

## Understanding NICE guidance

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Information for people who use NHS services

# Keyhole surgery to stitch the cervix to prevent repeated miscarriage

*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 keyhole surgery can be used to stitch the cervix in the NHS in England, Wales, Scotland and Northern Ireland to treat women who have had repeated miscarriages caused by a weak cervix. 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 people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe in detail what causes repeated miscarriage or a weak cervix, or the procedure – 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 stitch a woman's weak cervix using keyhole surgery, 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. The doctor should also explain that the woman will need to give birth by caesarean section. These explanations and discussions should happen before the woman agrees (or doesn't agree) to the procedure. The woman 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.

A team of experts should be involved in deciding whether the procedure is suitable for a particular woman. The team should have experience in managing repeated miscarriage, and should include a specialist who is trained in keyhole surgery.

## Other comments from NICE

NICE specifically looked at stitching the cervix using keyhole surgery. There is uncertainty about how well stitching the cervix works using any type of surgery (vaginal, open surgery or keyhole surgery).

The procedure may be carried out on pregnant women or women who have had miscarriages but are not currently pregnant. There were concerns about whether the stitch can be placed accurately and safely in women who are not pregnant.

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

## Stitching the cervix using keyhole surgery

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

Repeated miscarriage may be caused by a weak cervix that opens too early in pregnancy. The cervix may be naturally weak, or the weakness may have been caused during previous pregnancy or childbirth.

In this procedure, a stitch is put around the upper part of the cervix to keep it closed. The operation is often carried out through the vagina, but if there are problems with this method it may be carried out through the abdomen as either open surgery or keyhole surgery. Keyhole surgery is carried out under general anaesthesia through small cuts made in the abdomen. A camera connected to a video recorder and monitor is inserted through one of the cuts. By watching what is happening on the video monitor, the surgeon performs the operation using special instruments inserted through the remaining holes. The medical name for this keyhole surgery is laparoscopic surgery.

When the cervix has been stitched, the baby has to be born by caesarean section at the end of the pregnancy.

## What does this mean for me?

If your doctor has offered to stitch your cervix using keyhole surgery, 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 I might get?
- How good are my chances of getting those benefits?
- 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?

The majority of pregnancies did not miscarry and the babies were born alive at full term. In two studies of women who had their cervix stitched using keyhole surgery, 19 out of 20 and 10 out of 12 pregnancies did not miscarry and the babies were born alive. The majority of these babies were carried to term: 14 out of 20 and 8 out of 12 babies were carried to term. In the study of 20 women, one woman miscarried at 19 weeks following premature rupture of the membranes.

The expert advisers said that this procedure is new and that there is limited knowledge of how well it works.

*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 two studies, the blood vessels of the uterus (womb) were damaged in some women who had their cervix stitched using keyhole surgery (1 out of 3 women in one study, and 1 out of 20 women in the other study). In another study of 11 women who had their cervix stitched using keyhole surgery, one woman's bowel was injured, which resulted in a pelvic abscess.

The expert advisers said that in theory the procedure could cause problems with the pregnancy, such as injury to the uterus, haemorrhage, the baby dying in the uterus, the baby being born very prematurely, infection, damage to the bladder and the need for further procedures, including hysterectomy. Stitching the cervix could cause difficulties in removing the baby if the baby dies in the uterus.

## More information about repeated miscarriage and weak cervix

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/IPG228](http://www.nice.org.uk/IPG228)*

*You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1315).*