

Understanding NICE guidance

Information for people who use NHS services

Treating adults with severe acute respiratory failure using an artificial 'lung' to oxygenate the blood outside the body (ECMO)

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

This leaflet is about when and how an artificial 'lung' to oxygenate the blood outside the body (ECMO) can be used in the NHS to treat adults with severe respiratory failure. 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. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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 acute respiratory failure 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.

What has NICE said?

Although there is some evidence about the safety of ECMO in adults the evidence shows that there is a risk of serious side effects. In addition, it was difficult to draw firm conclusions from the evidence about how well the procedure works. If a doctor wants to use it, they should make sure that extra steps are taken to explain the uncertainty about the how well the procedure works and the potential risks. The patient and/or their family and carers should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE has said that ECMO should only be carried out by clinical teams with specific training and expertise.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the International Extracorporeal Life Support Organization so 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.

In an emergency, healthcare professionals may give treatment immediately, without obtaining informed consent, when it is in the patient's best interests.

Treating adults with severe acute respiratory failure using an artificial 'lung' to oxygenate the blood outside the body (ECMO)

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

The medical name for this procedure is 'extracorporeal membrane oxygenation (ECMO) for severe acute respiratory failure in adults'. The procedure is not described in detail here – please talk to your doctor for a full description.

Most critically ill patients with severe respiratory failure (where the lungs do not work effectively) will need a machine called a mechanical ventilator to 'breathe' for them. This usually involves passing a tube into the patient's mouth and down the windpipe.

Very occasionally a different procedure that adds oxygen and removes carbon dioxide from the blood may be used in some patients normally with gentle ventilation. An artificial lung (the membrane) oxygenates the blood outside the body (extracorporeal). The ECMO machine is very similar to the heart–lung machines used during open-heart surgery. Tubes (cannulae) are normally inserted into the major veins in the neck and the groin. These allow blood to divert into the ECMO machine, which removes carbon dioxide and then adds oxygen to it. The blood is then returned to the patient through another tube. A drug is given to stop the blood from clotting.

What does this mean for me?

Your doctor should tell your family and/or carers that NICE has decided that there are uncertainties about how well the procedure works and how safe it is. This does not mean that it should not be used, but that your doctor should fully explain what is involved and discuss the possible benefits and risks. Your doctor should provide written information, including this leaflet, and your family and/or carers should have the opportunity to discuss it with your doctor.

They may want to ask the questions below

- What does the procedure involve?
- What are the benefits?
- How good are the chances of getting those benefits? Could having the procedure make things 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 the patient need after the procedure?
- What happens if something goes wrong?
- What may happen if the patient doesn'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 7 studies on this procedure.

How well does the procedure work?

In 1 study, 33 out of 90 patients who had ECMO had died or were severely disabled when their progress was checked after 6 months, compared with 46 out of the 87 patients who had mechanical ventilation.

In 2 studies of 94 patients treated with ECMO, 51 patients survived.

A study of 180 patients showed that overall health quality was similar after 6 months, whether patients had ECMO or mechanical ventilation.

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 success factors include patients' ability to breathe unaided, improved survival and quality of life.

Risks and possible problems

In 1 study, 3 out of 62 patients who had ECMO developed a serious blood clotting problem. This also happened in 5% of patients in another study of 255 (exact numbers were not given).

Two studies reported problems when the cannulae used to carry the blood were inserted. In 1 study, 1 patient out of 68 treated by ECMO died because a blood vessel was perforated, and problems were reported in 5 out of 62 patients in another study.

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

In 2 studies involving 1535 patients who had ECMO, the tubing system ruptured in 67 patients. In 1 of these studies, 1 patient was diagnosed as brain dead after being resuscitated and treated by ECMO for a second time.

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 problems include air bubbles or blood clots entering the circulation, serious infection, multiple organ failure and mechanical failure (of the ECMO machine).

More information

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance, visit our website at www.nice.org.uk

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 'extracorporeal membrane oxygenation for severe acute respiratory failure in adults'. This leaflet and the full guidance aimed at healthcare professionals are available at

www.nice.org.uk/guidance/IPG391

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2513). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.