

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Interventional procedures consultation document

# Therapeutic hypothermia for acute ischaemic stroke

An ischaemic stroke happens when a blood clot stops the flow of blood to the brain. Brain tissue is then damaged because it does not get enough oxygen. In this procedure, a cooling device is used to reduce the body's temperature by 2°C to 4°C (creating hypothermia) for several hours immediately after a stroke. When the brain is cooler it needs less oxygen from the blood. The aim is to limit the damage to brain cells caused by the stroke.

The National Institute for Health and Care Excellence (NICE) is looking at therapeutic hypothermia for acute ischaemic stroke. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

**This is not our final guidance on this procedure. The recommendations may change after this consultation.**

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a

range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 30 January 2019

Target date for publication of guidance: April 2019

## **1 Draft recommendations**

- 1.1 Current evidence on the safety of therapeutic hypothermia for acute ischaemic stroke shows that there are serious complications. Evidence on efficacy does not show any meaningful improvement in outcomes. Therefore, this procedure should [not be used](#).

## **2 The condition, current treatments and procedure**

### ***The condition***

- 2.1 Acute ischaemic stroke is characterised by the sudden loss of blood circulation to an area of the brain and a corresponding loss of neurological function. This may lead to symptoms such as numbness or weakness of the face, arm or leg on 1 side of the body, and often problems with speech and swallowing. Stroke

severity can be measured using scales such as the National Institutes of Health Stroke scale and the Modified Rankin scale. Broadly, strokes are classified as either haemorrhagic or ischaemic. Acute ischaemic stroke refers to a stroke caused by an arterial thrombosis or embolism. It is more common than haemorrhagic stroke.

### ***Current treatments***

- 2.2 Patients suspected to be having an acute ischaemic stroke should have rapid assessment and early intervention with specialist care according to NICE's guideline on [stroke and transient ischaemic attack in over 16s: diagnosis and initial management](#).

Recanalisation strategies, such as thrombolysis, attempt to re-establish blood flow so that cells starved of oxygen can be rescued before they are irreversibly damaged. Effective stroke care also includes specialised supportive care and rehabilitation when appropriate.

### ***The procedure***

- 2.3 The optimum timing and duration of therapeutic hypothermia has not yet been determined. However, in trials, cooling has been typically attempted as close to stroke onset as possible (usually within 6 hours). Cooling may be continued for at least 12 to 24 hours, and body temperature maintained at 33°C to 35°C. The ideal target temperature for neuroprotection is unknown.

- 2.4 Before the procedure, the patient's temperature is measured, usually with an infrared tympanic thermometer. Further temperature monitoring is done continuously with an internal (intravesical, rectal or oesophageal) probe connected to the cooling device. Cooling devices can be classified into surface (ice-cold saline, surface cooling, cooling helmets and nasal cooling) and endovascular methods. After cooling, the body is slowly rewarmed, at a rate of 0.3°C to 0.5°C every hour. Rewarming takes about 8 hours. During

cooling, patients need close cardiovascular monitoring in an intensive care environment, and may also need intubation and sedation. Drugs such as buspirone or meperidine may be used to manage shivering.

2.5 The procedure may be used with thrombolysis (intravenous alteplase), mechanical thrombectomy or other vascular reperfusion techniques.

2.6 The aim of the procedure is to limit the damage to brain cells.

### **3 Committee considerations**

#### ***The evidence***

3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 1 systematic review, 3 randomised controlled trials (one of which was a conference abstract and used for safety data only), 3 non-randomised comparative studies and 2 case series. It is presented in table 2 of the [interventional procedures overview](#). Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in mortality and stroke morbidity, and improved quality of life.

3.3 The specialist advisers and the committee considered the key safety outcomes to be: worse neurological outcome, pneumonia and bleeding.

### ***Committee comments***

- 3.4 There are different methods and different devices used for the procedure.
- 3.5 The committee noted that there are variations in the degree of temperature control, both in the degree of cooling and the length of treatment period, and that target temperatures can be difficult to achieve.
- 3.6 The committee noted that pneumonia was more common in patients treated with this procedure.

Tom Clutton-Brock

Chairman, interventional procedures advisory committee

January 2019

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