

Consent – procedures for which the benefits and risks are uncertain

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Who is this leaflet for?

This leaflet is for patients offered procedures which NICE has said have uncertain risks and benefits.

Consent: your choice

Before a doctor, a nurse or anyone else looking after your health can treat you, they need your consent. That means they must get your agreement, and you need to understand the likely benefits and possible risks before agreeing. For some surgical operations or similar procedures, no one knows for certain what the results of treatment are going to be, and this may affect your decision about having the procedure. This leaflet is your guide to:

- why doctors don't have all the answers
- how the NHS deals with procedures for which the benefits and risks are uncertain
- what to think about if you are offered such a procedure.

Procedures are treatments that involve one of the following:

- Making a cut or a hole to gain access to the inside of a patient's body – for example, when carrying out an operation or inserting a tube into a blood vessel.

- Gaining access to a body cavity (such as the digestive system, lungs, womb or bladder) without cutting into the body – for example, examining or carrying out treatment on the inside of the stomach using an instrument inserted via the mouth.
- Using electromagnetic energy (which includes X-rays, lasers, gamma-rays and ultraviolet light) or ultrasound – for example, using a laser to treat eye problems.

Are the benefits and risks of procedures always clear?

No, they are not. Most of the procedures used in the NHS are not new, and we have learnt how well they work and what risks they have. But some procedures are too new to have all the information we need. We are not yet sure just how much benefit they give and which patients get the most from them. We know the short-term results of some procedures, but not the longer-term results. All procedures have side effects and risks, and it may take some time to discover exactly what the problems are and how common they are.

As well as new procedures, there may be concerns about the benefits and risks of older procedures – for example, if some people don't seem to do well after having them.

It may be right to choose a procedure for which the benefits and risks are uncertain if doctors think it is likely to help a patient, and the patient agrees, knowing that the outcomes are uncertain – but we must take special care when we haven't got all the answers about a procedure.

Who decides about these procedures?

The National Institute for Clinical Excellence (NICE) can help. NICE is part of the NHS, and its role is to provide patients, health professionals and the public with guidance on treatment and care for people using the NHS in England and Wales. As part of its work, NICE looks into new (and sometimes not so new) procedures which have been notified to it and decides whether we know enough about how well they work, and how safe they are, to use them routinely. NICE then gives doctors guidance on what to do. NICE also provides information for the public on each procedure it has looked at. If you would like NICE to look into a new procedure, you can notify it via the website (www.nice.org.uk/ip).

How can you find out about these procedures?

Your doctor should tell you if you are being offered a procedure where NICE thinks there is still uncertainty. You may then want to know more about the procedure before deciding whether to go ahead. You may want to know:

- What does the procedure involve?
- What are the benefits that you may get?
- How good are your chances of getting those benefits?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? And how likely are they?
- What may happen if you don't have the procedure?

You can put your questions to the doctors and nurses looking after you. You can also get information from NICE (see page 9) and you may want to contact a patients' organisation or charity concerned with your disease or procedure.

What does NICE do to get more answers?

For some procedures, NICE is collecting information about benefits and risks to get a better idea of how useful they are. If this is happening for a procedure that you are having, you will be asked whether you agree that information on the results of your procedure can be used in this way. The process is totally confidential and no one will reveal the results of individual patients' procedure. If you do not agree, it will not affect the procedure that you have.

What does this mean for you?

In the end, you choose whether to have the procedure. That is your legal and ethical right. There are special arrangements for people who cannot give their consent, perhaps because they are unconscious or very seriously ill. These arrangements are set out in another leaflet, called Consent – what you have a right to expect: a guide for adults (see the last page for details).

For some operations and similar procedures, it is hard to be certain what the results will be, because the treatments are new. But that does

not mean you should not have them. It means that, once you have all the information you would like, you need to decide whether you want to have the procedure even though the risks and benefits are uncertain.

Where can I get more information?

You can find out what NICE has said about the procedures it has looked at by visiting NICE's website (www.nice.org.uk/ip).

The NHS Response Line (telephone 0870 1555 455) will send you copies of NICE's guidance and Information for the Public, but you will need the reference number of the document, which is available on the website.

There is more information on consent to treatment in Consent – what you have a right to expect: a guide for adults. You can get this from the Department of Health website (www.doh.gov.uk/consent) or from the NHS Response Line (telephone 0870 1555 455).

The Welsh Assembly Government has also produced the following information on patient consent:

- Reference Guide for Consent to Examination or Treatment; and

- Good practice in consent implementation guide: consent to examination or treatment

These documents are available on the Assembly's website at:

<http://www.wales.gov.uk/subihealth/topics-e.htm#A&E>



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