

## Understanding NICE guidance

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Information for people who use NHS services

# Treatment of lower urinary tract blockage in an unborn baby using a vesico–amniotic shunt

*NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.*

This leaflet is about when and how a vesico–amniotic shunt can be used to treat unborn babies with lower urinary tract blockage in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 unborn babies will benefit most from it.

This leaflet is written to help parents who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe lower urinary tract blockage 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.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether 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.



## What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to carry out this procedure, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the parents agree (or don't agree) to the procedure. The parents 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.

This procedure should only be carried out in a specialist centre, by a team that may include a consultant in fetal medicine, a neonatologist, a paediatric urologist and a specialist midwife.

Further information on the safety of vesico–amniotic shunts and how well they work will be helpful. NICE has encouraged doctors to ask parents to take part in a clinical trial looking at vesico–amniotic shunts and allow details to be entered into an electronic database. This will mean that the safety of the procedure and how well it works can be checked over time. NICE may look at this procedure again if more information becomes available.

*This procedure may not be the only possible treatment for lower urinary tract blockage in an unborn baby. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.*

## Insertion of a vesico–amniotic shunt

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

While a baby is growing in the womb, the tube leading from the baby's bladder may become blocked. As a result the baby's lungs or kidneys may not develop properly. The baby may have breathing problems at birth, or may need kidney dialysis or a transplant. Some babies die in the womb, and some die soon after birth.

One way to treat the blockage is to insert a small tube (called a vesico–amniotic shunt) into the baby's bladder. A needle is inserted through the woman's abdomen into the womb, and into the bladder. A flexible, shaped tube is moved down the needle. This tube is positioned between the bladder and the amniotic fluid around the unborn baby. It allows any fluid in the bladder to drain away into the amniotic cavity. The shunt is removed as soon as the baby is born. This procedure is carried out using local anaesthetic.

## 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 six studies on this procedure.

## How well does the procedure work?

Insertion of a vesico–amniotic shunt increased the chances of the baby surviving to birth compared with no treatment. In four studies, 40–91% of babies survived into infancy.

In three studies, 25–33% of children needed dialysis or a kidney transplant. Another study reported ‘acceptable’ renal function in 8 out of 18 children (44%) and one reported ‘good’ renal function in 6 out of 8 children (75%). Three out of 18 children had bladder problems that required insertion of a catheter (drainage tube). Asthma was reported in 7 out of 18 children (39%) in one study, and repeated lung infections in 5 out of 18 children (28%).

Quality of life in children who had had a shunt inserted was similar to that of healthy children.

The expert advisers said that there was not enough information to assess how well the procedure works. It is not clear which babies will benefit most from the procedure.

## Risks and possible problems

The most common problem was the shunt moving or becoming dislodged, which happened in 22–60% of babies, and frequently needed a new shunt to be inserted. In one case, the amniotic membranes ruptured prematurely. Two babies had bladder problems at birth.

The expert advisers said that the main risks are preterm labour, miscarriage, blockage or displacement of the shunt, trauma and developmental problems in the unborn baby. Risks to the woman include damage to organs and infection.

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

### What does this mean for me?

If your doctor has offered to carry out this procedure on your baby, 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. 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 England and Wales. 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 my baby might get?
- How good are the chances of my baby getting those benefits? Could having the procedure make the situation 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 we need after the operation?
- What happens if something goes wrong?
- What may happen if my baby doesn't have the procedure?

### More information about lower urinary tract blockage in unborn babies

NHS Direct online ([www.nhsdirect.nhs.uk](http://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. 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](http://www.nice.org.uk/aboutguidance)*

*This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IIPG202](http://www.nice.org.uk/IIPG202)*

*You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1173).*