Medical Law as Applied to Paediatric Oncology Surgery

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Introduction

To describe the influence of medical law on as wide ranging a topic as paediatric oncology is a significant undertaking. But in a book destined to be read by surgeons working in multiple continents, Nations and States, there is the additional problem of describing the complex variations of the local legal rules existing in the diverse jurisdictions within which the surgeons work. Surgeons working in North America will sympathise with the claim that the heady mixture of (individual) State and Federal law can lead to some legal uncertainties. These are multiplied when considering the fundamental differences between the common law and civil legal systems as they are variously represented across the world.

This chapter is thus determinedly written on the basis on a single jurisdiction [1], that of England and Wales. The intention is to examine in depth the core subjects of capacity, disclosure, and some legal devices to facilitate treatment in this single common law system. The principles behind the rules described echo throughout many jurisdictions, and will, with some modification, be applicable to most.

Capacity to Provide Consent

In paediatric oncology surgery, the majority of patients will be unable to provide their own consent, since they will have insufficient capacity to do so. This burden will thus fall upon their parents, and the effect of this relationship is variously defined in different jurisdictions. In England and Wales, as a result of the Children Act 1989 and its supporting legislation, children are divided into three broad groups. Those under 16 years are presumed to lack capacity to provide consent, although a substantial number at the older end of this age range may rebut this presumption by proving their capacity for the decision that they are being asked to make. The others in this group, who cannot pass this threshold of capacity ('incompetent') need to have their consent provided by a competent person with parental responsibility. Children who are 16 and 17 are in a distinct group, 'young people', in whom the presumption has switched, so the starting position is that they possess capacity to provide consent for treatment. This may be challenged by their parents or clinicians; and this challenge is particularly engaged if the young person refuses to provide consent. On the 18th birthday, adulthood is reached, and the lingering rights of those with parental responsibility are extinguished. In our jurisdiction, the consent (or its refusal) by an adult found to be competent is unlikely to be challenged.

In England, a child is therefore someone who has not yet reached 18 years of age. Legal synonyms include 'minor' and 'infant'. The latter is instructive, since it is derived from the Latin: *Infans*, unable to speak. This reflects the legal rules which prevent children from speaking for themselves in court, although this impediment has been at least partly addressed over the last two decades. Nevertheless, it begs a fundamental question, as to whether children can provide their own consent, or whether they depend upon their parents to provide it for them.

Children under the Age of 16 Who Lack Capacity

This is the simplest group. Although presumed to lack capacity, some will be able to demonstrate their competence to provide independent consent for treatment (vide infra).

For those who cannot, a person with parental responsibility has the right to provide consent where necessary. The child's mother (the woman who gave birth to the baby, rather than the person who provided the egg from which he

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was conceived, if different) has parental responsibility automatically. The child's father gains parental responsibility automatically if he is married to mother at the time of the birth registration, or when they subsequently marry. Since 2003, unmarried fathers also get parental responsibility automatically, when they register the birth. Alternatively, parental responsibility can be acquired by the unmarried father; either with the agreement of the child's mother, or by application to a court.

Parental responsibility is passed to adoptive parents on legal adoption. It may be shared with guardians appointed by parents; with local authorities; and is linked to various legal orders[1].

The person with parental responsibility who provides consent for a child's surgery must act in the child's best interests in so doing. These are usually self evident, and the agreement between parents and surgeon is reached after full disclosure of the relevant information.

Having absorbed this description, the reader may well ask whether a failure accurately to identify the requisite adult with parental responsibility constitutes sub standard care. There is little indication in this jurisdiction to suggest that this is the case, although in general principles, a surgeon would be expected to ensure that the person providing consent has the authority to do so. In the first line of National Health Service consent forms, the signatory is required to assert their status as a person with parental responsibility. Emphatically, surgeons are not required to go behind this assertion, in pursuit of 'proof' of parenthood. We are, after all, surgeons, not police officers or social workers. Furthermore, the disclosure necessary properly to inform the consent for oncological surgery at times requires parents to absorb grave and complex risks. It is the manner and substance of this disclosure, and not the legal status of those who claim parentage of the child, that should be foremost on the surgeon's mind. Nevertheless, if there are reasonable grounds to doubt an assertion of parental responsibility, it may be in the child's best interests to take proportionate steps to clarify the situation.

Parental agreement with a surgical management plan is not invariable. In a case [3] concerning a child with biliary atresia, the clinicians wished to perform a liver transplant, and considered the prospects of success to be good. The parents refused their consent, on the grounds that the surgery was not in the child's best interests. The Court of Appeal held that the assessment of the child's best interests went wider than the narrower medical best interests, and that T's connection with his family held great weight in this regard. Accordingly, the court refused to enforce the hospital's request that the mother would bring T in for surgery. The judgement could be criticised, in failing to differentiate between the interests of the child and those of his mother. However, the case provides an example of the balancing act performed by courts, when faced with dissonance between surgeons and parents.

Such dissonance is foreseeable when dealing with the potential morbidity and mortality associated with major tumour resection, particularly in cases where the anatomical site of the tumour increases the risk of direct trauma to contiguous organs, or to major blood vessels, with resultant fields of ischaemic damage. The excision of neuroblastoma falls into this group; with the attendant risk that resection may not influence the eventual outcome of that child's disease. Irrespective of these risks, parents very rarely baulk at the prospect of resection, focussed as they usually are on removing the primary tumour, and perceiving little alternative to running the risk of perioperative harm.

In cases where there is tangible parental reluctance to consent, it is submitted that a second opinion, to repeat the explicit balancing exercise between the risks and benefits of resection for this particular child will almost always be beneficial, to the child, her parents, and the surgeon involved.

Parental disagreement with a surgical oncology plan is uncommon, but occasionally occurs in relation to the necessity for long term central venous access. Disclosure of the alternatives to any surgical management plan must be provided to ensure that consent is 'informed', and thus valid. In the case of venous access, it may be better to defer the final decision for a long term line by temporising, and suggesting intermediate peripheral access, with a PICC device. In this way, parents, surgeons and patient can mull over the additional risks and benefits of a more permanent device, whilst avoiding delay of early phase treatment.

Children under 16 Who Can Demonstrate Their Capacity

Depending on their maturity and the intervention that is proposed, children from a young age may be able to provide independent consent. A 4 year old may be able to consent to a blood pressure measurement; a 6 year old to a venepuncture; a 10 year old to the removal of a central venous catheter. It is not suggested that the parents should be excluded from this process; such an exclusion would be quite wrong. It is for the family as a whole to decide what part the child's potential capacity should play in the consenting process. But the involvement of children in this process will strengthen the therapeutic relationship, and is to be encouraged.

A child's previous experience is of great importance. It is submitted that following the very recent diagnosis of leukaemia, a 15 year old, who has been healthy up to this point, will be so horrified by the dissolution of his comfortable and well organised life as to be incoherent, and potentially incapable

[1]For a full account see Bainham [2].

of consenting for the necessary tunnelled central venous catheter (CVC). Contrast this child with a 10 year old on the same ward; suffering relapsed leukaemia. He has already undergone three line insertions and two removals. He knows (effectively) everything there is to know about CVC placement; together with the alternatives, complications and disadvantages. Now facing his fourth insertion, he may well be competent to provide independent consent.

Therefore, it is important objectively to determine whether a child of 15 years or younger has capacity to provide independent consent for the proposed intervention.

For this assessment, the *Gillick test* is used, derived from a landmark case where it was established that a child with capacity to provide consent should be allowed to do so, independently of her parents. The test requires that the child has sufficient understanding and intelligence to enable them to understand fully what is involved in a proposed intervention [4]. Thus, if a child can understand:

- That a choice exists
- The nature and purpose of the procedure
- The risks and side effects
- The alternatives to the procedure; and is able:
  - To retain the information long enough…
  - To weigh the information…..
  - To arrive at a decision
  - *And* to be free from undue pressure

Then she would be deemed competent for the proposed intervention. It will be seen that competence rests on intelligence, maturity and experience. Not on age.

Gillick provides a high threshold for consent, consistent with public policy. It would be highly undesirable to allow children to provide consent for interventions which they could not fully understand. The fact that a child has to 'prove' their competence places a barrier to children that is never experienced by adults, whose capacity is presumed. One can only speculate how many adults would 'pass' the test in *Gillick*.

The *Gillick* competent child does not enjoy an equal right to refuse treatment. Only those cases in which the refusal of life-saving treatments in these children is at issue have reached the English courts. But given this opportunity, courts have resolutely denied the (otherwise) competent minor the right to choose death. A 15 year old girl [5] refusing her consent for a life-saving heart transplant had her refusal overridden by the courts. M's reason was that she 'would rather die than have the transplant and have someone else's heart… "I would feel different with someone else's heart…that's a good enough reason not to have a heart transplant, even if it saved my life"….'

The court authorised the operation, as being in her best interests.

In another case [6], a 14 year old girl with serious scalding required a blood transfusion. She was a Jehovah's Witness, and refused the treatment. The court found that even if she had been Gillick competent, her grave condition would have led the court to authorise the transfusion. As it was, the girl was unaware of the manner of death from anaemia, and was basing her views of on those of her congregation, rather than on her own experiences. For these reasons, she was judged incompetent to make this decision for herself.

It must be remembered that the vast majority of Gillick competent children who (successfully) refuse treatment are refusing relatively trivial procedures. You would be entitled to rely upon their parent's consent if necessary, but it is a matter for clinical judgement whether the procedure could be deferred, to allow the child further time to consider, and be reconciled with what is likely to be an inevitable outcome. The problem of refusal in *Gillick* competent children is dealt with in the same way as for the 16 & 17 year age group, below.

Young People of 16 & 17 Years of Age

In this jurisdiction, young people of 16 & 17 years of age are presumed to have the capacity to provide consent for surgical, medical and dental treatment. This was made possible by a law enacted in 1969 [7], which recognised that the decisions that teenagers were taking, irrespective of the law, contrasted sharply with the age of majority (21 years, the legal start of adult life) at the time. The new law reduced the age of majority to 18 years, and introduced the presumption of capacity for 16 & 17 years olds.

What the new law did not do was extend this right to consent for research, or interventions that do not potentially provide direct health benefit to the individual concerned. However, if competent on the basis of the test in *Gillick*, a young person may be able to provide consent for these activities.

Young people of 16 & 17 are thus able to provide consent for treatment in absence of their parents. However, the parental right to provide consent for treatment lasts until the end of childhood. This has the effect of providing a 'safety net'; allowing a 16/17 year old the opportunity of consent for herself; or deferring to her parents, if she sees fit. Once the child reaches adulthood on her 18th birthday, her parents' right disappears. For the rest of her life, she alone can provide consent, either directly, in person; or in some circumstances, by a proxy method, her wishes embodied either in a deputy, or in a document.

If parents and a young person disagree over a matter of consent, it is wise to exercise caution.

If a young person, thus defined, wishes to exercise his right to consent, and his parents oppose the decision, then

you would be entitled to rely on his consent. However, it would be important to understand the basis for this disagreement. For instance, if you suspected that the young person was not competent, you should challenge the presumption. This can simply be done by establishing whether he understands the relevant information; can retain the information, believe it, weigh it up….and communicate his decision. If he can, then he has capacity. But it is still wise to tease out where the problem lies, since this is a most unusual situation, and it would be in the young person's best interests to resolve the issue before surgery, if that is feasible. This is because the value of parental support for their children's treatment is tangible, and severing this support of a child when they may need it could increase their vulnerability.

The problem, reversed, is of a young person who refuses treatment, but who is accompanied by a parent who wants to provide consent. Valid parental consent will make the procedure 'legal', but as with the situation of consent withdrawal, you will still have to make a clinical judgement as to whether proceeding with the treatment against the young person's wishes is both practicable, and in her best interests. In summary, it is recommended that an elective procedure should be abandoned until the dispute is resolved. If emergency treatment is required, but could be administered in a different way which was still consistent with her best interests, the alternative should be explored. If her life or limb is threatened, and there is no choice but to provide a definitive operation, then reluctantly, you may feel the need to restrain and proceed.

In theory, the teenager resisting central venous access to start treatment for a rapidly progressive non-Hodgkin's lymphoma could be an example of this situation. But it should be noted that in reality, the amount of resistance that a child of any age puts up is usually inversely proportional to their malaise and discomfort. In the gravely ill, refusal is rare.

There are those who are gravely ill, but needing urgent rather than emergency treatment. If a 16/17 year old in this category refuses treatment for the preservation of her life, such as the transfusion of blood [8], or feeding [9] (in anorexia), courts have invariably chosen to override the child's autonomy, and provide an order which allows lawful provision of the treatment against the child's wishes. This either upholds the parental wishes for treatment, or overrides parental refusal. These cases are rare, but the timescale within which the decision needs to be made allows sufficient time for the court to be contacted, providing the surgeon with the necessary authority.

In young people with cystic fibrosis who are refusing heart lung transplant in defiance of their parents' wishes, the reality of the situation may make the transplant service accede to the young person's wishes. The necessity for a high degree of compliance with post operative immunosuppression and its attendant management has led the clinicians to take a pragmatic approach, and centres will not attempt to enforce transplantation on the unwilling young person. In the competent young person with re-recurrence of their pulmonary metastases from osteosarcoma, the dogged determination of parents to fight for repetitive surgery is clinically supportable only whilst the patient shares his parents' resolution to fight on.

Disclosure

It is, frankly, trite to assert that in any topic relating to oncology surgery in children, a topic is 'difficult'; since that adjective aptly describes the entire clinical subject. But if there is a place to assign "difficulty", it persuasively sits in disclosure. Those of us familiar with the concept of 'therapeutic privilege' will recall the assertion that information that may distress the patient should be withheld from them; for their own good. The increasing predominance of citizens' autonomy has effectively washed this away. Academic law books no longer refer to therapeutic privilege; or alternatively, it is consigned to an historical reference. Without further discussion, although with some regret, the doctrine, irrevocably synonymous with paternalism, has been discarded.

It is submitted that disclosure in oncology surgery is more difficult than in other forms of surgery. Most of our major procedures are elective. Surgeons dealing with *emergency* life saving surgery have simply that remit; to save life. There is no feasible alternative but to operate, since non operative treatment will end in death. In the emergency situation, society presumes the paramountcy of life, and surgeons rely on the doctrine of necessity. This common law doctrine permits surgeons to save the life or limb of an incompetent person without their consent. Under these desperate circumstances, disclosure assumes a secondary importance.

But the doctrine of necessity has its limits. The unconsented laparotomy for otherwise uncontrollable bleeding does not give the surgeon licence to perform the synchronous excision of an unrelated but obviously malignant ovary, since this would fail to align with the primary purpose, of saving life and limb. This illustrates society's determination to retain individuals' autonomy to make decisions for themselves, whenever possible.

In most non-oncological elective surgery, there is an overwhelming imbalance between benefit and risk. Nuss repair of pectus excavatum, Meckel's diverticulectomy, hypospadias, herniotomy are obviously associated with risk, which must be disclosed, but in reality, the risks are low; and the benefits both obvious, and disproportionately greater.

Not so in elective oncology surgery, where the world literature acknowledges both the inherent risks of damage to

contiguous structures during tumour excision, and the uncertainty of the benefits that may accrue.

This leaves us all with the dilemma of what to tell the parents when seeking their consent for excisional surgery. Do we explicitly acknowledge that their child may die?

The Standard of the Particular Patient

The legal history of disclosure extends over 50 years; with the proposal in North American courts that the standard for valid consent was based on what the particular patient in question wished to know. This was the originally conceived doctrine of 'Informed consent' [10]. There were difficulties with its practical application. A disappointed patient might sue his doctor, on the grounds that he has been given insufficient information about his procedure….and asserting that if he had known the information, he would have refused to proceed. Even with a wide-ranging and comprehensive disclosure of preoperative information by the defendant doctor, a particular nugget of information will go unmentioned. This omitted material, the litigant patient asserts, (in retrospect), was crucial for him to know; and will establish his claim, however rare and obtuse that piece of information might have been. Such a doctrine could leave a door open to unsubstantiated claims, and has not been wholeheartedly supported in English law.

The Professional Standard

The next attempt, 20 years later, at setting a standard for disclosure was to suggest that it should be provided by expert medical evidence, the so-called 'professional' standard, akin to the standard setting in other aspects of clinical care. Although this was accepted for some years, it has fallen into disrepute. Courts became increasingly anxious that doctors were 'protecting their own', and acting in a paternalistic manner by, in effect, telling the patient what he *should* be worried about, rather than asking the patient what worried him.

The Reasonable Patient Standard

Subsequently, English courts' felt able to put themselves in the position of the claimant patient, asking themselves whether, in the circumstances of the case, they would regard the disclosure as adequate? The courts do not feel the need to ask an expert doctor's view on this matter. They consider themselves, as reasoning citizens, amply equipped to set the standard. Thus the stage is set for the 'reasonable patient'. This patient is a fictional creation of the court, imbued with all of the characteristics of the claimant patient, but whose sense of reasonableness is provided by the court. And the reasonable patient is thus employed:

> If there is a significant risk which would affect the judgement of a reasonable patient, then in the normal course it is the responsibility of a doctor to inform the patient of that significant risk, if the information is needed so that the patient can determine… what course he or she should adopt [11].

This leaves open to question what a 'significant risk' entails. However, if you apply your personal criteria to the phrase, you are likely to consider that most of the unintended harms that flow from surgery could be construed as 'significant'. The great difficulty is that there exists a gap between what you, as an experienced clinician (and what an average patient)…. might foresee as the result of surgery.

On how many citizens, that you might encounter walking down your local high street, will it dawn that surgery on a thoracic ganglioneuroma, adjacent to the vertebral column could result in lower limb weakness, or a drooping eyelid? Or that it is foreseeable that percutaneous central venous catheterisation might necessitate a thoracotomy, to stem the haemorrhage? Or that spillage of an ovarian tumour during laparoscopic removal might lead to recurrent or distant disease?

Whilst commonplace knowledge for surgeons, these potentials for disaster are not widely known by those who have not had a medical education.

And that is why they should be disclosed, when obtaining consent.

In addition to this gap in surgical knowledge is the reverse; the recognition that the patient is intimately acquainted with their own circumstances, of which you know little, or nothing. Their academic, sporting and social aspirations may be put at risk by surgical procedures. It is conceded that the priority of oncology surgery is likely to make other considerations peripheral by comparison. Nevertheless, on principle, disclosure of risks, so that the patient can at least decide to take the risk rather than have it imposed unwittingly upon them is consistent with good medical care.

You may not know that the young person with a suspicious posterior triangle lymph node is also a promising boxer, who would not willingly put at risk the functioning of his accessory nerve. He and his family may value a consideration of the alternatives to biopsy of this particular node; perhaps the equally accessible node in the groin? But until they have some awareness of these risks, why would they ask about them?

To address this gap created by a combination of the professional knowledge of the doctor and the patient's personal circumstances, the General Medical Council [12, para 32] makes it clear that the duty to disclose is onerous:

> You must tell patients if an investigation or treatment might result in a serious adverse outcome, even if the likelihood is very small

The risk may be tiny, but of great importance when deciding whether or not to have surgery, which may be elective.

Statistics are a valuable form of description when articulating risk to patients. In a recent case, the court confirmed the importance of comparative statistics when describing alternative procedures that a patient might want to consider in deciding which intervention she should consent for. Faced with a choice between a catheter cerebral angiography and an MR angiogram, the patient was not informed of the comparative risks of stroke [13]. The court held that the patient, as a result, could not provide properly informed consent.

The Numeric Threshold of Risk

The most serious risks faced by the paediatric oncology patient, when facing surgery, are very unusual. Damage to the blood vessels of contiguous organs during a Wilms' nephrectomy; death on the operating table from exsanguination during neuroblastoma excision are both reported, and foreseeable, but mercifully rare. Numerically, the incidence of these catastrophes would be expressed in fractions of a percentage point.

But the most commonly asked question relating to disclosure refers to the importance, or otherwise, of the numeric threshold for risk; how common does a risk have to be before we disclose it to the patient? This is a particularly apposite question for the parents of an oncology parent facing major surgery. Should they be troubled with such unlikely eventualities? Could this aspect of disclosure be placed behind the curtain of a numeric threshold, relieving the surgeon from the obligation of revealing the rarest (and most distressing) potential outcomes?

When describing the risk of a clinical intervention to a patient, there is a common and mistaken supposition by doctors that there exists a numeric threshold of improbability beyond which there is no need to disclose. Where the line should be drawn?

Doctors are comfortable with ubiquitous numeric thresholds to guide their interventions, and depend upon on plasma levels, physiological or radiological measurements to carry a patient across a threshold from non-treatment to treatment.

But the numerical risk of most complications of therapy is usually low, and may not be caught by a realistic threshold. Is it right that such a threshold should (inadvertently) conceal relevant matters from the putative patient's consideration?

Courts have briefly explored the notion of a numeric threshold. In the 1980, a Canadian court [14] held that a 10 % risk should automatically be disclosed when obtaining consent; in this case, to disclose the possibility of a stroke following surgery. This built on the American concept of a material risk, where a reasonable person in the patient's position is likely to attach significance to the risk.

Since then, courts have steadily distanced themselves from a numeric threshold. Three years later, an American [15] case determined that a 200/1 complication rate would not equate to a material risk. A 'landmark' English consent case [16] held that Mrs Sidaway, who had suffered spinal cord damage after surgery, failed to prove that a prudent patient would regard a <1 % complication rate as constituting a significant risk.

In 1997, it was held that there was no certainty that an unqualified duty to disclose a risk of around 1 % existed, in the context of a family who were not told that permanent neurological damage could flow from cardiac transplantation surgery [17]. An Australian case [18] had held that the failure to warn of the 14,000/1 risk of blindness following ophthalmic surgery fell below the reasonable standard of care. From the perspective of English law, this was the death knell of the numeric threshold. To disclose all risks of this frequency would be impractical. The court was demanding that significant risks should be disclosed, irrespective of the likelihood of occurrence. The UK courts followed this lead in 1995 [19], holding that failure to disclose the risk of spontaneous vasectomy reversal (2300/1) equated to substandard care.

The explicit switch from a quantitative to a qualitative approach came in a maternity case [11], when a patient lost her baby. She had reluctantly agreed to the deferral of her delivery, in the absence of full disclosure of the possible consequences of so doing. Lord Woolf, giving the leading judgement, held that it was not necessarily inappropriate to fail to disclose a risk in the order of 0.1–0.2 %; but that the correct standard was to disclose '…. A(ny) significant risk which would affect the judgement of the reasonable patient', as described above.

In a subsequent case [20] where it was held that there was a failure to warn parents of the risk of foetal abnormality of a pregnancy that coincided with maternal chickenpox, the threshold that the disclosure had to satisfy was that of the *patient's* determination of a risk, albeit insubstantial; the court accepted Ld Woolf's dictum proscribing the use of a numeric threshold.

Legal scholars support this trend, warning against reducing the meaning of 'substantial' or 'grave' (or 'significant') to quantifiable (numeric) risks [21], since such reduction misses the central point; that only the patient can judge what risk is material to them, irrespective of its frequency of occurrence.

The concept of a numeric threshold for disclosing risk is therefore outdated from the legal point of view. There is no reference whatsoever to a threshold either from the General Medical Council [12] or the Department of Health [22]; other than to give information about all significant adverse outcomes.

The commonest question asked by surgeons, when discussing the law of consent, is where to draw the line between

matters that must be disclosed, and those that require no mention. Invariably, they demand a numeric threshold, and are disappointed when this is not forthcoming. Although it is understandable that surgeons continue to use this artificial threshold, it is submitted that they should follow the lead of the courts, because a better formula that identifies what needs to be disclosed has been provided for our use.

It is better because it provides an assurance that patients will not be 'ambushed' by a serious complication which the surgeon could foresee, but of which the patient, or her parents, remained oblivious until it was too late for her to avoid it.

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