

Understanding NICE guidance

Information for people who use NHS services

Spinal fusion of the lowest spinal disc through a cut at the base of the spine

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how spinal fusion of the lowest spinal disc through a cut at the base of the spine can be used in the NHS to treat people with low back conditions. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe low back conditions or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use it, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the uncertainty surrounding potential risks of the procedure, including the small risk of rectal perforation particularly in patients with higher bowel disease, or who have previously had pelvic disease or surgery. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE has said that this procedure should only be carried out by surgeons with specific training in surgical treatment of spinal disease and in the procedure, and they should initially carry out the procedure with another experienced surgeon.

NICE has encouraged further research into this procedure and may review it if more evidence becomes available.

This procedure may not be the only possible treatment for low back conditions.

Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Spinal fusion of the lowest spinal disc through a cut at the base of the spine

The medical name for this procedure is 'transaxial interbody lumbosacral fusion'.

The procedure is not described in detail here – please talk to your specialist for a full description.

As a person gets older, the discs between the bones (vertebrae) in the spine start to shrink and joints between the bones can start to deteriorate. This can result in chronic (long-lasting) low back pain.

In most patients, symptoms improve spontaneously over time. Non-surgical treatments are usually tried first. For patients with severe, persistent symptoms not responding to these treatments, surgery such as spinal fusion, insertion of prosthetic discs or stabilization of the spine may be considered.

In this procedure, the patient is given a general anaesthetic and a small cut is made at the base of the spine. A probe is inserted using X-ray or 3-D computer guidance to reach the affected area, and special instruments are used to remove the damaged disc and fill the remaining space with bone graft material. The two vertebrae either side of the disc are then fastened together by a special rod. Potential benefits include a faster recovery time than conventional fusion surgery.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE looked at 6 studies on this procedure.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that it should not be done, but that your doctor should fully explain what is involved and discuss the possible benefits and risks with you, particularly the small risk of bowel perforation. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

How well does the procedure work?

Three studies of a total of 121 patients reported that successful fusion of the spine had occurred in 113 out of 121 patients.

Two studies of a total of 85 patients reported decreases in average level of disability (measured by a questionnaire) from 56% and 42% before the operation to 28% and 22% 1 year after the operation.

A study of 36 patients reported that at an average of 8 months after surgery, 14 out of 35 patients no longer had pain, and pain had significantly improved in 19 out of 35 patients.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the success of the procedure is measured by improved low back pain, and evidence the spine has fused from radiography such as X-rays.

Risks and possible problems

In a study of 50 patients, 1 patient had a tear in the rectum and an abscess. The patient had previously had abscesses in the area around the rectum. An injury to the rectum was separately reported in 1 woman who had

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

previously had spinal surgery and inflammation of the reproductive organs (pelvic inflammatory disease) and bowel (diverticulitis).

Failure of the fusion needing another procedure was reported in 1 patient in a study of 50 patients.

In the study of 36 patients, 1 patient had severe, lasting pain caused by a supplementary screw used during the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. Two advisers reported that they had seen infection, injury to the lining of the abdomen (peritoneum), and abscess in the pelvis. The advisers also said in theory, other problems could include: infection; tears in the bowel or bladder; damage to blood vessels and nerves; leaking of fluid from the spine due to tearing a membrane; movement, loosening or breakage of the implant; and difficulties with further surgery if the initial procedure fails.

More information about low back conditions

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on back pain, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'transaxial interbody lumbosacral fusion'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG387

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2485). The NICE website has a screen reader service called *Browsealoud*, which allows you to listen to our guidance. Click on the *Browsealoud* logo on the NICE website to use this service.*

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.