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GDC 'Highly Recommended' CPD topic
Legal and Ethical Issues

Informed Consent: What's New?

Abstract: Informed consent has long been tried in the English courts using the *Bolam* test. This primarily tested the degree of professional negligence against the collective opinions of medical professionals. This principle is now considered outdated and the test of materiality now gives the individual patient shared decision-making during the consent process. Obtaining valid consent that will stand in a court of law and hold strong now involves a little more thought and time from the prudent dentist.

CPD/Clinical Relevance: Obtaining valid consent is an extremely important risk minimizing application of time for a skilled health care professional (HCP). If undertaken skilfully it can lead to improved patient satisfaction, minimize patient complaints and ultimately lessen the risk of practising HCPs having a negligence case brought against them.

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Gone are the days where dentists relied on assumed, implied consent to carry out simple examinations to more complex and high risk procedures. Dental interventions were often carried out under the prescriptive work of a dentist, as he/she felt necessary, but always with the patients' best interests in mind. Patients were rarely given the menu of treatment options which we deliver today and seldom equipped with all the necessary information. The way the dental team plans, carries out and reviews treatment interventions has recently undergone a major shift, moving from being paternalistic in nature to a more ethically conscious, risk aware and patient-centred workforce.

The Consent Triangle

Three basic factors need to be present and employed when obtaining valid consent under common law[1] (Figure 1):

1. The patient must have capacity – this means the patient has the ability to make the decision in accordance with the Mental Capacity Act 2005;[2]
2. The decision from the patient must be voluntary – patients must come to their own decision without coercion and know that they can change their minds at any stage;
3. The patient must be informed – patients should receive specific and tailored information in an appropriate manner so that they understand the risk and benefits of the treatment, along with any alternative treatment options available to them.

The latter point will be the main focus of this article.

Medical bioethics

Patient autonomy is an essential part of the current medical bioethical quaternary (Figure 2). Autonomy defines patients as individual people capable, in the most part, of making their own decisions regarding their healthcare choices, as long as they are well advised and informed.

If, as dentists, we are to put patients on the 'frontline' when making decisions about their healthcare they are required to be made knowledgeable and kept informed of any examination, investigation and treatment intervention options available according to the General Dental Council (GDC) *Standards for the Dental Team*.[3] In order to meet the standard of the latter document, in the author's opinion, it is recommended that the following information be discussed with the patient:

- All details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- Any uncertainties about the diagnosis, including options for further investigation prior to treatment;
- All options for treatment or management of their condition, including the option not to treat;
- The purpose of a proposed investigation or treatment, and details of the procedures or therapies involved;
- Explanations of the likely benefits and the probabilities of success for each option, and discussion of any serious or frequently occurring risks;
- Advice about whether a proposed treatment is experimental;
- How and when the patient's condition, and any side-effects, will be monitored or reassessed;
- A reminder that they can change their minds about a decision at any time;
- A reminder that they have a right to seek a second opinion;

All of the above discussion points should to be tailored specifically to 'your' patient in his/her 'current' situation. It is important to realize that the current

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situation may not always be the 'status quo' and may be unpredictable. New information may be gathered or become apparent further into the course of treatment and the plasticity and flexibility of your care plan and consent processes needs to be given great thought.

An important part of gaining valid consent is the tricky practice of advising the patient about risks and benefits associated with the intended procedures. It is of paramount importance that we inform patients of the risks and benefits surrounding these procedures. How do we do this? Do we list all risks from the 'very common' to the 'most unlikely'? Do we explain the risk of grave adverse effects, risking that the patient may actually reject the treatment option they desperately require? It is noted that 'the fact that the patient may refuse treatment is not sufficient to act as justification for not informing the patient of any daunting risks'.[1] This latter effect is a very difficult balance for the modern dentist.

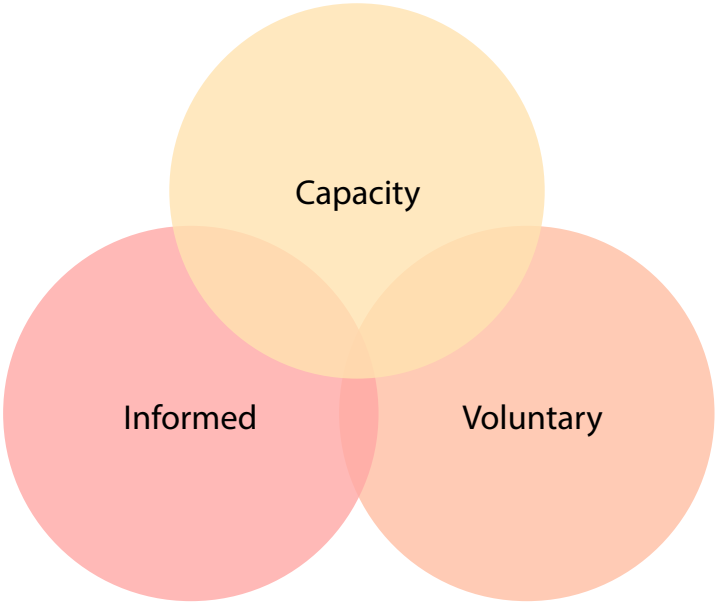

Figure 1. Informed consent. All three factors must be present.

Figure 2. Four major principles of medical bioethics. All have equal weighting.

Bolam Test vs Materiality Test

Dentists have traditionally been advised to inform patients of the severe uncommon and the less severe but more common risks as mutually agreed by peer medical professionals. The *Bolam* test arising out of *Bolam v Friern Hospital Management Committee*, 1957, states that 'if a doctor reaches the standard of a responsible body of medical opinion, he is not negligent'.[4] This statement is therefore heavily focused on the opinions of a body of medical professionals. The *Bolam* test was further revised in 1985 when *Sidaway* unsuccessfully sued *Bethlem Royal Hospital*.[5] *Sidaway* claimed that she was not informed of a critical surgical risk. The case was overruled on the grounds that it is not essential to counsel the patient about every conceivable risk, but the patient should be presented with enough information to make a balanced decision. For years this has been the accepted 'test' in the court of law and has been used historically in cases where negligence has been alleged against a skilled practitioner.

Again, in 1997, the *Bolam* test was further modified by a case *Bolitho v City and Hackney Health Authority*.[6] The case involved the care of a young boy who died from cardiac failure due to respiratory arrest. Despite being called to attend respiratory distress twice the defending doctor did not attend the child and she maintained that, had she attended, she still would not have made a medical intervention under the presenting circumstances at that time. There were bodies of medical opinion that both supported the defendant doctor claims and bodies that said that they would have acted differently. Accordingly, it was the judge that held the final decision. Therefore in rare cases where expert medical opinion is not found to be logical, the judge can hold the final opinion and not the medical body.

Until mid 2015, the modified *Bolam* judgement was the test used in court. An appeal case that changed the face of patient consent was brought to Supreme Court in April 2015 on appeal. *Montgomery v Lanarkshire Health Board*[7] describes how a doctor failed to inform the patient of low risks associated with a risk of the procedure itself. The claimant was able to establish

that she held great significance to the risks that later materialized, even though the risk was very small (9–10% risk of shoulder dystocia leading to 0.2% risk of brachial plexus injury with shoulder dystonia and leading to a very small, <0.1%, risk of cerebral palsy occurring during labour).

This case concluded that the *Bolam* test is no longer an acceptable test of negligence within a court of law. The informed consent process has to be tailored to the particular patient. The test of materiality now stands and is a very important move towards patient-centred consent. The principle tests whether the court is satisfied that a 'reasonable person in the patient's position would be likely to attach significance to the risk'[5] and this would be determined by the Court and not exclusively by experts in the field. The skilled medical professional should be reasonably aware of the likelihood that a particular patient will attach significance to a particular risk.

The following basic example tries to demonstrate the particular patient with a particular risk. Do you warn a patient of every risk that may be associated with surgical extraction of a lower right third molar tooth? For example, the risk of inferior alveolar nerve (IAN) injury resulting in permanent nerve paralysis in a tooth whose root apices are distant from the IAN canal is going to be much less than the quoted 1–4% in teeth whose root apices are close to the IAN canal,[8] and for the average person it is probably not deemed critical. On the other hand, if the patient has already lost left-hand side IAN supply, then this risk, although still small, will probably be of greater significance. Therefore this particular patient in this specific situation may reject the option of extraction in view of minimizing all risk to his/her remaining nerve supply.

It is notable to consider that current GDC guidance states that 'you should find out what your patients want to know as well as what you think they need to know'.[9] These guidelines are already much in line with current patient-centred care, but the new ruling by the UK Supreme Court has now brought the individual patient in the specific situation he/she presents under direct scrutiny. It means that it is of paramount importance that we consider the individual patient in his/her present state when gaining informed and valid consent.

Conveying verbal information to the patient highlights issues around communication and language skills of the dentist. These skills are integral to succinct and clear discussions with the patient. Communication and language should be native, simple, lay-minded and pitched at the appropriate level for the individual patient's understanding.

Discussion

The consent process now in place focuses on preserving patient autonomy, protects patients' best interests and also helps reduce ambiguity and disagreements in the dental setting. If carried out to common law and good practice standards, as briefly discussed in this article, it is also minimizes medico-legal complications.

GDC guidance clearly states that consent should be a shared decision-making process that is ultimately directed by what the patient wants to know.

Informed consent has long been tested in a court of law using the *Bolam* test. This test primarily focused on the opinions of medical professionals. It is considered to be outdated and the test of materiality now focuses on the patient and what the patient would want to know. The prudent dentist must therefore have the time and be willing to question the patient as well as be questioned by the patient.[10] We should probe and ask questions to gain the information we think that the patient would like to know. This means having an excellent insight into the patient's life and his/her concerns, which can be gained during a judicious history-taking process. This process may well be time consuming but cannot be overlooked.

It must be remembered that written, signed consent is not a legal or ethical obligation for dentists, unless general anaesthesia or conscious sedation are being provided, but it is good practice. It is not the fallback that can be used by dentists to ensure medico-legal protection. A generic tick box form does not constitute consent in a court of law just because the patient has signed on the dotted line. When consent forms are used and the patient does not understand the information he/she has signed against, the consent is not valid.

It must also be remembered that informed consent is a continuous process, involving all aspects of communication and can be withdrawn by the patient at any time during the treatment process.

Modern approaches and helpful points for readers to minimize medico-legal complications include:

- The provision of an adequate environment and adequate time. The future of patient consent procedures may bring the concept of separate, private consulting areas where consent for dental procedures can be gained in an appropriate environment with a reasonable and proportionate time allowance. This would free the working dental environment for continued practice and provide gold standard patient care.
- Accurate, succinct and full documentation of how and who has given the consent is of great importance. If patients want to know very little about the risks associated with their treatment, and are declining any information offered, it is essential to document this well in the notes.
- Undertaking optional professional communication and consultation courses may enhance your communication and language skills and allow easier and more effective discussion with patients.
- Ensuring you allow adequate 'thinking time' for patients by encouraging them to allow time to consider all options before making a decision. Perhaps a suggestion of discussing the situation with a friend or family member. This negates ineffective use of time and environmental pressures that the patient may feel. If there has been a significant amount of time between initial discussion and undertaking the intervention, it is good practice to re-confirm the consent to ensure that the patient is still happy to proceed.
- It is the author's opinion that it may be helpful to supplement verbal discussion with clear written information in the form of easy to read patient information leaflets (PILs). PILs can be procedure-based and tailored to the patient's individual risk with written additions. PILs can be referred to at any time by

patients, enhancing understanding and allowing reflection on the decisions they are making. They can also aid (not act as an alternative) as a point of evidence of the information provided, if required.

- If new information or additional treatment interventions become apparent during a course of treatment, it is strongly advisable to revisit the original consent process, review and update it.
- Always remember that you can seek advice from your defence association regarding any matter surrounding the consent process.
- Aim to keep up-to-date with legislation surrounding the consent process; consider yearly continuing professional development covering the issue.

Conclusion

As dentists we act as risk advisors and have no place to link medical statistical risk directly to patients without finding out how they perceive the severity of the risk. We should probe and question to find out what information the patient wants to know, then inform and advise them using appropriate language. The patients themselves should be allowed to attach their own significance to that risk. As HCPs we should then respect and follow the decisions made by the patient. Thorough contemporaneous documentation of this is key.

References

1. Department of Health. *Reference Guide to Consent for Examination or Treatment* 2nd edn. London: HMSO, 2009.
2. Department of Health. *Mental Capacity Act*. London: HMSO, 2005.
3. General Dental Council. *Standards: Standards for the Dental Team*. London: General Dental Council, 2013. **www.gdc-uk.org**
4. *Bolam v Friern Hospital Management Committee* (1957) 2 All ER 118.
5. *Sidaway v Bethlem Royal Hospital* (1984) All ER 1:1018-36.
6. *Bolitho v City and Hackney Health Authority* (1997) 4 All ER 771.
7. *Montgomery v Lanarkshire Health Board* (2015) UKSC 11.
8. Renton T, Hankins M, Sproate C, McGurk, M. A randomised controlled clinical trial to compare the incidence of injury to the inferior alveolar nerve as a result of coronectomy and removal of mandibular third molars. *Br J Oral Maxillofac Surg* 2005; **43**: 7–12.
9. General Dental Council. *Standards for Dental Professionals: Patient Consent*. London: General Dental Council, 2014. **www.gdc-uk.org**
10. Godlee F. New rules of consent: the patient decides. *Br Med J* 2015; **350**: h1534.