

The Write Stuff



Informed consent for patients: The process

by Simon Parsons

Over recent years informed consent has changed dramatically. Previously the health profession used the paternalistic approach. The doctor made the decision on behalf of the patient and the patient seemed to have little say in the process and was merely asked to sign the form to agree to have the procedure performed upon them.

Experiences from Bristol Royal Infirmary and the enquiry that followed, have taught us that this paternalistic approach is no longer acceptable. The Department of Health's "Reference Guide to Consent for examination or treatment" makes this clear; it states that "acquiescence where the person does not know what the intervention entails is not consent".

Recent guidelines produced by the GMC, Department of Health and other governing bodies give succinct guidance that patients

- must be given sufficient information in a way that they can understand in order to enable them to exercise their right to make an informed decision about their care
- need up-to-date written information to support this process of consent, and they
- need sufficient time to make that decision.

In practice, the guidelines should ensure that patients receive information about the benefits and risks of the proposed treatment and alternatives to the proposed treatment. Discussion of complications is essential for the patient to make their own judgment on whether the procedure is right for them.

Empowering the patient

The healthcare profession is moving towards a partnership between the patient and health professional where there is an open and free provision of accurate and up-to-date information for the patient provided in a timely manner. This will facilitate an open and honest relationship between health professional and patient and will empower the patient, enabling them to choose the most appropriate treatment option whilst being guided and supported by the healthcare professionals.

The process of informed consent

The process of informed consent must begin much earlier in the patient pathway, so that patients are not suddenly presented with all the information on the day of treatment. Hospitals are moving towards beginning the consent process in the outpatient clinic with treatment-specific patient information being given to the patients when treatment is recommended. The patient is then put on the list for treatment; during the waiting time, there is opportunity to consider the information thoroughly and perhaps to discuss it with family, friends and perhaps the GP.

The Write Stuff

Informed consent process

The patients will then return to the pre-assessment clinic and this is an ideal time for the health professional trained in consent (usually the person carrying out the procedure) to go through the patient information and confirm the consent with a signature on the new Department of Health consent forms.

Thus when the patient is admitted for their treatment, the consent has already been taken and this need not delay the various processes that have to take place on the day of treatment.

From the medico-legal viewpoint, it is essential the information given to the patient is documented in the clinical notes. Just as importantly, the patient information must support the clinical consultation, improving the efficiency of that consultation and the health professional's relationship with the patient.

Primary care in the process of informed consent

As many diagnoses are made in primary care, it would be optimal if information about treatment options for a particular condition were provided to the patient by the GP. The patient would then have time to read the information prior to their visit to hospital or treatment centre and move seamlessly into secondary care with consistent and appropriate information being given at each stage.

This depends on two factors: firstly that the diagnosis is correct and secondly that all the health professionals agree the information (ideally produced centrally but adapted to the local setting).

Ideal information for consent

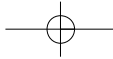
So what information represents the ideal patient information to support the consent process? Recommendations from the GMC, Department of Health and Bristol enquiry have made it clear that there needs to be an explanation of:

- the problem or condition
- the treatment options available, including the alternatives to the proposed treatment
- what the proposed treatment involves, including diagrams
- the risks and complications
- the benefits
- post-operative expectations

Information must be easy to read and understand. In the UK and other English-speaking countries, achieving the Plain English Campaign's Crystal Mark status on each information document is a good indicator that the information can be understood by most people at first read.

Information must be evidence-based with the evidence regularly reviewed and the information updated accordingly. There are a number of very good sources of high quality evidence-bases such as the Cochrane Library. It is best for research-trained clinicians who communicate regularly with patients in clinics (as opposed to research methodologists who often have minimal, if any, patient interaction) to review the evidence and decided what to include in patient information documents.

Information must be updated regularly and be date-stamped to indicate when the infor-



The Write Stuff

Informed consent process

mation 'expires'. It is often surprising how quickly treatment options and technical aspects of treatments adjust.

The patient should also be provided with local contact details should they have any questions or concerns before and after their treatment. They should also be aware of specialist services (for example, services for impaired sight or hearing). Furthermore, it is beneficial for patients to have pointers to sources of further information such as validated Internet sites and organizations that provide support for their condition.

The role of the medical writer

Medical writers have a role but their role should be considered carefully. It is often inefficient for the medical writer to develop informed consent patient information 'from scratch'. Their role should be focused on structural editing, subediting and proofing. In all the development stages, the development co-ordinator should involve the expert clinician on a regular basis to ensure the technical integrity of the information is maintained. This may be a different approach to 'normal' medical writing but bear in mind that the end product in the context of informed consent will be used as a risk management tool by hospitals. Any responsible provider of medical care will want evidence of professional indemnity insurance which will, in turn, demand technical expert involvement and sign off.

Involving patients

Patients should be consulted and their needs addressed. It is worth noting that the rigorous guidelines mentioned in his article have for the most part been developed following intensive research into patients' information needs, such as the research work done by Dr Angela Coulter at the King's Fund. However, on a regular basis, patient representative organizations, patient charities and individual patients should be asked to review and comment on patient information documents to ensure their needs, in the context of the consent process, are fully met.

Conclusion

Regulatory guidelines and medico-legal pressures are providing the impetus to patient empowerment. At the centre is the informed consent process that relies on the provision of high-quality treatment-specific patient information.

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Acknowledgement: Owain Tudor, Director and Head of Product Development, EIDO Healthcare contributed to the article.

