

Treatment of pleural effusion in unborn babies using a shunt

This leaflet is about when and how insertion of a pleuro-amniotic shunt can be used to treat unborn babies with pleural effusion 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 patients 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 pleural effusion 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.

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.

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 use this procedure in an unborn baby, 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 do not 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 includes a consultant in fetal medicine, a neonatologist and a specialist midwife.

This procedure may not be the only possible treatment for fetal pleural effusion. Your healthcare team should talk to you about whether it is suitable for your baby and about any other treatment options available. You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Insertion of pleuro–amniotic shunt

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

Pleural effusion is a build up of fluid in the space between the membranes that surround the lungs (the pleural cavity). It can prevent lungs from developing properly. It can also cause heart failure in the unborn baby (which is called hydrops fetalis).

One way to treat pleural effusion is to remove the fluid using a special needle. If the fluid builds up again, a special tube (called a pleuro–amniotic shunt) can be inserted. A needle is inserted through the woman's abdomen into the womb, through the baby's chest into the pleural cavity. A flexible, shaped tube is moved down the needle. This tube is positioned between the pleural cavity and the amniotic fluid around the unborn baby. It allows any fluid in the pleural cavity to drain away. The shunt is removed as soon as the baby is born. This procedure is carried out using local anaesthetic.

What does this mean for me?

If your doctor has offered to insert a pleuro–amniotic shunt in your unborn 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.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits for the unborn baby?
- How good are the chances of the 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 I and the unborn baby need after the operation?
- What happens if something goes wrong?
- What may happen if we 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 five studies on this procedure.

How well does the procedure work?

Insertion of a shunt allowed the fluid to drain and the lungs to expand properly in 98% (46/47) of babies in one study. Polyhydramnios (too much amniotic fluid) was corrected in 67% (20/30) of pregnancies and heart failure was corrected in 46% (13/28) of babies.

In two studies, none of the babies had lung problems after birth (babies were followed up for between 2 months and 6 years). In another study, 35% of babies had problems at some stage.

The number of babies who lived ranged from 48% to 100% in five studies, although the cause and size of the fluid build up varied widely in these studies.

Fluid built up again in 6% to 8% of unborn babies, and another drainage tube had to be inserted.

The expert advisers said that fluid can go away without treatment. This chance has to be balanced against the risks of the procedure. They also said it was not clear how to identify which babies need treatment.

Risks and possible problems

Only one study of 13 babies reported on problems during surgery. In this study, one baby needed another shunt because of bleeding during the procedure.

Most problems occurred straight after the procedure. In two studies, two out of a total of 19 babies died because of problems caused by the procedure. Another baby had a build up of fluid in its arm.

The shunt moved into the chest in three babies, but this didn't cause any problems.

The expert advisers said that there was a risk of problems associated with the shunt (blockage or movement), trauma to the unborn baby, infection in the woman, premature labour and death of the baby in the womb.

More information about pleural effusion 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/IPG190

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1119).

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