Perioperative hypothermia (Inadvertent)
Stakeholder comments and NCC responses on draft scope - consultation 9 May – 6 June 2006

Organisation	Order no.	Section no.	Comments	Responses
Actamed Ltd	1	4.3 c)	The means of detecting of temperature changes may be different at various points in the continuum of perioperative care. It may be that a different monitoring device should be used in a preoperative setting than one used in an intraoperative setting. The frequency of measurements may be different, too. I suggest the following change. "How should perioperative hypothermia be detected pre-, intra- and postoperatively and what is the optimum frequency of recorded temperature measurement pre-, intra- and postoperatively?"	Thank you for your comment. The guideline development group will consider this.
Addenbrookes NHS Trust			This organisation was approached but did not respond.	
Aintree Hospitals NHS Trust	1	General	This guideline should not be addressing hypothermia; it should be addressing perioperative ***heat loss***. These two terms are not the same. There are clear explanations in the textbooks of the difference. To summarise: hypothermia is the fall in temperature (in this case "core" temperature) ***as a result of heat loss***. Heat loss can occur with minimal change to the core temperature – but with dramatic reduction in peripheral tissue and skin temperature. During anaesthesia the homeostatic mechanisms which tend to preserve core temperature at the expense of peripheral tissue and skin temperature are impaired but not completely inactive. This results in greater heat loss than in the non-anaesthetised state. However there is still considerable scope for massive heat loss with relative preservation of the core temperature. It is because of the remaining homeostatic mechanisms that during prolonged surgery where no attempt is made to control heat loss the core temperature rarely falls below 35^{o}C – but the temperature of the peripheries falls to astonishingly cold temperatures.	Thank you for your comment. Mechanisms of heat loss and core temperature will be discussed but the Department of Health's remit is in the management of perioperative hypothermia. Thank you for your comment. The guideline development group will consider this.

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			It is particularly easy to forget heat balance and focus on core temperature and thereby grossly underestimate the heat loss present in a state of marginal hypothermia. See attached spreadsheet.	
Aintree Hospitals NHS Trust	2	3b	Definition is inappropriate. See above for why.	Thank you for your comment.
Aintree Hospitals NHS Trust	3	4.3c	The ability to measure heat loss by combining data from multiple temperature measures combined with certain basic data and mathematical assumptions allows the calculation of a reasonably accurate total body heat. Simply specifying how often to measure a core temperature grossly oversimplifies the issue. One relatively simple spreadsheet is enclosed. It is based upon a standard text on heat balance. It makes a variety of simple assumptions and uses simple constants and correction factors. The mathematics can be seen by analysing the formulae in the calculated cells. The data was collected not to demonstrate heat loss but to assess certain heat retention strategies: Scrupulous insulation of the non-operated areas during major vascular surgery, warming of IV fluids, under-patient temp controlled warming mattress, Humidity/moisture exchanger in ventilation circuit. (This work took place before the availability of forced air warming blankets.) Heat loss was allowed as normal during transport to theatre and induction of anaesthesia – resulting in the initial low core and periphery temperatures: substantial heat loss had already occurred.	Thank you for your comment. The subject of this guideline is perioperative hypothermia. Heat loss will form part of our remit. We will consider the total body temperature not just the core temperature.
Aintree Hospitals NHS Trust	4	General	Thermoregulation, mild perioperative hypothermia and post-anaesthetic shivering. BJA May 2000 p615 D J Buggy & A W A Crossley	Thank you for your comment.
Aintree Hospitals NHS Trust	5	3a	Attention should be given to improved heat retention pre-operatively and during induction of anaesthesia – as this is a widely neglected period.	Thank you for your comment. The guideline development group will be considering this as part of the guideline development.

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Association for Perioperative Practice	1	3 (c).2	Anaesthesia and analgesia-induced peripheral vasodilitation	Thank you for your comment. The scope has been amended to reflect this. This will be addressed in the risk factor review.
Association for Perioperative Practice	2	3 (c).3 3 C	…and exposure of the body during skin preparation, draping and during surgery (therefore omit skin prep methods in final comment) Include side effect of regional anaesthesia (i.e spinal or epidural blocks)	Thank you for your comment. The scope has been amended to reflect this.
Association for Perioperative Practice	3	4.1.1 CHANGE if Children included	It should not be ed that there are acute Trusts providing adult and paediatric surgery, who deem 16 year olds to be 'adults' if they have left school. I.e. they would be operated on by adult surgeons in adult theatres, not paediatric surgeons in paediatric theatres.	Thank you for your comment.
Association for Perioperative Practice	4	4.1.1 (a)	Should include regional analgesia	Thank you for your comment. This will be addressed in the risk factors review.
Association for Perioperative Practice	5	3f	Include : • Reduced patient satisfaction with clinical outcome • Pressure ulcers caused by peripheral shutdown and cell hypoxia • Increased need for blood transfusion postoperatively	Thank you for your comment. The scope has been amended to reflect this.
Association of Anaesthetists of Great Britain and Ireland			This organisation was approached but did not respond.	
Association of Paediatric Anaesthetists of Great Britain and Ireland	1	General	The Association of Paediatric Anaesthetists of Great Britain and Ireland welcomes NICE's proposal to develop a Guideline on Inadvertent Perioperative Hypothermia. However, it has deep concerns regarding the exclusion of infants and children from the draft scope. Children, especially infants, are at increased risk of inadvertent perioperative hypothermia compared with adults, which as we all know can increase morbidity and mortality. My colleagues and I in the APA feel it is absurd to exclude this especially vulnerable group.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.

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			Specific reasons why infants and children should be included: 1) The basic principles of heat conservation are common to all age groups. Extremes of age only amplify the importance of attending to this issue. 2) If the GDG is properly constituted there is no reason why timelines can't be adhered to. By this we mean recruiting at least one possibly two paediatric anaesthetists on the GDG. 3) The paediatric community in general attaches great importance to this issue. 4) It would cost more and take longer to do a separate guideline for children. However, we note there is no intention to do a separate guideline at present, which makes it all the more imperative that children (neonates, infants, children) are included in the present one. 5) Excluding children on the basis of expediency or cost would be similar to the "therapeutic orphaning" practiced by drug companies who market medicines without licences or labelling information for use in children.	
Barnsley Primary Care Trust			This organisation was approached but did not respond.	
Brighton & Sussex University Hospitals Trust	1	3a	The period of time from leaving the ward to arriving in theatres should be included in this. I have audit data showing that even when this is inside there can be significant temperature loss	Thank you for your comment. The scope has been amended to define the start of the preoperative period as the time the patient is prepared for surgery on the ward.
Brighton & Sussex University Hospitals Trust	2	3f	Shivering occurs post-operatively even when the temperature remains above 36 ºC. This may not be within the scope of the guideline but is an issue that should maybe flagged up. (see also 4.3.f)	Thank you for your comment. Interventions for prevention and treatment of shivering will be considered and the scope has been amended to reflect this.
Brighton & Sussex University Hospitals Trust	3	4.1.2 a	Why not? There are different technologies used and different issues involved in peri-operative temperature management in children which will never be covered if	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the

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			not addressed now	guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Brighton & Sussex University Hospitals Trust	4	4.1.2 b	Why not? This is something that is poorly done and needs to be improved (see: **Harper CM**, Alexander R. Hypothermia and spinal anaesthesia. *Anaesthesia* 2006; 61(6):616) I am currently undertaking a trial of a novel warming mattress which could well be the solution to this problem. This randomised trial is still recruiting and may well not be published in time for the guideline but its results should be. I think it will provide valuable information (as it may also have significant cost implications). Please contact me for further details.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Brighton & Sussex University Hospitals Trust	5	4.3 c	Temperature measurement devices are not as good as they should be. I am at the COREC stage with one at the moment which may not be published by the time the guideline is closed-I would be happy to pass on the information from this in advance as I think it will be valuable.	Thank you for your comment and the offer to share this with the guideline development group.
Brighton & Sussex University Hospitals Trust	6	4.3 f	Shivering interventions should be included	Thank you for your comment. Interventions for prevention and treatment of shivering will be considered and the scope has been amended to reflect this.
Brighton & Sussex University Hospitals Trust	7	GENERAL	At the risk of being forward, I would like to be considered for participation on the Guideline Development Group. I have already emailed the NCC in more detail about this. have lectured on the subject to many different audiences: at the PACE meetings (where I met x), on several occasions (on different aspects of the subject) at the North Thames Anaesthetic Meeting, to trainees and trainee ODPs, at the Association of Anaesthetist Summer Meeting, even to urologists and at the 2nd Evidence Based Peri-operative Medicine in High-risk Surgery Meeting. I have undertaken numerous audits on the subject which have been used to improve the management of peri-operative hypothermia. I am currently setting-up/running two trials which will be	Thank you for your comment.

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			extremely relevant to the NICE guidelines. The first (currently a quarter of the way through recruiting) is looking at a novel (and according to my prior audit, very effective) warming mattress. This is a prospective, randomised trial which could lead to a significant reduction in the cost and the need for disposables in peri-operative temperature management. The second is a trial comparing 2 means of measuring temperature (naso-pharyngeal and temporal artery compared with bladder temperature as a control). The three 'trial' devices are widely used as part of the peri-operative temperature management package, but there is very little evidence as to their effectiveness in this setting. I would also be delighted to conduct a prevalence survey on shivering as was suggested at the meeting. I hope you see that I can bring a lot to the Guideline group that will complement the other anaesthetic members and especially, having worked in the field with surgeons, nurses and ODPs, the members of the panel from other areas: not to mention having a (non-medical) wife who woke up from an anaesthetic feeling like she had been “left naked at the North Pole” It was mentioned that the group was not fixed and that anyone could propose members including themselves. If my own recommendation is not sufficient I am happy to provide you with further 'references' from the field of academia (such as …), the hypothermia industry (Acatmed, Inditherm) and my clinical/research colleagues.	
British Association of Paediatric Surgeons	1	General and in particular 4.1.1.(a) and 4.1.2.(a), (b) and (e)	We believe that this is an important exercise. Unintentional peri-operative hypothermia is potentially a significant problem for our patients. The risk of this complication is mainly related to the surface area to body mass ratio which is relatively greater in children compared to adults. This is particularly true of very small premature babies where management of body core temperature during and after surgery is particularly challenging. Unintentional hypothermia is known to be associated with significant morbidity and mortality by	Thank you for your comment.

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			causing disturbances of metabolism, depression of the immune response and an enhanced stress response with the release of certain cytokines such as TNFα. Compared to adults, this is relatively a greater problem the smaller and more immature the child is. The consequences for the patient and their families of hypothermia induced complications, (apart from death) can be, unnecessary prolongation of hospital stay, and in the long term, both physical and mental disability, with the associated physical suffering and burden to society. The financial implications during the lifetime of the child can therefore amount to many hundreds of thousands of pounds. For these reasons, I was surprised that children and infants had been excluded from the Scope of the Guideline when it is clear to us that this client group may be more at risk compared to adults, who are included. The fact that various groups associated with the care of children, such as RCPCH and BAPS were included in the Registered Stakeholder Group, implies to me that the original intention was to include children in the guideline. While the reasons for this exclusion are not clear, I suspect that there were concerns about cost and duration of producing the guideline. It would appear that the decision was taken in the mistaken belief that children were a lesser problem compared to adults and were thus excluded. Clearly there are concerns about unintentional peri-operative hypothermia generally and I think there are sufficient generic problems to justify inclusion all patient groups in the guideline. Where necessary, special reference could then be made, as required, to each patient category if there are specific points to be made concerning management (including prevention). Additionally, for children, some of the equipment	Thank you for this comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.

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			employed to reduce the risk of peri-operative hypothermia, may be very specialised and because of this, it is often expensive. Trusts may see insufficient need to make the expenditure to purchase such equipment, if there were no NICE guideline for children. For all of these reasons, we believe that it is absolutely essential to include all children under the age of 19 years in this exercise. Further, this should include premature infants, who are most at risk and in whom the consequences have such major long term implications for society, the patient and their families. With regard to other proposed exclusions, I see no good reason that all patients groups who are at risk of unintentional peri-operative hypothermia should not be included in the guideline. This, for example, should encompass women who are undergoing a caesarean section. In all other respects, the proposals for the NICE guideline, I found were appropriate.	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
British National Formulary (BNF)			This organisation was approached but did not respond.	
BUPA	1	4.1.2	It seems inappropriate that infants and children are a group that will not be covered by this guidance, as they are especially vulnerable to hypothermia, and there do not seem to be any plans to develop guidance specifically on paediatric surgery.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
BUPA	2	4.3 e	In the interests of pragmatism and getting useful guidance out quickly, we suggest that only warming devices that are currently available should be included. Those in R&D should be left to one side for this first iteration of the guidance.	Thank you for your comment. We will be reviewing the evidence for warming devices licensed for use in the UK.
Central Medical Supplies Ltd			This organisation was approached but did not respond.	

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Commission for Social Care Inspection			This organisation was approached but did not respond.	
Connecting for Health			This organisation was approached but did not respond.	
Conwy & Denbighshire NHS Trust			This organisation was approached but did not respond.	
Department of Health	1	General	Hypothermia is an extremely important and well recognised problem in neonates, infants, and small children. Heat loss is higher because of the higher surface area/mass ratio. We understand that temperature control is a routine part of the anaesthetic, surgical, and intensive care management of these patients.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Department of Health	2	General	A separate guideline on the Management of perioperative hypothermia in children could be considered, but would not come high on the child health priority list.	Thank you for your comment.
Department of Health	3	4.1	Would it be possible to make particular reference to patients with septicaemia?	Thank you for your comment. Management of sepsis will be considered as a subgroup.
Department of Health	4	4.1	Would it be possible to make particular reference to vulnerable groups of people and other at risk patients e.g. patients with low thyroxine levels as perioperative hypothermia is likely to affect temperature.	Thank you for your comment. This will be examined in the risk factors review.
East and North Herts. NHS Trust			This organisation was approached but did not respond.	
Great Ormond Street Hospital for Children NHS Trust			This organisation was approached but did not respond.	
Health and Safety Executive			This organisation was approached but did not respond.	
Health Protection Scotland	1	General	No time frame for monitoring clinical management approaches for prevention of intra operative hypothermia /interventions **pre** operatively i.e. 6hrs etc.	
Healthcare Commission			This organisation was approached but did not respond.	

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Heart of England NHS Foundation Trust	1		I regret to inform you that in this instance the **Heart of England NHS Foundation Trust** will not be submitting comments.	
Inditherm Medical	1	3 (d)	The duration of anaesthesia is more important than the duration of the surgical procedure. Consideration should be given to the possibility that patients already have depressed temperatures before induction of anaesthesia due to poor perfusion and environmental conditions. This means that onset of hypothermia as defined in the Scope will occur after less than half an hour of anaesthesia, which means surgical procedures lasting considerably less than 30 minutes.	Thank you for your comment. The guideline development group will take this into consideration and the scope has been amended in section 4.1.1.c
Inditherm Medical	2	4.1.2 (a)	This group are at high risk of hypothermia and it is our view that they should not be excluded.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Inditherm Medical	3	4.3 (e)	It can typically take a year to gain Ethics Committee approval for a clinical study. It can typically take at least a year to recruit sufficient patients to a study to demonstrate statistical significance in terms of efficacy. It can typically take more than 9 months to write, submit, peer review and publish a study. This gives a total of nearly 3 years. If a product clearly performs the function for which it is designed, many clinicians feel it is not valuable to carry out formal clinical studies, especially given the burden imposed by the process outlined above. It is our view therefore that in terms of devices for prevention of perioperative hypothermia the scope must include evidence other than peer reviewed publications. If this is not allowed then the most modern, innovative and cost-effective products will probably be excluded. This creates a risk that only less effective and more costly therapies are reviewed and/or recommended in the guideline.	Thank you for your comment. We will be reviewing the evidence for warming devices licensed for use in the UK. However, if stakeholders wish to submit in-confidence data for consideration, the guideline development group would welcome this.

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KCI Medical Ltd.	1	Section 4.1.2 d	We suggest that therapeutic hypothermia also be included within the scope of this guideline, potentially where it is used in conjunction with cardiac or neurological surgery, as the management framework will be broadly similar to that of patients who suffer inadvertent hypothermia. ILCOR have already written guidance on the use of therapeutic hypothermia for patients post cardiac arrest so it could be a relatively simple process to incorporate this important topic.	Thank you for your comment. This area is outside of the topic referral for this guideline, but the 'afterdrop' phase following therapeutic hypothermia and rewarming of such patients will be considered as indirect evidence
KCI Medical Ltd.	2	Section 4.3 b	A risk factor that should be considered is the presence of a large open wound (e.g. open abdomen for management of patients suffering abdominal compartment syndrome) or a large expanse of tissue loss (e.g. burn) in patients who also require surgery. A significant proportion of body heat is lost through open wounds, as the thermoregulation capacity of the skin is interrupted.	Thank you for your comment. This will be considered in the risk factor evidence review.
KCI Medical Ltd.	3	Section 4.3 e	Standard warming devices alone are important to consider but KCI would recommend that other methods of warming patients be included within this section. The uses of therapeutic low-air loss surfaces that include 'patient warming' facilities are important to consider as they allow for the prevention of pressure ulceration (risk is increased in hypothermic patients due to capillary shut down) whilst assisting with maintaining normothermia. Examples of these devices are: • TheraPulse® ATP™ (KCI Medical Ltd, Oxon) • TheraKair® Visio™ (KCI Medical Ltd, Oxon) KCI also request that the DeltaTherm™ is included as a warming device for the purpose of this guidance. DeltaTherm™ provides safe and non-invasive mild therapeutic patient cooling but of note is its ability for controlled patient re-warming and therefore could be used safely to bring hypothermic patients back to normothermia minimising the inherent risks of too rapid rewarming.	Thank you for your comment. We will be reviewing the evidence for warming devices licensed for use in the UK. We would welcome your submission of this evidence. Stakeholders are encouraged to submit relevant research evidence as described in The guideline development Process-An Overview for Stakeholders, the Public & the NHS (pg iv).

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KCI Medical Ltd.	4	General	KCI would like to propose 2 clinical question for consideration during the finalising of this scope and the guideline: 1. Is there evidence that low air-loss therapy surfaces can help to regain and maintain normothermia post-operatively, when used in conjunction with other non-invasive warming methods? • Is there evidence that patients who experience perioperative hypothermia are at increased risk of developing perioperative and/or post-operative tissue damage and/or oedema?	Thank you for the clinical questions. It is usual for the guideline development group to set the clinical questions at the outset of development. They will consider these questions.
Kimal Plc			This organisation was approached but did not respond.	
Kimberly-Clark Health Care	1	3(d) / 4.1.1 (a) / 4.1.2	Paediatrics should be included within the guideline as they are also a group at high risk. This group, given their higher sensitivity to temperature shifts, is subject to additional complications as is other groups listed such as the elderly and others with comorbidities.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Kimberly-Clark Health Care	2		The difficulty of maintaining paediatrics patients normothermic reinforces the need for an assessment of techniques and devices not currently used during these interventions	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed. We will be reviewing the evidence for warming devices licensed for use in the UK.
Kimberly-Clark Health Care	3	3 (e)	Clearer definition/distinction of therapeutic hypothermia. In regards to cardiothoracic procedures using a cardiopulmonary bypass, hypothermia is induced however for periods usually less then 60 minutes. After being disconnected from bypass, these patients are at the same risk as others to succumbing to inadvertent hypothermia (i.e. “afterdrop”).	Thank you for your comment. Thank you for your comment. Patients who subsequently develop inadvertent perioperative hypothermia will be considered and the scope has been amended to reflect this.

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Kimberly-Clark Health Care	4		The periods in which patients are engaged to the cardiopulmonary bypass and the warming techniques during such, should be excluded from this guideline	Thank you for your comment. The scope has been amended to reflect this.
Kimberly-Clark Health Care	5	4.1.1 (c)	Cardiothoracic surgery should be included as a subgroup as they qualify under the general scope (outlined 3(d)). As these procedures can be performed with cardiopulmonary bypass, they fall under special circumstances if compared to those without. However these patients are still at risk for inadvertent hypothermia (see comments for point 3 (e))	Thank you for your comment. The guideline development group will consider this.
Luton and Dunstable Hospital NHS Trust	1	1 Guideline Title	The title should be “Management of unintentional or inadvertent perioperative hypothermia”, to avoid searches pulling papers relating to therapeutic hypothermia, and to avoid un-necessary comments from those with an interest in this area complaining that you have missed the point.	Thank you for your comment.
Luton and Dunstable Hospital NHS Trust	2	2 Background (a)	If there is a conflict of interest between clinical evidence and cost, how will these differences be reconciled? Is there a commitment from the Government to fund any additional expenditure required by an enforced change of practice?	Thank you for your comment. All decisions relating to cost effectiveness are outlined in the following documents: NICE Guideline Manual- http://www.nice.org.uk/page.aspx?o=308639 Social Values Judgements report- Principles for the development of NICE guidance http://www.nice.org.uk/page.aspx?o=svjguidance
Luton and Dunstable Hospital NHS Trust	3	3 Clinical Need (a)	What is going to be considered the scope for the pre-operative period? Will it be 1 hour before induction or longer? Will the guideline recommend the patient’s temperature is taken immediately before they leave the ward or admission area, to provide a current baseline?	Thank you for your comment. The scope has been amended to define the start of the preoperative period from the time the patient is prepared for surgery in the ward. Part of the guideline development group’s remit will be to determine optimum frequency for temperature monitoring at the pre, intra and post operative phases.
Luton and Dunstable Hospital NHS Trust	4	3 Clinical Need (b)	I agree that a definition of hypothermia is needed, but would wish to point out that a septic patient with a pre-op temperature of 39°C whose temperature drops to 36°is physiologically a whole different ball game than an elective patient whose pre-op temperature may have only been 36.5°C. Some reference needs to be made of this within the guideline.	Thank you for your comment. The definition of hypothermia for the purpose of this guideline is 36 deg C, regardless of the patient’s baseline temperature. Management of sepsis will be considered as a subgroup.

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Luton and Dunstable Hospital NHS Trust	5	3 Clinical Need (c)	The use of rapid air-change systems in orthopaedic theatres which create increased airflow over vasodilated tissues during surgery. What is the level of evidence that this reduces infection? Is restriction of air-flow within the remit of this group to make recommendations?	Thank you for your comment. The reviews will consider the full clinical context, but specific recommendations will relate only to prevention of perioperative hypothermia.
Luton and Dunstable Hospital NHS Trust	6	3 Clinical Need (g)	Surely the aim is not merely to produce the guideline, but to ensure that the guidance it contains is acted upon throughout the Health system in all sectors to improve patient safety and optimise outcome. Merely identifying the optimum management is an academic exercise without clinical application.	Thank you for your comment. The purpose of any clinical guideline is to produce implementable recommendations to enable college, professional groups and the NICE implementation team to maximise its impact and address variations in practice.
Luton and Dunstable Hospital NHS Trust	7	4 The Guideline (b)	This document is the DRAFT scope. The finalised and agreed scope will be the document which defines what the guideline will and will not examine, and what the guideline developers will consider.	Thank you for your comment.
Luton and Dunstable Hospital NHS Trust	8	4.1 Population (a)	This is clearly the most contentious area of this scope. In English law, patients are deemed able to consent at 16 years of age. Why should the 16-18 year olds be excluded from this guideline? Surely thermoregulation is just as important to them as it is to a 19 year old.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Luton and Dunstable Hospital NHS Trust	9	4.1 Population (b)	Why stipulate emergency surgery for trauma as an inclusion criteria? What about patients undergoing emergency laparotomies, who are likely to need ITU post-op, and who are therefore most likely to benefit from improved thermoregulation? What about patients who have had a Caesarean section (not included) who then bleed and need an emergency laparotomy for bleeding which results in a hysterectomy? Are they to be included or excluded? I think the guideline needs to be applied to ALL surgery, with particular caveats or addendums for individual situations where particular issues are important which change the practicality or applicability of the routine measures. This would make it clearer, and make it a routine, rather than happening only in restricted circumstances.	Thank you for your comment. The scope has been amended to read 'Adults undergoing either elective or emergency surgery, including trauma, under general and regional anaesthesia'. Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.

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Luton and Dunstable Hospital NHS Trust	10	4.1 Population (c)	Subgroups have the potential to make the guideline too complex to be implemented. I would ask that the scope limits sub-group examination to Simple non-cavity vs other surgery, and expected duration of operation. I can't think of why any other subcategorisation might be useful.	Thank you for your comment. We will discuss this with the guideline development group during the development process.
Luton and Dunstable Hospital NHS Trust	11	4.1.2 Groups Not Covered (a)	This directive must cover ALL age groups. The paediatric anaesthetists are the ones who have the most experience in this area, and their contribution to this important guideline must not be excluded. Much published evidence around the efficacy of warming methods and devices is based on paediatric anaesthesia.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Luton and Dunstable Hospital NHS Trust	12	4.1.2 Groups Not Covered (b)	Because of fluid pre-loading, extreme vasodilation, and surgical opening of a body cabvity, Caesarean section SHOULD be included. Maternal cooling will be mirrored by fetal cooling, especially if delivery is delayed. These patients are at risk of large blood losses, and temperature maintenance is therefore vital to minimise blood loss and transfusion. I re-iterate that this guideline should cover ALL operative situations under regional or general anaesthetic. If Obstetrics needs to be a subgroup, so be it, but don't exclude them. The claim that warming devices interfere with the bonding process is not true, as the babies also benefit from being in a warmer environment.	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
Luton and Dunstable Hospital NHS Trust	13	4.1.2 Groups Not Covered (e)	Please add to this clause patients who for medical reasons have impaired thermoregulation, eg hypothyroid patients. Does the group need to consider patients where temperature regulation is impaired by medication eg steroids, anticholinergics, etc	Thank you for your comment. This would form part of the risk assessment work for the guideline. This has been included in the scope (4.1.1.c).
Luton and Dunstable Hospital NHS Trust	14	4.3 Clinical Management	Can I add a question to be considered: at what temperature should active warming be discontinued, and at what temperature should active cooling be commenced? These limits need to be set to prevent over-enthusiastic warming of patients to a dangerous level by those merely applying the guidelines to the letter. May be a small point, but one which the group need to consider the legal implications of to protect	Thank you for your question. We will ensure that this is considered by the guideline development group.

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			NICE and the GDG from liability. Will there need to be any differentiation between patients returning to a ward area and those going to ITU/HDU post-operatively? Staffing levels differ greatly, and this will influence the safety of warming devices being employed post-operatively.	Thank you for your comment. The guideline development group will consider this.
Luton and Dunstable Hospital NHS Trust	15		Having attended the launch meeting for this guideline, I would be very happy to be considered as a possible member of this GDG, and have a significant amount of experience relating to the detection and elimination of unintentional perioperative hypothermia. As Clinical Director of the Anaesthetic department at Luton & Dunstable Hospital, I am responsible for the implementation of the ten high impact changes being championed by the Institute for Health Improvement, one of which relates to the detection and elimination of post-operative hypothermia in the recovery room. As a Trauma anaesthetist who also anaesthetises small children, I have a significant wealth of personal experience in the field as well. I also anaesthetise regularly for a Caesarean Section list, hence I am keen to see this area included in the scope.	Thank you for your comment.
Maidstone and Tunbridge Wells NHS Trust			This organisation was approached but did not respond.	
Medicines and Healthcare Products Regulatory Agency (MHRA)			This organisation was approached but did not respond.	
National Patient Safety Agency	1	General	The NPSA is very pleased that this guidance is being developed and with the opportunity to comment at this early stage. In terms of the scope we feel that some consideration should be given to the patient on transfer to the ward from the operating department. Warming devices should be available for the post operative patient on the ward. We have anecdotal evidence from a few patients that they felt extremely cold and shivered	Thank you for your comment. The GDG will consider this. The evidence for warming devices for the preoperative, intraoperative, and postoperative phase will be reviewed.

Organisation	Order no.	Section no.	Comments	Responses
			for a few hours post operatively.	
National Patient Safety Agency	2	General	We feel it will be important to ensure adequate anaesthetic representation on the working group via the royal college of anaesthetists	Thank you for your comment. The guideline development group will include anaesthetists representing the College.
National Patient Safety Agency	3	4.1	The population to be covered by this guideline should be extended to include both paediatric and caesarean section patients.	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence. Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are outside the scope for this guideline.
National Patient Safety Agency	4	4.3	How will patients who present with pyrexia be considered under this guideline? A definition of hypothermia in this group of patients would be useful.	Thank you for your comment. For the purpose of this guideline, the definition of hypothermia is core temperature less that 36 deg C, regardless of the patient's baseline temperature.
National Public Health Service - Wales			This organisation was approached but did not respond.	
NCEPOD			This organisation was approached but did not respond.	
NHS Health and Social Care Information Centre			This organisation was approached but did not respond.	
NHS Plus			This organisation was approached but did not respond.	
NHS Purchasing & Supply Agency	1	4.3	NHS PASA feel that all devices and technologies should be evaluated as part of this guideline. Many newer technologies have been within the NHS for a number of years and users should provide an overview of their effectiveness. Categories of product could include the following- Forced air warming Blood and fluid warming – both disposable systems and some newly introduced reusable systems	Thank you for your comment. We will be reviewing evidence on devices and technologies.

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			Passive warming devices Chemically activated devices Reusable under patient devices Reusable over patient devices Radiant warming devices	
NHS Quality Improvement Scotland			This organisation was approached but did not respond.	
NICE - info for Jo			This organisation was approached but did not respond.	
Northwest London Hospitals NHS Trust			This organisation was approached but did not respond.	
Nottingham City PCT			This organisation was approached but did not respond.	
Obstetric Anaesthetists' Association	1	General	Concerning your query concerning hypothermia in pregnant women undergoing non-obstetric surgery: we consider due to the physiological changes in pregnancy etc the needs of pregnant women must be considered separately from non-pregnant women whatever type or aspect of surgery is under consideration. We would be very happy to contribute to the guideline in this respect in a role you think appropriate	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence. Thank you
Papworth Hospital NHS Trust	1	3	Hypothermia defined as core temperature <36 C but this differs significantly depending on how this is managed – I suggest the exact method of measuring is defined eg. aural or nasopharyngeal also	Thank you for your comment. This will be considered by the guideline development group.
Papworth Hospital NHS Trust	2	4.1.2	Guideline states that patients treated with therapeutic hypothermia will not be included. Many cardiac procedures have hypothermia induced on cardio-pulmonary bypass, then have normothermia restored by rewarming on bypass before disconnecting from bypass. The guideline should include cardiac surgery patients, and this needs to be made cleart	Thank you for your comment. Patients who subsequently develop inadvertent hypothermia will be considered and the scope has been amended to reflect this.
PERIGON (formerly The NHS Modernisation Agency)			This organisation was approached but did not respond.	

Organisation	Order no.	Section no.	Comments	Responses
Peterborough & Stamford NHS Trust	1	4.1.2 (a)	Why not paediatrics?	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Peterborough & Stamford NHS Trust	2	4.1.2.(b)	Why not obstetric patients following caesarean section?	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
Peterborough & Stamford NHS Trust	3		Are these groups of patients being covered in another document?	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
Queen Victoria Hospital NHS Foundation Trust			This organisation was approached but did not respond.	
Regional Public Health Group - London			This organisation was approached but did not respond.	
Royal Brompton and Harefield NHS Trust			This organisation was approached but did not respond.	
Royal College of Anaesthetists	1	4.1.2	Infants and children **should** be included in the study as this is a key area of concern.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Anaesthetists Patient Advocate	1	general	I am surprised and concerned that this proposal excludes all children. Children do constitute a different group but their need is as great as that of other	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the

Organisation	Order no.	Section no.	Comments	Responses
Patient Liaison Group			vulnerable groups such as the elderly.	guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Anaesthetists Patient Advocate Patient Liaison Group	2		In respect of this being a complication of paediatric perioperative care; children should be afforded the same urgency of attention as those groups included in this draft scope.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Anaesthetists Patient Advocate Patient Liaison Group	3		Although there may be little evidence that might inform best practice, this in itself is no justification for the exclusion of children. Is this not a reason for prioritising the inclusion of children rather than excluding it out of hand?	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Anaesthetists Patient Advocate Patient Liaison Group	4		Because of the physiology of children undergoing surgery, fluid management and control of body temperature for example, is likely to be more complicated and result in greater adverse events effecting the child's outcome. Is this not another good reason for prioritising the inclusion of children rather than excluding it out of hand?	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Anaesthetists Patient Advocate Patient Liaison Group	5		Whilst the proposed scope gives no reason for the exclusion of children and young people, neither does is provide any rational for the inclusion of elderly patients for whom complications are likely to be greater in number and kind andin whom co-morbidities are likely to complicate the management of perioperative hypothermia. Why include the elderly and not the young?	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Nursing	1	3a line 5	Suggest this should read "…drop to less than 35^0C during surgery."	Thank you for your comment. Agreed definition will be temperature drop less than 36 deg C, regardless of the patient's initial temperature.

Organisation	Order no.	Section no.	Comments	Responses
Royal College of Nursing	2	3b	This may not be the same for all age groups.	Thank you for your comment.
Royal College of Nursing	3	3c	This may include issues related to maturity.	Thank you for your comment.
Royal College of Nursing	4	3c 4th bullet point	Suggest delete "general" as patients often fasted prior to regional anaesthesia as well.	Thank you for your comment. The scope has been amended to reflect this.
Royal College of Nursing	5	4.1.1.b	Need to be sure that all emergency patients are included and not just trauma – perhaps this should read "Adults undergoing either elective or emergency surgery, including trauma"	Thank you for your comment. The scope has been amended to reflect this.
Royal College of Nursing	6	4.1.2 a	Infants and children are a high risk group and we do not think there is any justification for exclusion rather there is every justification for their being included.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Nursing	7	4.1.2.b	Not sure that Caesarean sections should be excluded either – no justification for this.	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
Royal College of Nursing	8	4.1.2	We recommend that premature infants, neonates, children and young people should be included.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Nursing	9	4.1.2	They have specific needs and this is a lost opportunity and will mean identifying separate guidance later.	Thank you for your comment.
Royal College of Nursing	10	4.2	We suggest the inclusion of day care centres.	Thank you for your comment. We will be including surgery in any setting.
Royal College of Nursing	11	4.3. e	Safety of warming devices is an important issue therefore; we suggest it should be included.	Thank you for your comment. Warming devices will be covered within the guideline and safety will be taken into account.

Organisation	Order no.	Section no.	Comments	Responses
Royal College of Nursing	12	4.3 G	We suggest the inclusion of non mechanical warming methods for example Kangaroo Care.	Thank you for your comment. We will include non mechanical warming methods within the guideline.
Royal College of Paediatrics and Child Health	1	General	On behalf of the RCPCH I am seeking some clarification on the proposed Guidelines for Prevention of Perioperative Hypothermia. The Scope document(draft May06) indicates that infants and children will not be considered by the guidelines. We would like some clarification as to why children are being excluded? Is there a plan to produce separate guidelines for children at a later date? Children, and in particular, infants are at significantly greater risk of perioperative hyothermia than adults. This in turn can lead to an avoidable increase in morbidity and mortality. We would emphasise therefore the importance of developing age appropriate guidelines that will help to minimise this risk.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Royal College of Pathologists			This organisation was approached but did not respond.	
Royal College of Surgeons of England			This organisation was approached but did not respond.	
Scottish Intercollegiate Guidelines Network (SIGN)			This organisation was approached but did not respond.	
Sheffield South West Primary Care Trust			This organisation was approached but did not respond.	
Sheffield Teaching Hospitals NHS Trust			This organisation was approached but did not respond.	
Society for Cardiothoracic Surgery	1	General	The majority of our patients undergo therapeutic hypothermia during cardiac surgery and therefore are excluded from your guidelines. Despite rewarming the patient to 37 degrees before discontinuation of cardiopulmonary bypass, these patients are usually returned to the intensive care in a hypothermic state	Thank you for your comment. Patients who subsequently develop inadvertent hypothermia will be considered and the scope has been amended to reflect this.

Organisation	Order no.	Section no.	Comments	Responses
			(<35 degrees). We would suggest increasing the scope of your document to include these patients, which number more than 30,000 per annum.	
Society for Cardiothoracic Surgery	2	General	We also perform many procedures where the patient is at risk of peri-operative hypothermia. Our operations are usually long procedures, greater than 2 hours in duration, and involve opening the mediastinum or the thorax. These are the main categories: 1. Coronary bypass graft operations performed without cardiopulmonary bypass (approx 3000 per annum) 2. Lung resections for carcinoma (4000 per annum) 3. Thoracotomies for other pathology (3000 per annum) 4. Oesophageal surgery (700 per annum).	Thank you for your comment.
Society for Cardiothoracic Surgery	3	General	We would like to be involved in this important document, and may we suggest that the Association of Cardiothoracic Anaesthetists are included – no doubt they have submitted their own comments proforma.	Thank you for your comment.
Staffordshire Moorlans Primary Care Trust			This organisation was approached but did not respond.	
Stockport PCT			This organisation was approached but did not respond.	
Tameside and Glossop Acute Services NHS Trust			This organisation was approached but did not respond.	
The Association of the British Pharmaceutical Industry (ABPI)			This organisation was approached but did not respond.	
The David Lewis Centre			This organisation was approached but did not respond.	
The National Association of Assistants in Surgical Practice			This organisation was approached but did not respond.	

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The North West London Hospitals NHS Trust			This organisation was approached but did not respond.	
The Royal Society of Medicine			This organisation was approached but did not respond.	
Tyco Healthcare			This organisation was approached but did not respond.	
University College London Hospitals NHS Trust			This organisation was approached but did not respond.	
University Hospital Birmingham NHS Trust			This organisation was approached but did not respond.	
University of Cardiff			This organisation was approached but did not respond.	
Walsall Teaching Primary Care Trust			This organisation was approached but did not respond.	
Welsh Assembly Government	1	4.1.1	As infants and children are a particularly vulnerable group in respect of inadvertent hypothermia, mainly because they have a large surface area in relation to their body mass, plus for younger children an immature thermoregulatory system, they must be included in the scope of this guidance.	Thank you for your comment. Following stakeholder comments it has been agreed that infants and children are not included in the guideline because an estimate of current practice is that temperature control in this population is robust and well managed.
Welsh Assembly Government	2	4.1.1	Suggest that it explicitly states that individuals who have diseases that impair their ability to regulate temperature will be included, eg hypothyroidism.	Thank you for your comment. The scope has been amended to reflect this.
Welsh Assembly Government	3	4.1.1	Suggest caesarean section clients are included in the remit	Women undergoing caesarean section will not be considered as a patient group and remain outside the scope of this guideline. Data on this patient group will be considered as indirect evidence for reviews where there is insufficient direct evidence.
Welsh Assembly Government	4	4.3	Older patients requiring operations on traction tables are particularly vulnerable to developing hypothermia. Please include this client group and type of equipment specifically in the guidance.	Thank you for your comment. Elderly patients will be included in the guideline. The guideline development group will consider this.
Welsh Assembly Government	5	General	Consider the implications of significant temperature drop for clients who have a pyrexia.	Thank you for your comment. Management of sepsis will be considered as a subgroup.

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Welsh Scientific Advisory Committee (WSAC)			This organisation was approached but did not respond.	
Withybush Hospital			This organisation was approached but did not respond.	
York Hospitals NHS Trust			This organisation was approached but did not respond.	