involved in the decision but a doctor is justified in giving advice and treatment. In these situations the patient should be encouraged to involve a parent. It is prudent to involve the child protection team in cases where the patient is under the age of 14 years.

Patients should either be screened for STI (Sexually transmitted infections) and treated if positive or given prophylactic antibiotics if there is a failure to investigate.

In women who are rhesus negative, anti D IgG should be given intramuscularly within 72 h of the abortion.

Retained products are more likely to cause litigation when there are identifiable fetal parts. When performing a surgical evacuation it is good practice to observe whether fetal and placental tissue has been removed. When a repeat evacuation is required for retained products this should be done under antibiotic cover by a senior clinician as the risk of perforation is greater. Women with features of infection should be identified and treated promptly. When there are features of severe sepsis/septic shock this should be acted on quickly and requires prompt evacuation of the uterus in a unit with facilities for undertaking the procedure. Where these skills are not available misoprostol can be used [2].

Women who develop a complication such as a perforation should be appropriately managed with laparoscopy or laparotomy and the uterine injury adequately treated.

Conscientious objection to an abortion can result in clinicians refusing to be involved in the process. Whereas a refusal to sign the consent form would be acceptable, a refusal to deal with

a patient who becomes critically ill or requires medical care whilst waiting for or following an abortion can lead to legal action against a medical professional. There is no legal or ethical right to refuse to provide care on grounds of a conscientious objection in such situations.

Another cause for litigation related to abortion is a failure to offer a termination, and it is good practice to have a detailed documented discussion about prognosis and outcomes where abnormalities are detected on the anomaly scan. A failure to offer a termination in this setting can result in litigation.

57.5 Case Study

A 33 year old with two children and a past history of salpingitis found she was pregnant so made an urgent appointment for an abortion. On the initial scan no intrauterine sac was seen, hence she was asked to return 10 days later. On her return and second scan an 8.5 mm intrauterine sac compatible with 5 weeks gestation was seen. A Surgical termination was carried out under local anaesthesia. The procedure was straightforward. As per policy, no histology was carried out. 10 days later the patient attended with dizziness and abdominal pain. She was treated for endometritis post abortion and was discharged home on antibiotics. A week later she collapsed and was brought back to hospital and was reviewed by the same doctor who diagnosed with acute appendicitis. When the ultrasound scan revealed a large amount of free fluid in the pelvis a pregnancy test revealed she was pregnant and had a ruptured ectopic. The patient received a pay out on the grounds of negligence. There was a failure to confirm an intrauterine pregnancy from the products removed at the time of the termination as well as the failure to perform a pregnancy test at subsequent hospital admissions.

Key Points: Abortion

- Women requesting an abortion should be adequately counselled about their options and the risks and complications of the procedure.
- Preoperative investigations include an ultrasound scan and STI screening.
- When undertaking early abortions it is important to confirm that it is complete.
- Special consideration is required when patients lacking mental capacity or is under 16 years old.
- Doctors with a Conscientious objection to abortions cannot refuse to treat a patient who requires urgent care.
- Women who carry a foetus with abnormalities should be given the option of an abortion.

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Hormone Replacement Therapy (HRT)

58

Nick Nicholas

58.1 Background

About 36% of post-menopausal women in Britain were taking HRT between 1996 and 2002 (38–40% in the USA). Use fell by 21% after 2001 [1] as a consequence of fear of cardiovascular disease and breast cancer attributable to HRT use.

The principal risks of HRT are thromboembolic disease (venous thromboembolism (VTE) and pulmonary embolism), stroke, breast and endometrial cancer, and gallbladder disease. Large studies, including the Women's' Health Initiative (WHI) and the Million Women Study (MWS), have cast concerns and controversy over the use of HRT.

58.1.1 Cochrane Review (2017) [2]

This review included 22 double-blinded randomized controlled trials (RCTs) (43,637 women). In relatively healthy postmenopausal women, using combined continuous HRT for 1 year increased the risk of a heart attack from about 2 per 1000 to between 3 and 7 per 1000, and increased the risk of venous thrombosis from about 2 per 1000 to between 4 and 11 per 1000.

With longer use, HRT also increased the risk of stroke, breast cancer, gallbladder disease and death from lung cancer.

Oestrogen-only HRT increased the risk of venous thrombosis after 1–2 years' use: from 2 per 1000 to 2–10 per 1000. With longer use, it also increased the risk of stroke and gallbladder disease, but it reduced the risk of breast cancer (after 7 years' use) from 25 per 1000 to between 15 and 25 per 1000.

Among women over 65 years of age taking continuous combined HRT, the incidence of dementia was increased. Risk of fracture was the only outcome for which results showed strong evidence of clinical benefit from HRT (both types).

This study agreed with the initial WHI study [3] although the coronary heart disease risk in younger women was reduced in women within 10 years of the menopause by −6/10000 women years. Whereas the risk increased in women given HRT >20 years past the menopause to +17/10000women years.

Reanalysis of the WHI data [4, 5] revealed that HRT had a complex pattern of risks and benefits and concluded that HRT did NOT support its use for chronic disease prevention but more so for symptomatic symptom management.

The Million Women Study [6] was an observational study looking at the risks of breast cancer in >800,000 women on HRT concluded that

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combined HRT increased the risk of breast cancer more than estrogen only or Tibolone. The risk increased with more prolonged use, and transdermal estrogen did not appear to be associated with any prothrombotic risk.

Other studies KEEPS [7] and Schierbeck et al. [8] looked at the timing and effect of long term HRT use and confirmed the cardioprotective effect of early HRT use, and persistence of beneficial effect for 6 years post stopping HRT.

58.2 Minimum Standards and Clinical Governance Issues

NICE [9] have published guidance on the management of the menopause. It refers to an 'individualised approach'. Menopausal women should be given information that includes:

- An explanation of the stages of menopause.
- Common symptoms and diagnosis.
- Lifestyle changes and interventions that could help general health and wellbeing.
- Benefits and risks of treatments for menopausal symptoms.
- Long-term health implications of menopause.

Women with menopausal symptoms should weigh up the pros and cons of symptomatic relief against the small absolute risk of harm arising from short-term use of low-dose HRT, provided they do not have specific contraindications such as an increased risk of Cardiovascular Disease (CVD), thromboembolic disease or breast and endometrial cancer.

Tibolone, a selective tissue estrogenic activity regulator, is effective in treating symptoms in postmenopausal women. The *LIBERATE* study [10] demonstrated the risk of breast cancer recurrence was higher for women on tibolone compared to placebo (HR: 1.40, 95% CI: 1.14–1.70, p = 0.01). The Million Women Study identified a significantly increased risk of breast cancer diagnosed in tibolone users (relative risk [RR] 1.5 [95% CI 1.3–1.7]), which is comparable with that for oestrogen-only HRT (1.3 [1.2–1.4]) and significantly lower than that for combined HRT (2.0 [1.9–2.1]).

There is limited evidence about HRT and risk of breast cancer for women with a family history of breast cancer. Available evidence suggests that family history has ***no additive*** impact on risk of breast cancer with HRT usage [11, 12].

- Women with a family history of breast cancer should be advised that family history does ***not*** appear to have an additive impact on risk of breast cancer with HRT usage.
- Women with a family history of breast cancer with a prior hysterectomy should be advised that short-term, oestrogen-only HRT would appear preferable to combined HRT.

58.2.1 BRCA Carriers

BRCA1 gene is associated with an increased risk of breast cancer by age 70 years of 60–65% and of ovarian cancer of 39–59%. BRCA2 gene is associated with risk of breast cancer by age 70 years of 45–55% and of ovarian cancer of 11–17%. Risk-reducing surgery with mastectomies and bilateral salpingo-oophorectomy (BSO) is usually carried out when the family is complete. The effect of this is a reduction in the incidence of ovarian, fallopian tube and peritoneal cancer risks by 72–80%, and reduction of breast cancer risks by 46–48% in premenopausal women [13].

Findings suggest that a short course of HRT should not be contraindicated for BRCA1 mutation carriers who have undergone menopause and who have no personal history of cancer [14]. The use of HRT following risk-reducing surgery appears to be safe with no additional increase of breast cancer, especially if estrogen-only therapy is used [15].

In April 2016 the **International Menopausal Society** [16] published guidance on the risks and benefits of HRT which differed with age and years since the last menstrual period.

The Key Points were:

58.2.2 Postmenopausal Osteoporosis

HRT is the most appropriate therapy for fracture prevention in early menopause [A].

Cardiovascular Disease

Key points

- In women under age 60 and recently postmenopausal with no evidence of cardiovascular disease, the initiation of estrogen-alone therapy ***reduces*** coronary heart disease (CHD) and all-cause mortality [A].
- Data on daily continuous combined estrogen–progestin are less robust but other combined therapy regimens appear to be protective as shown in Danish and Finnish studies [A].
- Recent meta-analyses and WHI 13-year follow-up data all show a ***consistent reduction*** in all-cause mortality for HRT users [A].
- It is ***not recommended*** to initiate HRT ***beyond age 60 years*** solely for primary prevention of CHD [A].

Venous Thrombolembolism

Key points

- A careful assessment of personal and family history of venous thromboembolism (VTE) is essential before prescribing HRT.
- Oral estrogen is contraindicated in women with a personal history of VTE [A].
- Transdermal estrogen should be first choice in obese women with Vasomotor symptoms (VMS) [B].
- VTE risk increases with age and with thrombophilic disorders.
- The risk of VTE increases with oral HRT but is rare below age 60.
- Observational studies and biological plausibility point to a lower risk with low-dose transdermal therapy.
- Some progestogens may be associated with a greater VTE risk [C].
- The incidence of VTE is less frequent amongst Asian women [C].
- Population screening for thrombophilia is ***not*** indicated prior to HRT use [C].

Breast Cancer

Key points

- The risk of breast cancer associated with HRT in women over 50 is complex.
- The increased risk is primarily associated with the addition of a synthetic progestogen to estrogen therapy and to duration of use [B].
- The risk may be lower with micronized progesterone or dydrogesterone [C].
- The HRT attributable risk is small and decreases when treatment stops [B].
- There is a lack of safety data supporting HRT use in breast cancer survivors.
- Breast cancer risk should be evaluated before HRT prescription [D].
- Any possible increased risk associated with HRT may be decreased by selecting women with lower baseline risk including low breast density and by providing education on preventive lifestyle measures (reducing weight, reducing alcohol intake, increasing physical activity) [D].

Endometrial Safety and Bleeding

Key points

- Postmenopausal bleeding is 'cancer until proven otherwise'.
- 1–14% of women with postmenopausal bleeding will have endometrial cancer.
- Blind endometrial sampling is an appropriate first-line investigation [B].
- Unopposed estrogen therapy is associated with a dose and duration-related increased risk of endometrial cancer [A].
- Endometrial protection requires an adequate dose and duration of progestogen [A].
- For doses of estradiol of 2 mg/50 μg, an adequate dose of micronized progesterone appears to be 200 mg for 10–14 days per month or 100 mg daily for continuous therapy [B].
- Higher doses of progesterone may be required for higher estradiol doses or in women with high body mass index.

Colorectal Cancer

Key points

- Observational studies show a reduced risk of colorectal cancer (CRC) amongst users of oral HRT [B].
- Three meta-analyses have reported a reduced risk of CRC with HRT use [A].
- Results from WHI showed no effect for estrogen-only therapy on CRC risk [A].
- Results from WHI showed reduced risk of CRC with estrogen + progestin therapy [A].
- There are limited data on the effect of non-oral HRT on CRC risk.
- One randomized, controlled trial in older osteoporotic women using tibolone reported a reduced risk of colorectal cancer [A].
- HRT should not be used solely for the prevention of CRC [D].

Other Cancers

Key points

- In WHI there was no increase in risk of cervical cancer [A].
- Long-term cohort studies have found no increase in cervical cancer with HRT use [B].
- The association between HRT and ovarian cancer remains unclear.
- In WHI neither estrogen or estrogen + progestin demonstrated a significant increase in lung cancer incidence [A].
- There is no clear association between HRT use and hepatocellular carcinoma [C].
- HRT use may be associated with reduced risk of gastric cancer [C].
- There are few good studies examining links between upper GI cancers, menopause and HRT use.

Androgen Therapy

- Testosterone therapy should be considered as a clinical trial which should not be continued if a woman has not experienced benefit by 6 months [A].

Complimentary Therapies and Bioidentical Therapies

Key points

- Complementary therapies have ***limited evidence*** of efficacy and are not regulated by medicines agencies [B].
- Cognitive behavioral therapy, mindfulness training, acupuncture, hypnosis and stellate ganglion blockade may be useful techniques to consider when treating VMS [A].
- Prescribing bioidentical hormone therapy (BHT) is not recommended due to lack of evidence of efficacy, lack of quality control and lack of regulatory oversight [B].
- The use of serum or salivary hormone levels is not recommended to assist in the management of HRT [B].

58.3 Reasons for Litigation

- Doctors considering prescribing HRT to menopausal women seeking treatment for distressing symptoms have a duty of care to give their patients the pros and cons of the proposed treatments. Patients expect to be given all 'material' risks regarding the HRT so that they can make an 'informed decision'.
- Estrogen only HRT given in women with a uterus.
- Unnecessary HRT prescribing.
- Failure to prescribe HRT when indicated.
- Complications arising from HRT including VTE, Breast Ca, Ovarian Cancer, lymphoma, strokes and heart attacks.
- Delay in diagnosis of these complications.

58.4 Avoidance of Litigation

There is still considerable confusion amongst GPs and hospital specialists as to what advice menopausal women should be given so that they can make an informed decision as to whether or not the risk/benefit ratio is acceptable to them.

Counseling patients on 'material risks' has to be documented and the doctor has a responsibility to make sure that the patient has understood and assimilated these risks.

Wherever possible, patients should be given absolute risks in order to be able to make an informed judgment of the actual magnitude of the risks involved. However, the risks are often based on inaccurate or skewed data and even with the best intentions RCTs can be open to selection bias and differences between study groups.

The law on consent has changed considerably in the past few year and is dealt with in detail in the chapter on Consent after Montgomery [14]. In relation to HRT a crucial part of the judgment in this case refers to ***'material risk'***.

'The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.' The question is how to translate these precise ideals into clinical practice.

When counseling patients about HRT, the doctor is advised to refer to national or professional guidelines on the use of HRT. Unfortunately, the data is not absolute and patients should be made aware of the potential problems with the data. Data must be given in a comprehensible non technical form. Any deviation from the guidelines must be clearly documented and the reasons given for doing so. Deviation from any guideline is a risky strategy best avoided. Table 58.1 is a useful guide to help quantify risks associated with HRT use. It is by no means absolute but helpful during counseling.

Wherever possible, patient information leaflets and any other available resources should be given to the patient. Time must be allowed for the patient to absorb and assimilate the information and time given for more questions to be answered and more than one appointment may be required. Complete and contemporaneous records of all consultations and discussions regarding risks and benefits of HRT usage should be documented.

When a potential complication is diagnosed it is important that appropriate steps are taken to exclude the diagnosis within a reasonable timescale and depending on the seriousness of the problem.

58.5 Case Study

A 51-year old woman first saw their GPT with menopausal symptoms. An FSH level of 66, indicated that the patient was menopausal.

Following a discussion of the pros and cons of HRT, the patient opted to commence treatment. Her GP prescribed Elleste-Solo tablets—an unopposed oestrogen treatment. She presented 8 months later with vaginal bleeding after intercourse. An Ultrasound scan reported a bulky uterus with several rounded mixed echo structures suggestive of fibroids. Due to the Postmenopausal bleeding she was referred to a gynaecologist who performed a diagnostic hysteroscopy and endometrial biopsy. The endometrial biopsy showed moderate atypical glandular hyperplasia with no features of malignancy.

Table 58.1 Medicines and Health Regulatory Agency (MHRA) Guidance taken from the British National Formulary [17]

Risk	Age range (years)	Background risk/1000 non HRT user women	Additional cases/1000 women on estrogen only		Additional cases/1000 women on E2 and progesterone		
Years of use		>5 year	>10 year	>5 year	>10 year	>5 year	>10 year
Breast	50–59	10	20	2	6	6	24
	60–69	15	20	3	9	9	36
Endometrial	50–59	2	4	4	32	NS	NS
	60–69	3	6	6	48	NS	NS
Ovarian	50–59	2	4	<1	1	<1	1
	60–69	3	6	<1	2	<1	2
VTE	50–59	5	–	2	–	7	–
	60–69	8	–	2	–	10	–
Stroke	50–59	4	–	1	–	1	–
	60–69	9	–	3	–	3	–
CHD	70–79	29–44	–	NS	–	15	–

The patient was seen for follow up 1 month later. The consultant explained that the findings indicated that the endometrium had been affected by the course of unopposed oestrogen. Although there was no absolute indication for a hysterectomy, the patient was very anxious about the results and opted to have a hysterectomy.

A claim for compensation was made on the basis that it had been negligent to prescribe unopposed oestrogen to a patient with an intact uterus, leading to the patient undergoing an unnecessary hysterectomy. The GP had documented in the notes that the patient would need combined therapy because she had a uterus, but inadvertently the wrong product had been selected from the computer medication list, which went unnoticed and was issued on repeat prescription. The GP accepted responsibility and the expert gynaecologist concluded that the moderate atypical glandular hyperplasia was caused by the unopposed oestrogen.

The patients gynaecologist accepted that there was no absolute indication for a hysterectomy in this case and the the claim was subsequently settled for a sum of £28,000 in damages and £14,000 in legal costs.

Key Points: HRT

- Women experiencing a spontaneous or iatrogenic menopause before age 45 and particularly before age 40 are at higher risk of cardiovascular disease and osteoporosis. In these women, in the absence of contraindications, HRT is advised at least until the average age of menopause.
- Counseling on HRT should convey risks and benefits in *clear and comprehensible terms*, ideally expressed as absolute risk in real numbers.
- HRT should not be recommended without a clear indication for its use.
- Women taking HRT should have at least an *annual* medical consultation.
- There are *no reasons* to place a mandatory limit on the duration of HRT.
- Dose and duration of HRT should be consistent with treatment goals.
- Whether or not to continue should be decided at the *discretion of the well-informed woman and her health professional.*

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Long-Acting Reversible Contraception

59

Raj Mathur and Swati Jha

59.1 Background

Access to safe and effective contraception is a cornerstone of reproductive right and women's health. Long-acting Reversible Contraception (LARC) methods are an important part of the options available to women and their doctors in providing good woman-centred care. In contrast to some other commonly used methods, such as oral contraceptives and barriers, the effectiveness of LARC does not depend on daily administration or consistent techniques.

LARC refers to both hormonal and non-hormonal methods that require use less frequently than once every month or every cycle. Methods include the copper Intra-uterine device, progestagen-releasing intra-uterine system, depot progestogen and progestogen implant.

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59.2 Minimum Standards and Clinical Governance Issues

NICE guidance covering the use of LARC (CG30) was published in 2005 and last updated in 2014 [1]. It specifically aims at increasing the uptake of LARC among women in the UK, by improving professionals' awareness and ability to offer this as a choice to women. The guideline stresses the importance of informed consent and addressing patient preference. As in any other clinical situation, guidance on consent is relevant. In women with reduced capacity, the Mental Capacity Act and Deprivation of Liberty Safeguards provide further guidance for clinicians.

When prescribing LARCs in teenagers (under 16 years of age) in the absence of an adult, it is important to establish they are Gillick competent. If felt to be Gillick competent, it should be discussed with the patient whether she has intent to discuss or inform a trusted adult. If the child is under 13 and seeking advice about contraception or sexual activity, the safe guarding lead should be informed. This should also be discussed with the child.

NICE CG30 lays down specific requirements for counselling patients, including the provision of detailed verbal and written information about contraceptive efficacy, duration of use, risks and possible side effects, non-contraceptive benefits, the procedure for initiation and removal/discontinuation as well as when to

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seek help while using the method. Healthcare professionals advising women on these options should have the relevant competence, and those carrying out insertion of intra-uterine and subdermal contraceptives should have specific training for these.

Clinical guidance on specific LARC techniques has been published by the Faculty of Sexual and Reproductive Health (FSRH)—Intra-Uterine Contraception (IUC) [2], Progestogen-only implants [3], Progestogen-only injectable contraception [4]. Health professional should be familiar with UK Medical Eligibility Criteria (UKMEC) updated in 2016 [5].

The need for testing for sexually-transmitted infections should be based on an individual assessment. In asymptomatic women, there is no requirement to await the results of testing before inserting an intra-uterine device, provided the woman can be contacted and treated promptly in the event of a positive result. The rate of uterine perforation associated with IUC is up to 2 per 1000 insertions and is approximately sixfold higher in breastfeeding women. The risk of expulsion with IUC is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion. Women should be advised on how to check for threads and, to seek medical advice and use alternative methods of contraception if the threads are not palpable. A follow-up visit after insertion is not essential, provided appropriate information has been provided.

The overall risk of ectopic pregnancy is reduced with use of IUC when compared to using no contraception, but if pregnancy does occur the risk of an ectopic pregnancy is increased. FSRH guidance states 'IUC users should be informed about symptoms of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in women with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If a pregnancy test is positive an ultrasound scan is urgently required to locate the pregnancy.'

For progestogen-only implants, FSRH guidance states that no additional measures are required if re-insertion occurs within 3 years of first insertion. If pregnancy is not desired immediately, contraceptive measures are needed following removal of an implant. Women should be advised to seek medical help if they cannot feel the contraceptive or it appears to have changed shape. If the implant is not palpable, alternative contraception should be advised until the location has been established. Removal of mislocated implants should be carried out by an expert, aided by imaging to determine the location of the implant. In the event of pregnancy, women should be advised removal of the implant although there is no clear evidence of harm if it is not removed. Women should be informed that certain medications may reduce the effectiveness of the implant and additional contraceptive measures should be used for 28 days after the use of these medicines.

FSRH guidance on the use of Depo Medroxy-Progesterone Acetate (DMPA) advises that women using this method should be reviewed every 2 years to assess benefits and potential risks. DMPA use is associated with weight gain, particularly in women under the age of 18 who are obese. Women should be advised to return every 13 weeks for a repeat DMPA injection, but repeat injections can be given up to 14 weeks apart without the need for additional precautions. Following stopping DMPA, unless she wishes to conceive, the woman should be advised to use contraception from the date when her next injection would have been due, even if she is still amenorrheic. Women should be advised that fertility may take up to a year to return following discontinuation of DMPA, hence this may not be a suitable method for women who may wish to start trying for a baby in the near future, particularly if they are older than their early thirties.

Both implants and DMPA are associated with a reduction in bone density though this is relatively small and stabilises after a few years. Cessation of use is followed by improvement in bone density. Caution is therefore required when prescribing these in adolescents, women over the age of 40, with other risk factors for osteoporosis or planning on using this long term.

59.3 Reasons for Litigation

1. IUC—uterine perforation, insertion of second IUC with previous one in situ, insertion while pregnant, unrecognized expulsion.
2. Progestogen-only implants—non-insertion, deep insertion, neurovascular injury, adverse cosmetic outcome (scarring).
3. Progestogen-only injections—undiagnosed vaginal bleeding due to unrelated organic pathology, delayed return of fertility.
4. All methods—confidentiality, communication and consent.

59.4 Avoidance of Litigation

NICE and FSRH guidance offers clinicians a reliable set of principles upon which to base their care. However, not all clinical situations can be covered by guidance and good clinical judgment and patient information is key. Counselling should take into account patient preferences and alternatives informed by evidence and good practice. Patients should be informed of failure rates, risks and complications. Appropriate follow up should be set up.

Adequate clinical records are critical in delivering high quality care and handling complaints and may help prevent litigation in the first place. The FSRH has developed service standards for record-keeping in contraception [6]. Concordance with UKMEC should be recorded, along with patient consent, offer of chaperone and patient participation in decision making. The information provided should be recorded, along with source and date. All letter, referrals and communication by email, text and other means should be recorded. A note should be made of the preferred mode of communication and any restrictions on communication.

Adequate measures must be taken to exclude pregnancy prior to starting any form of LARC. FSRH guidance advises that Health professionals can be 'reasonably certain' that a woman is not currently pregnant if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since last normal menses.
- She has been correctly and consistently using a reliable method of contraception.
- She is within the first 7 days of the onset of a normal menstrual period.
- She is not breastfeeding and less than 4 weeks from giving birth.
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months' postpartum. She is within the first 7 days postabortion or miscarriage.

A negative pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if ≥3 weeks since the last episode of unprotected sexual intercourse (UPSI). In addition, health professionals should also consider whether a woman is at risk of becoming pregnant as a result of unprotected sexual intercourse within the last 7 days.

Ensuring adequate training and continued competence is crucial for professionals providing intra-uterine or subdermal contraceptives. With subdermal contraceptives, the introduction of the single rod Nexplanon system is likely to reduce the risk of unrecognized non-insertion. Nexplanon is radio-opaque, allowing easier localization with X-ray. Manufacturer's instructions on the site of insertion have been modified to reduce the risk of injury to the neurovascular bundle.

Uterine perforation at the time of insertion of an IUC should be suspected if the inserter or uterine sound passes a greater distance into the uterus than expected. In such a situation, the device should be withdrawn and the procedure abandoned. More often, the perforation manifests as pelvic pain persisting a few days after insertion. IUC threads may not be present in the vagina if the device has migrated through the myometrium. An ultrasound scan should be arranged without delay, usually in a hospital setting.

It should not always be assumed that missing IUC threads are due to expulsion of the device. An ultrasound scan may show that the device is within the uterus, but the threads are not visible due to short length or increased uterine size due

to fibroids. In this situation, removal of the *in situ* device is required before inserting a new IUC (or advising another contraceptive method).

59.5 Case Study

Case 1: Mrs. Blyth (Blyth vs. Bloomsbury Health Authority (1993) 4 Med LR 151) brought an action of negligence for being prescribed the depot without being informed of the unpleasant side effects including spotting. This was in spite of the patients manifest desire to be informed of these risks. Though there was no proof that this actually was the case, it was accepted that there had been some miscommunication and a nominal pay out was made. Issues surrounding this case relate to consent and disclosure and in the court of appeal it was felt that the standard of disclosure should not be any different in cases where the patient has requested information.

Case 2: A patient attended her GP practice to have a coil fitted. Although asked about the date of her last period her GP failed to enquire whether she had had intercourse since this date. A Mirena was fitted uneventful. Three months later, the patient experienced heavy bleeding and was prescribed hormonal treatment to regulate her periods. Wishing a second opinion the patient attended the walk in centre where a pregnancy test was positive. A subsequent scan revealed a 17 week pregnancy. The fetus was abnormal and she went on to have a termination.

There was a failure to follow national guidelines for fitting and was therefore felt to be negligent. The coil should have been fitted within 7 days of the onset of menstruation or the possibility of pregnancy should have been excluded. Though the patient conceded that she would still have undergone a termination had the pregnancy been diagnosed prior to the fitting of the coil, this would have been less traumatic and avoided the discomfort, anxiety and bleeding caused by the Coil being fitted when pregnant. The patient reported the doctor to the GMC and received a pay out of £10,000.

Key Points: LARC

- LARC refers to both hormonal and non-hormonal methods that require use less frequently than once every month or every cycle and include the copper Intra-uterine device, progestagen-releasing intra-uterine system, depot progestogen and progestogen implant.
- Women considering LARC methods should receive detailed information-verbal and written to enable them to choose a method and use it effectively.
- Women should be informed of the efficacy, duration of use, risks and possible side effects, non contraceptive benefits, the procedure for insertion and removal and when to seek help. Informed consent is essential before fitting.
- Pregnancy should always be excluded before commencing a LARC.
- Healthcare professionals should have adequate training and experience of providing these methods.
- In women with learning difficulties and teenagers under 16, special caution is required.

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Sterilisation

60

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60.1 Background

Female sterilisation was one of the commonest procedures carried out in the UK but there has been a decline over the past decade due to increased use of alternative contraceptives e.g. long acting reversible contraception (LARC). Female sterilisation is a permanent, non-reversible procedure. Therefore, patients need to be certain that they have been counselled appropriately before undergoing such a procedure. There is now only one main type of female sterilisation: Filshie clip laparoscopic sterilisation. The previous availability of the Essure hysteroscopic sterilisation procedure has now been withdrawn from the UK market as of September 2017.

60.2 Minimal Standards and Clinical Governance Issues

Guidance on standards for female sterilisation have been issued by the RCOG and Clinical Effectiveness Unit (CEU) of the Faculty of Sexual & Reproductive Healthcare (FSRH) [1–3].

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There should be clear, contemporaneous documentation within the medical records and a preoperative check list should be completed with written consent obtained. This should include appropriate medical history and any clinical examination. The records should document the discussion that took place, requests made by the individual and any information provided. The reason for the sterilisation should be documented.

Legal advice should be sought if there is any doubt as to whether a person has the mental capacity to consent to a procedure that will permanently remove their fertility.

Counselling for the permanency of the procedure and lifetime failure rate of 1:200, with a possibly increased failure risk if the sterilisation is performed in the postpartum or post abortion period. In the postpartum period, the use of Filshie clip and modified Pomeroy technique are equally effective except that Filshie clip application is quicker to perform. Mechanical occlusion using the Filshie clip should be the method of choice for laparoscopic tubal occlusion.

Alternatives for permanent methods of sterilisation should be discussed e.g. Mirena coil and/or vasectomy. Women should be informed that some of these procedures have a lower failure rate (vasectomy), whereas others such as long-acting reversible contraceptives (which include injections, intrauterine devices (IUDs) and subdermal contraceptive implants) have a similar

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failure rate and confer additional benefits related to menstrual cycles.

There are few situations which preclude a sterilisation but greater precautions are needed in women on anticoagulation therapy, cardiovascular disease, previous abdominal surgery and in those who are obese. For a hysteroscopic sterilisation, nickel allergy would be a contraindication. Higher regret rate are known to occur if sterilisation is performed in under 30 year olds, in nulliparous women, following a recent pregnancy or in women who have relationship issues. When sterilisation is performed during a Caesarean section, counselling and consent should be given at least 2 weeks in advance of the procedure.

It would be routine to provide a current valid written patient information leaflet, that includes operative risks from laparoscopy, that could lead to a laparotomy, particularly if there are co-existing risks e.g. obesity or prior abdominal surgery.

Assessment pre-operatively should include routine use of pregnancy test, record of last menstrual period, use of contraception during the cycle. Tubal occlusion can be performed at any time during the menstrual cycle as long as the woman has used an effective method of contraception up to the day of the procedure. However, a luteal phase pregnancy cannot be excluded with a negative pregnancy test hence the importance of emphasising the use of contraceptive in the cycle that the sterilisation is performed.

The procedure should be performed by an experienced surgeon undertaking at least 25 procedures per year.

The laparoscopic tubal occlusion should be with the use of a Filshie clip applied at the thinnest part of the fallopian tube i.e. at the isthmus level of the fallopian tube. It should be applied perpendicular to the fallopian tube and the clip should be applied to fully envelope the fallopian tube without leaving a knuckle of fallopian tube. This can be assured by having the ante-mesenteric border of the fallopian tube sit at the level of the hinge with no obvious gap between the hinge and the fallopian tube. Steri-Shot™ disposable Filshie clip applicators should now be used in preference to the older applicators that required maintenance on a yearly basis or every 100 applications. The new disposable applicators have removed the need to ensure that correct pressure closes and locks the Filshie clip. The Filshie clip should only be applied after identification of the fimbrial end of the fallopian tube so that the correct structure is occluded. Filshie clip should be applied slowly without tearing the fallopian tubes, as this can result in a subsequent tubo-tubo fistula.

Common mistakes are applying the Filshie clip to the wrong structure i.e. the round ligament. Photographs should be taken post procedure for good clinical practice. The routine use of more than one Filshie clip on each fallopian tube is not recommended.

The use of other methods such as electrocautery, Hulka, fallope rings should not be used as the failure rates are much higher than the 2–3: 1000 associated with the Filshie clip method.

Post procedure contraception should be continued preferably until the next menstrual period starts. Removing a coil during the sterilisation may inadvertently result in unintended pregnancy if ovulation has occurred prior to the procedure and a blastocyst has already passed the site of the tubal occlusion.

60.2.1 Specific Additional Aspects for Hysteroscopic Sterilisation

This procedure can be carried out without any anaesthesia. Local anaesthesia may be used if there is difficulty in passing the hysteroscope through the cervix.

Specific consent requires that contraception should be used for an additional 3 months until tubal occlusion has been confirmed by ultrasound scan or hysterosalpingogram. The latter is used if there was a difficulty in placing the Essure devices. Counselling should also include the failure of placement of the second device in up to 0–19% of cases, whereby an additional method

may be required i.e. a repeat attempt for hysteroscopic sterilisation or undergoing a laparoscopic sterilisation procedure.

Women who do not attend for confirmatory tubal occlusion testing should continue using a reliable form of contraception. Essure is as effective as laparoscopic tubal occlusion with a failure rate of approximately 1:200.

There is evidence that there is a 6–10 times more likely increased risk of operative intervention within one year of Essure sterilisation procedures [4–6]. Around 2% of women within one year require alternative methods of sterilisation because of the inability to place the devices, have the devices removed because of incorrect placement or due to symptoms causing pelvic pain (https://www.fsrh.org/documents/fsrh-statementessurebmj/fsrhstatementessurebmj.pdf).

As a result of the continued debate regarding the safety of the Essure method [7], the Essure method has now been withdrawn from the UK market. However, patients who have already had these devices fitted may present to clinicians in the coming years and request them to be removed.

Late failures resulting in a pregnancy can occur at any time after tubal occlusion with both methods. There is a higher risk of ectopic pregnancy when failures occur. When a pregnancy occurs while an individual is on a waiting list for sterilisation they should be offered further counselling about future contraceptive choices due to change in their circumstances.

60.3 Reasons for Litigation

The main reasons for litigation in cases of female sterilisation relate to:

- Counselling
- Patient pregnant at the time of sterilisation (luteal phase pregnancy)
- Procedure related complications
- Post-operative care
- Failure
- Litigation occurs when the wrong structure has been occluded e.g. round ligament rather than the fallopian tube. There is evidence that failure that occurs within 12 months of laparoscopic tubal occlusion this is likely to be due to operator error rather than a non-negligent tubo-tubo fistula [8].

60.4 Avoidance of Litigation

It is important to follow the principles set out in the checklists given above for each type of sterilisation method.

Adequate documentation of the reasons for the sterilisation as well as the permanency of the procedure, its alternatives, failure, ectopic pregnancy and risks associated with the actual procedure need to be clearly documented. Contraceptive advice leading up to and following the procedure must be given. Due care and diligence when performing the procedure should be taken to avoid failure. When a laparoscopic procedure is undertaken the fimbrial end of the tube should be identified before application of the Filshie clip which should be placed over the isthmic (thinnest) portion of the tube to ensure complete tubal occlusion. When a hysteroscopic procedure is performed additional counselling should include the need for contraception following the procedure and until confirmation of tubal occlusion as well as the higher re-operation rate in the first year.

Female sterilisation still represents a good method for permanent contraception but patient counselling and up to date written information is important to avoid litigation in the future.

60.5 Case Study

A 27-year-old woman with 3 normal vaginal deliveries was sterilised with placement of two Filshie clips on the right fallopian tube and one on the left. She had been appropriately counselled and the appropriate consent was taken. During the application of the first Flishie clip

application to the right fallopian tube, the pneumoperitoneum was not maintained and therefore a second Filshie clip was applied. She was found to be pregnant 14 months later and delivered a healthy baby. The photographs taken at the time of sterilisation indicated that both of the right fallopian tube Filshie clips were applied distal to the isthmus i.e. beyond the thinnest part of the fallopian tube. It is likely that the occlusion was not complete with an obvious gap between the fallopian tube and the hinge of the Filshie clip indicating that there was likely to be a knuckle of tube left unoccluded. The left Filshie clip was appropriately applied.

Ultimately identification of the failure can only be determined by removal of both fallopian tubes to assess histologically for the reasons of failure and to complete the sterilisation effect.

Key Points: Sterilisation

- There are two main methods for female sterilisation: laparoscopic by Filshie clips (usually by general anaesthesia) and hysteroscopic using Essure (outpatient under local anaesthesia). The latter is now withdrawn from the UK marker as of September 2017.
- Essure hysteroscopic methods are associated with a higher re-operation rate in the first year.
- Clear, contemporaneous documentation and a valid consent should be obtained.
- Counselling of permanency, failure, alternatives, risks, complications and regret.
- Contraceptive advice before and after the procedure depending on the procedure undertaken.
- Due diligence when performing the procedure to avoid failure.

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Part VII

Oncology

Swati Jha and John Murdoch

61 Fast Track Referrals and GP Perspectives

Rahul Kacker

61.1 Background

In providing clinical care from "cradle to grave" General practitioners are presented, in the paradigm of Obstetrics, from pre-conception to the postpartum and Gynaecological conditions from menarche to post menopause. Unlike a hospital clinic, patients present to a General Practice surgery, in an undifferentiated way, that is to say with symptoms that often have differential diagnoses rather than a specific disease entity. General practitioners therefore manage symptoms not only across a woman's life span but also across the entire reproductive tract. Some GPs have just a basic working knowledge the basis of which may have been their Undergraduate studies only whereas others may have worked in a hospital post as part of their Vocational training and may or may not, have taken the a Post graduate exam in the field (The Diploma of the Royal College of Obstetricians & Gynaecologists i.e. (DRCOG)). Yet others may had more specialist training in Obstetrics and Gynaecology and been awarded the MRCOG before changing career paths to become a General Practitioner, and some may be General practitioners with special interests (GPwSI) with or without formal qualification but have acquired the necessary knowledge skills and through numerous patient contacts developed the experience.

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61.2 Minimum Standards and Clinical Governance Issues

To improve care and cancerous disease detection NICE introduce the "Fast track referral system". This, by active practicising GPs, is better known as the "2 week wait referral" (2ww) after the time within which the patient much be seen by the relevant Consultant. Review of the publication will show that there are specific symptoms in specific age groups of women that on their own, necessitate a "2ww": this is a common notation seen when reviewing computerised GP records [1]. The outcome is unpredictable and, that this process although well established in contemporary practice has not significantly improved gynaecological cancer rates is out of the scope of this publication, but knowledge that the process exists is empirical for both GPs managing such patients and medico-legal experts acting for either the Plaintiff or Defendant. Borne out of the prevailing austerity, and aside from the "cancer 2-week-wait referrals" are the local guidelines for the management of women' health symptoms. The purpose of these are to optimise the management by the General Practitioner of a symptom and if

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the symptom does not improve only then to refer to secondary care**.** The authors of these are usually CCG GPs in collaboration with local Consultants, usually based on NICE guidance for that conditions but refined and made more specific in the knowledge of what investigations can and cannot be accessed by GPs locally. In addressing Standards and Governance, attention is drawn to when a GP does not manage a patient within the guidelines: but reflection and thought is called for they are after just that "guide"-lines not tramlines. Here the "art" of General Practice comes to the fore.

61.3 Reasons for Litigation

Common reasons for Litigation include:

- Missed diagnosis or a delay in referral. This is usually due to a failure to investigate appropriately for persistent or frequent symptoms.
- Failure to identify the criteria for referral as stipulated in NICE Guidelines 12 (NG12) [1].
- Failure to make patients aware of what to expect in the referral pathway and how soon to expect a hospital appointment.
- Failure to document discussions with the patient about the reasons for the referral and the advice provided.
- When a patient is not referred immediately, failure to schedule either a further review or in what circumstances they need to seek further advice.
- Failure to ensure systems are in place to follow up investigation results. Where the requesting physician is unable to do so, this should be delegated appropriately.

61.4 Avoidance of Litigation

The Claimants Expert may be instructed to opine justifiably on what the standard of note-keeping in the case being deliberated is thought to be. The RCGP Good Medical Practice may well be cited and or used to benchmark the standard of record keeping This state's "documents should enable you, other doctors and other clinical staff to understand the care the patients have been given. Medical records provide the basis for future care and are the main way to share information with other members of the practice team who may be providing care for a patient. Records of consultations should include the presenting problems, results of relevant examinations or investigations undertaken, and an indication of the management plan, including expressed patient wishes." This provides a recognised and authoritative bench mark against which the GPs records of the consultations regarding the care given will be measured. In claims of negligence, not only is the standard of care called into question so is the standard of note keeping, To mitigate against litigation keeping records as described above is the necessary goal and therein lies the challenge to General Practitioners when a patient presents with an undifferentiated women's health symptom as opposed to a definitive diagnosis. A defence Expert and the legal team's role will be greatly facilitated and more robust if notes are written to the standard described above, indeed, notes of the quality described above may even thwart any potential action by the claimant at the screening stage.

Having detailed why the notes are as important as described, we turn now to suggest how the notes could be structured to meet this description. One suggested method is that the clinician having documented the presenting symptom or symptoms, then, ideally, asks and then documents all the positive and negative associated symptoms in the history of the presenting complaint. Asking and documenting of a familial history of women's health illness in particular cancers and or the fact that they were screened for this, might prove a powerful piece of evidence, should ones care be questioned. Asking and then documenting the patients thoughts and then later in the notes under diagnosis or plan, addressing these, with a clinical justification, also could proves helpful to one's Defence team. As can be seen form the description form Good Medical Practice there is no set method, the method suggested here is but one and is easy to reproduce day-in day-out, but the failure to ask, or least documents this information might provide the chink that can be made a chiasm by the Claimants team:, on the other end

its presence may make the negligence claim untenable: two sides of the same coin.

Timely referral of suspicious gynaecological symptoms should avoid litigation. To achieve this knowledge of the current guidelines is needed. With the breadth and pace of the advancement of knowledge across the specialities that make up Clinical Medicine lies the challenge to keep up to date. This is especially challenging as female patients often self select, where one is available, female doctors therein over time serruptiously deskilling male General Practitioners. It is important to ensure one is practising contemporarily by using appropriate investigations, treatments and ensuring timely referral is best achieved and maintained. By identifying their Educational Needs and then by reading and documenting that these have been addressed in the annual appraisal process, GPs demonstrate they are up-to-date with the latest guidance. A more immediate way of addressing a patient's clinical need is triangulation with other General Practice Colleagues in the practice and documentation there of as to "*what would you do … in this case*" might offer some mitigation should the care ever be scrutinised.

NICE or in the Consultation Room the readily accessible CKS: Clinical Knowledge Summaries (https://cks.nice.org.uk) are accessible and arranged alphabetically. Most of the letters have at least one women's health related condition. In an attempt to improve Cancer detection rates the threshold of the specificity of a symptom warranting a "2ww" was reduced from 5 to 3% and hence a GP faces the following guidance on, to take one example, When to suspect Ovarian Cancers (https://cks.nice.org.uk/ovarian-cancer):

- Suspect ovarian cancer and carry out tests:
  - In any woman (particularly if over 50 years of age), if any of the following symptoms are persistent or frequent (particularly more than 12 times per month):
    Abdominal distension (bloating).
    Feeling full (early satiety) or loss of appetite, or both.
    Pelvic or abdominal pain.
    Increased urinary urgency or frequency, or both.
  - In any woman over 50 years of age, if she has had:
    Symptoms suggestive of irritable bowel syndrome (IBS) within the last 12 months.
- Consider the possibility of ovarian cancer and consider carrying out tests in any woman who reports any of the following *unexplained* symptoms:
  - Weight loss.
  - Malaise or fatigue.
  - Change in bowel habit.
- Other symptoms of ovarian cancer that may be present include:
  - Abnormal or postmenopausal bleeding.
  - Gastrointestinal symptoms such as dyspepsia, nausea, or bowel obstruction.
  - Shortness of breath (due to pleural effusion).

A General practitioner will recognise that these symptoms do not often present as such a clear cut constellation of symptoms, if they did; it would be more likely than not that the condition was very advanced, perhaps incurable. The General practitioner is faced with a plethora of symptoms but the favourable safeguard for the GP, in this guidance, is the presence of definition of "frequent" but this is countered by the absence of a definition of "persistent". The purpose of citing this often emotional illness is to highlight that the "guidelines" are not bespoke but can be used to challenge and question care and it is only good record keeping justifying an action not to refer in the presence of such symptoms.

Given the nature of this specialty then the role of Chaperones is a chapter in itself. In General practice, whether a chaperone is offered or not should be documented, and where one is refused this should also should be documented.

61.5 Case Study

Mrs. A consulted her GP and was the last patient on the list on a Friday afternoon. She was known to suffer Irritable Bowel syndrome and was

worsened by stress. She accepted that she was struggling to manage the multiple pressures she was under both on the domestic front and her professional life. During the examination she was noted to have abdominal tenderness but no palpable masses. The GP asked her to return for a blood test (Ca125) the next week, but advised that the IBS was the probable cause of her symptoms. He advised her to contact one of the other doctors regarding her results.

When she was not contacted by the GP practice she assumed that the pain was indeed IBS related. She returned three and a half months later to the practice to see a doctor for fatigue, increased abdominal swelling and worsening pain. She was found to have significant ascites and it was recognised that the Ca125 though performed, the results had not been received. The laboratory confirmed this was significantly raised and an urgent referral made to gynaecology. Mrs. A underwent a staging laparotomy and was diagnosed with advanced Ovarian cancer with a poor prognosis.

The learning points included the lack of a robust system to follow up test results. It was also identified that though the GP Mrs. A saw initially had concerns about ovarian cancer, he failed to relay these concerns to the patient and failed to put systems in place for her follow up.

The case was settled with a modest payout.

Key Points: Fast Track Referrals and GP Perspectives

- Note keeping: notes documenting the presence or absence of relevant symptoms and signs.
- Ensure knowledge of investigations and treatments are up to date and contemporary.
- GPs should be familiar with investigations that should be done in primary care and indications for referral through the 2ww.
- When a GP suspects a diagnosis of Cancer this should be discussed with the patient and documented in the notes.
- There should be systems in place to follow up investigation results.
- When patients are not being referred for non-specific symptoms, systems should be in place to ensure these resolve and adequate follow up arrangements made or the patient advised of subsequent steps if symptoms persist.

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Running a Safe Rapid Access Clinic

62

Vivek Nama

62.1 Background

The last decade has seen a change in the provision of cancer services in the NHS. Previous reports have highlighted poorer survival outcomes in the UK compared to other European nations [1]. Delayed diagnosis and poorly coordinated services are noted as significant contributing factors. As a result, there is a restructuring of cancer services aiming for closer collaboration between primary care, local cancer units and regional cancer centres. This is facilitated by a 2 week rule which states that all patients with suspected cancer referred by the GP on the urgent referral pathway must be seen within 2 weeks of the referral and a further 2 weeks to arrive at a diagnosis. A further limit of 4 weeks is set to provide treatment.

62.2 Minimum Standards and Clinical Governance Issues

There are increasing calls for the NHS to be accountable for the quality of care and services rendered. Safe delivery of services includes participation in activities such as multidisciplinary team (MDT) meetings, adhering to national cancer waiting time targets and performing audits. Delayed diagnosis is the single most important factor responsible for poor survival rates in the UK. Therefore, meeting cancer waiting times is a priority for rapid access clinics.

The data generated is required to be entered in the National Cancer Waiting Times Monitoring Data Set Overview databases. Trusts are required to submit these data within 25 working days of the month. Findings are used to evaluate the performance of local units, highlighting areas of improvement to meet clinical standards.

It is also mandatory for local cancer units to hold regular MDT meetings attended by the named gynaecology lead, radiologist and a histopathologist. The gynaecology lead is also responsible for attending the MDT at the regional cancer centre where all newly diagnosed cancer cases are discussed and management plans formulated. Centralisation, specialisation and MDT input have minimised variations in clinical practice. However, it is vital that all experts are present during discussions as this can influence decisions regarding management leading to recommendations for the core member team.

Referrals to RAC clinic often fall into five categories: postmenopausal bleeding, suspected ovarian, cervical, vulval or endometrial cancer. Standardised forms allow a broader category 'other' to include non-specific concerns.

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62.2.1 Postmenopausal Bleeding and Pitfalls

Postmenopausal bleeding (PMB) warrants an urgent referral to gynaecological services and occurs in 10% of women over the age of 55. The risk of endometrial cancer in those presenting with PMB is approximately 10% [2].

An accepted protocol for managing women with postmenopausal bleeding include clinical assessment, ultrasound to delineate endometrial thickness, opportunistic adnexal scanning, endometrial biopsy if the endometrial thickness was more than 4 mm and hysteroscopy if the ultrasound raised the possibility of a focal lesion.

62.2.2 Ovarian Cancer and Pitfalls

The National guidance recommends the use the risk of Malignancy Index (RMI) to characterise adnexal masses as low (RMI < 25), moderate (25–250), or high (above >250) risk of ovarian cancer [3]. RMI is calculated according to menopausal status, CA 125 and transvaginal ultrasound features. CA 125 levels require careful interpretation as they can be non-specific. Levels are raised in heart failure, liver cirrhosis and non-gynaecological malignancies. Additionally, they are only increased in 50% of stage one epithelial ovarian cancers. The overall sensitivity of this algorithm for diagnosing all borderline, invasive ovarian, or primary peritoneal lesions was 87.4%, and the positive predictive value was 86.8 [4].

Other models such as the International Ovarian Tumour Analysis (IOTA) group collected a large database of women with an adnexal mass and developed logistic regression models to calculate the risk of malignancy in adnexal masses using clinical information and features derived from ultrasonography [5]. A meta-analysis conducted demonstrated that a management protocol based on triaging women using the IOTA logistic regression model LR2 performs significantly better than the RMI-based protocol that is currently proposed by the RCOG [3, 5].

Magnetic resonance imaging (MRI) may be used as an adjunct imaging modality when the initial ultrasound characterisation of an adnexal mass as benign or malignant is inconclusive. A recent meta-analysis found that the sensitivity and specificity of MRI for correct detection of malignancy may reach 92 and 88%, respectively [6].

62.2.3 Suspected Cervical Cancer

Patients with persistent post coital bleeding or intermenstrual bleeding are often referred as suspicious of cervical cancer. In the presence of a normal smear that is adequately performed, including an endobrush the incidence of cervical cancer is very low. Persistent symptoms, however, warrant a colposcopy unless there is another cause found for these symptoms.

The incidence of cervical cancer is higher in patients who present with postmenopausal bleeding and have a thin endometrium. Smear history is crucial, and an update smear test is indicated in this group of patients.

The safe and effective running of an urgent suspected cancer referral also involves providing adequate information about the service, investigations involved and a specialist nurse to provide support for anxious patients. Many units have a patient liaison officer, who helps patients with their appointments and answers queries. This is crucial to keep the patient informed and avoid complaints.

62.3 Reasons For Litigation

Postmenopausal bleeding:

1. Failure to investigate recurrent postmenopausal bleeding despite normal ultrasound.
2. Decision based on biopsy from a polyp rather than polypectomy.
3. Failure to discuss alternatives, including doing nothing for complex medical patients.

4. Failure to recognize a fibroid polyp which has undergone sarcomatous change in the post-menopausal group and not arranging immediate surgery or investigations.

Ovarian cysts:

1. Failure to discuss complex ovarian cyst in MDT.
2. Rupturing of the cyst during surgery, converting the staging to Ic.
3. Failure to arrange appropriate follow up for complex ovarian cyst with normal CA 125.
4. Failure to evaluate un explained CA 125.

Vulval cancer:

1. Failure to recognize vulval cancer.
2. Failure to refer for ongoing long standing vulval symptoms.
3. Excision of vulva cancer with inadequate margins by a benign gynaecologist, which needs further excision and sentinel node assessment, which is not proven by evidence.

Cervical cancer:

1. Failure to refer persistent intermenstrual or postcoital bleeding in young women.
2. Hysterectomy for cervical cancer without appropriate preoperative staging.

62.4 Avoidance of Litigation

62.4.1 Clinical Assessment

Many care providers ignore this aspect of the evaluation. With the cancer services under pressure, there is an increasing drive to move straight to test. But with post-menopausal bleeding age and other risk factors for endometrial cancer like obesity, hypertension, hormone replacement therapy usage [7] play a role. Though the models of prediction have a poor positive predictive value and an excellent negative predictive value [7] it is worth noting the risk factors before discharging both symptomatic and asymptomatic patients without endometrial biopsy [8].

62.4.2 Transvaginal Ultrasound (TVS)

TVS is the first line investigation to determine the endometrial thickness (ET) and to rule out focal pathology. The endometrial thickness is subsequently used to recommend further investigations such as outpatient endometrial sampling or hysteroscopy and biopsy.

62.4.3 Endometrial Thickness

Various units across the UK will implement values between 3 and 5 mm. Values of >3 mm have a sensitivity of 98% and specificity of 0.6%, an ET > 5 mm has a sensitivity of 90% and specificity of 1% [9]. Wong et al. [10] showed that the sensitivity for 3-, 4-, and 5-mm cut-offs were 97.0% (95% CI 94.5–99.6%), 94.1% (95% CI 90.5–97.6%), and 93.5% (95% CI 89.7–97.2%), respectively. The corresponding estimates of specificity at these thresholds were 45.3% (95% CI 43.8–46.8%), 66.8% (65.4–68.2%), and 74.0% (72.7–75.4%). Both these studies suggest using 3 mm as the cut off for screening endometrial cancers.

62.4.4 Tamoxifen

Women using Tamoxifen have a risk of 10% of endometrial cancer. Transvaginal ultrasound is poor at differentiating between a thickened endometrium secondary to endometrial cancer or long-term Tamoxifen use. Typically, tamoxifen associated thickened endometrium has cystic spaces [11] on USS and using just endometrial thickness becomes unreliable. Therefore, women on Tamoxifen presenting with a PMB will require a hysteroscopy and biopsy as a first-line investigation to exclude endometrial pathology. However, there is no evidence to suggest

annual scans in patients on tamoxifen improve outcomes [12].

62.4.5 Hormone Replacement Therapy (HRT)

Bleeding within the first months of using continuous HRT does not need any investigations. An ultrasound performed after 6 months, a 4 mm cut off for endometrial thickness is appropriate. This increases the sensitivity but decreases the specificity [13].

62.4.6 Endometrial Biopsy

Thick Endometrium with no focal lesion: In the presence of thick endometrium and an absence of focal lesion, outpatient based endometrial biopsies are sufficient. Various devices are compared, and a pipelle aspirator seems to have the maximum sampling rate. However, there is a 7% risk of inadequate sampling [14] with such methods. Women with an inadequate sample, or who remain symptomatic despite previous normal sampling require a hysteroscopy and directed biopsy for further evaluation.

Thick endometrium with focal lesions/ endometrium not visible will need hysteroscopy and directed biopsy. Minimal evidence suggests that if the endometrium is not visualized there is a higher chance of malignancy.

Fluid in the cavity: An ultrasound report should mention, the echogenicity of the fluid. If the fluid is echogenic, an endometrial biopsy is indicated. If the fluid is clear could be excluded before calculating the endometrial thickness.

62.4.7 Office Hysteroscopy

OPH is indicated in the presences of a thick endometrium with a possibility of a focal lesion or if the is endometrium not visualised clearly. Hysteroscopic assessment enables visualisation of the uterine cavity. However, there is a reported 2–4% false-negative rate secondary to operator error in detecting abnormal endometrial lesions [15]. Endometrial hyperplasia accounts for 10–15% of postmenopausal bleeding and can occur as focal lesions or diffusely within the endometrium. Diagnosis can be difficult during hysteroscopy as fluid distension compresses the endometrium therefore discerning projections of hyperplastic tissue are difficult.

62.4.8 Recurrent Post-Menopausal Bleeding

An episode of postmenopausal bleeding with an endometrium of less than 4 mm, still increases the risk of endometrial cancer in the first four years [16] and many suggest a repeat USS in 6 months to identify an increasing thickness. Repeated negative biopsies of the endometrium should warrant a hysterectomy as recurrent PMB raises the possibility of endometrial cancer though the incidence is less than patients with the first episode of PMB [17].

62.4.9 Asymptomatic Women with Thickened Endometrium

There is no consensus in the management of women with incidental thick endometrium in the absence of symptoms. Poorly conducted studies have suggested that a cut off of 11 mm be used [18, 19]. Smith-Bindman showed that an ET of >11 mm would give an estimated risk of cancer of 6.7% and if less than 11 mm an estimated risk of 0.002% [20]. UKCTOCS divided the endometrium into quartiles based on known risk factors and defined high-risk as 6.75 mm [21]. Hence consideration of risk factors rather than the thickness of the endometrium is essential before advising biopsy in asymptomatic women.

62.4.10 Unexplained Raised CA 125

There is no management protocol at present for post-menopausal women with an unexplained rise in CA 125 level. Data from the Prostate, Lung, Colorectal, and Ovarian Cancer Screening

Randomised Controlled (PLCO) Trial indicated that approximately 3% of postmenopausal women were found to have an abnormal CA 125 level in the absence of ovarian cancer. Results indicated that patients had a significantly higher mortality than patients with all normal CA 125 levels ($p < 0.0001$). This increased risk extended throughout the follow-up period. Analysis of cause of death showed an excess mortality attributable to lung cancer, digestive disease, and endocrine, nutritional, and metabolic disease. Evaluation of false positive screening test was associated with complications of 15% [22]. Therefore, an elevated CA 125 in a menopausal female without ovarian cancer should be regarded with concern. These individuals appeared to be at risk for premature mortality and continued health surveillance would appear prudent [23].

62.5 Case Study

62.5.1 Case Study 1 (Direct Harm)

A 69-year-old lady, presented with PMB. USS showed an endometrial polyp and a complex ovarian cyst. CA 125 was 39. She went for an outpatient hysteroscopy and as the polypectomy was not successful, was posted for polypectomy and BSO. RMI was calculated to be 351 (39x3x3). She underwent a polypectomy and Bilateral Salpingoopherectomy. Intraoperative spillage occurred as the surgeon punctured the cyst to aid removal. The doctor did not perform either an omental biopsy nor peritoneal washings. Final histology turned out to be a high-grade serous cancer. She needed to have another staging laparoscopy and chemotherapy.

62.5.2 Case Study 2 (No Direct Harm, but Substandard Care)

A 59-year-old referred with postmenopausal bleeding to the 2WW clinic. Outpatient hysteroscopy showed a large necrotic submucous fibroid. She had a hysterectomy performed without biopsy of the polyp. The final histology turned out to be a uterine sarcoma. Though there was no direct harm to the patient, the clinician did not follow the usual standard of care. Ideally, she would have had a biopsy, which would have confirmed the sarcoma. If the staging CT showed metastasis, she wouldn't have had a hysterectomy. Fortunately, the staging CT showed no metastasis. Peer review recommendation is that a person who is part of the MDT and participates in peer review process operates all cancers. The patient was also given the diagnosis without confirming the histology at the MDT and in the absence of the gyn oncology specialist nurse, which is also a recommendation, by the NCRI.

Key Points: Running a Safe Rapid Access Clinic

- There should be clear pathways for referral of women into the Rapid Access Clinic (RAC).
- In women with PMB who do not undergo a biopsy, risk factor assessment plays an important role.
- With recurrent PMB and negative biopsy a hysteroscopy should be considered.
- Bleeding within the first few months of HRT use does not need investigation, however if problems persist an USS is recommended.
- There is no consensus to the management of women with a thickened endometrium in asymptomatic women, and units will have local guidelines in place.
- Post menopausal women with raised CA 125 but no ovarian cancer should be investigated to rule out malignancy elsewhere.

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Cervical Screening, Cytology and Histology Laboratory Issues

63

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63.1 Background

The factors leading to development of cervical cancer are well understood. In virtually all women, the initial event is infection with the Human papilloma Virus, HPV. This is a very common event with 80% of sexually active women acquiring infection at some point in their lives. Up to 40% of women aged 24 in England test positive for HPV, but most women will clear the infection spontaneously within 2 years.

In a small proportion or women, the HPV changes the host DNA on a molecular level which causes cells on the surface of the cervix to develop abnormalities which, if left untreated, may develop into cervical cancer. This process can spontaneously reverse before cervical cancer develops.

In most cases, it takes a minimum of 10 years to progress from HPV infection to cervical cancer, and often much longer. This offers opportunities for screening before the cancer has become invasive.

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63.2 Minimum Standards and Clinical Governance Issues

63.2.1 Cervical Screening Principles

England, Wales, Scotland and Northern Ireland have separate but closely related programmes for cervical screening, which aim to prevent the development of cervical cancer by detection and treatment of pre-malignant lesions.

These programmes are highly effective, preventing an estimated 80% of cases from occurring. It is a common misconception that, for every woman who develops cervical cancer despite being screened, something must have "gone wrong", however this is not necessarily the case.

The programmes are nationally specified and all aspects of the process are standardised. There is a deeply embedded culture of quality assurance within delivery of the programmes.

63.2.2 Cervical Screening Programme Components

- GP registration, inclusion on national population data base.
- Invitation at specified age and intervals.
- Sample taken by sample taker, usually a nurse in a primary care setting.
- Sample submitted to laboratory for testing.

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- Result and management requirement communicated to patient and national data base, next test date recorded.
- Colposcopy referral (if required).
- Biopsy and /or treatment. May produce a histology sample.
- Multidisciplinary consideration of selected cases.
- Failsafe.

The cervical screening pathway is complex, and no single provider organisation is responsible for the whole pathway.

63.2.3 Investigation of Symptoms

The investigation of symptoms which might be attributable to cervical cancer, (chiefly intermenstrual or post coital bleeding) is not part of the cervical screening programme. Guidance exists for the investigation of such symptoms [1].

In a number of cases, reliance by sample takers on a negative cervical cytology result in the presence of symptoms has delayed the diagnosis of cervical cancer.

63.2.4 Cervical Cytology

This is currently the way in which samples are primarily screened. There are systems in use, ThinPrep and SurePath. Each laboratory uses only one system but some laboratories have changed between them. Conventional cervical cytology ("Smear") has not been used in the UK since 2008 at the very latest. Most staff interpreting cervical cytology are only trained and experienced in one technique.

Samples are prepared onto a glass slide which must be screened. This means that, using a microscope, a screener must look at all the cells (number ranges from 10,000 to over 100,000) and identify any which might be abnormal. This is known as primary screening, and the person doing this will be trained but is employed at a relatively junior level.

If negative, the sample is checked by a second screener (rapid review) and then reported. This is meant to detect obvious abnormalities but not subtle or low grade changes.

If abnormal cells are suspected at any stage, the slide is passed to a second, more highly trained, member of staff, usually a biomedical scientist but sometimes a consultant.

Cells with confirmed abnormality are reported by a consultant cytologist or cytopathologist.

Abnormalities can be very subtle. This is essentially a clinical interpretation process and differences in interpretation do occur. There are well-recognised types of appearance likely to cause difficulty ("pitfalls"), and these are the subject of regular training and updates. High-grade intraepithelial lesions are usually not encountered in routine practice and there are many mimics of benign and neoplastic changes that may lead to errors in diagnosis. Pitfalls in cervical cytology may therefore be divided into three categories:

- Potential false negatives
- Potential false positives
- Unnecessary atypical/borderline reports

Algorithms exist to specify which samples require an HPV test (see below).

63.2.5 Cervical Histology

Histological samples may be taken for diagnostic biopsy or treatment purposes. These are reported by a consultant histopathologist. Diagnosis again depends on clinical interpretation, but there are extensive guidelines on how to report certain abnormalities.

There are two main conditions which are diagnosed, Cervical Intraepithelial neoplasia (CIN) and cervical glandular intraepithelial neoplasia (CGIN). These are the precursor lesions of squamous and adenocarcinoma respectively.

Cervical histology reporting of high grade abnormalities is generally very reliable, though errors may occur. More common areas of difficulty are failure to identify very small areas of abnormality, errors regarding completeness of excision and failure to identify foci of invasion. CGIN is particularly prone to

being missed if there are other abnormalities also present.

It is important to ensure that all processes have been correctly followed including the number of levels taken, appropriate use of immunohistochemistry and issuing a report which contains the complete minimum data set. Histology results which do not explain cytology findings should prompt a discussion at a multidisciplinary team meeting.

63.2.6 Testing for Human Papilloma Virus (HPV)

HPV testing has been part of the English cervical screening programme since 2001 in some areas, and fully implemented in England in 2008. Practice in Scotland and Wales differs significantly from England. HPV testing is a numerical analytic test which does not rely on clinical interpretation but must be subject to laboratory quality assurance processes. Since 2013, six laboratories in England have been piloting the use of HPV as a primary screening test, and there is a plan to fully implement this change by April 2019.

There are numerous HPV test platforms in existence but only a few are approved for use in England. Their use is subject to rigorous internal and external quality control, and they are extremely reliable. A sample which tests negative for high risk HPV can be accepted as negative. A negative HPV test has an extremely high negative predictive value for cervical cancer, even in the presence of slightly abnormal cytology. However, very rarely, cervical cancers do occur in HPV negative women, and the test does not detect non-cervical cancers (e.g. of endometrial and ovarian origin).

63.2.7 Management and Communication of Results

All women receive their results in writing, to their registered address. Onward referral to colposcopy is achieved by direct referral in the majority of laboratories in England, but it is still acceptable to require the sample taker to make the onwards referral. It is not uncommon for an expert in primary care to contribute a report on liability and causation in these circumstances. All such GP practices must operate a failsafe system to ensure referral has been made.

63.2.8 Audit

There is a mandatory audit of all cases of cervical cancer in England. This is undertaken to a standard national protocol [2] and is intended to be educational. The approach taken on review of cervical cytology material is not that used in a medicolegal review.

Women are routinely offered the results of this audit, which looks at the whole cancer pathway. Results of the national audit have been published [3].

Cervical cytology slides are retained for 10 years, after which they will not be available for review.

63.3 Reasons for Litigation

- Missed abnormalities on cytology.
- Incorrect attribution of adequacy on cytology.
- Failure to undertake investigation of symptoms.
- Missed abnormalities on histology, including incomplete excision of abnormality and early invasive lesions.
- Failure of communication.
- Failure to refer.
- Multiple features may affect a single case, often involving multiple organisations.

63.4 Avoidance of Litigation

As with other areas of practice, adherence by the lab to the many quality standards and protocols of the cervical screening programme in terms of quality processes, training and education, and technical standards will give some grounds for defence.

Many features of cervical cytology medico-legal practice date back to the Kent and Canterbury enquiry of 1997 [4]. This involved a laboratory with very poor quality management and many abnormalities were missed on cytology, resulting in harm to women. Many cases were settled but the cases of several women with subtle abnormalities in their cervical cytology were contested, and subsequently referred to the Court of Appeal. This resulted in a judgement introducing the concept of "absolute certainly", whereby a sample could not be reported as negative at screening in the absence of absolute certainty that there were no abnormal cells present. This concept has made it challenging to defend any case where an expert has identified abnormal cells missed at the screening stage, and most such cases are settled. An exception is where the abnormal cells are very few in number, when it can be successfully argued that any reasonable screener could have failed to identify them (Bolam test). There is research evidence for this in conventional smears [5]. This study showed that if less than 50 abnormal cells were present, a competent screener was much less likely to identify them than if there were more than 200 cells present. However, the equivalent number for Liquid based cytology is not known (but is certainly much lower). Conventional smears are now almost never at issue in cases of cervical cancer.

The Bolam Test applies to primary screening, and also in cases where cells have been queried at primary screening but a consultant has decided they were not abnormal.

A further area of contention is around samples incorrectly reported as adequate. Criteria for adequacy have varied, with an agreed range but no single national standard being agreed.

Review of cytology and histology material will be a feature of many cases. Cytology material is irreplaceable and all efforts must be made to ensure the glass slides do not get lost or broken. If for whatever reason they do, the balance of probability will be that they were correctly reported as there is no recent UK publication showing that more than 50% of any type of abnormality is missed.

Histology samples are slightly less irreplaceable, in that additional sections (levels) can be cut from the original wax block. However these will be very slightly different and very focal changes may not be reliably present in the same way as in the original.

Cervical screening is a complex pathway requiring a high degree of quality management, and in general standards in the UK are very high. Cervical screening detects most cases of premalignant disease before cancer has arisen, but can never prevent all cases.

The biggest risk factor for development of cervical cancer is failure to take up the offer of regular screening, but there are a number of cases where cytology or histology diagnosis may be revised on review.

Because treatment of non-invasive disease has very low morbidity and is highly effective, missed opportunities to detect abnormalities will often contribute strongly to causation in cervical cancer with its associated morbidty of treatment and significant mortality, often of young women.

63.5 Case Study

Penney v East Kent HA [1999] Lloyd's Rep. Med. 123 (QBD).

P alleged that her cervical smear which was screened by biomedical scientists and screeners had been negligently reported as negative. Her smear should have been referred to a checker who, if endorsing the classification, would pass it on to a pathologist. P alleged that she was deprived of the opportunity of obtaining early treatment. The judge turned down the evidence by the defendant that a reasonable body of screeners would have given a similar report.

The court held, giving judgment for P, that [1] the screeners' observations were negligent in that borderline smears had been incorrectly classified and not referred for further checking; [2] the experts agreed the screeners had been wrong, the

Bolam principle did not apply because it was concerned with disapproval or disagreement of aspects of professional conduct, and [3] even if the *Bolam* principle had applied, the defendants opinions were not logical as the screeners did not have the ability to distinguish between pre cancerous and benign cells, so should have classified the cells as borderline.

Key Points: Cervical Screening, Cervical Cytology and Histology

- Symptoms which might be attributable to cervical cancer, (chiefly intermenstrual or post coital bleeding) is not part of the cervical screening programme but should be investigated through other pathways.
- Algorithms which specify which samples require an HPV test should be followed.
- There should be absolute certainty when reporting a smear as "normal".
- Guidelines on interpretation of histological abnormalities should be followed.
- All clinicians involved in cervical cytology should keep upto date with their training.
- Cervical screening detects most cases of premalignant disease before cancer has arisen, but can never prevent all cases.

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MDT Function and the Law

64

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64.1 Background

The Multidisciplinary Team (MDT) and its regular meeting (Multidisciplinary Meeting or MDM) have been the cornerstone of specialist services for many decades. Most clinicians looking to provide excellence in clinical care would have a regular meeting with radiological expert colleagues to run through images of their patients in order to help determine the best course of management. Similarly they would often sit down with the pathologist to discuss the appearance of a particular tumour microscopically especially if the tissue type was rare. Such discussion would often be informal and poorly documented but the purpose was to seek the best possible opinions from those who knew their subject in order to recommend to the patient the best plan of treatment.

In 1995 the Calman Hine report [1] was published in England and Wales suggesting a reorganization of cancer services into a model where the diagnosis and some straightforward treatment was given in a Cancer Unit and the difficult or multimodal treatments were given in a cancer Centre that would have within it all the necessary resources and expertise to provide such care.

A fundamental part of providing this expert care was the necessity to set up a formal Multidisciplinary Meeting each week in order to discuss the management of patients. The hope was that this would prevent individual clinicians from treating patients in different ways and make cancer care across the country consistent.

The National Cancer Plan published in 2000 [2] further supported the importance of the MDT and laid down a series of standards on which the team were to be judged in a process known as Peer Review.

All of this seems extremely logical and would undoubtedly improve the standard of care offered to our patients.

64.2 Minimum Standards and Clinical Governance Issues

"The characteristics of an effective Multidisciplinary team (MDT)" was published in 2010 by NHS England [3] and details the necessity to have a Chair who takes responsibility for the performance of the MDT. Core members are required and they need to attend in order to make any discussions meaningful. A basic or minimum set of data needs to be compiled prior to any discussion on a patient in order to give the MDT a chance to make correct recommendations. The outcomes from an MDT meeting need to be appropriately recorded and communicated to all the relevant clinicians including the GP and in many cases the patient.

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This document is so detailed and prescriptive that it even states that mobile phones should be switched off and anyone answering one should leave the room to do so.

Within Gynaecology the core members need to include a minimum of two surgeons, a medical oncologist, a clinical oncologist, a Clinical Nurse Specialist, a radiologist and pathologist with many other extended members such as palliative care physicians, urologists, plastics and colorectal surgeons.

All new patients need to be discussed in the MDT along with anyone with recurrent disease.

There are number of practical issues that arise from the necessity to have an MDT

1. Resource

The resource required to manage the meetings is substantial. Filtering referrals, determining which patients need discussion, acquiring the imaging from other hospitals, sending for pathology slides and compiling the list of patients for discussion in most circumstances requires at least one fulltime administrator. Recording results, communicating these and keeping the database often requires additional assistance.

The Chair requires time to prepare for the meeting and time to coordinate the results. The radiologist and pathologist will often spend many hours in advance of the meeting preparing by looking through images that have already been reported by colleagues.

The meeting itself is often attended by up to 30 individuals all of whom are being paid for that session.

There is no question that the advent of MDTs has improved the quality of care offered to some individuals but it has come at a significant cost. This ongoing significant expense will be the subject of much debate as we determine how best to use limited resources in the future.

2. Attendance

The MDT is supposed to be attended by all core members on a regular basis and it is a Peer review criteria they attend more than 67% of the time. However that still leaves many occasions where an expert may not be present.

The plan published in 2010 [3] states prompt arrival time is essential but the practicalities of the environment in which we work mean that we will have to compromise on occasions. The post operative patient on the ward having life threatening complications will undoubtedly take priority over arriving promptly for the start of the MDT.

Many of the senior and more experienced clinicians will have a greater demands on their time with the need to lecture, attend meetings both clinical and managerial and using segments of the MDT for these can be common practice.

3. Accuracy of decision making

Many patients referred from other hospitals will be discussed prior to any member of the team actually meeting them. Alternatively, a patient might have been met but that particular team member may not be present in the meeting. The data available in the MDT may not be complete.

In order to make a sensible recommendation for treatment all the various factors affecting that patient need to be taken into consideration. Clearly the pathology can be presented and the images debated but in many circumstances the correct management for a patient can only be determined by talking to her and her family. An obvious example is debulking surgery for advanced ovarian cancer. The pathology may make the diagnosis and the radiology may indicate a certain type of surgery is necessary but only clinical assessment of the patient will determine whether that patient is fit enough to undergo an extensive operation.

It is only by talking to the patient that the options can be discussed fully. It is commonplace for the MDT to make a recommendation for treatment such as in early stage cervical cancer where a radical hysterectomy may be suggested. Talking to the patient in detail and determining her fertility wishes, presenting the data (so far as we know it) on the risks of alternative treatments and balancing a desire to be

cured against a desire to have children is not something that can be fully recorded in an MDT without the patient present.

The MDT sounds like a body with authority but it is no more than its constituent parts. Individuals make recommendations and those go out in the name of the MDT. It is akin to blaming "The Government" or "The College" for rules and regulations when it is in fact individuals within that organization who make the decisions. It is therefore possible for individual clinicians to make wrong decisions. This is particularly likely where an individual is rather dominant in their opinion or the way they express that opinion.

Although two surgeons need to be core members it only requires one chemotherapy expert and one radiotherapy expert. It is perfectly possible for their opinions to differ from a body of chemotherapy experts or a body of radiotherapy experts. Hence the decision recommended by the MDT is not necessarily the same across the entire country.

4. Communication of results

Many MDT summaries will be short and to the point. Example "recommend laparoscopic hysterectomy and removal of ovaries for endometrial cancer". It is sometimes difficult for the summary to include the 10 or 15 min discussion which preceded this conclusion. Subsequent team members including the GP may not fully appreciate the complexity of the discussion which led to that conclusion and recording all the factors or options that should be communicated to the patient is difficult.

5. The patient should be the centre of any decision making

It is clear that modern medical practice requires the clinician to discuss the options with the patient including all the pros and cons. The patient will not be present at any MDT discussion that results in a recommendation for management. It is therefore inevitable that the clinician who subsequently sees the patient in the clinic needs to have a much more extensive discussion than the one had by the MDT.

The MDT cannot be expected to take responsibility for a clinician who is unable to properly discuss the management and its consequences. An example once again would be ovarian cancer debulking surgery. The MDT may recommend extensive surgery which would aim to remove all areas of disease. Unless that patient is carefully consented including the understanding that a bowel resection may be required which may result in a colostomy the clinician has not had an appropriate discussion on the pros and cons of the proposed management. A patient who is extremely averse to this risk may benefit more from having chemotherapy first.

64.3 Reasons for Litigation

There is no doubt that the clinicians who discuss their patients in an MDT feel some security that, as a body of others also agreed, the management is defensible. Litigation can occur in the following situations:

- Decision reached by the MDT fail to fulfil the Bolam principle in that a body of experts would disagree with the treatment.
- Failure to discuss a patient in an MDT which implies they will not have been through the accepted or recommended processes. This opens up the possibility of an allegation of incompetence simply in not following due process.
- Decisions reached in the MDT can become so defining that deviation from this decision automatically gets regarded as negligent.
- MDT decisions made are incorrect.
- Where there are deviations from decisions made in the MDT. This may arise in circumstances where the MDT has made one recommendation but subsequent information shows there is a better form of management. In these cases it is sensible to have a discussion with colleagues.

An example would be the patient who is recommended to have a laparoscopic hysterectomy with node removal for endometrial cancer but the referring letter failed to mention her previous three laparotomies and vascular disease that mean she is at particularly high risk of thrombosis. A documented discussion with a colleague who was present in the MDT and recording that the laparoscopic route and the lymphadenectomy might be contraindicated would be sensible when changing the management plan.

Equally in this example, going ahead and booking the laparoscopic hysterectomy and node removal because the MDT suggested it and failing to take into consideration the contraindications is indefensible.

64.4 Avoidance of Litigation

The purpose of the MDT and its expected outputs should be clearly defined locally. The operating of the MDT should be based on agreed policies, guidelines and protocols. This should also determine the core and extended members and their roles. These policies should also be reviewed annually.

There should be mechanisms in place to record the MDT recommendation versus the actual treatment and to alert the MDT if their recommendation are not adopted as well as the reasons for this. When serious treatment complications arise the MDT should be alerted to this.

Discrepancies in pathology, radiology or clinical findings between local and specialist MDTs should be recorded and audited.

64.5 Case Study

A 54 year old presented to the GP with Postmenopausal bleeding and was referred via the two week wait. Following an ultrasound and pipelle biopsy a referral made to the regional cancer centre. The referral letter read “Please see this delightful 54 years old lady who used to be a Ballet dancer and now works at her local primary school supervising music lessons. She has a grade 3 endometrial cancer diagnosed on pipelle biopsy. I have organised an MRI and CT scan which should be available in time for your MDT. She is supported by her husband, who is an extremely busy garage mechanic, and two daughters who live close by”.

At the MDT the diagnosis of grade 3 endometrioid endometrial cancer was noted and the imaging demonstrated extension into the outer half of myometrium with no metastases visible. A recommendation for laparoscopic hysterectomy with pelvic and para-arotic lymph node dissection was made.

When the surgeon saw her the following week, they realised the patient had been previously treated for lymphoma with radiotherapy to the paraaortic region and she had a BMI of 40 with bilateral leg lymphoedema causing her to be wheel chair bound. Recognising that the MDT recommendation was not the most sensible way forward. A plan was made to proceed to a simple laparoscopic hysterectomy. The modified plan was presented to the MDT post operatively when it was agreed that the use of adjunctive radiotherapy was contraindicated and chemotherapy would be likely to have more side effects than benefits.This subsequent recommendation was then discussed with the patient by the medical oncologist.

Learning points include:

1. The meeting at which management is suggested (MDT) does not always have the available facts and the data that comes out of the MDT can only be as good as the data that goes in.
2. The Doctor seeing the patient has a duty to re-evaluate the clinical situation when new evidence becomes available.
3. It would have been medicolegally difficult to defend surgical trauma to the Inferior Vena Cava during a para-aortic node dissection that was done simply because the MDT recommended it.

Key Points: MDT

- All new patients are to be discussed in an MDT and this is documented.
- Ensure all the relevant details required for decision making are given to the MDT.
- Do not take the MDT recommendation as law. Think, reason and take all factors into consideration.
- Do not present the conclusions of the MDT to the patient as her only option. The MDT does not excuse the clinician from using their medical training, powers of assessment or discussing alternative treatments and their pros and cons.
- If changing an MDT recommendation, document the process by which that change was considered sensible.

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65 Colposcopy and Surgical Management of Early Stage Cervical Cancer

John Murdoch

65.1 Background

The assessment and treatment of patients with abnormal cervical cytology is tightly controlled in the UK. There are strong audit and quality assurance mechanisms. Deviation from well-established pathways of care has a high risk of litigation if there is an adverse outcome unless that alternative treatment fits with that which would be offered by a responsible body of gynaecologists (Bolam) and has been discussed and documented with the patient (McDonald).

Colposcopy was first described by Hans Hinselmann in Hamburg in 1925. A combination of complex polysyllabic German terminology and the political upheavals of the first half of the twentieth Century ensured that it was not introduced generally until Papanicolaou [1] brought cervical cytology to the fore. In the 1960s the only response to an abnormal smear was surgery with unacceptably high morbidity [2].

Colposcopy is the effector arm of the cervical screening loop. Its function is to diagnose histological abnormalities in women with abnormal cervical screening tests so that progression to cervical cancer can be prevented, or early treatment instituted to maximise cancer cure rates, while minimising morbidity to their physical, reproductive and psycho-sexual health.

The core requirements of colposcopy are that the lesion and its extent are clearly defined including documentation of the upper limit in the endocervical canal; estimate of the severity of the lesion in the context of the referral smear; appropriate diagnostic biopsies are taken; and finally sufficient treatment is performed.

In the UK, with minor national variations, the cervical screening programme is tightly controlled by guidelines, which are effectively evolved instructions, governing the delivery of service and quality standards. These are promulgated by the British Society for Colposcopy and Cervical Pathology (BSCCP) and the National Health Service Cervical Screening Programme (NHSCCP). Deviation from these guidelines has to be fully justified and recorded to avoid the risk of litigation. The latest iteration of the guidelines is Colposcopy and Programme Management NHSCSP Publication number 20 [3].

The surgical management of early organ-confined cervical cancer has similarly progressively moved towards the goal of maintaining cure rates achieved by radical surgery whilst minimising morbidity and maintaining function. Modern practice disconnects treatment of the cervical primary and assessment of the draining lymphatics and lymph nodes. It stratifies surgery according to sub-stage and related risk of recurrence. The management of early cervical cancer is generally fairly clear-cut but clinicians need to

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be cautious about the introduction of more conservative treatments without an evidence base which requires detailed counselling and documented agreement with the patient.

65.2 Minimum Standards, and Clinical Governance Issues

65.2.1 Colposcopy

The NHS Cervical Screening Programme Colposcopy and Programme Management NHSCSP, publication 20 [3] is a comprehensive prescription of minimum standards and governance issues.

Sections 4.9–4.11 of publication 20 cover the requirement for patients with moderate dyskaryosis, severe dyskaryosis and query glandular neoplasia to be seen by a colposcopist within 2 weeks of referral by the screening lab in 93% cases. Section 4.15.1 considers symptomatic patients who should again be seen within 2 weeks (93%) "by a gynaecologist experienced in the management of cervical disease".

These targets are a potential difficulty as a result of the enthusiasm GPs exhibit for using the 2 week wait system for a variety of reasons. In many hospitals this has meant utilisation of varying grades of gynaecologists with varying areas of expertise in a dedicated 2 week wait clinic. Such is the degree of sub-specialisation within gynaecology that there are now gynaecologists without the expertise to recognise cervical cancer. It can be difficult or impossible to differentiate a benign ectopy from one with a small cancer in it with the naked eye especially in the under 25 year old where a cervical smear is contraindicated for screening purposes and unreliable as a diagnostic test. The solution is to stream these referrals through the colposcopy clinic where the patient will be seen by colposcopists who must be certified through the BSCCP/Royal College of Obstetricians and Gynaecologists (RCOG) scheme (Sect. 5.1.6). This is efficient but stretches colposcopy services further.

Colposcopist error in identification of invasive cervical cancer is an issue with 2/3 of missed cancers at colposcopy due to colposcopist error (Sect. 6.4). Most cases have one or more of the following:

- High-grade cytological abnormality.
- Endocervical extension of lesions, even when the upper limit of these was thought to be visible.
- Multifocal lesions.
- Large, complex lesions with raised irregular surfaces.
- Under-evaluation of lesions by colposcopically directed biopsy.

The recognition of these pitfalls is a basic requirement of a competent colposcopist. To err on the side of ensuring an adequate excision biopsy is wise. Difficulty occurs when there is a conflict between the reproductive aspirations of young women and the need to avoid progressive cancer. Clear assessment of the relevant risk and clear documentation is essential to ensure the patient makes an informed choice knowing the risks involved.

Section 8.4.3 deals with the depth of excision of cervical tissue required to remove all the abnormal epithelium. The wording of the section is worth reproducing:

"Type I cervical transformation zone: for treating ectocervical lesions, excisional techniques should remove tissue to a depth/length of more than 7 mm (95%), though the aim should be to remove <10 mm in women of reproductive age.

Type II cervical transformation zone: excisional techniques should remove tissue to depth/length of 10–15 mm, depending on the position of the squamo-columnar junction within the endocervical canal.

Type III cervical transformation zone: excisional techniques should remove tissue to a depth/length of 15–25 mm".

CIN extending to the resection margins of a LLETZ is a risk factor for recurrent CIN both in the short and long term but is not a justification for routine re-excision. "Incomplete" excision to the endocervical margin in cases where the rele-

vant depths of excision mentioned above is not achieved requires repeat LLETZ (see Sect. 8.6.1). However, when there is competition between reproductive aspirations and re-treatment the clinician is obliged to ensure that the patient makes an informed risk assessment and choice with clear documentation of the outcome of the discussion.

Finally, solicitors supporting a woman who is contemplating litigation when cervical cancer is diagnosed know that the last 10 years of available smears will be reviewed internally and that the results should be made available to their Client (Chapter 63). It is essential that a mechanism for full sensitive disclosure of the outcome is in place (Sect. 5.1.4). Identified failures supported by independent expert opinion on the standard of reporting will lead to successful litigation and any obstruction to this process is wrong professionally and against GMC duty of candour requirements.

65.2.2 Early Invasive Cancer

Since the introduction of the Improving Outcomes Guidance for gynaecological oncology in 1999 [4], there was a period where litigation centred on inappropriate treatment offered out-with the Multidisciplinary Team (MDT) structure. That has now passed. The great strength of MDTs is the inherent self-governance of team working where ill-conceived decisions are far less likely. This is explored more fully in chapter 64.

There are some absolutes in the spectrum of treatment options which would attract litigation if not adhered to, such as:

- Micro-invasive cervical cancer can be managed with complete local excision or simple hysterectomy in the presence of other gynaecological indications or patient request. It does not require radical surgery.
- Stage 1b1 cancer requires lymph-node assessment.
- Removal of healthy ovaries of women in the reproductive era with early squamous cancer is not required.

However, there are many areas where there is a range of responsible opinion and properly documented reasoning for a particular course of action would provide a solid defence, such as:

- Selective histological assessment of lymph nodes in stage 1a2 disease.
- The stratification of surgical radicality for early stage 1 disease (a big cone, a trachelectomy or possibly a simple hysterectomy).
- The place of radical fertility sparing surgery.
- The place of sentinel node assessment versus systematic dissection.
- The boundary between the use of primary surgery and chemo-radiotherapy.

The key legal issue in the latter group is the quality of informed consent with the proper documentation of discussion of all reasonable treatment options and agreement between the gynaecological oncologist and the patient on the treatment plan. While the vast majority of surgeons and patients agree about the optimal choice, the surgeon must accept that a responsible patient may have a different view of the balance of risk in any treatment and may choose a reasonable option which is not the first choice of the surgeon. This includes options that the surgeon or the centre may not be able to provide and referral on to an appropriate centre or surgeon is required. If the patient's choice is not reasonable in the view of the surgeon, (s)he has the right to decline to treat but has an obligation to offer a second opinion.

With the change from a paternalistic to a patient centred approach over the last 20 years lately codified in case law, the issue of informed consent has become very important in the management of early cervical cancer. There is no one size fits all for the treatment of stage 1 disease. This mandates the careful counselling of patients whose priorities and risk assessment may be very different from the attending doctor.

Full counselling of all patients with stage 1b disease should include consideration of the risks and benefits of fertility sparing surgery, radical hysterectomy and radical chemo-radiation with

documentation of the agreed decision. Failure to achieve this is against the spirit and intent of the Montgomery decision.

65.3 Reasons for Litigation

Common causes for litigation include

- Failure to achieve the 93% 2 week target in referral of moderate to severe dyskaryosis.
- Failure to adequately counsel patients about subsequent pregnancy complications especially when CIN1/2 is diagnosed.
- Colposcopist error in identification of invasive cervical cancer.

In practice, many colposcopy services fail to achieve the 93% target but avoid complaint because the vast majority of patients do not have cancer. It is possible that litigation against the Trust hosting the service could be based on a Claimant with cancer who is not seen within 2 weeks and the service does not achieve the 93% target. This argument is unlikely to succeed because the Courts would have difficulty with the idea that 7% of all patients are negligently managed and causation or harm is likely to be minimal. The only argument would be based on causation where the Claimant would have to demonstrate harm from the delay. This would be confined to anxiety and distress rather than a worsening prognosis or morbidity from unnecessary treatment except in extreme cases when the culpable delay spanned months.

Clarity that a single treatment to 7–10 mm in colposcopy has a minimal impact on future pregnancy but repeat or deep treatment probably has, is a recent cause for litigation if the patient has been denied the option of observation of low grade CIN or if the patient has not been informed of the risk of miscarriage or prematurity when deeper treatment is justified in the presence of CIN3 [5].

Failure to identify a cancer is a reason for litigation which depends on the size and assessability of a cancer at a given examination date. Arguments often arise about Causation related to the size of a tumour at some point in the past as a measure of whether the tumour should have been diagnosed or what treatment would have been available with avoidance of an adverse outcome such as radiotherapy complications, loss of fertility or length of survival.

In recent years the concept of tumour doubling times has been used to calculate retrospectively from a given tumour volume at diagnosis to important past events in the case. Some experts used a paper by Steel [6] who attempted to summarise knowledge in this area. Steel used the formula pi/6 (product of the three largest diameters) to measure the volume of 15 metastatic adenocarcinomas from the uterus (not otherwise specified) serially measured on chest x-rays. He arrived at a mean tumour volume doubling time of 78 days. Despite Steel's caveats and the multiple biological and statistical flaws in such an analysis, these data have been used to calculate tumour volumes which have been used to inform legal decisions. However, the author has seen tumours measured by MRI of 1/4th of the size which would have been arrived at using the formula and has had discussions with experts whose opinions about volume doubling time ranged from 78 to 120 days.

In summary, there are no data to support the existence of a useful mean doubling time for primary cervical cancer which is precise enough to identify when a cervical cancer passed any significant watershed volumes which radically altered treatment plans or outcomes. Such calculations are no better in assessing the size of a tumour at a given time than study of information about symptoms and signs available in the clinical records.

In cases where there is good MRI or CT data from two or more examinations in that patient then a case specific doubling time may be helpful.

65.4 Avoidance of Litigation

Publication 20 is a highly prescriptive document and deviation can only be justified if the reasons are clearly documented and the patient clearly understands and accepts the plan. Careful documentation of findings in the management of early invasive cancer with full justification of the treatment plan and clear informed consent from the patient are a good defence for the clinician.

65.5 Case Studies

1. A near miss

A 40 year old woman presented with irregular vaginal bleeding with a negative pelvic examination and transvaginal scan. Her smear history was complete and unblemished. She was seen by an experienced nurse practitioner working alongside the author. The nurse practitioner asked for a second opinion because she was unhappy with the patient's cervix but could not say what was wrong. The cervix looked bulky in keeping with a parous cervix but was otherwise normal, except that it felt firm to the touch and there was a trickle of fresh blood issuing from the os. The unusual manoeuvre of an endocervical curettage revealed the large stage 1b endocervical adenocarcinoma which could easily have been missed by less experienced clinicians with resultant delay in diagnosis and a worse prognosis. It was of a size that it would have been difficult to argue that it was not detectable at the time.

2. Another near miss

A 44 year old woman again with irregular bleeding and a negative pelvic examination including a normal cervix, a negative transvaginal ultrasound and a negative smear history was assessed by an experienced consultant general gynaecologist. By chance her smear was due and was taken. It showed mild dyskaryosis and when she was seen in the colposcopy clinic 4 weeks later, the cervix was still normal but the high endocervical squamous carcinoma had invaded laterally and had broken through the skin of the right fornix. Again, given the size of the lesion, it would have been difficult to defend the case if the smear had not been taken, even though the first consultant's assessment was not substandard.

3. An inadequate LLETZ

A 30 year old woman had a high grade smear and the colposcopy assessment revealed a lesion in the endocervical canal. A fragmented LLETZ was performed and CIN 3 was diagnosed but no piece had a measured depth greater than 4 mm. The colposcopist blindly followed the protocol to not routinely offer re-excision and arranged follow-up in 6 months when the endocervical cancer was diagnosed. Compensation was awarded.

4. Tumour doubling times

In a judgement, McGlone v GGHB [7], Lord Tyre explored the question of tumour doubling times. The case centred on mis-reporting of two cervical smears and a missed diagnosis of either glandular intraepithelial neoplasia or an early adenocarcinoma of the cervix of a size which could have been treated with fertility sparing surgery and radiotherapy could have been avoided. The size of the tumour was estimated by mean tumour doubling times according to Steel [6] from tumour dimensions 2 years later at diagnosis. Lord Tyre's opinion was that these calculations were not accurate enough to "afford a reliable estimate of the size of the pursuer's tumour" at the time of the breach. Lord Tyre found a number of points in Steel [6] to support that judgement. The interested reader will find the judgement a fascinating insight into the approach of a legal mind to a clinical issue and the way in which lawyers assess and give credence to medical opinion.

Key Points: Colposcopy and Early Stage Cervical Cancer

- Colposcopy services should be organised to ensure waiting time targets are met.
- Treatment should be sufficient to remove CIN lesions.
- Colposcopists should be aware of characteristics of cases where early cancer is missed and have failsafe mechanisms in place to prevent missed diagnosis.
- Rapid access referrals for suspicious cervices should be directed to coloposcopy.
- Patients must be informed of any risk to future reproductive performance after treatment.

- Patients must give informed consent for management of early invasive cervical cancer, taking into account their future reproductive needs.
- Deviation from established protocols should be carefully justified.
- Retrospective estimations of tumour size and the ability to diagnose a cancer at a given time point are not precise.

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Vulval Disorders and Neoplasia

66

Helen Bolton and Peter Baldwin

66.1 Background

The management of vulval disorders can be complex. They represent a wide group of conditions including inflammatory dermatoses, infection, pain-syndromes, premalignant, and malignant disorders. Vulval carcinoma is rare, and delay in diagnosis is common. Clinicians should be familiar with the potential range of disorders, and know when to refer for specialist advice.

66.2 Minimum Standards and Clinical Governance Issues

National Guidance has been published on the management of vulval conditions, including cancer [1, 2]. Many cases require a multi-disciplinary approach, and clinicians should have access to a specialist multidisciplinary vulval service, or there should be clear working arrangements between disciplines to ensure patients receive appropriate care. NICE guidance recommends that when a woman presents with unexplained vulval ulceration, bleeding or a lump, then consideration should be given to an urgent suspected cancer pathway referral and she should receive an appointment within two weeks [3]. Vulval carcinoma must be managed in a cancer centre with appropriate multidisciplinary expertise.

66.2.1 Vulval Dermatoses with Malignant Potential

Vulval skin disorders can predispose to vulval cancer. Vulval lichen sclerosus and lichen planus are inflammatory conditions that are associated with an increased risk of invasive squamous cell carcinoma (up to 5%). Symptoms frequently include itch, soreness, irritation, urinary symptoms and dyspareunia. Introital narrowing and scarring with subsequent sexual dysfunction can occur if left untreated. Both conditions have a characteristic features, but biopsy may be required to make the diagnosis. Management includes provision of information about the condition and general advice on avoiding contact with potential irritants, the use of emollients, and avoidance of tight-fitting clothes. Patients must be made aware of the small but significant risk of malignancy, and given clear instructions to seek medical advice if they notice any change in appearance, texture or symptoms. First-line treatment is with very potent topical steroids, administered initially as an intense regime until symptoms are brought under control, then reducing slowly to a maintenance or 'as required' regime. Biopsy is absolutely essential whenever the diag-

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nosis is uncertain, if there are atypical appearances, if vulval intraepithelial neoplasia (VIN) or malignancy is suspected, or if there has been an inadequate response to treatment. These cases should also be referred onto a specialist vulval clinic. Follow-up is essential. All women should undergo early review to assess response to treatment. Women with stable disease can then be reviewed annually, which can be with their GP, provided their condition is well controlled. An individualised follow-up plan should be in place for women with less well-controlled disease.

66.2.2 Vulval Intraepithelial Neoplasia (VIN)

Lichen sclerosus and high-risk human papilloma virus (HPV) infection are associated with VIN, a rare vulval condition that can progress to invasion, particularly if untreated. A high index of suspicion is required, especially for HPV-related VIN, which tends to affect younger women. Symptoms and signs may be non-specific, and the appearance can be variable. Vulvoscopy can be helpful, but biopsy is essential for diagnosis. Multiple biopsies may be required to exclude invasion. Women with HPV-related VIN should be assessed for associated cervical, vaginal and perianal intraepithelial neoplasia (20%). Advice on smoking cessation is essential where appropriate. Standard treatment of unifocal disease is by local excision, but the management of multifocal disease can be complex and recurrence risks are high. Preservation of function is important and a highly individualised approach may be required, with the options of specialist treatments such as reconstructive surgery, ablative and medical therapies available. VIN is therefore best managed within a specialist vulval service. Close follow-up is mandatory. Other pre-invasive conditions such as vulval Paget's disease and melanoma in situ also require highly specialist management.

66.2.3 Vulval Cancer

Women with suspected vulval cancer should be referred to a cancer centre. Diagnosis should be confirmed by a representative incisional biopsy, typically from the interface of normal and abnormal skin. Removal of the entire lesion by excisional biopsy should be avoided, as this may have an adverse impact on subsequent definitive treatment. Examination under anaesthesia may be appropriate for locally advanced disease. Imaging is used to evaluate groin nodes, and any suspicious nodes should be sampled prior to definitive treatment plans. Histology and imaging should be reviewed by the multidisciplinary cancer team prior to treatment. Treatment primarily consists of radical excision of the vulval lesion, with the aim of achieving a minimum of 10 mm of disease-free tissue. This may require excision of the clitoris, and / or plastic surgical reconstruction. Treatment to the groin nodes is required for all but the earliest of tumours, and is usually surgical. Radiotherapy is predominantly used as an adjuvant to surgery. Treatment, particularly of the groins, may be associated with significant morbidity. The use of sentinel node dissection for selected early cancers may help to reduce morbidity. The management of patients with medical co-morbidities, and those with large tumours or lesions involving important perineal structures will be complex, and require a highly individualised approach. Patients require long-term follow-up so that recurrences are detected as early as possible.

66.3 Reasons for Litigation

Potential reasons for litigation include:

- Delay in diagnosis of cancer.
- Failure to consider multi-centric disease in HPV-related VIN.
- Failure to advise of potential impact of treatment on sexual function or change in appearance of the vulva.
- Inappropriate radical surgery and failure to discuss or offer alternative more conservative treatment options.
- Failure to advise on, or appropriately manage, short and long term complications related to treatment.

There should be a low threshold for biopsy and / or referral to a specialist service in patients with vulval complaints. Robust communication

with the patient and their GP should minimise the risk of missing early malignancy and loss to follow-up. Patients with HPV-related disease should be assessed for multi-centric disease. Patients' expectations require careful management to ensure they are adequately prepared for, and supported through, the potential consequences of their treatment. Ideally the operating surgeon should undertake pre-operative counselling. If this is not possible, then the surgeon must personally inspect the lesion prior to anaesthesia, and not rely solely on a colleague's assessment. Detailed documentation is essential. Photographic records of lesions can be invaluable, provided consent is given and appropriate information governance protocols are adhered to. A drawing can suffice if photographs are not possible. Definitive histology must be available before radical treatment is carried out. Complications must be managed proactively, and with an open and honest approach when things have gone wrong. Units providing specialist services should undertake regular audit of their process, outcomes and complications, and benchmark their performance against nationally published guidance and datasets [1, 2, 4].

66.4 Avoidance of Litigation

Clinicians must be familiar with published national guidance, be aware of their own limitations, and recognise when specialist referral is required.

Communication and managing patient expectations is key to avoiding litigation. Patients must be provided with sufficient appropriate information about their condition, especially the potential risk of malignancy. The importance of attending for follow-up should be emphasized, and patients advised of symptoms that should prompt them to seek earlier medical review. The patient's GP and referring clinician should be informed in writing.

If surgery is required, then careful and sensitive pre-operative counselling is essential and must cover all options, including non-surgical approaches. Discussion should include an explanation of potential risks, benefits and likely consequences of surgery and also of the other possible management options. Where relevant, issues such as sexual function and changes in appearance should be addressed directly by the clinician, as patients may feel too embarrassed to ask. Care must be taken not to make assumptions about these sensitive issues. Radical surgery can be associated with significant short and long-term morbidity. This must be anticipated and discussed prior to embarking on treatment. Patients should be offered appropriate support, including the involvement of Specialist nurses and psychosexual services. Counselling should be supplemented with patient-specific written information, and thoroughly documented in the medical records.

Surgery should only be carried out by those with appropriate training, expertise and sufficient caseload. A meticulous surgical technique must be employed, and steps to mitigate the impact on vulval function should be utilised wherever possible, for instance by the use of multi-modality therapy or reconstructive techniques. When complications arise, the surgeon should remain closely involved and committed to solving the problem.

66.5 Case Study

66.5.1 P v Salford Royal Hospitals NHS Trust [2002]

A 40-year old woman was diagnosed with an early vulval carcinoma arising in the posterior fourchette. The nearby tissue showed pre-malignant change, but the anterior aspect of her vulva was normal. She was advised to undergo surgery to remove the abnormalities, and her surgeon carried out a vulvectomy. This included removal of her entire vulva and clitoris. Consequently she was unable to resume sexual activity, and subsequent surgical reconstruction failed. She alleged that her treatment was negligent on three counts: (1) vulvectomy was inappropriate, as she should have had wide local excision; (2) she did not receive appropriate pre-operative counselling; and (3) she was not expressly informed that she may not be able to resume normal sexual relations. Liability was admitted, and the court awarded her £65,786.63 in total damages. This case illustrates

the importance of providing the correct treatment, and addressing the potential impact on sexual function.

66.5.2 WR v Birmingham Women's Healthcare NHS Trust (2004)

A 37-year old woman underwent treatment for removal of a Bartholin's cyst. During the procedure she sustained a tear in her labia minora, resulting in a persistent skin tag, which required surgical revision six months later. The case was settled out of court, and she received £12,000 in damages for pain, suffering and loss of amenity. This case demonstrates the importance of meticulous surgical technique and the post-surgical appearance of the vulva to patients. This is applicable in cases of vulval neoplasia as well.

Key Points: Vulval Neoplasia

- A multidisciplinary approach is essential.
- There should be a low threshold for biopsy.
- The follow-up of stable vulval dermatoses with malignant potential does not have to be in a specialist setting, provided the disease is stable and both the patient and the GP are provided with robust information on the condition.
- VIN and vulval malignancy must be managed by specialist services with sufficient caseload, expertise and MDT set-up.
- Expectation management and careful counselling is essential, with adequate documentation of discussions.
- Definitive histology should be obtained before radical treatment is carried out.
- Fail-safe systems should be in place to prevent loss to follow-up.

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Uterine Cancer

67

Amit Patel

67.1 Background

With the incidence on the rise since 1970s, uterine cancer is now the most common gynaecological cancer in the United Kingdom (UK). About 9000 cases of endometrial cancer are diagnosed every year with life time risk in general population at about 1:40 [1]. Although there is no screening programme for endometrial cancer, a majority of the cases are diagnosed in early stage due to early presentation with abnormal vaginal bleeding. Peak incidence by age is 70–74 years. Postmenopausal bleeding (PMB) is considered suspicious and GPs are expected to refer women urgently to a clinic (2WW clinic) to be seen within two weeks [1, 2] to rule out cancer. High BMI, Diabetes, Hypertension and unopposed use of oestrogen hormonal therapy are important risk factors along with nulliparity and late menopause.

The most common type of endometrial cancer is endometrioid type which carries a good prognosis. Less common high-grade serous and clear cell morphology have a poorer prognosis.

The 2WW service for PMB is designed for the early detection and a diagnostic pathway for most women with endometrial cancer. Guidance on who to refer to this service is provided by The National Institute for Health and Care Excellence (NICE) [2]. There is heterogeneity in the assessment methods offered at 2WW clinic. A pipelle® endometrial sampling or hysteroscopic guided biopsy along with ultrasound scan is used alone or often in combination. British Gynaecological Cancer Society (BGCS) guidelines on endometrial cancer recommend use of ultrasound as the first line triage to select women with endometrial thickness of 4 mm or more for endometrial sampling preferably with pipelle® or if pipelle® fails with out-patient hysteroscopy [3]. It is inevitable that this may not be possible, suitable or even yield intended results where an alternative plan may be required including but not limited to tests such as a day-case general anaesthetic (GA) hysteroscopy, MRI, CT scan or even hysterectomy. Full documentation of the investigations with findings, difficulties, overall impression, tracking of the results and future plans in timely fashion is expected from the clinician performing assessment.

Occasionally cancer may be diagnosed incidentally after having a hysterectomy for other reasons. All women with endometrial cancer should have as a minimum an x-ray of the chest. CT scan or MRI of pelvis may help with treatment decisions but is not essential and their role in early stage of disease is limited. However their use in suspected advanced stage disease may alter the treatment regime [3].

Treatment of uterine cancer is initially with surgery. Role of lymphadenectomy in early stage

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endometrial cancer has remained controversial. Two RCTs, a Cochrane review and a SEPAL study has failed to show a clear survival benefit although the quality of some of these studies have been criticised [4–7]. There are, therefore, two schools of thought; those who perform full surgical staging including full nodal assessment followed by selective adjuvant treatment based on lymph node status and those who perform only hysterectomy without lymph node excision and offer liberal adjuvant treatment based on tumour characteristics. Either of these is considered acceptable and would not form a ground for a claim of substandard treatment. New technology of sentinel node detection shows good promise in early research and in time may help resolve the dilemma of lymph node assessment [8, 9]. However if offered, sentinel node assessment should be thoroughly explained and consent should be sought with documentation of its role compared to full and no lymph node assessment at all [8].

Adjuvant treatment with external-beam radiotherapy and vaginal brachytherapy in stage 1 and 2 endometrial cancer is based on risk-stratification (see Table 67.1) [3]. For low-risk no adjuvant therapy, for intermediate-risk vaginal brachytherapy therapy alone, for node negative high-risk vaginal brachytherapy therapy alone and for remaining scenarios vaginal brachytherapy with external-beam radiotherapy and consideration for chemotherapy is recommended by the BGCS guidelines.

FIGO Stage 3 and 4 patients may be offered surgery but if advanced stage is known pre-operatively they may have surgery after evidence of response to pre-operative chemotherapy or radiotherapy.

Women suitable but not fit for surgery may be offered palliative chemotherapy or hormonal treatment with radiotherapy reserved for symptom control.

Survival in uterine cancer depends on many factors but mainly on the FIGO stage, grade, morphology, age and fitness of patient. Although overall 5 year survival is 84%, survival in stage 1 is in excess of 95%. Survival has improved gradually over last four decades [1].

Table 67.1 Risk stratification of early stage endometrial cancer for adjuvant treatment decisions (as described in BGCS guideline)

Low risk	FIGO grade 1, Stage Ia, Ib, no LVSI FIGO grade 2, Stage Ia, no LVSI	No adjuvant treatment
Intermediate risk	FIGO grade 2, Stage Ib, no LVSI FIGO grade 3, Stage Ia, no LVSI	Vaginal brachytherapy
High-intermediate risk	FIGO grade 3, Stage Ia, regardless of LVSI FIGO grade 1, grade 2, LVSI unequivocally positive, regardless of depth of invasion	Consider external beam radiation versus vaginal brachytherapy if nodal status unknown. Consider adjuvant brachytherapy versus no adjuvant therapy if node negative
High risk	FIGO grade 3, Stage Ib	Consider external beam radiation versus vaginal brachytherapy. Consider adjuvant chemotherapy.

67.2 Minimum Standards and Clinical Governance Issues

The most up-to-date guidance on the management of endometrial cancer is published by BGCS [3]. Although variations in the assessment of suspected endometrial cancer and treatment of confirmed cancer exists and is allowed within the scope of guideline due mainly to the lack of evidence, there are few points of absolute certainty that, if remembered and practised, risk of litigation can be reduced.

1. All suspected endometrial cancer referral with endometrial thickness of 4 mm or more should have one or other form of endometrial biopsy.
2. All women with negative biopsy or endometrial thickness less than 4 mm should be

advised to see their GP again if their symptoms persist due to small false negative test risk. This should be no more than six months and preferably at the 3 months mark.
3. In women where biopsy is not possible (including consideration of GA), a choice of MRI or hysterectomy should be discussed with woman and documented.
4. All women with completed family diagnosed with atypical complex hyperplasia should be offered hysterectomy [10].
5. All confirmed endometrial cancer cases should be discussed and registered with regional cancer MDT prior to treatment.
6. Grade 1 and 2 endometrial cancer requiring simple hysterectomy can be managed at diagnostic centre by clinician who is a member of regional cancer MDT.
7. All women with endometrial cancer should have at minimum x-ray of chest.
8. Grade 1 endometrial cancers confined to uterus do not require lymph node excision.
9. Ovaries and tubes should be removed at the hysterectomy baring exceptional circumstances in young premenopausal women.
10. Low-risk endometrial cancer (see Table 67.1) do not require post-hysterectomy adjuvant treatment with radiotherapy or chemotherapy.
11. There is no proven therapeutic value of removal of lymph nodes. Only prognostic value and value in triaging for adjuvant treatment.

67.3 Reasons for Litigation

- Missing indications for an urgent referral.
- Prescribing Oestrogen only HRT to women with a uterus.
- Delay in diagnosis.
- Lack of or miscommunication.
- Failure to implement Montgomery ruling in clinical practice.
- Failure to recognise and take account of full clinical problem.
- Deviation from the normal pathway for 2WW.
- In cases of failure of investigation failure to discuss and document altered plan of actions and its rationale.
- Acting outside guideline recommendations without justifiable rationale.

67.4 Avoidance of Litigation

When discussing the treatment options with a woman, all available options of treatment (including those not available in the department) should be discussed without prior judgement allowing for her to weigh the information and decide for herself. Consent and clinical documentation should be thorough and woman's right of second opinion should be respected. A clinician has the right to decline to offer the treatment of her choice but in such circumstances a second opinion must be offered to woman. When care is shared, it is crucial to have a clear communication with colleagues and patients regarding the process and steps in the patient pathway. This remains one of the common causes of litigation.

Following areas are accepted as reasonable area of heterogeneity. Most of these are due to the lack of evidence one way or other. If proper documentation of reasoning and rationale in exercising these options is carried out, it would offer good protection against litigation.

1. Temporary fertility sparing conservative treatment in an early stage endometrial cancer following a recognised practising body guideline (e.g. ESGO) in a thoroughly counselled woman is acceptable. There is a high-risk of poor outcome and higher risk of litigation particularly if any deviation from the guideline occurs.
2. Lymph node dissection in grade 2+ and non-endometrioid endometrial cancers.
3. External beam radiotherapy and chemotherapy in high-risk endometrial cancer.
4. Sentinel node assessment in endometrial cancer verses full or no lymph node assessment.
5. Open laparotomy surgery in cases where justification can be offered for not performing through minimal access route.

67.4.1 Special Situations

1. Incidental thickened endometrium in absence of PMB

There is no guidance available on incidentally diagnosed thick endometrium in post-menopausal women in absence of PMB. However published literature and clinical consensus in these women would be to not offer assessment unless they have one of the aforementioned risk factors. These women should be counselled to contact their GP as soon as possible if they have any PMB in the future.

2. Detection of polyp on ultrasound scan in absence of PMB

If a polyp is seen during the clinical examination and is deemed feasible to remove in outpatient settings then removal should be attempted. Asymptomatic polyp detected on ultrasound scan does not require removal unless women have high risk factors for endometrial cancer. These women should be counselled to contact GP as soon as possible if they have any PMB in the future.

67.5 Case Studies

1. A missed endometrial cancer

A 55 year old woman with post-menopausal bleeding was seen by consultant in a 2WW clinic. The history taken by the GP included additional symptoms of unintentional weight loss and abdominal pain. Ultrasound scan in clinic suggested 2 cm uterine tumour likely polyp. GA hysteroscopy was arranged. This was carried out by another consultant who found normal endometrial cavity and endometrial biopsy was reported benign. Details of additional suspicious symptoms were not discovered and 2 cm tumour on ultrasound scan remained unexplained. Woman was discharged with no further follow-up. Women returned to 2WW after several months with continued bleeding and later on further investigation was found to have a high-grade endometrial cancer. Learning points here were the mismatch between obvious uterine lesion on scan and unexplained negative endometrial assessment and failure of sharing and tracking of additional suspicious symptoms at the time of discharge. A further imaging such as MRI to exclude myometrial pathology would have been justified prior to discharging woman and she should have been advised to return to clinic or GP if bleeding persisted. Outcome of her rare cancer despite aggressive treatment was poor. Whilst negative hysteroscopy and histology can be defended with false negative rates of these tests it would have been difficult to argue why mismatch of investigation was not further pursued.

2. Another cases of harm not contested in the court

A 61 year old asymptomatic woman with thickened endometrium (8 mm) was referred to 2WW clinic where Pipelle® failed to obtain any sample. Woman was then subjected to general anaesthetic hysteroscopy and polypectomy was carried out by senior registrar on an afternoon list. Woman stayed overnight due to pain and following a CT scan for continued pain returned to theatre for suspected intestinal perforation. Three perforations were found and managed by intestinal resection, anastomosis and protective temporary ileostomy. Histology was benign. This case if went to litigation would have been difficult to defend.

Key Points: Uterine Cancer

- Referral standards: As described in 2015 National Institute for Health and Care Excellence (NICE) guidance; Suspected cancer: recognition and referral.
- Endometrial cancer treatment standards: As described in 2017 British Gynaecological Cancer Society (BGCS) guidance; Uterine Cancer Guidelines: Recommendations for Practice.

- Endometrial hyperplasia treatment standards: As described in 2016 Royal College of Obstetricians and Gynaecologists (RCOG) / British Society of Gynaecological Endoscopy (BSGE) Joint Guideline on the Management of Endometrial Hyperplasia.
- Any deviation from recommended practice or situation not covered by guidance should be thoroughly discussed with patient and documented in details including rationale taking into account recent Montgomery ruling.

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Ovarian and Tubal Cancer

68

Richard Clayton

68.1 Background

The commonest type of ovarian cancer is epithelial ovarian cancer (EOC) and within EOC, high grade serous histology is the commonest. Non-epithelial types of cancer include sex cord-stromal tumours (15–20%) and germ cell tumours (5%).

Epithelial ovarian cancer and fallopian tube cancer are usually grouped together with primary peritoneal cancer and are all managed in a similar fashion. The exact site of origin is often unclear, although there is increasing evidence that most high grade serous 'ovarian' cancers in fact arise from the fallopian tube. When there is no obvious tumour involving the ovary or fallopian tube, the tumour will be regarded as primary peritoneal.

There were approximately 7400 new cases of ovarian cancer diagnosed in the UK in 2014 with approximately 4100 deaths from ovarian cancer. The high death rate compared to many other cancers is because the majority of ovarian cancer will be diagnosed at an advanced stage i.e. stage 3 or 4 (60–70%) as initial symptoms may be vague leading to inevitable delays in diagnosis. Ovarian cancer is staged according to FIGO criteria (see appendix).

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68.2 Minimum Standards and Clinical Governance Issues

NICE issued guidance on the management of ovarian cancer in 2011; "Ovarian cancer, recognition and intial management" [1].

The British Gynaecological Cancer Society (BGCS) [2] have recently issued comprehensive guidelines for the management of epithelial ovarian/tubal/peritoneal cancer covering all aspects of care. These incorporate aspects of the NICE guidance, where relevant.

68.2.1 Initial Recognition and Diagnosis

NICE recommends referral to secondary care if ascites or a pelvic mass is detected, which is not obviously fibroids. Otherwise a process of 'sequential testing' in primary care is recommended;

> *"if a woman (especially if 50 or over) reports having any of the following symptoms on a persistent or frequent basis—particularly more than 12 times per month; persistent abdominal distension (women often refer to this as 'bloating'); feeling full (early satiety) and/or loss of appetite; pelvic or abdominal pain; increased urinary urgency and/or frequency. Consider carrying out tests in primary care if a woman reports unexplained weight loss, fatigue or changes in bowel habit."*

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Initially a serum CA125 should be measured (this is a marker which is raised in some cases of ovarian cancer) and if this is above the normal range, an ultrasound of the pelvis should be requested. If both are abnormal then referral into secondary care should take place, potentially urgently, depending on the ultrasound results.

68.2.2 Screening and Prevention of Ovarian Cancer

There is currently no established national program for screening in the UK, even in women who are known to have an increased risk of ovarian cancer based on their family history, or genetic testing for the presence of predisposing genes (BRCA1 and BRCA2). This is because the benefits of screening, unlike the situation with some other cancers (e.g. cervix) are unclear. There are several on-going research studies looking at this area. The most effective technique for risk reduction in women at significantly increased risk is prophylactic bilateral salpingo-oophorectomy. This may be considered in women over the age of 35 who have completed their families.

68.2.3 Management in Secondary Care

When a pelvic mass is found on ultrasound imaging, the risk of malignancy will be assessed using an RMI (Risk of Malignancy Index) scoring system, based on the ultrasound findings and the CA125 level. This will be used to triage the patient for further management; A high risk of malignancy will indicate management in a designated cancer centre. All patients thought to be at high risk of malignancy must be discussed in a multidisciplinary team meeting (MDT) to determine optimal management.

The BGCS guidelines state; "*Women with suspected epithelial ovarian cancer should undergo surgery at a cancer centre by specialised surgeons who are core members of a specialist MDT. The aim of surgery for early ovarian cancer (stage I and II) is complete macroscopic tumour resection and adequate surgical staging. Patients suitable for fertility-sparing surgery should be identified by the MDT and the pros and cons of this discussed with them, so that they can make an informed choice".*

When there is evidence of advanced disease e.g. ascites or a raised CA125, a CT scan will be requested to assess the extent of any metastatic tumour. An MDT assessment should then take place to review the findings on CT, in conjunction with information about the patient's performance status and general health.

The standard of care in epithelial ovarian cancer is to offer initial surgical 'debulking' i.e. removal of all areas of cancer. 'Maximal surgical effort', which may involve surgical techniques such as bowel resection or peritoneal stripping, should be employed to facilitate this. Considerable morbidity may be associated with this and the potential benefits have to be balanced against the risks of the surgery, particularly in a patient whose performance status or pre-existing medical conditions suggest that prolonged and extensive surgery may cause significant complications. This decision is often not clear-cut and will involve assessment by the MDT and discussion with the patient.

The alternative option of using initial chemotherapy (neo-adjuvant) with surgery at the midpoint of the treatment (interval debulking) is thought to be non-inferior to initial surgery. This may be employed, particularly if there are thought to be areas of non-resectable disease initially, or when the patient's medical condition precludes aggressive surgery. A radiological guided biopsy of the tumour to confirm an epithelial ovarian-type cancer is required before commencing chemotherapy.

68.2.4 Chemotherapy for Epithelial Ovarian Cancer

Chemotherapy is not required following surgery for stage 1a/b grade 1/2 disease. Carboplatin is the main chemotherapy agent used and in advanced disease, it is usually combined with Paclitaxel. The treatment is given for 6 cycles at

three weekly intervals. There are alternative options for dosage and drug types depending on response or allergy/tolerance to these agents. Bevacizumab, an anti-angiogenic agent can be used in some advanced disease settings and results in a delay in progression of the disease (progression free survival) but does not affect overall survival.

68.2.5 Follow-Up

The BGCS guidelines recommend regular clinical follow-up visits with holistic assessment of the patient and examination to exclude recurrence. Most centres will follow-up for 5 years at decreasing frequency. The guidelines point out however, that there is no good evidence to support regular follow-up of this type compared with an "individualized and symptom-led approach". The use of CA125 during follow-up is not mandatory, as there is no survival benefit associated with its routine use. In practice, however, most centres will measure this.

68.2.6 Recurrent Cancer

The mainstay of treatment for recurrent epithelial ovarian disease is further chemotherapy. The type of chemotherapy will depend on the interval since completion of previous chemotherapy; when a patient is sensitive to platinum based chemotherapy, re-treatment will usually be given with further similar chemotherapy. Bevacizumab may also be considered.

When there are a limited number of sites of recurrent disease, a careful MDT discussion should take place regarding the use of surgery to remove the recurrent disease. There is currently limited evidence to support this approach.

68.2.7 Non-Epithelial Ovarian Cancer

Sex cord-stromal tumours; treatment is primarily surgical. The tumours are relatively insensitive to chemotherapy but unlike epithelial ovarian cancer, repeated surgical excision in advanced or recurrent situations can be used. Consideration may be given to the use of hormonal manipulation as the tumours may be sensitive to the effects of oestrogen on their growth.

Germ cell tumours; generally occur in young women. Germ cell tumour markers should be measured prior to surgery in any woman under 40, to try to exclude the diagnosis. It is usually possible to preserve fertility when the patient wishes; removal of the primary tumour with adjuvant chemotherapy for high-risk or advanced disease, is the mainstay of treatment. The disease is usually extremely sensitive to chemotherapy, and cure is usual even in advanced disease.

68.3 Reasons for Litigation

- Delay in diagnosis—particularly in primary care.
- Failure to act on suspicious or concerning imaging findings in secondary care.
- Failure to consent and discuss risk of complications appropriately.
- Surgical complications; specifically injury to viscera or major vessels. This is common to all gynaecological surgical procedures. Due to the often extensive nature of the surgery the risk of complications will be higher than in otherwise uncomplicated gynaecological procedures.
- Failure to discuss or appropriately consider fertility sparing surgery.
- Failure to recognise and manage post-operative complications promptly.
- Failure to detect, or delay in detection of, recurrence of tumbour.

68.4 Avoidance of Litigation

- In General Practice, recognition that frequent but often non-specific symptoms as outlined in NICE guidance, should lead to use of sequential testing i.e. use of CA125 measurement followed by ultrasound scan if required.
- Documentation of appropriate history and pelvic examination in General Practice in order to exclude a pelvic mass.

- Appropriate referral to secondary care when the patient meets the NICE criteria for referral.
- Evidence of MDT discussion and agreed management plan when the RMI is raised.
- Documentation that discussion has taken place regarding fertility preservation where appropriate.
- Careful operative description detailing any difficulties encountered during surgery and any departure from 'straightforward' surgery e.g. requirement to mobilise ureters in order to perform a hysterectomy.
- Appropriate prescription of antibiotics and prophylaxis for venous thromboembolism.
- Careful post-operative documentation to recognise and assess potential post-operative complications with minimal delay.

68.5 Case Study

R v BUH NHS FT: Claimant was diagnosed with advanced ovarian cancer in 2012. She was treated with a combination of chemotherapy and surgery, however the treatment was unsuccessful. Prior to the diagnosis she suffered from abdominal symptoms which had started approximately 18 months before diagnosis.

Imaging review suggested that a CT scan had been misreported shortly after symptoms had started. Earlier diagnosis should have taken place approximately 1 year before eventual diagnosis. Earlier diagnosis would have led to a reduced duration of pain and suffering. Based on the finding of advanced metastatic disease at diagnosis, there was thought to be probable metastatic disease one year before eventual diagnosis. The chance of long term survival would only marginally have improved with earlier diagnosis.

Key Points: Ovarian/Tubal Cancer

- Recognition of concerning symptoms in General Practice with appropriate use of sequential testing and referral when NICE criteria are met.
- Referral and management in a cancer centre when the RMI is raised.
- Discussion and documentation by MDT of management plan.
- Careful documentation of operative difficulties encountered.
- Careful documentation post-operatively to recognise and address complications promptly.

Appendix: FIGO Staging System

FIGO Ovarian Cancer Staging
Effective Jan. 1, 2014
(Changes are in italics.)

Stage III: Tumor involves 1 or both ovaries with cytologically or histologically confirmed spread to the peritoneum outside the pelvis and/or metastasis to the retroperitoneal lymph nodes

Old		New		
IIIA	Microscopic metastasis beyond the pelvis.	*IIIA (positive retroperitoneal lymph nodes and/or microscopic metastasis beyond the pelvis)*		
		IIIA1	*Positive retroperitoneal lymph nodes only*	
			IIIA1(i)	*Metastasis ≤ 10 mm*
			IIIA1(ii)	*Metastasis > 10 mm*
		IIIA2	*Microscopic, extrapelvic (above the brim) peritoneal involvement ± positive retroperitoneal lymph nodes*	
IIIB	Macroscopic, extrapelvic, peritoneal metastasis ≤2 cm in greatest dimension.	IIIB	*Macroscopic, extrapelvic, peritoneal metastasis ≤ 2 cm ± positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen.*	
IIIC	Macroscopic, extrapelvic, peritoneal metastasis >2 cm in greatest dimension and/or regional lymph node metastasis.	IIIC	*Macroscopic, extrapelvic, peritoneal metastasis > 2 cm ± positive retroperitoneal lymph nodes. Includes extension to capsule of liver/spleen.*	

Stage IV: Distant metastasis excluding peritoneal metastasis

Old		New	
IV	Distant metastasis excluding peritoneal metastasis. Includes hepatic parenchymal metastasis.	*IVA*	*Pleural effusion with positive cytology*
		IVB	Hepatic and/or *splenic parenchymal* metastasis, metastasis to extra- abdominal organs (including inguinal lymph nodes and lymph nodes outside of the abdominal cavity)

Other major recommendations are as follows:

- Histologic type including grading should be designated at staging.
- Primary site (ovary, Fallopian tube or peritoneum) should be designated where possible.
- Tumors that may otherwise qualify for stage I but involved with dense adhesions justify upgrading to stage II if tumor cells are histologically proven to be present in the adhesions.

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Gestational Trophoblastic Disease

69

John Tidy

69.1 Background

Gestational Trophoblastic Disease (GTD) is relatively rare in the UK with an incidence of 1 in 714 births. GTD includes complete and partial molar pregnancies. The incidence is higher in women of Asian ethnicity (1 in 450) and more common at the extremes of reproductive age with an incidence of 1 in 500 in women under 15 years of age and 1 in 8 in women over 50 years. Gestational Trophoblastic Neoplastic (GTN) can develop after complete or partial moles, miscarriage or a term pregnancy. Women who develop GTN require treatment with chemotherapy. Women treated for GTN in the UK have very high cure rates, 100% for low risk GTN and 94% for high risk GTN.

69.2 Minimum Standards and Clinical Governance Issues

Guidance on the management of GTD is issued by the Royal College of Obstetricians and Gynaecologists (RCOG), Green Top Guidance No 38. All women with confirmed or suspected GTD must be registered with one of three screening centre, Ninewells Hospital, Dundee for Scotland, Charing Cross Hospital, London, for southern England, South Wales and Northern Ireland and Weston Park Hospital for the north of England and North Wales. Categories of suspected GTD to be registered include:

- Complete hydatidiform mole.
- Partial hydatidiform mole.
- Twin pregnancy with complete or partial hydatidiform mole.
- Limited macroscopic or microscopic molar change suggesting possible partial or early complete molar change.
- Choriocarcinoma.
- Epithelioid trophoblastic tumour.
- Placental site trophoblastic tumour.
- Atypical placental site nodules.

Most women with GTD now present with a history of abnormal vaginal bleeding in early pregnancy. Late presentation with an enlarged uterus, hyperemesis, early onset pre-eclampsia or thyrotoxicosis is very rare. The diagnosis of molar pregnancy by ultrasound is unreliable in the early part of the first trimester, over 66% of women with a complete mole will not be diagnosed as a complete mole by ultrasound prior to uterine evacuation. The most common ultrasound diagnosis is an anembryonic or delayed miscarriage. Products of conception from all failing

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pregnancies must be sent for histological examination to exclude GTD. All women with GTD must be reviewed following the pathological diagnosis of GTD to inform them of the diagnosis and gain consent for registration at one of the screening centres. Registration can be online or by paper form sent by fax or by post. Women with suspected molar pregnancy should undergo surgical management and not medical or conservative management. Conservative or medical management are associated with higher rates of GTN. All hospitals should audit the management of women with suspected or confirmed GTD to ensure all cases are registered. When there is difficulty in reaching a pathological diagnosis the local pathologist can seek help from the expert pathologists associated with the screening centres. If uncertainty persists the safest option is to register the patient with the screening centre.

Women who develop GTN after a miscarriage or a term pregnancy can be difficult to diagnose. Women with persistent and unexplained vaginal bleeding after any pregnancy event may have GTN, a pregnancy test—urinary or serum should be performed in such cases.

Rarely women can present with symptoms of metastatic GTN including haemoptysis and seizures.

69.3 Reasons for Litigation

The reasons for litigation following a GTD are related to:

- Delay in diagnosis [delay in producing pathology report, failure to diagnose after non molar pregnancy].
- Delay in referring the woman to the screening centre.
- Complications during/arising from the procedure [Inexperienced surgeon, uterine perforation, excessive bleeding leading to hysterectomy].
- Misdiagnosis of 'pregnancy of unknown location' instead of GTD.
- Failure to follow-up women with GTD.
- Rare variants of GTN—Placental site trophoblastic tumour and epithelioid trophoblastic tumour—can be difficult to diagnose.

69.4 Avoidance of Litigation

The wide availability of emergency pregnancy units and early recourse to ultrasound scanning of pregnancy has resulted in women being referred at earlier gestations. The pathognomonic ultrasound and histological features of complete molar pregnancies are present only at more advanced gestation. The absence of any ultrasound features of a molar pregnancy when investigating a failing pregnancy does not exclude a molar pregnancy hence the need for histological assessment of all failing pregnancies. In one study 67% of women with a molar pregnancy had only features of an anembryonic pregnancy or delayed miscarriage.

Prolonged use of prostaglandins to induce termination should be avoided however the use of agents such as misoprostol, to ripen the cervix, administered per vaginum 1 hour before surgical evacuation is acceptable. The surgical evacuation of an enlarged uterus with a suspected molar pregnancy should be performed by an experienced gynaecologist. Women should be counselled about the risk of perforation and hysterectomy if excessive bleeding cannot be controlled. Intra-uterine contraceptive systems should not be inserted at the time of evacuation for a suspected molar pregnancy. The use of ultrasound at the time of uterine evacuation is not mandatory and has yet to be of any proven value in reducing the risk of GTN. In cases of suspected molar pregnancy the products of conception should be sent for histological examination and appropriate follow up made to discuss the results in a timely manner. All women with a molar pregnancy must be registered at one of the three screening centres and must consent to registration and follow-up. Women may be prescribed the combined oral contraceptive pill even when a

molar pregnancy is suspected as there is no evidence of an increased risk of GTN. Ideally women should only undergo a repeat uterine evacuation after discussion with the screening centre unless the patient is in extremis due to profuse vaginal bleeding.

The development of GTN can occur after any pregnancy event. Women who present with abnormal vaginal bleeding after any pregnancy, which has failed to respond to appropriate treatment should have a urine or serum pregnancy test performed.

Audit of practice as recommended in RCOG No 38 should be undertaken.

69.5 Case Study

A 25-year-old woman attended an early pregnancy assessment unit in 2014 with a 4 day history of vaginal bleeding. Her last menstrual period was 8 weeks ago. Clinical examination revealed some old blood in the vagina, the cervical os was closed. She was haemodynamically stable. Transvaginal ultrasound was suggestive of a molar pregnancy and a surgical evacuation of the uterus was performed. Tissue was sent for histological examination, however the report, an early complete mole, was filed in the patient's notes without being reviewed by the medical staff.

Six months later the woman presented to accident and emergency with a massive vaginal bleed. A dark blue nodule was noted on the anterior vaginal wall and there was fresh bleeding from the cervical os. The beta hCG was more than 1,000,000 mIU/mL. The patient was haemodynamically unstable with a pulse of 124 bpm and blood pressure 70/30. An emergency hysterectomy was performed to control bleeding. After the surgery the patient was referred to a trophoblast screening centre. Examination confirmed a vaginal metastasis and metastatic disease in the lungs. The patient underwent several months of multi-agent chemotherapy, and experienced nausea, vomiting, fatigue, and hair loss. She also developed depression related to her inability to have any children.

In this case the medical staff were unaware of the results following the initial uterine evacuation. The patient was not notified of the results and not registered with a trophoblast screening centre. The patient represented with heavy vaginal bleeding which was only controlled by hysterectomy. She had also developed vaginal and lung metastases. The patient took legal action in light of the outcome claiming she had undergone a hysterectomy, causing infertility, and multi-agent chemotherapy because of the failure to review the initial histology report and register her with a trophoblast screening centre. An out of court settlement was made between the patient and the hospital.

Key Points: Gestational Trophoblastic Disease

- Adequate assessment and investigation of all failing pregnancies.
- All complete molar pregnancies managed by surgical evacuation.
- Procedure undertaken by adequately trained surgeons with risk of excessive bleeding and potential for hysterectomy explained.
- Prompt diagnosis, review of patient in clinic and registration of patient at a screening centre.
- Audit of management of molar pregnancies.

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Chemotherapy and Radiotherapy in Gynaecological Cancer

70

Paul Symonds

70.1 Background

Radiotherapy and/or chemotherapy following surgery for cervix, endometrial, ovary or vulval cancer can decrease recurrence rates and improve prognosis. Combined radiotherapy and chemotherapy can cure inoperable cervix cancer in a substantial number of cases (5 year survival stage IIb-68%, IIIb-48%) but is associated with damage to pelvic organs in 5–10% of patients. Litigation following treatment for gynaecological cancer is often centred round failure to give adjuvant treatment or complications of treatment which is claimed to be inappropriate or negligently applied.

Radiotherapy is the use of ionising radiation to kill cancers. It is usually given in multiple treatments (fractions) to minimise damage to normal tissue. Radiation can be administered by linear accelerators (external beam) or by inserting gamma ray sources into the tumour (brachytherapy). Side-effects of radiotherapy during treatment such as diarrhoea are common but usually settle rapidly. Ten percent or less of patients develop serious late complications which may occur 6 months to 5 years after treatment. These include occlusion of the vagina, narrowing of the bowel requiring surgery or fistulae in bladder or bowel.

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Chemotherapy kills cancer largely by damaging tumour DNA and preventing replication. It can be used for cure, symptom control, to reduce risks of recurrence or to make other cancer treatments such as radiotherapy more effective. Side effects are seen in other rapidly dividing normal tissue such as bone marrow.

70.2 Minimum Standards and Clinical Governance Issues

70.2.1 Cervical Cancer

Occasionally general gynaecologists will carry out a simple hysterectomy containing an undiagnosed cervical cancer. Such patients require postoperative radiotherapy or chemo-radiotherapy. In a retrospective study the 5 year survival for patients treated by non-radical hysterectomy was 51.4% which rose to 71.4% if the patient received postoperative radiotherapy [1]. Patients with high risk of pelvic recurrence after radical hysterectomy should receive postoperative radiotherapy or chemo-radiotherapy. There is no absolute agreement on indications but these include pelvic lymph node spread, positive or narrow excision margins (<5 mm) parametrial spread and in some MDT's lymphovascular space involvement. A large randomised trial [2] has shown chemo-radiotherapy is superior to radiotherapy alone in

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patients who have spread to pelvic lymph nodes, positive parametrial involvement or a positive surgical margin following radical hysterectomy. The progression free survival at four years was 63% in the radiotherapy group and 80% in the radiotherapy and chemotherapy arm.

70.2.2 Chemoradiotherapy for Cervix Cancer

Chemoradiotherapy is now the standard of care in the UK for patients suffering from bulky stage Ib, stage II, III or IVa carcinoma of cervix. The chemotherapy mainly used is weekly Cisplatin. A systematic review and meta-analysis has shown that the addition of chemotherapy to radiotherapy resulted in an absolute benefit in overall survival of 12% [3].

Typical UK survival and complication rates can be found in results of a Royal College of Radiologists audit [4]. Following chemoradiotherapy the 5 year disease free survival for Stage IIb disease was 68% and for those with Stage IIIb 48%.

Serious late effects were seen in 10% of the patients. Gross narrowing of the vagina was seen in 5% of patients which may be inevitable if the vagina was heavily involved by tumour as healing would be with fibrosis leading to stenosis. Serious damage to bladder or bowel requiring surgery was seen in 1–3% depending on the site of organ damage.

70.2.3 Endometrial Cancer

The mainstay of treatment is simple hysterectomy. Overall cure rates are in excess of 75% five year survival and only 20–30% of patients require any form of adjuvant treatment in the form of radiotherapy or chemotherapy. Such is the state of knowledge at present that the case could be made for administering or withholding adjuvant therapy in some patients. There is no case for giving routine postoperative external beam radiotherapy in patients with intermediate risk tumours as shown in the Dutch PORTEC-1 trial [5]. Locoregional recurrence was reduced but overall survival was similar in patients treated by external beam radiotherapy or just followed up carefully. Brachytherapy, as shown in the PORTEC-2 trial can reduce vaginal recurrence from about 14 to 0.9% [6]. Brachytherapy is easy to administer via a vaginal cylinder that can be inserted without an anaesthetic. Using a high dose rate brachytherapy machine the treatment takes only a few minutes and is normally given in two or three fractions 1–2 weeks apart.

It is usual practice to offer patients suitable for vaginal brachytherapy a choice between immediate treatment or close observation. If there is recurrence in the vagina, delayed radiotherapy can eliminate tumour in about 65% of cases [5]. In practice about three quarters of patients choose immediate brachytherapy and a quarter a policy of close observation.

There remains a case for giving external beam radiotherapy to patients with poorly differentiated tumours penetrating more than halfway through the myometrium. A meta-analysis and systemic review [7] showed that pelvic radiotherapy gave a 10% survival advantage to this group of patients. It is common UK practice to offer such patients and patients with Stage 2 (involvement of cervix) endometrial cancer immediate radiotherapy or until recently entry into the Anglo-Dutch PORTEC-3 trial. In the PORTEC-3 trial the patients were randomised to radiotherapy or chemoradiotherapy. The basis of this was the incidence of distant metastasis is higher among patients with high risk disease and there is some evidence that postoperative chemoradiotherapy can reduce the development of distant metastasis [8]. The results of the PORTEC-3 are awaited but the use of chemotherapy as adjuvant treatment in patients with endometrial cancer is still an open question.

70.2.4 Ovarian Cancer

Chemotherapy is an essential part of the treatment regime for ovarian cancer patients.

Response rates of 70% are seen in Stage III/IV disease. The standard chemotherapy is Carboplatin and Paclitaxel and when factors such as second line chemotherapy and possible secondary debulking surgery are taken into account the five year survival in Stage III/IV ovarian cancer as shown in the ICON7 trial [9] is 50%. However it must be noted that only between one third and one half of those patients surviving to five years are cured. Paclitaxel and Carboplatin have more toxicity than Carboplatin alone. In particular Paclitaxel causes hair loss (not seen with Carboplatin) and about 20% of patients develop a peripheral neuropathy which in a minority of patients can be permanent. The evidence for the use of Paclitaxel and Carboplatin, albeit the standard therapy is in fact thin. The ICON 3 randomised trial showed no advantage between single agent Carboplatin or Paclitaxel and Carboplatin [9]. The ICON 4 trial did show a small survival advantage in patients relapsing after primary chemotherapy with Paclitaxel plus Carboplatin rather than Carboplatin alone [10]. In elderly and frail patients, or women who do not want to lose their hair, Carboplatin alone, which is well tolerated is the treatment of choice. The NICE advice is to discuss the advantages and disadvantages of single agent Carboplatin alone versus combinations with the patient.

More recently Bevacizumab, a monoclonal antibody against VEGF (vascular endothelial growth factor) has shown in the ICON 7 trial to increase progression free survival but not overall survival [11]. Clearly the use of Bevacizumab has got to be balanced against side effects including hypertension, proteinuria and gastrointestinal fistula.

70.2.5 Vulval Cancer

Surgery is the treatment of choice. However preoperative radiotherapy combined with Cisplatin can result in tumour shrinkage and potentially sphincter saving operations especially in young women with HPV associated vulval cancer.

The literature quotes complete response rates of up to 71% [12] but personal experience is of a lower pathological complete response rate of about one third which enables more conservative surgery to be carried out successfully. Preoperative chemoradiotherapy should be discussed with suitable patients prior to any surgery that may result in the loss of rectum or bladder in patients or very extensive reconstruction.

Tumours which spread to inguinal lymph nodes have a much poorer prognosis than those without nodal metastasis. Generally inguinal spread results in a five year survival of less than 50%. Randomised trials [13, 14] and retrospective studies [15] have shown radiotherapy and chemoradiotherapy improve 5 year survival in node positive patients.

70.3 Reasons for Litigation

70.3.1 Cervical Cancer

In the past increased toxicity was associated with badly placed applicators for brachytherapy treatment and administering doses higher than tolerated by critical organs such as the rectum. Serious complications occur in less than 10% of patients [4]. When serious late damage has occurred it is always worthwhile reviewing the radiotherapy planning imaging to check radiotherapy planning and the position of applicators. Radiotherapy doses, especially to critical organs should be carefully reviewed to see that they are in line with accepted tolerable dosage.

As radiotherapy for cervical cancer patients is now concentrated in a relatively few hands and most centres treat according to well established protocols, negligent radiotherapy treatment is much rarer than would have been seen 20 years ago. In the vast majority of cases radiation complications are due to the fact that the patient had abnormal anatomy or unusually radiosensitive normal tissues.

Many oncology centres have a separate set of case notes. When notes are requested by a solicitor only the main hospital case records are provided unless the solicitor specifically requests the oncology notes.

70.3.2 Endometrial Cancer

As the indications for adjuvant treatment in endometrial cancer have changed and are changing, attempts at litigation centre round failure to offer adjuvant treatment or side effects from alleged inappropriate treatment.

70.3.3 Ovarian Cancer

In a medico-legal context chemotherapy dosage should be checked for eligibility factors for chemotherapy such as white blood cell count, platelet count and renal function prior to administering chemotherapy. The use of electronic prescribing systems has reduced drug dosage errors but has not eliminated them completely.

Neutropenia and thrombocytopenia are recognised hazards of chemotherapy treatment and provided the neutrophil count, platelets and other factors such as renal function were adequate prior to chemotherapy these complications cannot be judged as negligence. Patients with suspected or confirmed neutropenic sepsis should have a broad spectrum antibiotic administered within an hour of attending hospital. Delayed administration of antibiotics can result in death.

70.3.4 Vulval Cancer

Vulval skin is thin and is easily damaged by radiation doses which are very well tolerated elsewhere in the body. Medico-legal allegations include toxicity induced by treatment or paradoxically failure to offer these therapies.

70.4 Avoidance of Litigation

- Appropriate patients after surgery for cervical or endometrial cancer should be considered for adjuvant treatment.
- Chemoradiotherapy is standard of care for patients with bulky Stage Ib to Stage IVa cervical cancer.
- Serious complications such as fistula or bowel damage can develop in <10% of cervical cancer patients treated by chemoradiotherapy and can be minimised by adhering to accepted critical organ tolerance dosage and precise positioning of brachytherapy applicators. Allegations of using too high a dose or treating too big a volume can be rebutted if normal tissue tolerance limits have not been exceeded and treatment doses are consistent with international practice.
- Chemotherapy is an essential part of the treatment of the majority of ovarian cancer patients. Even if eligibility protocols are followed exactly <5% may develop potentially life threatening neutropenic sepsis which must be recognised and treated promptly. Adherence to standard chemotherapy protocols, often derived from clinical trials, with appropriate adjustments for renal function and bone marrow capacity usually prevent allegations of under or over dosage.
- Extravasation of chemotherapy (especially anthracyclines) is rare but can cause devastating normal tissue damage. Extravasation of Carboplatin and Cisplatin (the most commonly used agents in gynaecological cancer) rarely results in normal tissue damage.
- The vulval skin is very radiosensitive and easily damaged but judiciously applied chemoradiotherapy can reduce the extent of surgery and improve prognosis in node positive patients.

70.5 Case Study

A problem can arise if the computer has initially been programmed incorrectly as occurred in a much publicised case of bleomycin induced lethal pulmonary toxicity [16].

The patient was suffering from poor prognosis metastatic testicular cancer. He was entered into an MRC trial and was randomised to the high dose arm. The dose of bleomycin was incorrectly entered into a computer and this error remained unnoticed until the patient developed severe bleomycin lung toxicity which ultimately proved fatal. This led to a successful compensation claim and referral of the clinician to the GMC. Although this is a non-gynaecology case it is in the public domain and illustrates an important general principle that clinicians may be too trusting of computer derived data.

Key Points: Chemotherapy and Radiotherapy

- When discussing treatment options, the pros and cons of chemotherapy and radiotherapy should be discussed in addition to any alternative treatments.
- Patients should be informed of risks of chemotherapy and radiotherapy.
- Patients should be involved in the decisions relating to their treatment.
- Prior to administering chemotherapy the usual checks of white cell and platelet counts and renal function should be done to check eligibility.
- Chemotherapy protocols should be followed.
- Diligence to dose calculation is important to avoid toxicity when administering chemotherapy.
- Careful applications for brachytherapy and due caution with dose calculations avoids toxicity from Radiotherapy.

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