NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP863/2 Targeted temperature management to improve neurological outcomes after cardiac arrest

Your information

Name:	Click here to enter text. Prof Gavin Perkins
Job title:	Click here to enter text. Professor of Critical Care Medicine and Director of Warwick Clinical Trials Unit
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Professional organisation or society membership/affiliation:	Click here to enter text. Resuscitation Council UK
Nominated/ratified by (if applicable):	Click here to enter text. Resuscitation Council UK
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC 4195067

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of the process of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	I have current personal experience of using surface cooling devices and intravenous fluids to effect cooling of patients following out of hospital cardiac arrest. I have previous experience of the use of intravascular catheters to effect cooling in this patient group. Yes Mostly my speciality (critical care) but also emergency medicine Yes. As critical care consultant I am the decision maker in relation to the use of cooling following cardiac arrest.
2	− Please indicate your research experience relating to this procedure	I have done bibliographic research on this procedure. I have published this research.

	(please choose one or more if relevant):	Member Resuscitation Council UK Clinical Guideline Group Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It has until recently been the standard of care Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Likely to lead to a recommendation to restrict use

Current management

5	Please describe the current standard of care that is used in the NHS.	Current guidelines are Actively prevent fever (T < 37.7 C) for 72 hours Manage temperature by exposure, anti-pyretic drugs or cooling device (target temperature 37.5) Insufficient evidence to support temperature control 32-36 in sub-groups or earlier / rapid cooling

		Avoid active re-warming for mild hypothermia Avoid rapid infusion large volumes of cold IV fluids https://pubmed.ncbi.nlm.nih.gov/35131119/
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Potential to reduce post cardiac arrest brain injury
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, but characteristics are uncertain
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	No
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	This technology is already embedded in the NHS so there are likely few additional capital costs at the current time Current guidelines reduce rather than increase the use of this technology
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Current guidelines favour reducing rather than increase the use of this technology Resource impact would be negative (less use)
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	None. Technology already embedded in NHS

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Clinical protocols and continuous temperature monitoring required

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Arrythmia, increased duration of sedation, premature withdrawal of life sustaining treatment (if insufficient time allowed for sedatives to clear) Invasive cooling systems risk infection, thrombosis, embolization, bleeding
15	Please list the key efficacy outcomes for this procedure/technology?	Temperature control Survival Favourable neurological outcome
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes. Some believe the intervention is beneficial in their hands and in specific cohorts of patients. However the literature have yet to identify the characteristics of cohorts who might definitively benefit. Similarly it is unclear from the literature if there are specific cohorts with a greater risk of harm.

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	https://pubmed.ncbi.nlm.nih.gov/35131119/ https://pubmed.ncbi.nlm.nih.gov/34389870/ https://pubmed.ncbi.nlm.nih.gov/34474143/ https://pubmed.ncbi.nlm.nih.gov/34665203/
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Pediatric Influence of Cooling Duration on Efficacy in **Cardiac Arrest** Patients (P-ICECAP) Influence of Cooling Duration on Efficacy in **Cardiac Arrest** Patients

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	7,500 from out of hospital cardiac arrest (based on NHS England data indicating that 25% achieve return of spontaneous circulation amongst 33k arrests) Estimated 5000 from in-hospital cardiac arrest (uncertain)
22	Are there any issues with the usability or practical aspects of the procedure/technology?	Not particularly
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	It has already been widely adopted in the NHS but is now likely declining in use
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Yes – in cohorts of patients at greater risk of brain injury e.g. unwitnessed, non-shockable rhythms Bayesian network meta-analysis suggests existing trials likely underpowered for likely size of effect https://pubmed.ncbi.nlm.nih.gov/34389870/
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post	Beneficial outcome measures: Survival (ICU discharge, hospital discharge, 90d, 180d) Favourable neurological outcome (discharge, 90d, 180d) Adverse outcome measures: Arrythmia Infection

	procedure timescales over which these should be measured:	Duration of intensive care stay Death Unfavourable neurological outcome
26	Is there any other data (published or otherwise) that you would like to share with the committee?	

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text. Prof Gavin Perkins**
Dated:	**Click here to enter text. 13 September 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP863/2 Targeted temperature management to improve neurological outcomes after cardiac arrest**

Your information

Name:	Dr Jasmeet SOAR
Job title:	Consultant in Intensive Care Medicine
Organisation:	Southmead Hospital, North Bristol NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Resuscitation Council UK
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 346 7499

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1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this	As Chair of the ALS Task Force of the International Liaison Committee on Resuscitation, I chaired a GRADE evaluation of this topic using expert systematic reviewers, an expert panel from all continents and a public consultation process. I Chair the ALS committees of both the European Resuscitation Council (ALS Science chair) and Resuscitation Council UK – i have had lead roles on producing European and UK clinical guidance on this topic I am a fulltime clinician working in intensive care and manage patient temperature after cardiac arrest as part of my routine work. Temperature control after cardiac arrest is already widely used in the NHS - what varies is the choice of temperature target between ICUs - most do not target hypothermia I estimate about 10,000 + patients a year

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. Other (please comment) - I have been involved in observational studies in patients which are published. I have been involved in systematic reviews and guidelines that have been published. I led a global review process and consensus on science using GRADE methods for use of temperature management.
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Cooling methods have not changed in recent years - when or when not to use them has changed in recent years - the choice of temperature target has changed since previous guidance based on RCTs and the draft guidance is not correct based on the most recent RCT, systematic review and guidelines Dankiewicz J, et al; TTM2 Trial Investigators. Hypothermia versus Normothermia after Out-of-Hospital Cardiac Arrest. N Engl J Med. 2021 Jun 17;384(24):2283-2294. Granfeldt A, Holmberg MJ, Nolan JP, Soar J, Andersen LW; International Liaison Committee on Resuscitation (ILCOR) Advanced Life Support Task Force. Targeted temperature management in adult cardiac arrest: Systematic review and meta-analysis. Resuscitation. 2021 Oct;167:160-172. Sandroni C, Nolan JP, Andersen LW, Böttiger BW, Cariou A, Cronberg T, Friberg H, Genbrugge C, Lilja G, Morley PT, Nikolaou N, Olasveengen TM, Skrifvars MB, Taccone FS, Soar J. ERC-ESICM guidelines on temperature control after cardiac arrest in adults. Intensive Care Med. 2022 Mar;48(3):261-269. Temperature control after cardiac arrest is in common use - the targets have changed since previous guidance
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Current standard of care is prevention of fever/maintaining a normal temperature for most patients after cardiac arrest – this will probably mean fewer patients will require the intervention or devices for temperature control

Current management

5	Please describe the current standard of care that is used in the NHS.	Current standard of care in UK is the Resuscitation Council UK (RCUK) and European (ERC/ESICM) guideline - this recommends avoidance of fever in comatose patients post cardiac arrest for 72 hours based on a large RCT and systematic review, but leaves the door open to those clinicians who wish to use a target of 32 to 36 C for the first 24 hours. No specific method of cooling is recommended. The need for continuous temperature monitoring is highlighted. The RCUK guidelines was produced using a NICE accredited process.
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	A variety of invasive and non-invasive devices and interventions are used to initiate and maintain temperature control e.g. surface or intravascular cooling devices with continuous temperature monitoring and feedback technology Current procedures/technologies are similar to those described in the original NICE appraisal

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Good functional outcomes following cardiac arrest
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Comatose patients after cardiac arrest both in and out of hospital
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Fewer patients requiring cooling intervention if fever prevention is the standard of care for most patients
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Nil

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Device specific training needs for staff - most non-invasive techniques are very easy to use. Intravascular devices require trained staff to insert vascular catheter.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Minimal harms from interventions to avoid fever. Greater risks (that remain small) associated with the hypothermia option stated in the draft guidance e.g. arrhythmia/bradycardias.
15	Please list the key efficacy outcomes for this procedure/technology?	Survival to hospital discharge/30 days or 90 days/180 days with good functional outcome (modified Rankins Scale 0-3)
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Most post cardiac arrest patients do not require cooling interventions - there may be some subgroups that may benefit from cooling (no good evidence that any subgroups that benefit from colling interventions exists).
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	There is still strong support for cooling/hypothermia treatments (not in UK, some in Europe, mainly in USA).
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	See https://costr.ilcor.org/document/systematic-review-temperature-management-in-adult-cardiac-arrest-als International evaluation using GRADE process and evidence to decision tables and public consultation Dankiewicz J, et al; TTM2 Trial Investigators. Hypothermia versus Normothermia after Out-of-Hospital Cardiac Arrest. N Engl J Med. 2021 Jun 17;384(24):2283-2294. Granfeldt A, Holmberg MJ, Nolan JP, Soar J, Andersen LW; International Liaison Committee on Resuscitation (ILCOR) Advanced Life Support Task Force. Targeted temperature management in adult cardiac arrest: Systematic review and meta-analysis. Resuscitation. 2021 Oct;167:160-172. Sandroni C, Nolan JP, Andersen LW, Böttiger BW, Cariou A, Cronberg T, Friberg H, Genbrugge C, Lilja G, Morley PT, Nikolaou N, Olasveengen TM, Skrifvars MB, Taccone FS, Soar J. ERC-ESICM guidelines on temperature control after cardiac arrest in adults. Intensive Care Med. 2022 Mar;48(3):261-269.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	USA ICE CAP study https://clinicaltrials.gov/ct2/show/NCT04217551

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	there were about 8.5K patients admitted to ICUs in England, Wales and Northern Ireland in 2014 who were post cardiac arrest – this number was rising at the time and I would estimate its now more than 10K patients per year who would be considered for this intervention
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No
23	Are you aware of any issues which would prevent (or have prevented) this	No

	procedure/technology being adopted in your organisation or across the wider NHS?	
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	yes: Trial of no temperature interventions versus temperature control in this group. Inclusion of patients with primary cardiac arrest and other causes of cardiac arrest
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Time to achieve target temperature Proportion of time within target temperature range Further outcomes according to international guidelines and public focus groups are described in: Haywood K, eta al ; COSCA Collaborators. COSCA (Core Outcome Set for Cardiac Arrest) in Adults: An Advisory Statement From the International Liaison Committee on Resuscitation. Circulation. 2018 May 29;137(22):e783-e801. Adverse outcome measures: Harms as measured in the TTM3 trial
26	Is there any other data (published or otherwise) that you would like to share with the committee?	Observational studies hypothesise that those patients with the worse brain injury benefit from hypothermia but this has not been shown in the two largest RCTs TTM and TTM2 Nielsen N, Wetterslev J, Cronberg T, et al. Targeted temperature management at 33 degrees C versus 36 degrees C after cardiac arrest. N Engl J Med. 2013;369(23):2197-2206. Dankiewicz J, Cronberg T, Lilja G, et al. Hypothermia versus Normothermia after Out-of-Hospital Cardiac Arrest. N Engl J Med. 2021;384(24):2283-2294.

		A smaller looking at a subgroup of studies suggested benefit in the subgroup with a fragility index of 1 and, a potential harmful intervention (warming) in the control group Lascarrou JB, Merdji H, Le Gouge A, et al. Targeted Temperature Management for Cardiac Arrest with Nonshockable Rhythm. N Engl J Med. 2019;381(24):2327-2337.

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	Chair International liaison Committee on Resuscitation ALS (advanced life support) Task Force - unpaid, chaired international consensus on science and treatment recommendations on this topic using GRADE methods.	**2012**	**December 2021**
Non-financial professional	Chair European Resuscitation Council ALS Science group that writes guidelines used in Europe including on this topic - unpaid volunteer	**2015**	**Ongoing**
Non-financial professional	Chair Resuscitation Council UK, ALS subcommittee : writes guidelines (using a NICE accredited process) and training materials used in UK including on this topic - unpaid volunteer	**2016**	**Ongoing**

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Print name:	**JASMEET SOAR**
Dated:	**1 SEPTEMBER 2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP863/2 Targeted temperature management to improve neurological outcomes after cardiac arrest

Your information

Name:	Prof. Jerry Nolan
Job title:	Consultant in Anaesthesia and Intensive Care Medicine
Organisation:	Royal United Hospitals Bath NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Resuscitation Council UK, Royal College of Anaesthetists
Nominated/ratified by (if applicable):	N/A
Registration number (e.g. GMC, NMC, HCPC)	2805063

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Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes – I regularly use this technology and I am familiar with temperature control after cardiac arrest
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	Temperature control in general is widely used in the NHS It is used mainly by intensive care clinicians but in sone hospitals it may also be used by emergency physicians Intensive care clinicians will select the patients for treatment and implement themselves

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. YES I have done research on this procedure in laboratory settings (e.g. device-related research). NO I have done clinical research on this procedure involving patients or healthy volunteers. I have undertaken observational research involving pateints I have published this research. Yes – observational studies only I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is currently the standard of care Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	N/A

Current management

5	Please describe the current standard of care that is used in the NHS.	Clinical guidelines have changed recently. Until this year, the standard of care was to use hypothermic temperature control (in the range of 32–36oC) for 24 h in comatose post-cardiac arrest patients. Recent evidence has shown similar outcomes with temperature control aimed at normothermia and this is now the standard of care recommended by existing guidelines. The 2022 European Resuscitation Council and European Society for Intensive Care Medicine guidelines on temperature control state: 1. We recommend continuous monitoring of core temperature in patients who remain comatose after ROSC from cardiac arrest (good practice statement). 2. We recommend actively preventing fever (defined as a temperature > 37.7 °C) in post-cardiac arrest patients who remain comatose (weak recommendation, low-certainty evidence). 3. We recommend actively preventing fever for at least 72 hours in post-cardiac arrest patients who remain comatose (good practice statement). 4. Temperature control can be achieved by exposing the patient, using anti-pyretic drugs, or if this is insufficient, by using a cooling device with a target temperature of 37.5 °C (good practice statement).

		5. There is currently insufficient evidence to recommend for or against temperature control at 32–36 °C in sub-populations of cardiac arrest patients or using early cooling, and future research may help elucidate this. We recommend not actively rewarming comatose patients with mild hypothermia after ROSC to achieve normothermia (good practice statement). 6. We recommend not using prehospital cooling with rapid infusion of large volumes of cold IV fluid immediately after ROSC (strong recommendation; moderate certainty evidence).
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Temperature control can be undertaken using simple methods (e.g. ice and wet towels) or with more sophisticated devices with feedback control (e.g. intravascular temperature control or adhesive external pads). N/A

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Initial RCTs suggested higher survival rates and better neurological outcomes with hypothermic temperature control but the recent TTM2 study showed no difference in survival with temperature control at 33°C and normothermic temperature control (prevention of fever). Until further evidence is available, international guidelines suggest active prevention of fever rather than hypothermic temperature control.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Comatose survivors of cardiac arrest.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The current technology is in widespread use. The main change is a move from hypothermic target temperatures to active prevention of fever (i.e. maintaining normothermia).
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	By adopting normothermic temperature targets up to half of post-cardiac arrest patients would not need sophisticated temperature control devices.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	If sophisticated temperature control devices are only required for half the number of patients the costs should be reduced.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Simply changing local SOPs

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Not if already used. Any hospital starting to use active temperature control devices for the first time would need training for all staff using the devices.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Intravascular temperature control devices can cause bleeding at the insertion site and like any intravascular device, there is risk of infection. There may be an increased risk of thrombus, particularly if left in for more than a few days. Hypothermic temperature control may cause: Shivering Bradycardia Peripheral vasoconstriction with increased afterload Use of neuromuscular blockers may mask seizures. Injury to skin from some external cooling systems
15	Please list the key efficacy outcomes for this procedure/technology?	Survival Functional outcome Rates of developing pyrexia (> 37.7^{o}C)
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Following the TTM 1 and TTM 2 studies, there is considerable debate about whether there is any benefit from hypothermic temperature control. There are currently no RCTs comparing active normothermia (prevention of fever) with hypothermic temperature control (this will be addressed in TTM3). The 2022 ERC-ESICM Guidelines explain the controversies in detail.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	See above

18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Studies that should be addressed are: TTM 1 TTM 2 Hyperion Capital-Chill Trial The ERC-ESICM 2022 Guidelines provide an important background to the controversies.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The TTM-3 trial will start soon

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an	Based on work we did with ICNARC and published in 2016, I would estimate that there are now at least 10,000 patients admitted to UK ICUs comatose after cardiac arrest. All these patients would be eligible for temperature control.

	estimated number, or a proportion of the target population)?	
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The intravascular systems requires skilled and experienced individuals to insert the venous catheter.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	Costs of the disposable items – typically about £500 per patient
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Survival to hospital discharge 6-month survival 1 year survival Functional outcomes using modified Rankin scale (mRS) or cerebral performance category (CPC) at discharge and 6 months Cognitive outcome, e.g. Montreal Cognitive Assessment (MOCA) at 6 months or 1 year Adverse outcome measures: Bleeding or thrombosis associated with intravascular catheters Fever (> 37.7oC) in first 72 hours

26	Is there any other data (published or otherwise) that you would like to share with the committee?	A German study of TTM for in-hospital cardiac arrest will soon be published in Circulation

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	The use of hypothermic TTM is controversial. Despite international guidelines now advocating prevention of fever (normothermia), many experts are adamant that hypothermic TTM is effective in some post-cardiac arrest patients. Unfortunately, there are no high-certainty data to support this. Whether sophisticated temperature control devices (versus simpler methods) are required to effectively prevent fever is unknown.

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

X I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Jerry Nolan**
Dated:	**07 September 2022**

View results

Respondent

1 Anonymous

25:25
Time to complete

Your information

1. Name: *

Jonathan Bannard-Smith

2. Job title: *

Consultant in Adult Critical Care & Anaesthesia

3. Organisation: *

Manchester University NHS Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

Faculty of Intensive Care Medicine, Royal College of Anaesthetists

6. Nominated/ratified by (if applicable):

7. Registration number (e.g. GMC, NMC, HCPC) *

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How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

I have led the roll-out of active TTM management for unconscious survivors of OOHCA in our tertiary critical care unit of approximately 60 beds in Manchester. I have trained our clinical staff on a protocolled care pathway using a body surface TTM device with continuous feedback control, which we use routinely for all our patients.

I was also local principal investigator for the TTM2 trial (https://ttm2trial.org/), the largest international randomised controlled trial of TTM to date. This required expansion in the delivery of TTM to clinical areas outside the ICU, including our emergency and radiology departments and our coronary catheter lab, all of which our OOHCA patients pass through before they arrive on ICU.

My experience during the TTM2 trial has also required development of neuroprognostication infrastructure in our hospital. I led this initiative, including the training of our staff on how to accurately measure important outcomes in patients who have suffered OOHCA.

10. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

TTM is in widespread use in the UK critical care community, using a broad spectrum of methods. It is also occasionally used for other patient groups, including septic patients with persistent pyrexia, but the evidence base for these other indications is limited.

I am not aware of specialties other than critical care using this technology

N/A – we lead the delivery of TTM

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

Yes

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Many centres already use this technology, which has been available for many years now.

15. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- (•) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Optional method to ensure TTM reliably and robustly delivered to our patients.

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Only changes relate to the actual temperature target, which changes as the evidence base evolves.

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes

Current management

19. Please describe the current standard of care that is used in the NHS.

TTM & avoidance of hyperthermia/fever as per UK Resuscitation Guidleines

20. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

There are a number of technologies using slightly different methods to deliver TTM. e.g. surface cooling/warming devices vs. intra-vascular devices.

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using this procedure/technology?

Accurate, reliable and continuous delivery of TTM with minimum fluctuations in their body temperature.

22. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Unknown

23. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Unknown, the evidence to date has actually questioned whether active TTM is of benefit or not. The next international RCT will randomise patients to active TTM versus none, but this has yet to open to recruitment.

24. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Training
    Disposable means to continuously measure temperature (orogastric probe or urinary catheter)

25. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    All clinical users will require training specific to the device used to deliver TTM. Those who measure patient outcomes also require training on their assessment in order to minimise the risk of bias.

Safety and efficacy of the procedure/technology

26. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Adverse events include:
    - shivering
    - skin burns & pressure areas
    - problems with coagulation
    - bradyrrhythmias
    - hypotension
    - prolonged need for sedation

27. Please list the key efficacy outcomes for this procedure/technology?

    Mortality
    Long-term measures of brain injury including cerebral performance scale, Glascow Outcome Scales

28. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    There is great uncertainty around the actual temperature target to aim for and whether investment in these technologies can be justified. The radnomised studies to date have failed to show any difference in longterm outcomes for patients managed with hypothermia compared to normothermia targets

29. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Yes, see above. Further research is planned

30. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- Most or all district general hospitals.
- A minority of hospitals, but at least 10 in the UK.
- Fewer than 10 specialist centres in the UK.
- Cannot predict at present.

Abstracts and ongoing studies

31. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    Simpson RFG, Dankiewicz J, Karamasis GV, Pelosi P, Haenggi M, Young PJ, Jakobsen JC, Bannard-Smith J, Wendel-Garcia PD, Taccone FS, Nordberg P, Wise MP, Grejs AM, Lilja G, Olsen RB, Cariou A, Lascarrou JB, Saxena M, Hovdenes J, Thomas M, Friberg H, Davies JR, Nielsen N, Keeble TR. Speed of cooling after cardiac arrest in relation to the intervention effect: a sub-study from the TTM2-trial. Crit Care. 2022 Nov 15;26(1):356. doi: 10.1186/s13054-022-04231-6. PMID: 36380332; PMCID: PMC9667681.

    Dankiewicz J, Cronberg T, Lilja G, Jakobsen JC, Levin H, Ullén S, Rylander C, Wise MP, Oddo M, Cariou A, Bělohlávek J, Hovdenes J, Saxena M, Kirkegaard H, Young PJ, Pelosi P, Storm C, Taccone FS, Joannidis M, Callaway C, Eastwood GM, Morgan MPG, Nordberg P, Erlinge D, Nichol AD, Chew MS, Hollenberg J, Thomas M, Bewley J, Sweet K, Grejs AM, Christensen S, Haenggi M, Levis A, Lundin A, Düring J, Schmidbauer S, Keeble TR, Karamasis GV, Schrag C, Faessler E, Smid O, Otáhal M, Maggiorini M, Wendel Garcia PD, Jaubert P, Cole JM, Solar M, Borgquist O, Leithner C, Abed-Maillard S, Navarra L, Annborn M, Undén J, Brunetti I, Awad A, McGuigan P, Bjørkholt Olsen R, Cassina T, Vignon P, Langeland H, Lange T, Friberg H, Nielsen N; TTM2 Trial Investigators. Hypothermia versus Normothermia after Out-of-Hospital Cardiac Arrest. N Engl J Med. 2021 Jun 17;384(24):2283-2294. doi: 10.1056/NEJMoa2100591. PMID: 34133859.

    UK Resus Council guidelines on post-resuscitaiton care: https://www.resus.org.uk/library/2021-resuscitation-guidelines/post-resuscitation-care-guidelines

    STEP-CARE trial due to open next year: https://clinicaltrials.gov/ct2/show/NCT05564754

32. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    https://clinicaltrials.gov/ct2/show/NCT05564754

33. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

34. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

>20,000

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Glasgow outcome score extended (GOSE)
EQ5D-5L
6, 12 & 24 months

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Shivering
Coagulapathy
Haemodynamic instability (including bradycardia)

Further comments

37. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

We need to await further research on whether these technologies are required at all. The planned STEP-CARE trial should help to resolve this incertainty.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

38. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

39. Description of interests, including relevant dates of when the interest arose and ceased. *

None

40. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

    Please note, all declarations of interest will be made publicly available on the NICE website. *

    - (●) I agree
    - ( ) I disagree

Signature

41. Name: *

    Jonathan Bannard-Smith

42. Date: *

    14/12/2022

View results

Respondent

2 Anonymous

95:43
Time to complete

Your information

1. Name: *

Nawaf Al-Subaie

2. Job title: *

Consultant in Critical Care Medicine

3. Organisation: *

St George's University Hospitals NHS Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC

6. Nominated/ratified by (if applicable):

7. Registration number (e.g. GMC, NMC, HCPC) *

4673396

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

8. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

9. Please describe your level of experience with the procedure/technology, for example:

   Are you familiar with the procedure/technology?

   Frequent clinical use and a published author in the field

10. Have you used it or are you currently using it?

    - Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

    - Is this procedure/technology performed/used by clinicians in specialities other than your own?

    - If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

    I routinely use Targeted Temperature Management (TTM) to manage patients following out of hospital cardiac arrest (OHCA). We have 100 to 120 cases per year presenting to our intensive care unit. TTM is also used in other patients' cohorts when deemed clinically appropriate

11. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. Is the proposed indication appropriate? If not, please explain

Yes

14. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

TTM is used routinely in critical care settings. In OHCA, it is routine practice to target temperatures between 33-36 based on previous literature.

15. Which of the following best describes the procedure:

- (●) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

16. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

The role of active TTM in this population remains an area of active research. The TTM1 and 2 studies challenged pre-existing practices targeting 32-34 C following OHCA. Many units routinely use active cooling devices to target temperatures between 33 and 36 C and maintain normothermia for the subsequent 24-72 hours.

17. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Many TTM protocols and active cooling devices are used without clear guidance on what should form best practice.

18. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Publication pending.

Current management

19. Please describe the current standard of care that is used in the NHS.

A temperature of 36 C is targeted in the first 24 hours in comatose patients following OHCA. Sedation is stopped subsequently and a neurological assessment is made. If the patient remains unconscious, then the temperature is controlled at 37 C for 48 hours.

20. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

Alternatives are no cooling or passive cooling.

Potential patient benefits and impact on the health system

21. What do you consider to be the potential benefits to patients from using this procedure/technology?

Potential improvement in mortality and neurological outcome

22. Are there any groups of patients who would particularly benefit from using this procedure/technology?

OHCA

23. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Better neurological recovery and reduced long term impact on social and healthcare services

24. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

ICU

25. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Training in relation to the overall management of OHCA patients and training on the use of active cooling devices

Safety and efficacy of the procedure/technology

26. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

Thromboembolism
Hospital acquired infections
Erroneoustemperature measurements leading to inappropiate temperature managment
Coagulopathy

27. Please list the key efficacy outcomes for this procedure/technology?

Time to reach the target temperature
Time within target
Rewarming
Clinical outcomes

28. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

See above

29. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

30. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ○ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ◉ Cannot predict at present.

Abstracts and ongoing studies

31. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

32. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    STEPCARE : recruitment to start next year

33. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

34. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    Over 1500 OHCA patients present to intensive care facilities, where consideration for TTM is made.

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    See previous section (time to achieve target temperature and time spent in target temperature/Clinical outcomes)

36. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Further comments

37. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

No further comments

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

38. Type of interest: *

- [ ] Direct: financial
- [x] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

39. Description of interests, including relevant dates of when the interest arose and ceased. *

Ran a course sponsored by BARD: no personal financial gain.

40. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

41. Name: *

Nawaf Al-Subaie

42. Date: *

20/12/2022