

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage

When blood flow in the brain is suddenly interrupted by a blockage (ischaemia) or bleeding (haemorrhage), brain cells can be damaged. This may result in an abnormal body temperature which can further damage brain cells. In this procedure, a temperature modulation device is used to cool the body using pads placed on the skin or tubes put into the body. This gradually brings the body temperature within a normal range (normothermia) and keeps it there. The aim is to reduce brain damage and improve neurological outcomes.

NICE is looking at inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

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

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation 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: 25 March 2021

Target date for publication of guidance: July 2021

1 Draft recommendations

- 1.1 Evidence on the safety and efficacy of inducing and maintaining normothermia using temperature modulation devices to improve outcomes after stroke or subarachnoid haemorrhage is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should preferably be randomised controlled trials. It should report details of patient selection (including severity of stroke and neurological injury), method and duration of cooling, time to initiate normothermic treatment after onset of fever, device-related complications, neurological outcomes assessed using validated measures, and patient-reported outcomes (including quality of life) in the long term.

2 The condition, current treatments and procedure

The condition

- 2.1 Stroke (ischaemic stroke and intracerebral haemorrhage [ICH]) is a clinical syndrome, of presumed vascular origin, typified by rapidly developing signs of focal or global disturbance of cerebral functions lasting more than 24 hours or leading to death. Subarachnoid haemorrhage (SAH) is a haemorrhage from a cerebral blood vessel, aneurysm or vascular malformation into the subarachnoid space.
- 2.2 Both conditions can interrupt blood flow around or inside the brain, damage brain cells and cause abnormalities of thermoregulation and an abnormal body temperature (a non-infectious fever). The abnormal temperature may result in secondary neurological injury and is associated with greater morbidity and mortality.

Current treatments

- 2.3 Causes of fever should be identified and treated. In addition to treating stroke, SAH or other complications, fever management includes antipyretic medications and the use of standard or advanced temperature modulation systems to lower body temperature. Diagnosis and initial management of stroke is described in [NICE's guideline on stroke and transient ischaemic attack in over 16s](#).

The procedure

- 2.4 In this procedure, a temperature modulation device is used to maintain the patient's core temperature within normal limits. Either surface techniques (such as heat exchange cooling pads) or internal techniques (such as an endovascular cooling device) may be used. Heat is exchanged between the patient and the device to

allow the body temperature to be controlled to a pre-set point determined by the clinician.

- 2.5 This procedure aims to reduce brain injury and improve neurological outcomes after stroke or SAH by maintaining normothermia.

3 Committee considerations

The evidence

- 3.1 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 7 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial, 3 non-randomised comparative studies and 3 case series. It is presented in [the summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improved quality of life, reduction in disability and neurological injury.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, cardiovascular complications, worsening neurological outcomes, shivering and infection.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee noted that the evidence reviewed compared the use of special temperature modulation devices to achieve normothermia with conventional fever management, including

antipyretic medications and standard cooling (such as surface cooling blankets).

- 3.6 The committee noted that the evidence reviewed showed many complications, but it was difficult to identify whether these were related to the neurological injury or the procedure.
- 3.7 The committee noted that there are various techniques used and that the safety profiles of the various techniques may be different.

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Chair, interventional procedures advisory committee

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