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Consent - a commonly understood concept?

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Debbie Chippington Derrick explores the professional and legal position on consent

Consent is a commonly understood concept, the Oxford English dictionary defines consent as 'permission for something to happen or agreement to do something' and defines informed consent as 'permission granted in full knowledge of the possible consequences, typically that which is given by a patient to a doctor for treatment with knowledge of the possible risks and benefits.' AIMS feels that this should be a very simple concept to implement, but it is clear from the women who contact AIMS that most maternity care falls very short of this mark.

Hearing, as we do at AIMS on a regular basis, about women being led to believe that they have no choice about what is done to them during the birth of their baby we were interested in what various institutions have to say about consent and how the autonomy that this simple concept should ensure seems to be lost in the provision of maternity care.

The Department of Health

The Department of Health (DH) has a reference guide to consent for examination or treatment[1] the first edition was published in 2001 and the current, second edition was published in 2009. This document states that since 2001 the DH has required NHS Trusts to adopt a model consent policy, model forms and information leaflets with the aim of ensuring that good practice in seeking consent was put in place throughout the NHS. The DH makes the following statement on needing a consent policy:

'*We are aware of the importance to Trusts of having up to date guidance available to them to ensure they continue to have in place effective and legal consent processes. This is especially so at a time when the Care Quality Commission is developing its regulatory framework (and associated guidance) and that there is a continuing need for Trusts to meet the risk management standards required by the NHS Litigation Authority.*'

This suggests that the guidance is more about making sure that institutions are covered on a legal basis than about the quality of the care of patients. The fact that the DH document on consent is 52 pages in length makes it clear that they do not consider it to be a simple issue. The document states that:

'For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question (this will be the patient or someone with parental responsibility for a patient under the age of 18, someone authorised to do so under a Lasting Power of Attorney (LPA) or someone who has the authority to make treatment decisions as a court appointed deputy).'

It also states that: *'Acquiescence where the person does not know what the intervention entails is not "consent".'*

And goes on to consider issues such as:

- Is the consent given voluntarily?
- Has the person received sufficient information?
- Duration of consent
- Withdrawal of consent
- When consent is refused

In the case of consent being refused it says:

'If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment (whether contemporaneously or in advance), this decision must be respected, except in certain circumstances as defined by the Mental Health Act 1983 (see chapter 5). This is the case even where this may result in the death of the person (and/or the death of an unborn child, whatever the stage of the pregnancy).'

It seems that none of this should be controversial or difficult to understand, the guidance statements are quite clear, everyone has a right to full information about the risks and benefits of any examination or treatment and they are free to decline, even if the professional would advise against it.

The NHS

The NHS choices website has a page on consent[2] which addresses consent in a broadly similar way adding that:

'The principle of consent is an important part of medical ethics and the international human rights law.

Consent is the principle that a person must give their permission before they receive any type of medical treatment.

'Consent is required from a patient regardless of the type of treatment being given, from a blood test to an organ donation.

'For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision.'

They say *'from a blood test to an organ donation'*, however, it is not only invasive procedures that require consent, so is the NHS missing something here and does this give some idea about why there is a failure

to obtain consent that covers all aspects of care?'

The NHS Litigation Authority's Risk Management Standards 2012-133 is very clear about what consent means, they state:

'A principle of consent is that it is given voluntarily and that sufficient information has been imparted to allow the consent to be valid. It is a legal and ethical principle that valid consent is obtained for every person.'

'When deciding on the approach for consent, organisations are reminded of the need not only to consider legal requirements but the standards expected of healthcare professionals by their regulatory bodies. All practical and appropriate steps must be taken to enable a person to make the decision themselves. Information should be communicated in an appropriate way, include the nature and purpose of procedures, and the provision of any other relevant information.'

'If there is a failure to obtain proper consent and the patient subsequently suffers harm as a result of treatment, this may give rise to a valid negligence claim.'

'Analysis of the NHSLA claims database shows a significant number of claims where consent is an issue. The majority of these are in relation to surgical procedures or treatments. A major factor is the apparent lack of adequate, clear information for patients, due to issues with verbal or written communication, or competence contributing to these failures.' **(page 122)**

So, the NHS legal defence teams have a very clear statement on what constitutes consent and the potential pitfalls of not gaining proper and informed consent. To not gain consent and to not ensure it is properly informed is negligence. It is expected by CNST (Clinical Negligence Scheme for Trusts) that NHS Trusts and contracted-in services will comply for the purposes of their clinical negligence insurance.

NICE

NICE, the body responsible for producing guidance on evidence-based practice, does not seem to provide an overview on consent, but it is addressed in various ways within the different guidance covering different issues. For example the pathway for caesarean section[4] says:

'A pregnant woman is entitled to decline the offer of treatment such as caesarean section, even when the treatment would clearly benefit her or her baby's health. Refusal of treatment needs to be one of the woman's options.'

'Request consent after providing evidence-based information and in a manner that respects the woman's dignity, privacy, views and culture, while taking into consideration the clinical situation.'

All is clear and relatively consistent so far, so, what do the professional bodies have to say?

The GMC and the NMC

The regulatory bodies for both doctors and midwives provide significant guidance on consent.

Information about consent from the GMC can be found in their document Consent Guidance: patients and doctors making decisions together[5] and there is a 64 page document Guidance for Doctors which lays out the duties of a doctor registered with the General Medical Council[6] There are some excellent points, and obvious points are made clear, for example:

'You should give information to patients in a balanced way. If you recommend a particular treatment or course of action, you should explain your reasons for doing so. But you must not put pressure on a patient to accept your advice.' **(page 13)**

'You should do your best to understand the patient's views and preferences about any proposed investigation or treatment, and the adverse outcomes they are most concerned about. You must not make assumptions about a patient's understanding of risk or the importance they attach to different outcomes. You should discuss these issues with your patient.' **(page 17)**

*'You must respect a patient's decision to refuse an investigation or treatment, even if you think their decision is wrong or irrational. You should explain your concerns clearly to the patient and outline the possible consequences of their decision. You must not, however, put pressure on a patient to accept your advice.'***(page 19)**

*'You must not assume that a patient lacks capacity to make a decision solely because of their age, disability, appearance, behaviour, medical condition (including mental illness), their beliefs, their apparent inability to communicate, or the fact that they make a decision that you disagree with.'***(page 29)**

Information from the NMC about consent[7] states that:

'Nurses and midwives have three over-riding professional responsibilities with regard to obtaining consent.

'To make the care of people their first concern and ensure they gain consent before they begin any treatment or care.

'Ensure that the process of establishing consent is rigorous, transparent and demonstrates a clear level of professional accountability.

'Accurately record all discussions and decisions relating to obtaining consent.'

The RCOG and RCM

RCOG Clinical Governance Advice[8] states:

'Before seeking a woman's consent for a test, treatment, intervention or operation, you should ensure that she understands the nature of the condition for which it is being proposed, its prognosis, likely consequences and the risks of receiving no treatment, as well as any reasonable or accepted alternative treatments. Uncertainties should be discussed.'

It specifically mentions consent for screening tests, ultrasound, caesareans, vaginal examinations and the

presence of students. It also says:

'If consent has to be obtained from a woman during painful labour, such as to perform a vaginal examination, operative delivery or to site an epidural, information should be given between contractions.'

RCOG produce over 50 guidelines on various conditions and treatments; the full list of available guidelines can be found at www.rcog.org.uk/guidelines Few of the guidelines mention consent specifically, and again consent was more likely to be included for an invasive procedure. If the argument for its omission is that it is covered elsewhere then we would appeal on the basis of women's experiences for them to reconsider.

For example, on giving Anti-D *'Consent should be obtained and recorded in the case notes.'*(GTG22).

The wording for ECV was interesting and may give an insight into how consent is being viewed, particularly the comment:

'All women undergoing ECV should be offered detailed information (preferably written) concerning the risks and benefits of the procedure. Consent may also be appropriate.'(GTG 20a - ECV page 5).

We would hope that no one would actually really consider that consent for ECV was sometimes unnecessary and we assume that what should have been written here was that 'Written consent may also be appropriate'. It also shows how information is not being used as part of obtaining consent to a procedure as it is advising that the information is given to women 'undergoing' rather than those being offered or considering ECV. Such apparent misunderstanding of the basis for making informed decisions, and providing for informed consent or informed refusal are leading to regular assaults on pregnant women around the country on a daily basis, as to administer treatment or care without valid consent constitutes criminal assault as well as medical negligence.

The RCM also did not seem to have a separate document, but they include discussion of consent in some of their practice guidelines.[9]

It was interesting to see when consent was included and when it was not; again like the NHS and RCOG there was more discussion of consent with invasive procedures. The guidance on vaginal examinations and immediate care of the newborn, both for the examination and the administration of vitamin K explicitly refer to consent being obtained.

However, none of the rest of the guidance, covering such aspects as fetal heart rate monitoring, care of the perineum, supporting women in labour, use of water or the third stage of labour, explicitly consider consent. Although issues around decision making are discussed in many of the other practice guidelines, there seems to be a significant gap between practice guidance and what is the bottom line in terms of a woman consenting to things being done to her. For example in the guidance on 'Rupturing Membranes in Labour' it does say:

'The decision to rupture membranes should only be taken in direct consultation with the woman, when the evidence is discussed and the intervention is not minimised. This discussion should form part of the birth plan, and not take place just before or during a vaginal examination.'

But what it fails to make absolutely clear by not including the issue of consent it that this is the woman's decision and no one else's.

Similarly in the 'Third stage of Labour' guidance it says:

'Women at low risk of postparum [sic] haemorrhage who request physiological management of the third stage should be supported in their choice.'

Does this imply that other women do not have the option to reject this intervention? This runs completely contrary to all other guidance on obtaining consent for interventions.

The Law

So legally where do women stand in retaining their autonomy? The courts have been examining the question of consent to medical treatment for 250 years. In the 1950s, the High Court held that the same test should be applied both to the standard of treatment and whether or not there had been a failure to warn the patient of the risks of that treatment - the requisite standard in each case being that recognised as proper by a competent body of professional opinion.9

In the 1980s the courts again considered consent. The House of Lords upheld the previous decisions and found that the duty to disclose information and obtain consent was defined by what a reasonable doctor would do rather than what a reasonable patient would expect.9

Although this caselaw with its paternalistic approach remains the main legal authority on consent, the courts have been more sympathetic to the patient's right to autonomy and dignity when looking at questions around consent more recently. There has been greater recognition of the concept of a 'reasonable patient' who requires information on risks to reach his or her own decisions about treatment. One judge referred to the right of patients 'to make important medical decisions affecting their lives for themselves: they have the right to make decisions which doctors regard as ill advised' and asserted that '[t]he court is the final arbiter of what constitutes informed consent.'9 However, there is still a lack of certainty and clarity as to how to apply the legal test for whether or not the necessary consent was obtained.

Conclusion

So, overall, there seems to be a fairly clear and consistent approach from Government, institutions, health professionals and the law, one that says that individuals should be provided with accurate and unbiased information and allowed to make their own decision which should be respected regardless of whether the health professionals agree with them or not; and that to harass or bully a woman into giving

consent means that the consent is not valid. Yet, in day-to-day practice, women seem to be struggling to retain control over their bodies and their decisions and the dilution of the strength of the second statement by NICE (page 4) with the phrase 'while taking into consideration the clinical situation' may give some insight into how health professionals may be led astray by a belief that they may be in a better position to decide what should happen to a woman.

It seems that although the issue of consent is being considered, there is a lack of clarity about how it should be implemented in the day-to-day practices of our obstetricians and midwives. The experiences of women make it clear that the routines of maternity care are enforced upon women, without women being enabled to provide or decline consent.

For informed consent for any form of care, a woman not only requires information and the chance to provide consent, she needs alternative options to be made fully accessible, she needs to know that she will not be bullied or threatened should she decline routine or preferred treatments or practices and she needs our health professionals to fully support informed refusal as well as informed consent; and for their professional bodies to spell this out clearly in their guidance.

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