Informed consent in clinical research


Abstract
Since increasing numbers of patients are asked to take part in clinical trials, nurses need to be aware of the principles of valid, informed consent. This article explores consent, which aims to protect the rights, safety and wellbeing of patients. In particular, the history of consent in research and the elements involved in obtaining informed consent from potential participants in research studies are discussed.

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History of informed consent in research
In the past, the rights and welfare of people who took part in research were often disregarded. Before 1946, informed consent was not considered necessary in medical research. There was little in the way of a written, ethical code governing research involving human subjects, and researchers were essentially free to do as they liked (Fluss 2004). Abuse of participants in scientific experiments was common; one of the most horrific examples being the medical experiments performed by researchers on prisoners in Nazi concentration camps during the second world war. The trial of the doctors who ran these experiments led to the creation of the Nuremburg Code, which was described by Shuster (1997) as the most significant document in the history of medical research ethics. Another infamous example is the Tuskegee trial in the United States (US), in which hundreds of African American men with syphilis were left untreated to study the long-term effects of the disease (Gamble 1997).

The most important concepts of the Nuremburg Code are that voluntary consent by human participants is essential, consent must be given freely without any form of coercion, and participants should have sufficient information and comprehension to be able to make a knowledgeable decision (Shuster 1997). The most important concepts of the Nuremburg Code are that voluntary consent by human participants is essential, consent must be given freely without any form of coercion, and participants should have sufficient information and comprehension to be able to make a knowledgeable decision (Shuster 1997).

The doctrines of the Nuremburg Code were later incorporated into the WMA Declaration of Helsinki in 1964, a statement of ethical principles for medical research worldwide, providing guidelines for physicians working in biomedical research involving human subjects (WMA 2008). Regulatory agency and industry representatives from the European Union (EU), US and Japan published the ICH (1996) good clinical practice guideline, with the aim of unifying international research standards.
ethical and scientific standards for the design, conduct and reporting of clinical trials involving human subjects. These recommendations have since been enshrined in EU and UK directives.

**Definition of valid, informed consent**

Nurses need to be aware of the principles underpinning informed consent. Participants consent ‘is legally valid and professionally acceptable only if they have the capacity to decide whether to take part in the research, have been properly informed, and have agreed to participate without pressure or coercion’ (General Medical Council (GMC) 2010). Informed consent is the process by which a person freely agrees to undergo a treatment or procedure, or to participate in research. He or she must have been given all the information needed to make a decision. For consent to be valid, participants must have the capacity to comprehend the information given and be able to decide whether or not to proceed. It is vital that no form of pressure or undue influence is used to persuade individuals to participate (ICH 1996).

**Elements of informed consent**

**Adequate disclosure of information**

The provision of clear, accurate information is central to gaining informed consent (RCN Research Society 2011). The WMA Declaration of Helsinki asserts that potential participants must be adequately informed about what entering into a study will mean for them, especially the purpose of the research, the benefits and risks of taking part and the alternatives if they decide not to proceed (WMA 2008). The RCN Research Society (2011) offers a comprehensive checklist of essential information that potential participants should receive to give informed consent. This includes what will happen to them if they are recruited and what they may be expected to do, how long their participation will last, and how data about them will be used, managed and stored. Patients must also be advised that their participation is voluntary and that they are free to withdraw from the study at any time. In addition, patients should be advised that choosing to withdraw from the study will not compromise their treatment in any way. If any new or additional facts emerge later that might affect their decision to continue in the study, participating patients must be informed.

The National Research Ethics Service (NRES) (2011) recommends that the person seeking consent should present the necessary information in written form and through discussion. In its guidance for researchers, the NRES (2011) stresses the importance of taking time to talk about the information with potential participants and not simply giving them a leaflet to read on their own. This information is usually provided by doctors and research nurses. Other healthcare professionals may also be involved, for example physiotherapists or dieticians, depending on the nature of the study. Those responsible for the informed consent process are identified in the application for approval of a research study.

**Patient information sheet**

Individuals considering whether to take part in a research study should be provided with a patient information leaflet. This document, which must have been approved by a research ethics committee, invites the person to participate in the research and outlines the main points of the study. The leaflet should be easy to read and understand, free from jargon and appropriate for potential participants. Where applicable, it should include any diagrams or illustrations that might help to explain the research. As well as reinforcing the information given verbally, the information sheet should also provide details of who patients can contact if they have any further questions or if they later decide to withdraw from the study (RCN Research Society 2011). It is considered good practice to allow a certain amount of time for patients to consider the information before deciding to give consent. There is no universally recommended length of time for this, but allowing at least 24 hours is common.

**Consent form**

Consent may be given verbally, non-verbally (for example, when a patient rolls up his or her sleeve to allow a blood sample to be taken) or in writing. The participant should be asked to sign a consent form before any research activity is undertaken. In most cases it is not a legal requirement to complete a consent form, but it is considered good practice (DH 2009). Exceptions include certain requirements of the Mental Health Act 1983 and the Human Fertilisation and Embryology Act 1990 (as amended by the Human Fertilisation and Embryology Act 2008), where completion of a consent form is mandatory. It is important to note that although this document provides evidence that consent was obtained, the fact a patient has signed the form does not prove that consent is informed and legally valid (DH 2009).

The Medical Protection Society (MPS) (2013) recommends that the main elements of discussions with the patient regarding consent are documented in his or her medical notes, including a summary of the information given and any anxieties or concerns the patient may have expressed. Consent is a process involving open dialogue between the
patient and researcher. It begins when the patient is first approached and given information, and continues indefinitely after the consent form has been signed. The patient is free to change his or her mind and withdraw consent at any time without having to give a reason for doing so (MPS 2013). For this reason, the signing of a consent form cannot be considered the end of the process. During the research study, it is important to ensure that participants continue to understand what the research involves, what taking part means for them, and that they are willing to continue being in the research study. If any new information becomes available that might affect the decision to give consent, the patient must be made aware of it and his or her willingness to consent reviewed (RCN Research Society 2011).

Capacity to consent
Particular care must be taken when approaching patients who may be vulnerable or lack the capacity to consent. This includes children, people with learning difficulties, offenders, ethnic minorities and those who have poor understanding of English (RCN 2009).

The Mental Capacity Act 2005 defines a person who lacks capacity as one who has an impairment or disturbance in the functioning of the mind or brain, which renders him or her unable to understand the information given, make a decision and communicate that decision. It is a requirement of the Nursing and Midwifery Council’s (2008) code of conduct to be aware of the legislation concerning mental capacity. In addition, nurses have a duty to act as advocates for patients who lack capacity and ensure their rights are protected.

Children are legally competent to give consent from the age of 16 (DH 2001), although it is considered good practice to encourage them to involve their family in the process. Younger children are only presumed able to give consent if they can demonstrate sufficient insight and comprehension of what is being proposed. As is the case with older children, it is still good practice to involve the family in decision making. Where a child does not have the capacity to give consent, it should be sought from a person who has parental responsibility, usually a parent or legally appointed guardian (DH 2001).

For people with learning disabilities, it may be necessary to take more time to explain the research study, and using simpler language or pictures may aid understanding. Every effort should be made to give people with learning disabilities the opportunity to choose whether or not to take part in research so that their views and needs may be represented in the evidence base (Cameron and Murphy 2007). The same principles apply to patients who have a poor understanding of English. In these cases, a professional interpreter should be involved in the consent process. It is not advisable to rely on family members to interpret as the quality of translation cannot be guaranteed (RCN Research Society 2011).

It could be argued that every patient is in some way potentially vulnerable. Therefore, it is essential to assess the individual’s capacity to give valid, informed consent autonomously. The best interests of the patient should always take precedence over those of science or society (RCN 2009).

Role of the research nurse
The part played by research nurses in clinical research has become increasingly important because having dedicated research nurses to assist clinicians in running trials can make the difference between success and failure. Research nurses have a central role in clinical research as patient advocates, especially during the process of obtaining consent. They are responsible for protecting the interests of those who participate in clinical trials and ensuring patients are advised and supported to make a decision and give valid informed consent (RCN Research Society 2011).

The lead researcher in any clinical trial is responsible for gaining the informed consent of study participants. However, the GMC (2008) advises that doctors may delegate this duty to other appropriately trained and qualified members of the research team, including research nurses. This must be documented clearly and the person obtaining consent must also sign the consent form (GMC 2008). Nurses should not feel they have to assume this responsibility, unless they are confident to do so and are sufficiently informed about the research (RCN 2009). Croudass et al (2008) pointed out that ambiguity remains about the degree of responsibility nurses can assume when formally obtaining consent. In some interventional trials, the role of the research nurse in obtaining informed consent is restricted to that of giving information, answering questions and supporting participants; the actual signing of the consent form is mediated by doctors.

The person who conducted the informed consent discussion should sign the consent form along with the participant (ICH 1996). However, although the doctor may sign the consent form, it is frequently the research nurse who has spent the most time with the patient explaining the research and making sure he or she has understood all the information. Many readers may recognise the scenario where a patient is willing to sign anything at the request of a doctor, without really...
knowing what it is he or she is agreeing to. The concern is that patients may be unduly influenced to participate by a physician who has a vested interest in recruiting as many patients as possible to the research study. Flory and Emanuel (2004), in a review of methods for increasing research participants’ understanding of information provided, recognised this risk and concluded that nurses spending time with patients during one-to-one discussions could provide an effective safeguard against this.

Nurses have an important role in ensuring the patient is appropriately informed and has understood what he or she has consented to. Non-research nurses are not directly involved in the informed consent process, but they do spend a lot of time with patients. Patients might wish to discuss the research with them and they may have questions or doubts about the research, which they had not expressed to the doctor or research nurse. A non-research nurse might also become aware that the patient has not understood fully the research trial that he or she has consented to. This is where the nurse’s role as advocate becomes important. If the nurse is concerned about a particular patient, he or she might need to liaise with the research team to ensure that informed consent has been given.

Informed consent is an ongoing process and does not end with signing the consent form (DH 2009, RCN Research Society 2011). It is often the nurse who continues to work closely with participants throughout the process, keeping them informed of any changes and making sure they are willing to continue to give consent. If a patient at any stage has doubts or changes his or her mind about participating in a trial, the nurse may be the first to be aware of it and may need to take appropriate action.

**Conclusion**

Nurses have a duty to act as advocates for patients, supporting and protecting them throughout the consent process. This includes making sure that patients who are considering taking part in research have all the facts to make an informed decision and that they are able to understand the information they have been given. Where patients do not appear adequately informed, are expressing doubts or concerns about participating in research, or are at risk of being persuaded to take part in a trial they would not otherwise agree to, nurses have a crucial role in recognising these issues and bringing them to the attention of the research team NS.

**References**


