

Understanding NICE guidance

Information for people who use NHS services

Image-guided implantation of a new pulmonary valve

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

This leaflet is about when and how image-guided implantation of a new pulmonary valve can be used in the NHS to treat people who have a faulty pulmonary valve. 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. The word 'procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity. 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 faulty heart valves 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?

This procedure seems to work in the short term, but there is not a lot of information about how well it works in the long term. In addition, the studies only involved small numbers of patients. There are no major safety worries. If a doctor wants to use image-guided implantation of a new pulmonary valve, they should make sure that extra steps are taken to explain the uncertainty about whether the procedure works in the long term, and that patients will need further procedures. 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 after the procedure.

NICE has said that this is a difficult procedure and it should only be done by doctors with special training and experience in interventional paediatric cardiology, and only in hospitals with specialist units and cardiac surgical support in case of complications. Patients should be chosen by a team that includes a paediatric cardiologist, an interventional cardiologist, a radiologist and a cardiothoracic surgeon with a special interest in congenital heart disease.

NICE is asking doctors to send information about every patient who has the operation and what happens to them afterwards to a central store of information at the UK Central Cardiac Audit Database (www.ccad.org.uk) so that the safety of the procedure and/or how well it works can be checked over time.

Other comments from NICE

The technology involved in this procedure is continuing to develop.

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

Image-guided implantation of a new pulmonary valve

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

The heart has four valves that keep blood moving in the right direction through the heart. If a heart valve is faulty it may not close tightly enough so blood leaks back, or it may not open widely enough to allow the blood to flow through properly. The medical name for the valve that controls blood flow from the right side of the heart to the lungs is the pulmonary valve.

Pulmonary valve problems are rare and tend to be present from birth. If left untreated, a faulty heart valve can reduce life expectancy. Faulty heart valves are usually repaired or replaced using open heart surgery.

Image-guided implantation of a new valve is an alternative, less invasive procedure because it does not involve opening up the chest. The patient is given a general anaesthetic. The doctor passes a narrow tube called a catheter into a vein (usually in the groin), then passes a guide wire through the catheter (using special imagery of the bloodstream) into the pulmonary

artery. The replacement valve is attached to an expandable tube called a stent, which is then positioned in the correct place over the guide wire.

Because this procedure is mainly performed in children and adolescents, the replaced valve will usually need to be updated as the patient grows.

What does this mean for me?

If your doctor has offered you image-guided implantation of a new pulmonary valve, they 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. 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, so it has recommended that some details should be collected about every patient who has this procedure in the UK. These details will be held confidentially in an electronic database and will not include patients' names. If you do not agree to your details being entered into the database, you can still have the procedure.

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 four studies on this procedure.

How well does the procedure work?

In one study, 58 out of 59 patients had a working replacement valve 10 months after the procedure, and in another study the procedure was successful in all 8 patients included in the study. After the procedure, the right heart's blood pressure was improved by approximately 40% in the larger study and by up to 30% in the smaller study.

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

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 procedure is still new and it is not yet known how well the valve works over years rather than months.

Risks and possible problems

The new procedure appears to carry few risks when performed in expert hands.

In the study of 59 patients, one experienced heavy bleeding with blood leaking into the tissues surrounding the heart.

In the study of eight patients, one experienced complications that required the replacement valve to be placed in a position that was not ideal.

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 a number of complications could occur, including failure to correctly position the replacement valve, unwanted movement of the valve, leakage from the valve, dangerously low blood pressure during valve placement, valve damage during the procedure, damage to red blood cells, structural damage to the heart, narrowing of the pulmonary vein and stent fracture. Other theoretical complications include death, coronary artery compression, inflammation of the inner lining of the heart (called endocarditis) and injury to the large veins in the groin through which the procedure is carried out.

More information about faulty heart valves

Your local Patient Advice and Liaison Service (PALS) may 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 'Percutaneous pulmonary valve implantation for right ventricular outflow tract dysfunction'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IIPG237

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1409).

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA; www.nice.org.uk

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