

Understanding NICE guidance

Information for people who use NHS services

Diagnosing and treating lower urinary tract blockage in an unborn baby using fetal cystoscopy

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 fetal cystoscopy can be used to diagnose and 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 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 blockages in the lower urinary tract 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 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.



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 specialist centres by a multidisciplinary team that should usually include a consultant in fetal medicine, a paediatric urologist, a neonatologist and a specialist midwife.

Further information on the safety of fetal cystoscopy and how well it works will be helpful. NICE has encouraged doctors to consider asking parents to take part in a research study (called a clinical trial) looking at fetal cystoscopy for blockages of the lower urinary tract. NICE may look at this procedure again if more information becomes available.

Other comments from NICE

NICE advised that the instruments used in this procedure need more development.

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 your baby and about any other treatment options available.

Fetal cystoscopy

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. In some baby boys, this can be caused by a condition known as posterior urethral valves (sometimes shortened to PUV). PUV only affects boys and means that there is a blockage in the tube leading from the bladder. If a baby has a lower urinary tract blockage, their 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 soon after birth.

Fetal cystoscopy can be done under local or general anaesthetic. A tube is inserted into the baby's bladder through a small cut in the mother's abdomen. A flexible camera is pushed through the tube to allow the surgeon to see any signs of a blockage in the baby's urinary tract, and then open the blockage.

Your specialist should only recommend fetal cystoscopy if your baby's kidneys seem to be working normally.

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 five studies on this procedure.

How well does the procedure work?

In one study, the procedure allowed the surgeon to see the bladder in 12 out of 13 unborn babies. The surgeon was able to identify the location of the blockage in 5 out of 12 unborn babies.

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 and my child?

If your doctor has offered to carry out 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. 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 woman 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?

In a second study, posterior urethral valves were successfully removed from the urinary tract of 6 out of 13 unborn babies. Of the eight babies who survived to a live birth, five had healthy, working kidneys. In a third study, the blockage was cleared in 1 out of 11 unborn babies.

The expert advisers stated that because the procedure is new, there is little information on how safe it is and how well it works.

Risks and possible problems

In one study, unusual swelling due to the accumulation of urine was reported in 5 out of 13 unborn babies after the procedure. In another study of 11 unborn babies, small tears in the bladder were noticed in one unborn baby. In three studies looking at a total of four unborn babies, one baby died after the mother's membranes ruptured a few days after the procedure.

The expert advisers stated that other possible problems include miscarriage, premature birth, premature rupture of the membranes, infection in the mother and damage to the bladder or abdominal wall of the unborn baby.

More information about lower urinary tract blockage in unborn babies

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. 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 and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG205

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1194).