

Understanding NICE guidance

Information for people who use NHS services

Hand transplant surgery

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 hand transplant surgery can be used in the NHS. 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 the procedure in detail – a member of your healthcare team should also give you full information and advice about this. The leaflet includes some questions you may want to ask your doctor to help you reach a decision.

What has NICE said?

There is not much good evidence about how well this procedure works or how safe it is. In addition, there are risks from the long-term immunosuppressive drugs required afterwards (to protect the transplanted hand from being attacked by the patient's immune system). If a doctor wants to carry out a hand transplant, they should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure. The doctor should explain the need for long-term immunosuppressive drugs and the potential side effects of these, and the fact that the functioning of the new hand may be both delayed and limited. 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.

The procedure should only be done in units that have surgical teams with experience and expertise in limb reimplantation (reattaching healthy hands that have been severed during accidents) and limb transplant surgery. Patients should be carefully assessed to find out whether transplant surgery is the best option for them. Other management options, as well as rehabilitation, should also be discussed.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to the International Registry on Hand and Composite Tissue Transplantation (www.handregistry.com) and Transplant UK, so that the safety of the procedure and how well it works can be checked over time.

Finally, NICE has encouraged further research into hand transplantation and may review the procedure if more evidence becomes available.

This procedure may not be the only possible treatment option.

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

Hand transplant surgery

The medical name for this procedure is 'hand allotransplantation'. The word 'allotransplantation' means that the hand comes from a donor.

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

People with a hand that has been severely damaged by injury or disease may undergo amputation and wear an artificial hand over the stump (called a prosthesis). The aims of this procedure are to provide a hand that is more natural than a standard mechanical prosthesis, and to improve function. Before the procedure patients should be carefully assessed to see whether they understand and accept that long-term rehabilitation following surgery and life-long immunosuppressive medication will be needed after the procedure.

The procedure is carried out with the patient under general anaesthesia. It involves transplanting a hand from a recently deceased donor onto the amputated stump. The donor limb (chosen to match the patient as far as possible in terms of sex, size and appearance) is surgically removed below

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 the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. They should explain the importance of long-term immunosuppression medication and the risks that this carries, and they should explain that the functioning of the hand may be delayed and limited. 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.

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?

the elbow joint and prepared for transplantation. The donor forearm bones are joined to those of the patient, followed by the blood vessels, nerves, tendons and skin.

Following the procedure the limb may be set in plaster for several weeks. The patient will need intensive rehabilitation, including physiotherapy, occupational therapy and possibly electrostimulation to restore as much function to the transplanted hand as possible. Long-term immunosuppressive drugs are needed to reduce the possibility of the patient's body rejecting the donor hand.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 3 studies on this procedure.

How well does the procedure work?

A study of 30 patients (38 hands) followed patients' progress for up to 9 years and reported that 90% of patients could feel pressure and 72% could feel different sensations after the procedure. In addition, 70% of patients felt they had improved quality of life and most returned to work. In the first year 85% of patients experienced acute rejection episodes (where the

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

body starts to reject the transplant) but all were reversed when reported and treated promptly. All transplants were still functioning after 2 years, but 10 later failed because patients did not take the immunosuppression drugs as prescribed. In 2 studies involving 6 patients, 2 hands had to be re-amputated because of blood flow problems.

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 success factors are hand function, rejection-free survival of the transplant and patient satisfaction.

Risks and possible problems

The study of 30 patients reported 2 cases of blood clots and 1 case of blood flow problems that required further surgery. The study also reported problems linked to the immunosuppression therapy: 65% of patients experienced infections, most of which resolved with treatment, and 52% reported metabolic complications, such as high blood sugar.

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 complications listed in the studies include rejection, poor functioning of the hand and diabetes related to the immunosuppression therapy. In theory, other problems include cancerous changes and tumour development.

More information about hand transplantation

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 transplantation, 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 'hand allotransplantation'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/IPG383

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2476). 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.