LAW AND MEDICAL ETHICS

Consent, sectionalisation and the concept of a medical procedure

A R Maclean

Consent transforms an otherwise illegitimate act into a legitimate one. To be valid, however, it must be adequately informed. The legal requirement is vague and provides little assistance in predicting when it will be satisfied. This is particularly so when a patient consents to a procedure and the physician subsequently varies one of the components of that procedure. Using three legal judgments and one General Medical Council (GMC) decision as a springboard, I have explored the concept of a medical procedure within the context of consent and developed a theoretical model to elucidate a more predictable and consistent informational requirement.

Before performing a medical procedure, a doctor must obtain her patient’s consent. This obtains legally, professionally, and ethically. The “magic” of the patient’s consent is that it transforms the status of an act from illegitimate to legitimate.1 Both morally and legally, the patient’s right to give or withhold consent flows from his right to (respect for) autonomy.2 Although the meaning of autonomy is debated it is not contentious to suggest that, at a minimum, autonomy requires the capacity to make a decision. Similarly, it is perhaps fair to suggest that knowledge of the decision is a prerequisite for exercising decision making capacity.

In the context of a medical procedure, knowledge of the decision demands that the patient have a sufficient understanding of what that procedure entails to be able to determine how it would likely affect him and, on that basis, whether or not to give his consent. To gain a sufficient understanding requires information and that information lies with the doctor. At present the law simply requires that the patient is informed “in broad terms” about the nature of a procedure.3 Without determining what is—or should be—meant by the “nature” of a procedure, however, it is difficult to predict when sufficient information is imparted. This engenders the risk of inconsistency and uncertainty. In particular, a difficulty arises in determining whether altering a component of a medical procedure invalidates a prior consent. Based on three legal judgments and one GMC decision, I will develop a theoretical model of a medical procedure with the aim of constraining inconsistency and enhancing the communication process of consent.

THE CASES

Davis v Barking, Havering and Brentwood Health Authority4

The claimant consented to a general anaesthetic for a minor gynaecological operation. No mention was made of the caudal anaesthetic subsequently performed after she had been anaesthetised.5 Following the procedure, she was left with a “minor but significant” bladder disorder and sensory abnormality in her left leg. She sued in trespass (battery) claiming “minor but significant” bladder disorder and sensory abnormality in her left leg. She sued in trespass (battery) claiming

The US cases

Both cases involved a claim that the claimants had not consented to the use of forceps during a vaginal delivery. In Rizzo v Schiller, the defendant used forceps once it became clear that the claimant was unable to push out her baby without assistance. Unfortunately this resulted in brain injury. Although the defendant informed the claimant that he was going to use forceps immediately before applying them to the baby’s head, there was no opportunity for discussion and her

[1] Both morally and legally, the patient’s right to give or withhold consent flows from his right to (respect for) autonomy.
[2] Although the meaning of autonomy is debated it is not contentious to suggest that, at a minimum, autonomy requires the capacity to make a decision.
[3] Without determining what is—or should be—meant by the “nature” of a procedure, however, it is difficult to predict when sufficient information is imparted.
[4] The claimant consented to a general anaesthetic for a minor gynaecological operation. No mention was made of the caudal anaesthetic subsequently performed after she had been anaesthetised.
[5] Following the procedure, she was left with a “minor but significant” bladder disorder and sensory abnormality in her left leg.
consent was not sought at this point. The claimant had, however, signed a general consent form authorising the performance of “diagnostic or therapeutic medical and surgical procedures.” Although there was no specific mention that the use of forceps may be necessary, the defendant argued that the claimant “was allowed to participate in the decision to use forceps”. The Supreme Court of Virginia disagreed and argued that a discussion of the specific procedure was required. It held that there was sufficient evidence to establish a prima facie case of negligence for failing to obtain an informed consent. Since there was no complaint in relation to the consent for manual vaginal delivery, it is implicit that the court did not believe consent for forceps to be subsumed within that consent.

In contrast, in Sinclair by Sinclair v Block, the Supreme Court of Pennsylvania held that the physician was not liable. Because descent had “arrested” and the baby’s heart had slowed, the defendant attempted a forceps delivery. This attempt failed and the baby was delivered by a caesarean section. Unfortunately, the attempted forceps delivery fractured the baby’s skull and left him with epilepsy. As in Rizzo, the claimant signed a general consent form that referred to “delivery care . . . and/or caesarean section”. In holding that the doctrine of informed consent did not apply, Nix C J stated: “Under the circumstances of this case . . . we find that the physician’s attempt to use forceps is part of one event: the natural delivery process. Thus, the physician’s use of forceps to facilitate natural delivery is not a distinct surgical or operative procedure and, as a result, does not require additional consent.”

**DISCUSSION**

It is clear from these cases that completely disparate results may be arrived at despite working with the same basic principle, namely, respect for autonomy. I will argue that the approach adopted by the GMC and by the court in Rizzo is preferable to the one used by the court in Davis and Sinclair. To do that, I will discuss the concept of a medical procedure and develop a theoretical model to support that claim.

The main difficulty with Davis and Sinclair is that the concept of a medical procedure was oversimplified. Whilst the concept of a medical procedure may be straightforward in an everyday sense—a blood test is a single procedure, as is an appendicectomy—it becomes more complicated when looked at more closely. My starting point for this inquiry is to consider concepts in general, how we organise our concepts, and the utility of that organisation.

**Concepts and concept hierarchies**

There are many theories of concepts, such as prototype or exemplar theories, but this is not the place to discuss their pros and cons. For the purpose of this paper I will adopt the “theory based” view of concepts, which suggests concepts are categorised and individuated on the basis of their attributes, and an underlying theory that explains those attributes. The concepts we possess tend to be organised in hierarchies (see figure 1). When communicating, the particular concept we choose depends on its utility. This depends on the context of its use, but involves a trade-off between distinctiveness and informativeness. Thus, high level concepts carry little information but are easy to distinguish, while low level concepts are more informative but harder to individuate.

At this point, it may be useful to provide an example. Consider a hierarchical classification of “living things”. It is easier to distinguish an animal from a plant than it is to distinguish a dog from a rabbit and to understand what an animal is requires less information than to understand the concepts of rabbit and dog. Similarly, it is easier to distinguish a dog from a rabbit than a labrador from a golden retriever and understanding the concept of a labrador requires more information than is needed to grasp the concept of a dog. The converse is equally true. Just as more information is required to understand the concept of a labrador as opposed to a dog, so using the term “dog” as a referent tells the hearer less about the object referred to than if the “dog” is described as a labrador or a golden retriever.

The level of the hierarchy that a person uses will depend on their knowledge of the concepts within that hierarchy and the information they wish to communicate. Non-experts tend to choose concepts that achieve a reasonable balance between both information and distinctiveness, and this level in the hierarchy is termed the “basic level”. Experts operate at a “subordinate level” to this. This is relevant because the amount of information that must be communicated to allow the recipient to grasp a lower level concept is greater than that required to grasp a high level concept. Thus, returning to my earlier example, to grasp the concept of a labrador the hearer must understand the concept of dog, the concept of breeds of dogs, and the attributes possessed by a labrador that distinguish it from other breeds of dog. In the context of consent, this is important because the higher up the hierarchy we operate (dog being higher than labrador), the easier it is to satisfy the informational requirements of the concept.

Using an anaesthetic hierarchy as an example (see figure 2), if consent operates at the basic level or higher (superordinate level) then the informational requirements are minimal. If we assume (for the present purpose) that <general anaesthetic> and <local anaesthetic> are basic level concepts then it would be unnecessary to discuss any variation of the components of the anaesthetic. Providing the patient grasped that it was either a <general anaesthetic> or a <local anaesthetic> the physician’s duty to inform would be satisfied. This is the approach adopted in Davis and in Sinclair. It is submitted, however, that this is inadequate to satisfy the patient’s informational needs. To demonstrate this, it is necessary to consider the concept of a medical procedure in greater depth.
The concept of a medical procedure

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Time course</th>
<th>Purpose</th>
<th>Aim</th>
<th>Mechanics</th>
<th>Effects</th>
<th>Risks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Every procedure must have a beginning and an end although the duration may be extremely variable and will be both operator and patient dependent;</td>
<td>Each procedure must have a particular purpose, thus, the purpose of taking a blood sample is to obtain sufficient blood for the laboratory to perform the requisite diagnostic test;</td>
<td>Each procedure must aim to provide a benefit. The purpose of the procedure, and the means adopted to effect that purpose, generate the attributes associated with the procedure. Together with an underlying theory that relates means to aim, the values of these attributes distinguish one medical procedure from another. The further down the hierarchy one goes, the more discrete these attribute values become and the more information they entail. The attributes that may be associated with a medical procedure include:</td>
<td>Each procedure must have a particular purpose, and the means adopted to effect that purpose, generate the attributes associated with the procedure.</td>
<td>The mechanics of a procedure include:</td>
<td>These are the characteristic consequences of the procedure which may be:</td>
<td>The potential consequences that may result when the procedure has not gone according to plan, such as a dural puncture when performing an epidural local anaesthetic.</td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1. Direct—treatment procedures that aim to cure, control or retard a disease process and those that aim to alleviate particular symptoms;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2. Indirect—diagnostic procedures that, by increasing the accuracy of the doctor’s diagnosis, indirectly benefit the patient because a more accurate diagnosis allows a more appropriate treatment;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3. Altruistic—these procedures primarily benefit others. Thus, live organ transplants benefit the recipient and non-therapeutic research may benefit future patients.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1. A number of actions on the patient that are unified by the underlying theory of the procedure;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2. One or more anatomical sites;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.3. A mechanism—for example, repair, removal, ablation, transplantation, excision, implantation, injection, insertion, and inhalation;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1. Intended—The loss of a patient’s spleen is an intended consequence of a splenectomy;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.2. Unintended—The side effects of a procedure, such as the susceptibility to pneumococcal infections that follows a splenectomy;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.1. Intended—The loss of a patient’s spleen is an intended consequence of a splenectomy;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.2. Unintended—The side effects of a procedure, such as the susceptibility to pneumococcal infections that follows a splenectomy;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2 Anaesthetic procedure hierarchy (incomplete).
for his consent beforehand. Equally, a variation that does not affect any of those elements does not need to be communicated to the patient.

ii) Sectionalisation

In Davis, McCullough J introduced the concept of sectionalisation. While his judgment does not fully explicate the meaning of sectionalisation certain inferences are possible. An intuitive approach to the use of such a term would suggest that McCullough J meant that a separate consent is not required for each step of the procedure. To ask the patient whether he agrees to an incision, and subsequent closure, of each abdominal layer when gaining consent for an appendicectomy would be to push the information demands of consent to a ridiculous extreme. In this sense, the concept of sectionalisation epitomises the judiciary's distaste for an action performed on two occasions or one.

It is submitted that McCullough's use of the concept of sectionalisation epitomises the judiciary's distaste for an action bought in trespass. It is also suggested, however, that he has oversimplified the concept of a medical procedure by delimiting the type of information that should be communicated to the patient. McCullough's concept, however, appears to go further than this. Thus, he states: 'once this degree of sectionalisation is accepted, how long will it be before the court is invited to say that separate consent should be sought for separate steps in the surgical procedure?'. Although his concept goes beyond the steps of a procedure it does not extend to obviously different operations. As he explains: 'Clearly, if it is proposed that a patient should undergo two separate operations it is the duty of the doctors to give the patient appropriately full information about each of them. This is so whether they are to be performed on two occasions or one'.

It is submitted that McCullough's use of the concept of sectionalisation epitomises the judiciary's distaste for an action bought in trespass. It is also suggested, however, that he has oversimplified the concept of a medical procedure by delimiting the type of information that should be communicated to the patient. McCullough's concept, however, appears to go further than this. Thus, he states: 'once this degree of sectionalisation is accepted, how long will it be before the court is invited to say that separate consent should be sought for separate steps in the surgical procedure?'. Although his concept goes beyond the steps of a procedure it does not extend to obviously different operations. As he explains: 'Clearly, if it is proposed that a patient should undergo two separate operations it is the duty of the doctors to give the patient appropriately full information about each of them. This is so whether they are to be performed on two occasions or one'.

iii) The components of a medical procedure

The argument in Davis and Sinclair was that if $x$ is a part of $y$ then consent for $x$ will be subsumed by consent for $y$. In Rizzo and the GMC case, this argument was implicitly rejected, and where a component of a procedure was varied in a way that had actual or potential consequences for the patient, the prior consent would be inadequate. The judgments in Davis and Sinclair are open to criticism because they drew false conclusions about the nature of the procedure based on a deficient conception of a medical procedure. The implication of Davis is, an anaesthetic is an anaesthetic is an anaesthetic. Similarly, Sinclair implies that, providing the baby is born through the vagina, a vaginal delivery is always a vaginal delivery regardless of what else is done. These conceptions of a medical procedure ignore both the hierarchical and the intraconceptual complexities.

The conceptual relationships that need to be distinguished are (see figure 3):

- a procedure;
- a sub-procedure (major and minor);
- a combined procedure;
- an example-of a procedure;
- the parts-of a procedure; and
- the types-of a procedure.

A sub-procedure may exist both as a part-of a larger procedure or as a procedure in its own right. If the sub-procedure is separated from the procedure then we are left with the main body of the procedure. Each individual occurrence of a particular concept is an example-of that concept. Just as the whole procedure, when performed, is an example-of the concept so the main body of the procedure remains an example-of the concept (when categorised at the basic level of the hierarchy), albeit a deficient one. How deficient an example-of the concept depends on the role played by the sub-procedure. If removal or variation of a component means that the concept has become a different concept the component is best viewed as an essential part-of the procedure rather than as a sub-procedure.

As an example, a general anaesthetic is essentially the administration of an anaesthetic drug to render the patient reversibly unconscious and allow an unpleasant or painful procedure to be performed. An intravenous analgesic may be administered as a sub-procedure within a general anaesthetic. Administration of an intravenous analgesic is a procedure in its own right. When given as an adjunct to a general anaesthetic it augments the procedure, but does not alter it sufficiently to require a new concept. If the analgesic is not given, the procedure remains a general anaesthetic although perhaps a less than adequate example of one. A sub-procedure,
then, is a lesser procedure performed in conjunction with a greater procedure.

Sub-procedures may be sub-divided into major and minor sub-procedures. The distinction is necessary because sub-procedures vary in the effect they have on the nature of the procedure. Minor sub-procedures do not require the creation of a sub-category concept while major sub-procedures do affect the nature of the procedure sufficiently for a new concept to be created. This new concept exists in a parent-child relationship with the original procedure. By including a major sub-procedure, the relationship has been altered from an example-of to a type-of the parent procedure concept. I will discuss the difference between major and minor sub-procedures in the context of the cases, which should help explain the distinction (see below).

A combined procedure is one in which two or more separate procedures are performed together, generating a new procedure. If the component procedures are separated we are left with two or more complete procedures and the combined procedure is made non-existent. For example, the operation of hysterectomy and bilateral salpingo-oophorectomy is a combined procedure. Both the hysterectomy and oophorectomy are procedures in their own rights that may be performed independently, but in neither case could performance of the individual procedure be considered performance of the combined procedure.

The parts-of a procedure are the components of a procedure that are not normally stand alone procedures, although they may be separated spatially, temporally or through being performed by different actors. For example, the skin incision, and the incision through the various layers of the abdominal wall are parts-of an abdominal procedure such as an appendicectomy. The characteristics of these concepts are summarised in Table 1.

The type-of a procedure refers to subordinate level concepts in a classification hierarchy. Thus, if the procedure is cholecystectomy, the type-of of cholecystectomy might include: "standard incision" cholecystectomy, "mini-laparotomy" cholecystectomy, and laparoscopic cholecystectomy.

### Table 1: Characteristics of procedure typology

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Parts-of</th>
<th>Subprocedure</th>
<th>Combined procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entailment</td>
<td>Entailed by procedure</td>
<td>Not entailed by main procedure</td>
<td>Not entailed by primary procedure</td>
</tr>
<tr>
<td>Effect of inclusion</td>
<td>Does not change the nature of the procedure</td>
<td>May change the nature of the procedure</td>
<td>Will always change the nature of the procedure</td>
</tr>
<tr>
<td>Purpose</td>
<td>Enables/further the purpose</td>
<td>Adjunctive to the purpose of the procedure</td>
<td>Different purpose to the primary procedure</td>
</tr>
<tr>
<td>Existence</td>
<td>Is only a stand alone procedure</td>
<td>May exist as a stand alone procedure</td>
<td>May exist as a stand alone procedure</td>
</tr>
</tbody>
</table>

### CONCLUSION

It is apparent from the cases that it is not always intuitive or a matter of common sense to decide when a variation in a procedure alters the procedure sufficiently for the patient’s consent to be invalidated. Some variations, when they involve parts-of the procedure or minor sub-procedures may be subsumed by the procedure and the prior consent will remain valid. Where the variation involves a major sub-procedure (or the addition of a new procedure) then the prior consent will be inadequate. I have developed a model that should assist in determining when a variation is significant enough to require specific consent.22

If the function of “all propositions which have a factual content . . . is to provide a rule for the anticipation of experience”,21 then it is important that the propositions are accurate and sufficient to allow “the exclusion of relevant alternatives.” Thus, the information provided as part of the consent process should place the patient in a position where knowledge of the risks and effects of that procedure is entailed.
by the patient’s grasp of the procedure. It is hoped that the model will facilitate this and clarify the physician’s duty to disclose.

Some support for the model already exists in the literature. In one study 98% of patients believed that rectal administration of analgesia should always be discussed in advance. Specific comments included adjectives such as “degrading” and “horrible”. Similarly, in another study, 74% of patients preferred the intravenous to the rectal route which they said was “undignified”, an “invasion”, “embarrassing”, and “humiliating”; 7.6% even considered it an “assault”. Since these studies were performed for other reasons, however, the support they provide is limited. Thus, further studies are necessary to specify address some of the relevant issues.

ACKNOWLEDGEMENT
I would like to thank Professor Sheila McLean for helpful criticism of an initial draft, and Professor Jonathan Montgomery, whose services as a sounding board were invaluable. I would also like to thank the anonymous assessors for their helpful criticism.

REFERENCES AND NOTES
3. Chatterton v Gerson [1981] 1 All ER 257. This standard relates to trespass. An additional information requirement, notably in relation to risks, is required in negligence. However, the distinction, although important, is not relevant for the purposes of this paper. In this article, I am addressing the overall adequacy of the disclosed information rather than whether that information is regulated in trespass or negligence. Of the cases, only Davis v Barking, Havering and Brentwood Health Authority [1993] 4 Medical Law Reports 85.
4. Davis v Barking, Havering and Brentwood Health Authority [1993] 4 Medical Law Reports 85.
5. A caudal anaesthetic is a type of epidural anaesthetic, which involves the insertion of a needle into the patient’s lower back (at the level of the cleft of the buttocks) and the injection of local anaesthetic into the “space” just outside the tissues surrounding the spinal cord. It is most effective in the ano-genital region.
17. Assuming possession of the relevant concept.
18. Rosch E, Mervis CB, Gray WD, et al. Basic objects in natural categories. Cognitive Psychology 1976;8:382–439. The term “basic level” may appear counterintuitive since it refers to the level of usage rather than the level of classification. I am grateful to the anonymous reviewer for indicating this difficulty inherent in the Rosch et al's terminology.
20. See, for example: Kane RE. Neurological deficits following epidural or spinal anaesthesia. Anaesthesia & Analgesia 1981;60:150–61. Since a caudal block is a type of epidural the nature of the risks is similar. However, the probability of their eventuating is lower.
21. It is recognised that the proposed model may have implications for those patients who do not want to know. This issue will need to be addressed and will form the subject of a future article.