

Understanding NICE guidance

Information for people who use NHS services

Transplanting donated pancreatic islet cells for patients with type 1 diabetes

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 transplanting donated pancreatic islet cells can be used in the NHS to treat people with type 1 diabetes. 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.

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 type 1 diabetes 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?

In hospitals with experience of pancreatic islet cell transplantation, this procedure can be offered routinely as a treatment option for people with type 1 diabetes provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

If a doctor wants to use this procedure, they should make sure that extra steps are taken to explain the potential risks of the procedure and the uncertainty about how well it works in the long term. 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.

A team of specialist doctors should decide which patients should have this procedure. They should take into account the fact that it is particularly suited for patients who may have sudden hypoglycaemic episodes without any warning signs or who are already taking immunosuppressant medicines because of a kidney transplant.

NICE has also decided that more information about how this procedure affects quality of life and how well it works in the long term will be helpful.

Other comments from NICE

The National Commissioning Group is an organisation that plans, funds and monitors NHS treatment of very rare conditions, separately from primary care trusts. It has developed service standards for this procedure that residents throughout the UK can access.

Transplanting donated pancreatic islet cells for patients with type 1 diabetes

The medical name for this procedure is 'allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus'. The word 'allogeneic' means taken from a donor.

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

This procedure is used for people whose bodies cannot make insulin (or whose bodies cannot make as much as they need). Insulin is important for controlling the balance of sugar in the body. It is made in special cells in the pancreas called islet cells.

In pancreatic islet cell transplantation, a patient's islet cells are supplemented with islet cells from a donated pancreas from a person(s) who has recently died. The patient is either given a local anaesthetic or sedation. A thin flexible tube called a catheter is inserted through the patient's upper abdominal wall and into the portal vein which is the vein that carries blood and nutrients from the bowel to the liver. The islet cells are then injected into the portal vein of the patient's liver. If the procedure is successful, the donor cells start making insulin. Medicines called immunosuppressants need to be taken to protect the donor cells from being attacked by the patient's immune system. Insulin therapy may be reduced or stopped if the transplant is successful.

This procedure may not be the only possible treatment for type 1 diabetes. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in NHS hospitals with experience in pancreatic islet cell transplantation. If your doctor thinks transplanting pancreatic islet cells is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it. Your doctor should tell you about the possible risks of the procedure and the uncertainties about how well it works in the long term. 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 how this procedure affects quality of life and how well it works in the long term. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. If this is the case, your doctor will give you more information.

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?

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 eight studies on this procedure.

How well does the procedure work?

One study looked at 112 patients. In the year before the transplant, 82% of the patients had experienced a severe hypoglycaemic episode. In the year after the transplant only 5% of patients experienced a hypoglycaemic episode. Similarly, another study of 36 patients reported that no severe hypoglycaemic episodes occurred after the transplant.

A different study followed the progress of 65 patients for 4 years after the transplant, and showed that diabetes was better controlled after the transplant, with improved awareness of hypoglycaemia.

In the study of 112 patients, 67% no longer required insulin 6 months after the transplant and 58% no longer required insulin 1 year after it. The patients who still needed insulin needed less of it, with their insulin requirements reducing by an average of 57% after 6 months and 69% after 1 year. In this study, the transplant failed in 15 patients. In the other study of 36 patients, 21 did not need insulin at some stage over a 41 month period, but out of these 21, 16 patients needed insulin again 2 years after the transplant.

Finally, a study of 99 patients showed that patients' fear of a hypoglycaemic episode reduced as a result of the transplant.

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 main aims of the procedure are to reduce the need for insulin and to reduce the number of hypoglycaemic episodes.

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

Risks and possible problems

In three studies involving a total of 152 patients, bleeding into the abdomen was reported in 26 patients and a blood clot in the portal vein was reported in 9 patients. In two studies of 101 patients, the gall bladder was damaged in 3 patients.

In the study of 112 patients, there were 77 serious problems. Out of these, 17 were life-threatening and 45 resulted in a hospital stay. Out of the 77, 73 were dealt with without any lasting 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 possible problems are bleeding, a blood clot in the portal vein, high blood pressure in the liver, problems caused by the patient's lowered immune system, and the possibility of the donor cells carrying infections or cancerous cells.

More information about type 1 diabetes

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

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 'Allogeneic pancreatic islet cell transplantation for type 1 diabetes mellitus'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG257

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1550).

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