Chapter 1
Why and How Is Consent Obtained?

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'Choice' has achieved high priority in many developed countries, reflecting the fundamental role of autonomy. That is, the right of every citizen to influence their own destiny. In English health care terms, this has two important consequences, and these are shared in many jurisdictions.

Firstly, that there must be agreement with the patient or the parent before any clinical intervention can ensue.

Secondly, that there must be similar agreement before any of the confidential information revealed during clinical management can be further disclosed.

These two agreements can occur only after a formal conversation, during which is disclosed information about the matter itself, its benefits, risks and alternatives. The parent or child must have the mental capacity to engage in the conversation, and be able to make the relevant decision. The final agreement to treatment (or information sharing) is known as consent.

Consent is the legal key that makes both physical intervention and sharing of information lawful. The standard of clinical management that patients receive is judged against several yardsticks.

(i) The most straightforward of these is that clinicians should not touch patients without their consent.

The need for consent for the otherwise unwanted touch is self evident. Unwelcome attentions from another person, who tries to touch you against your wishes, are repellent. There are times when such touches are unavoidable…packed like sardines on the London Underground or jostling fellow shoppers (and their baggage) in the supermarket during shopping frenzies, there is little choice but to resign yourself to being touched, irrespective of your lack of consent.

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But in less frenetic circumstances, there is an absolute understanding that we are entitled to choose who touches us, and when. The patient who is lying on her hospital bed, when suddenly confronted with a surgeon who puts his hand on her abdomen without first asking if he may do so, would justifiably complain that her treatment fell below the reasonable standard she was entitled to expect. Such behaviour is simple rudeness, irrespective of the legal context. However, the legal context is suddenly placed into stark relief when a patient complains that an intimate examination was performed without consent; and further still when such an examination was irrelevant to her clinical presentation.

These latter actions move the lack of consent into the arena of professional disciplinary regulation, as well as civil litigation and potentially criminal prosecution. The medical defence organisations' case reports are a testament to this frequent (and potentially devastating) error of judgement.

(ii) A second standard that clinicians must attain is that they should supply the patient with enough information to make an informed decision as to whether they wish to undergo the proposed intervention. This allows the patient to judge whether allowing themselves to be subjected to an otherwise unwanted touch is worthwhile.

Doctors often fail to appreciate how little patients understand about the consequences of intervention. How many parents or patients appreciate that surgery on the spine may lead them to urinary and faecal incontinence, or failure to move their legs? Or that misdirection of a subclavian needle may lead to a thoracotomy, to arrest the hemorrhage thus caused? Or that a difficult inguinal hernia repair could lead to loss of the ipsilateral testicle?

Trained surgeons are acutely aware of these hazards, but our patients are not. The process of consent, with disclosure of risks and side effects, is designed to allow patients an insight into the risks that they and the surgeon jointly face. Furthermore, patients cannot be expected to anticipate the limitations of treatment, or the possible alternatives. A 14 year old facing the excision of his pulmonary metastases from osteosarcoma may be blissfully unaware that cure is unlikely. If he had known, he might have chosen to accept a different route to palliation, and avoided thoracic intervention. A 15 year old preparing to be a bridesmaid at her mother's wedding tomorrow morning might just elect, tonight, to have her acute appendicitis treated with antibiotics, at least for 24 h….and accept any consequent risk. Disclosing alternatives to treatment may be very important to a patient who is otherwise unaware that they had a choice.

It is very unusual for cases where patients claim that they were not provided with valid disclosure (and thus their consent was invalid) to reach court. However, when this happens, English courts do not rely on expert witnesses to set the standard for what the appropriate disclosure should have been. This is in contradistinction to the great majority of clinical negligence cases, where a medical expert will be asked to set the standard of care,[1] against which the defendant doctor will be judged.

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[1] Bolam v, Friern Barnet Hospital Management Committee [1957] 1 WLR 582.

This gives an insight into the importance that the judiciary set on disclosure for consent. Judges put themselves in the shoes of the 'reasonable' patient…and enquire what such a person would want to know, before giving consent in the particular set of clinical circumstances. This position was articulated in 1999, and reinforced by the United Kingdom's Supreme Court in 2015[2], providing the standard for disclosure of risk:

> …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.[3]

Seeking consent from a person who is fully aware of the clinical risks and benefits should concentrate the mind of both surgeon and patient. If the process has failed to dispel doubts in either mind that intervention is the right thing to do, abandon the procedure, reconsider the situation, and do something different.

Statistics are a valuable when articulating risk to patients. The risk may be tiny, but of great importance when deciding whether or not to have surgery, particularly in the elective setting. In a recent case, the court confirmed the importance of comparative statistics when setting out the therapeutic alternatives 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.[4] The court held that the patient, as a result, could not provide properly informed consent for the cerebral catheter whilst remaining oblivious to the excess risk of stroke that this entailed.

The most commonly asked question relating to disclosure refers to the importance, or otherwise, of the numeric threshold for risk; how common does a foreseeable risk have to be before we must disclose it to the patient? Doubtless, surgeons 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. Perhaps this explains the existence of a common but mistaken supposition by English surgeons that there exists a numeric threshold of improbability beyond which there is no need to disclose; leading them to the awkward but inevitable question of where should such a threshold line be drawn?

One problem with a threshold is that 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?

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[2] Montgomery v Lanarkshire HB (Scotland) [2015] UKSC 11.

[3] Montgomery v Lanarkshire HB (Scotland) [2015] UKSC 11 para 87.

[4] Birch v University College London Hospital NHSFT [2008] EWHC 2237.

Internationally, courts have explored the notion of a numeric threshold. In the 1980, a Canadian court[5] 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.

But since then, courts have steadily distanced themselves from a numeric threshold. An American[6] case determined that a 200/1 complication rate would not equate to a material risk. A 'landmark' English consent case[7] 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.[8] An Australian court [9] found 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 legal perspective, 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,[10] holding that failure to disclose the risk of spontaneous vasectomy reversal (2,300/1) 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 in the general rule for disclosure in the United Kingdom, the most recent Supreme Court decision in Montgomery makes it clear that the assessment of whether a risk is significant cannot be reduced to percentages. The significance of any given numerical risk is '…likely to reflect a variety of factors besides its magnitude, including 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, together with the alternatives available, and the risks involved in those alternatives'.[12] The assessment thus becomes fact sensitive, rather than founded on a numeric threshold.

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[5] Reibl v Hughes. *DLR* Canada 1980; 114: 11.

[6] F v R. *South Australian Supreme Court* 1983;33: 189.

[7] Sidaway v Board of Governors of the Bethlem Royal Hospital. *All England Reports*, House of Lords 1985; 1: 643.

[8] Poynter v Hillingdon Health Authority. *Butterworths Medical Law Reports* 1997; 37: 192.

[9] Rogers v Whittaker. *CLR HC Australia* 1993;175: 479.

[10] Newell v Goldenberg. Medical Law Reports 1995;6: 371.

[11] Pearce v United Bristol Healthcare Trust. *Butterworths Medical Law Reports* 1999;48:118.

[12] Montgomery v Lanarkshire HB (Scotland) [2015] UKSC 11 para 89.

Who Should Disclose the Information?

There is no clear rule in England. However, since it is very clear that significant risks should be disclosed, perhaps a surgeon familiar with the procedure is best placed to provide the disclosure. Some surgeons prefer to delegate this duty to trainees or nurses who are unable to perform the intervention, but who are armed with an information sheet; and have been 'trained' in consenting patients. One wonders whether they would wish their own families to be treated in this way. It is recommended that consent, and the disclosure that makes it valid, should be taken by the person who is about to perform, or at least who is capable of performing the procedure.

How Should Consent Be Recorded, and for What Procedures?

Consent is necessary for any intervention, but the form of consent, and it's mode of recording, differ widely in surgical practice. Individual hospitals often have their own view of what type of procedures merit written consent, and it is prudent to adhere to local rules. However, from a broader perspective, there is no doubt that oral consent is good consent. There is no English statutory requirement to obtain written consent for surgery, although written consent is required for fertility treatment.[13]

But the reality remains; that the existence of oral consent is very hard to prove in retrospect, and this difficulty is proportionate to the time that has elapsed since the intervention in question took place. For this reason, our Department of Health advocates written consent for all forms of surgery.[14] However, neither the form of the written consent, nor the definition of 'surgery' is stated.

Which interventions are 'so serious' that formal consent form must be completed? It may be difficult, months later, confidently to recall that you obtained consent orally, and what you disclosed in obtaining it. If in doubt, make a note in the case notes. This will usually have been decided for you, codified by the local Trust's consent policy. Commonly, any surgical or interventional radiology procedure will require a consent form, as will any procedure which requires local or general anaesthesia. If in doubt, it is prudent to use a form, but please ensure that it is properly filled in. The disclosure that leads to valid consent is infinitely more important than the signature.

Indeed, errors such as; failure to ensure that the patient has capacity; inadequate disclosure of information; or failing to ensure that the patient provides consent voluntarily; all these invalidate the consent, irrespective of a signature: 'Consent expressed "in form only" is no consent at all'.[15]

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[13] Human Fertilisation and Embryology Act 1990 Sch3.

[14] DH, Reference guide to consent for examination or treatment, Second edition, 2009.

[15] Chatterton v Gerson [1981] 1 All ER 257 @ 265.

For this reason, providing evidence by a handwritten entry in the case notes becomes potent evidence of a diligent approach to consent. This is also a prudent move when you have completed a consent form with a patient, but still remain anxious that the form does not wholeheartedly reflect the conversation, or the inherent uncertainties of the procedure. You may have spent an hour with some parents, weighing up the risks and benefits of excising their infant's thoracic neuroblastoma. The local consent form gives precious little space for a full account of your deliberations, or a relevant diagram which better describes the surgical dilemma. Putting your thoughts on paper will allow you to state your position, beyond doubt; and remember it years later.

Oral consent is valid, but writing provides a record. Get consent for any intervention, but take a proportionate approach as to what form of documentation is necessary.

Who Should Provide Consent?

From the English perspective, a child is a citizen 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 must depend upon their parents to provide it for them.

People under 18 years are considered in three broad groups in England and Wales. Bearing in mind that the law is different even in Scotland, a country nevertheless within the United Kingdom, it is hoped that readers outside these small islands will forgive a parochial approach, since a comprehensive international review of child law is not feasible here.

Young People: 16 and 17 Years of Age

Citizens of 16 and 17 years of age are described as young people, presumed to have the capacity to provide consent for surgical, medical and dental treatment. (*Capacity* rather than *competence* is used to describe this attribute, a convention only necessary to acknowledge the words of the Mental Capacity Act 2005, which applies to those of 16 years and above).

The presumption of capacity in young people was made possible by a law enacted in 1969,[16] which recognised that the 'lifestyle' decisions that teenagers were taking, irrespective of the law, contrasted sharply with the age of majority (21 years) at the

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[16] Family Law Reform Act 1969s8.

time. The new law reduced the age of majority to 18 years, and introduced the presumption of capacity for 16 and 17 years olds.

The new law did not extend this right to consent for research, or to interventions that do not potentially provide direct health benefit to the individual concerned. However, if competent along ‘Gillick’ lines, a young person may be able to provide consent for these activities.

Young people of 16 and 17 are thus able to provide consent for treatment in absence of their parents. However, the parental right to provide consent for treatment prevails 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 young person reaches adulthood on her 18th birthday, her parents’ rights evaporate. For the rest of her life, she alone can provide consent, either directly, in person; or in some circumstances by a proxy method.

If parents and a young person disagree over consent for surgery, it is wise to exercise caution. In the situation where a 16/17 year old wishes to exercise his right to consent, whilst his parents oppose his decision, then you would be entitled to rely on his consent. However, it would be important to understand the basis for their disagreement. For instance, if you suspected that the young person lacked capacity, you should challenge the presumption that he is able to provide consent for himself. This can simply be done by establishing whether he understands the relevant information; can retain the information, believe it, weigh it up, use it….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 an unusual situation, and it would be in the young person’s interests to resolve the issue before surgery, if that is feasible.

The problem, reversed, is of a young person who refuses treatment, but who is accompanied by a parent who provides consent. Valid parental consent will make the procedure ‘legal’, but as with the situation of consent withdrawal, you will 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 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, that 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. A supracondylar fracture of the humerus that has resulted in an ischaemic hand could be an example of this situation. 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 need 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,[17] or feeding[18] (in anorexia), English courts have invariably chosen to override the young person’s autonomy, providing an order

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[17] Re P (Medical Treatment: Best Interests) [2004] 2 All ER 1117.

[18] Re W (A Minor) (Medical Treatment: Court’s Jurisdiction) [1992] 3 WLR 758.

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 clinical treatment needs to be provided usually allows sufficient time (perhaps measured in hours) for the court to be contacted, providing the surgeon with the necessary authority.

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 pulse measurement; a 7 year old to a venepuncture; a 10 year old to the removal of an early stage appendicitis. It is not suggested that the parents should be excluded from this process. Rather, 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 in this context. It is submitted that following the very recent diagnosis of leukaemia, a 13 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, incapable 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. She has already undergone three line insertions and two removals. She knows (effectively) everything there is to know about CVC placement, complications and disadvantages. Now facing her fourth insertion, she may 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 who is competent to provide consent can 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.[19] 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

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[19] Gillick v West Norfolk & Wisbech AHA [1986] AC 112.

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.

During the Gillick case, an additional set of guidelines were suggested by Lord Fraser, specifically for doctors who assist with reproductive decision-making by children under 16. It should be noted that these do not replace the Gillick test, nor are they synonymous with it.[20]

Gillick provides a high threshold for consent, consistent with public policy. It would be highly undesirable to allow incompetent 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 not immediately faced 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 court. But given this opportunity, courts have resolutely denied the (otherwise) competent minor the right to choose death. A 15 year old girl[21] 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,[22] 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 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 become 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 and 17 year age group, above.

Children Under the Age of 16 Who Lack Competence

For children lacking competence, a person with parental responsibility has the right to provide consent for treatment.

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[20] Wheeler RA. Gillick or Fraser? A plea for consistency over competence in children BMJ 2006 332 807.

[21] Re M (Medical Treatment: Consent) [1999] 2 FLR 1097.

[22] Re L (Medical Treatment: Gillick Competency) [1998] 2 FLR 810.

Who Can Provide Consent in England and Wales?

The child's mother (the woman who gave birth to the baby, rather than the person who provided the egg from which the baby was conceived, if different) has parental responsibility automatically. The child's father gains parental responsibility automatically if married at the time of the birth registration. Since 2003, unmarried fathers achieve parental responsibility by their registration of 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, or by subsequent marriage to the mother.

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.[23]

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.

This agreement is not invariable. In a case[24] 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, a common activity when there are disputes over the best interests of the child.

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[23] For a full account see Bainham A, *Children*: *The Modern Law*' 2005 Family Law, Jordan Publishing, Bristol.

[24] Re T (Wardship: Medical Treatment) [1997] 1 FLR 502.