NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Centre for Clinical Practice

Review of Clinical Guideline (CG65) – Management of inadvertent perioperative hypothermia in adults

Background information

Guideline issue date: 2008

3 year review: 2011

National Collaborating Centre: Nursing and supportive care

Review recommendation

- The guideline should be updated at this time.

Factors influencing the decision

Literature search

1. From initial intelligence gathering and a high-level randomised control trial (RCT) search clinical areas were identified to inform the development of clinical questions for focused searches. Through this stage of the process 30 studies were identified relevant to the guideline scope. The identified studies were related to the following clinical areas within the guideline:
    - Warming devices for preventing inadvertent perioperative hypothermia (IPH)
    - Pharmacology for preventing IPH

2. Two clinical questions were developed for more focused literature searches based on the clinical areas above, qualitative feedback from other NICE departments and the views expressed by the Guideline

Development Group. A series of Cochrane reviews on IPH is in development and so a collaboration between NICE and the Cochrane Collaboration was established to undertake this focused searching. In total, 33 studies were identified through the focused searches. There is new evidence which supports current guideline recommendation(s) in relation to:

- Warming devices. The evidence reviewed does not invalidate current guideline recommendations that forced air warming should be used to warm patients intraoperatively.

3. New evidence was identified which directly answered the research recommendations presented in the original guideline in relation to the effectiveness of different types of warming devices, although there is some heterogeneity across the studies.

4. Three on-going clinical trials were identified that fell within the scope of the existing guideline and includes:

    - A randomised controlled trial on carbon polymer warming blankets in comparison to forced air warming blankets (completes data collection September 2011)

    - A randomised controlled trial of 4 different types of conditioning of insufflated gases on hypothermia prevention (completes data collection by January 2012)

    - A randomised controlled trial on inditherm warming mattress in comparison to forced air warming blankets (completes data collection by March 2012).

    - A further randomised controlled trial on inditherm warming mattress in comparison to no warming in an obstetric setting is currently outside of the scope, but may be included if the scope is widened.

Guideline Development Group and National Collaborating Centre perspective

5. A questionnaire was distributed to GDG members and the National Collaborating Centre to consult them on the need for an update of the guideline. Two responses were received with respondents highlighting that since publication of the guideline more literature has become available:
    - New evidence for alternatives to forced air warming, particularly the inditherm mattress (no references were provided).
    - A reluctance amongst medical staff to monitor patient temperature
    - Potential to widen the scope to include obstetrics
6. Ongoing research was mentioned by GDG members, but no citations were provided.
7. Both respondents agreed that there is sufficient variation in current practice supported by adequate evidence at this time to warrant an update of the guideline.

Implementation and post publication feedback

8. Key themes emerging from post-publication feedback were:
    - General enquiries
    - Concern about the safety of forced air warmers: this was investigated and the Medicines and Healthcare products Regulatory Agency (MHRA) confirmed that there was no evidence that forced air warming was unsafe or violated any health and safety regulations.
9. No specific feedback was provided by the NICE implementation team.

Relationship to other NICE guidance

10. NICE guidance related to CG65 can be viewed in Appendix 1.

Summary of Stakeholder Feedback

Review proposal put to consultees:
The guideline should not be updated at this time.
The guideline will be reviewed again according to current processes.

11. In total 12 stakeholders commented on the review proposal recommendation during the 2 week consultation period. All comments can be viewed in appendix 2

12. Seven stakeholders agreed with the review proposal recommendation that this guideline should not be updated at this time.

13. Although the majority of stakeholders agreed with the consultation proposal not to update the guideline at this time, there was some disagreement particularly in relation to the following points:
    - That forced air warming should not be stipulated as there is new evidence that supports alternative devices, and that the cost and clinical effectiveness of the different devices should be addressed. Although the evidence relating to different types of warming device was heterogeneous, stakeholders still felt that this warrants further detailed examination in order to keep guideline recommendations contemporary, and in light of the recent publication of the Medical Technology Guidance which recommends that the inditherm patient warming mattresses can be used (MTG7, Inditherm patient warming mattress for the prevention of perioperative hypothermia, published August 2011).

    - Although the review was consulted on prior to final publication some stakeholders raised the issue of an apparent inconsistency

with the recent publication of Medical Technology Guidance (MTG7, Inditherm patient warming mattress for the prevention of perioperative hypothermia, published August 2011) which recommends that the inditherm patient warming mattress can be used. The current guideline does not recommend its use and this may be confusing for the NHS. Three stakeholders who agreed with the decision not to update also felt this issue needed to be addressed.

14. Literature was submitted through stakeholder consultation relating to warming devices, although these studies had been included in the current review or had been excluded according to the review protocol.

15. During consultation, stakeholders suggested new areas to consider in an update of the guideline including:
    - Widening the scope to include day surgery, and obstetrics.

Anti-discrimination and equalities considerations

16. No evidence was identified to indicate that the guideline scope does not comply with anti-discrimination and equalities legislation. The original scope is inclusive of adults (over 18 years of age) undergoing elective and emergency surgery (including surgery for trauma), under general and regional (central neuraxial block) anaesthesia.

Conclusion

17. The original review decision noted the heterogeneity of the identified evidence in relation to the warming devices. However, given stakeholder feedback and the recent Medical Technology Guidance regarding Inditherm warming mattresses, and further to discussions with MTEP team, it would be appropriate to consider the guideline for review at this time. However, scheduling for the review should take into consideration potential publication dates of the ongoing trials (listed in section 4 above).

18. From the evidence and intelligence identified through the process, it suggests that some areas of the guideline may need updating at this stage, particularly in relation to:
    - Alternatives to forced air warming for the prevention of inadvertent perioperative hypothermia
    - Consider additional areas to the scope identified during consultation such as day surgery and obstetrics, pre-warming, and the optimum method(s) and frequency of recording temperature which was not addressed by the original guideline.
19. The guideline should be updated at this time.

Relationship to quality standards

20. This topic has not currently been referred for a quality standard
21. This guideline is related to a topic (perioperative care) being considered in the proposed core library of healthcare topics.
22. Guidance Executive is asked to approve this guideline for update.

Fergus Macbeth – Centre Director
Sarah Willett – Associate Director
Sheryl Warttig – Technical Analyst

Centre for Clinical Practice
01.11.11

Appendix 1

The following NICE guidance is related to CG65:

Guidance	Review date
Related NICE guidance not included in CG65	
CG3 Perioperative tests: the routine use of perioperative tests in elective surgery	Published: 2003 Last reviewed: 2010 Next review: 2013
Inditherm Mattress for the prevention of inadvertent perioperative hypothermia. Medical Technologies guidance	Published: 2011 Review: TBC

Appendix 2

National Institute for Health and Clinical Excellence

Review of CG65: The management of inadvertent perioperative hypothermia in adults

.Guideline Review Consultation Comments Table:

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
Sheffield Teaching Hospitals NHS Foundation Trust (GDG member))	Disagree	There is obviously new evidence to further support the original guidelines. This has been highlighted in the references supplied. Evidence supporting prewarming does seem to be emerging however I am uncertain if this is robust enough yet to warrant an update to suggest prewarming in high risk groups? Could this area be highlighted further as an important area for research?			Thank you. The guideline will be updated and the issue regarding pre-warming that you have raised will be considered during the scoping phase.
Sheffield Teaching Hospitals NHS Foundation Trust	Agree	I am concerned that the related Medical Technology Evaluation Programme is overlapping with this Review consultation. The level of evidence needed for the MTEP to recommend a change is much less robust than that used for full NICE guideline. This review has clearly shown that to date insufficient evidence exists to recommend other warming techniques other than forced air warming. I would like some reassurance that the			This issue will be considered when this guideline is updated.

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		NICE guidelines will be the ones followed nationally, I agree however that this area is important one for further research.			
Department of Health		I wish to confirm that the Department of Health has no substantive comments to make regarding this consultation.			Thank you.
Central Medical Supplies Ltd (CMS)	Agree	Please note that there are also clinical studies planned which will examine the effectiveness of the Kanmed OP300 Patient Warming System. This product is a third generation product manufactured by Kanmed AB in Sweden, which utilises conductive heat exchange as the method of warming. This is an electronic under-body heating pad system which uses a novel method of temperature control, and which is used by many UK hospitals, and in many other countries. We will provide evidence to support this NICE guideline update in the future.			Thank you.
Inditherm plc	Agree	The Review Consultation Document highlights the related NICE guidance in progress. This identifies that the Medical Technology Evaluation Programme is considering the Inditherm mattress for the prevention of inadvertent perioperative hypothermia. The Draft Guidance on this subject, if confirmed, would indicate that CG65 should be amended wherever patient warming is advised to replace “forced air warming” with “Inditherm mattress or forced air warming”.			Thank you. The guideline will be updated and this issue will be considered
Inditherm plc	Agree	If amendment of wording in CG65 as above is not			This will be considered when the

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		possible due to process considerations, then we request that a clear statement is made either in the CG65 document itself, or in a document accessed in the same location, about related guidance. We request that this statement references the NICE MTAC Recommendations relating to the Inditherm mattress, if and when published, making it clear that the recommendation of MTAC in relation to the Inditherm mattress is valid for meeting the patient warming recommendations of CG65. We also request that a similar statement is made in the MTAC recommendations, or in a separate document accessed in the same location as them, that clearly states that the MTAC recommendations validate the Inditherm mattress as suitable for meeting the patient warming recommendations of NICE CG65.			guideline is updated
British Association of Day Surgery (BADS)	Disagree	Guidance should not stipulate only FAW, several comparative studies (refs 34-40) show alternative devices are not inferior and therefore their use should not be discriminated against			Thank you. This evidence will be appraised and systematically reviewed in the update.
British Association of Day Surgery (BADS)	Disagree	Ref 29 shows pre-warmed fluids (from a fluid cabinet) were equivalent to in-line warming. Current guidelines specifically state that warming cabinets for iv fluids should not be used. This advice is contrary to ref 29 and could unnecessarily increase costs			Thank you. This evidence will be appraised and systematically reviewed in the update to establish whether existing recommendations on fluid warming should be changed.
British Association of	Disagree	Postoperative shivering is not necessarily due to hypothermia. Therefore, pharmacological			Studies measuring shivering alone were excluded from this review.

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
Day Surgery (BADS)		interventions which prevent shivering anr not necessarily effecting hypothermia or core temperature			The study you refer to did examine core body temperature in addition to shivering and so both these outcomes were provided in the summary of this study.
British Association of Day Surgery (BADS)	Disagree		Original review does not address Day Surgery as such. In our collective experience, mild hypothermia is not uncommon after brief (30-60 min procedures), but this is rarely associated with any of the serious consequences covered in the review. In addition, FAW and other devices rarely prevent this mild hypothermia when the duration of surgery (and hence warming) is brief. Consequently, the cost-effectiveness equations do not relate to this patient group and implementing these guidelines in the majority of day surgery cases is unlikely to yield		Thank you. The guideline will be updated and this will be considered in the scoping phase.

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
			patient benefit while greatly increasing costs		
GDG member	Agree	Non	Non	non	Thank you.
Patient Advocate	Agree	Insufficient new data to justify update	None	none	Thank you. In light of new evidence and issues raised by stakeholders, the original guideline will be updated.
Augustine Temperature Management LLC	Disagree	There is ample evidence that over-the-body resistive polymer conductive warming blankets transfer heat to surgical patients as effectively as forced-air warming blankets. The Review Committee, however, seems to have concluded that, absent clear error or unequivocal proof of the superiority of an alternative technology, the recommendation of a single warming modality (dominated by a single company) should not be changed. This does not serve the interest of the NHS. To make recommendations so narrowly can only impair competition and increase costs for the NHS. Broader recommendations will encourage the entry of more competitors into the field...and ultimately drive down the price that the NHS must pay for surgical normothermia. In 2009, a similar decision was made in the United States by CMS and the Joint Commission when the Surgical Care Improvement Project defined “active warming” to include multiple			Thank you. The guideline will be updated and the evidence for alternatives to forced air warming devices will be considered. The studies that you have listed by Brandt et al, Perl et al, and Fanelli et al, were included in this review. The other studies you have listed were identified and excluded from the review because they either (a) used healthy volunteers rather than patients , (b) were conference papers not published peer reviewed papers, or (c) because the paper was published prior to 2008 and was therefore available during the development of the original guideline.

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		technologies, including forced-air warming and conductive warming blankets. Recently published research establishing that resistive polymer conductive warming blankets are at least as effective as forced-air includes the following: **Kimberger O, et al. Resistive polymer versus forced-air warming: Comparable heat transfer and core rewarming rates in volunteers. Anesth Analg 2008; 107: 1621-26**The full body HotDog blanket was compared with the full body Bair Hugger blanket in re-warming anesthetized hypothermic volunteers in a controlled cross-over study. The warming rates of the two technologies were virtually identical. **Brandt S, Kimberger O, et al. Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients. Anesth Analg 2010; 110:834-8.**80 elective orthopedic surgery patients were randomized to upper-body FAW (Bair Hugger) or resistive polymer warming (HotDog) upper body blanket during surgery. The warming rates were comparable for the two groups. No differences in mean skin and mean core temperatures. "Resistive polymer warming performed as efficiently as FAW in			

Stakeholder	Agree Disagree with proposal to not update?	Comments	Comments on areas excluded from original scope	Comments on equality issues	Response
		patients undergoing orthopedic surgery." **Nguyen H, Kimberger O, et al. A New Underbody Resistive Warming Device vs. Forced Air Warming To Prevent Perioperative Hypothermia. A087. Presented at the American Society of Anesthesiologists Annual Meeting, October 2010.** 24 elective orthopedic surgery patients were randomized to upper-body FAW or resistive polymer warming (HotDog) with combined upper body blanket and underbody mattress during surgery. The warming results were nearly identical for the two groups. "The efficacy of resistive polymer warming with the HotDog resistive warming system was not inferior to an established FAW system in patients undergoing elective orthopedic surgery." Several other studies have shown that various forms of resistive warming devices are as effective as forced-air warming: 1. Perl T, et al. Comparison of forced-air warming and resistive heating. Minerva Anestesiol 2008; 74: 687-90 2. Matsuzaki Y, et al. Warming by resistive heating maintains perioperative normothermia as well as forced air heating. Br J Anaesth 2003; 90: 689-91			

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		3. Camus Y, et al. Prevention of hypothermia by cutaneous warming with new electric blankets during abdominal surgery. Br J Anaesth 1997; 79: 796-97 4. Camus Y, et al. Leg warming minimizes core hypothermia during abdominal surgery. Anesth Analg 1993; 77: 995-99 5. Pathi V, et al. The benefits of active rewarming after cardiac operations: A randomized prospective trial. J Thor CV Surg 1996; 111: 637-41 6. Fanelli A, et al. The efficacy of a resistive heating under-patient blanket versus a forced-air warming system: A randomized controlled trial. Anesth Analg 2009; 108: 199-201 7. Wong P, et al. Randomized clinical trial of perioperative systemic warming in major elective abdominal surgery. Br J Surg 2007; 94: 421-426 8. van der Horst M, et al. Preoperative warming reduces the incidence of hypothermia in total hip and knee replacement surgery under spinal anesthesia. Abstract presented Dutch Anesth Soc. 2009 9. Kober A, et al. Effectiveness of resistive heating compared with passive warming in treating hypothermia associated with minor trauma: A randomized trial. Mayo Clin Proc 2001; 76: 369-75 10. Negishi C, et al. Resistive-heating and forced-air warming are comparably effective. Anesth Analg 2003; 96:1683-7 11. Ng V, et al. Comparison of forced-air warming and			

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		electric heating pad for maintenance of body temperature during total knee replacement. Anaesthesia 2006; 61: 1100-04 12. Engelen S, et al. Resistive heating during off-pump coronary bypass surgery. Acta Anaesth Belg 2007; 58: 27-31 13. Sheck T, et al. Active warming of critically ill trauma patients during intrahospital transfer: A prospective, randomized trial. Wien Klin Wochenschr 2004; 116: 94-97			
Augustine Temperature Management LLC		The following statement at 1.4.3 is misleading: "One study found that even with using a resistive heating blanket patients still ended surgery in mild hypothermia." The comment suggests that the study involved an over-the-body blanket. In fact, the study involved an under-the-body heated pad. The difference is significant. The use of under body electrically conductive warming by itself is not supported in the published research as sufficient for maintaining normothermia. Over-body warming in general is more effective than under-body warming because, in addition to actively warming, it blocks the primary route for heat loss from the patient to the environment. The foam OR pad supporting the patient provides a much greater degree of thermal insulation than the drapes placed			Thank you. The wording used in the review reflects the wording used by the authors of the paper. Since the guideline is being updated any references to warming devices will be clear based on their mechanisms of action.

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		over the patient, and, therefore, the majority of body heat is lost from the upper surface of the patient. Over-body warming, therefore, has a greater net effect on the overall thermal energy balance of a patient than under body warming. However, a system capable of providing under- and over-body warming simultaneously would have the greatest effect on increasing core temperature.			
Augustine Temperature Management LLC		The conclusion, at 1.4.3, that "the majority of studies found that other types of warming devices were not inferior to FAW" seems to have carried little weight. The Review Committee seemed more impressed with the two decades of research confirming the effectiveness of forced-air warming. This attitude is detrimental to the interests of the NHS. Older, incumbent technologies will always have more published research than newer technologies. Simply comparing the quantities of published studies illogically favors the current norm and discourages innovation. The question should be whether the newer technology meets the threshold requirement of effectiveness.			Thank you. The studies that you refer to will be appraised and reviewed systematically in the update of the guideline to establish whether existing recommendations on patient warming should be changed.
Augustine Temperature Management LLC		In response to an inquiry about the safety of forced-air warming, the Committee stated that MHRA confirmed that there was no evidence to support the claims that forced-air warming was unsafe. This is inaccurate; there is ample evidence.			NICE have consulted with the MHRA and their response is as follows: 'We were asked to comment as to whether it was appropriate to

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		Please consider the following published studies: **Albrecht M, Leaper D et al: Forced Air Warming Blowers: An Evaluation of Filtration Adequacy and Airborne Contamination Emissions in the Operating Room.** ***American Journal of Infection Control,*** **May 2011.** 52 Bair Hugger blowers were sampled in their operating room environments. Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers. 58% of the Bair Hugger blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3 mm in size (germ size), up to 35,272 particles per ft3 of air (80 million particles per hour). The tested blowers had a filtration efficiency of 93.8%, which is consistent with the known efficiency of the "older rev C" Bair Hugger filters. Five of the "newer rev D" filters, however, were tested and showed a filtration efficiency of only 61.3%. **Leaper D, Albrecht M, Gauthier R: Forced-air warming: a source of airborne contamination in the operating room? Published in Orthopedic Rev.**			reconsider the guidelines regarding CG65. We assessed the existing guidelines and responded that as the guidelines stand they are fine with regards to the medical device regulation point of view. No device can be 100% safe, however, the clinical benefit should outweigh the potential risk for it to be used. The MHRA was not stating that forced air warmers are completely risk free, indeed we do get occasional reports of patient burns secondary to these devices we have not however had multiple reports of infection. The MHRA was stating that from a device regulation point of view and with regards to adverse incidents reported to ourselves we had nothing to add to the existing guidelines.'

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		2009; 3;1(2):e28. 25 Bair Hugger blowers were sampled in their operating room environment. Pathogenic bacteria were cultured from the internal airflow paths of 94% of the blowers. 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria. 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination." "…[F]indings in this study and those of others suggest that bacteria colonize the internal air path surfaces of the majority of FAW blowers. The findings also suggest that a significant percentage of FAW blowers are emitting particulates, which were shown to originate inside the blowers." "Clinicians should be aware that FAW blowers emit more than just hot air…".			
Augustine Temperature Management LLC		The Review Committee seems not to have considered the significant savings that would be available to the NHS if hospitals had the option of choosing reusable patient warming products rather than expensive disposables. The several UK hospitals that have switched from disposable forced-air warming to			Thank you. The review was based on a high level abstract review and so it was not possible to appraise the cost effectiveness of the patient warming products. The guideline will be updated and this issue will

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		reusable conductive fabric warming have experienced savings of 40% to 65%.			be considered.
Nordic Surgical Limited	Disagree	There is a good deal of evidence that resistive polymer warming blankets and mattresses transfer heat to patients as effectively as forced-air warming blankets. Currently, this market is dominated by a single company – a fact which has been brought into question by many procurement officers as most people are under the impression that a NICE Clinical Guideline is independent. The continued recommendation of one technology – in the face of direct and obvious evidence that other technologies work just as well surely flies in the face of NICEs independence, as CG65 effectively recommends a single commercial organization rather than a technology. Moreover, the interests of the NHS are not being served in any way. Recommendation on one hand that more and more warming needs to be carried out and on the other hand, recommendation of – essentially - one commercial organization only makes the demand on already compromised NHS budgets even more severe. Competition drives innovation. It also drives prices down. To use another cliché, necessity is the mother of invention and in this case, the necessity – already			Thank you. The guideline will be updated and this issue will be considered.

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		clarified by CG65 – is that IPH is avoided. Other technologies – now fully established – have been invented to answer this demand and if CG65 is to remain unaltered, the losers will be the patients (SSIs, reduced pain threshold, longer stays in hospital), the clinicians and the already strained budgets. The winners will be the commercial organization(s) already dominant in the Forced-Air market. FAW was developed more than 20 years ago. I doubt very much that anyone involved with CG65 would like a 20 year old surgical operation using 20 year old surgical instruments and technologies. In the last 20 years, 5 year survival from cancer has increased by over 68% (American Cancer Society). In the last 20 years, heart disease and stroke survival in Canada has increased by 50% (Heart & Stroke Foundation, Canada). Things have moved on significantly in the rest of the world during the period since FAW was invented. It's now time to let patients, clinicians and budgets benefit from that period of development and innovation. If independent studies have already concluded that other warming devices are 'not inferior' to FAW, then why is CG65 not being updated?			

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		A few examples: **Kimberger O, et al. Resistive polymer versus forced-air warming: Comparable heat transfer and core rewarming rates in volunteers. Anesth Analg 2008; 107: 1621-26** The full body HotDog blanket was compared with the full body Bair Hugger blanket in re-warming anesthetized hypothermic volunteers in a controlled cross-over study. The warming rates of the two technologies were virtually identical. **Brandt S, Kimberger O, et al. Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients. Anesth Analg 2010; 110:834-8.** 80 elective orthopedic surgery patients were randomized to upper-body FAW (Bair Hugger) or resistive polymer warming (HotDog) upper body blanket during surgery. The warming rates were comparable for the two groups. No differences in mean skin and mean core temperatures. "Resistive polymer warming performed as efficiently as FAW in patients undergoing orthopedic surgery." **Nguyen H, Kimberger O, et al. A New Underbody Resistive Warming Device vs. Forced Air Warming To Prevent Perioperative Hypothermia. A087. Presented at the**			

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		American Society of Anesthesiologists Annual Meeting, October 2010. 24 elective orthopedic surgery patients were randomized to upper-body FAW or resistive polymer warming (HotDog) with combined upper body blanket and underbody mattress during surgery. The warming results were nearly identical for the two groups. "The efficacy of resistive polymer warming with the HotDog resistive warming system was not inferior to an established FAW system in patients undergoing elective orthopedic surgery." The many hospitals in the UK who have – to my knowledge – successfully been using Conductive Polymer Warming for the last 2 years whilst saving a small fortune by not buying FAW blankets, not paying a levy to dispose of clinical waste and using equipment that draws only 10% of the power of a Forced Air Blower would, and have, questioned why NICE continues to maintain that there is a 'lack of evidence' that CPW is as good as the 20 + year old FAW. My company is the UK distributor for a Conductive Polymer warming device currently used across the UK in many Trusts. The technology behind the product I distribute is cleaner than FAW, greener than FAW and significantly less expensive than FAW.			

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		What's more is that it's been consistently demonstrated to be all of these things. However, one of the interesting things for NHS Trusts is the frankly enormous cost savings that can be achieved using an alternative to FAW. It's time that the Review Committee considered exactly how much money could be saved by using alternatives to FAW. An example using NICEs own figures: At NICE pricing, the additional spend preventing IPH costs £20624000 per year. Using an average cost of £11 per FAW disposable blanket, this means that there would be an additional 1874909 warming episodes per year. The total 5 year additional cost would be over £103million. The product we distribute would – according to independent studies - do exactly the same job. **However, it would only cost the NHS just over £25 million – but that is for ALL WARMING.** Not only does this produce **a saving of over £78 million** on the projected overspend, but it would most of the current spend as well – in total, a **saving of well over £100 million**. Let's be clear about this, **every single patient could be warmed** for over **£100 million less** as the			

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		technology is reusable. I would suggest that for this reason alone, the Review Committee would be in dereliction in their duty not to consider updating CG65 with more appropriate guidelines with regard to alternative warming technologies that have been proved to work. Stating that there is less evidence available to support a new technology than one that is over 20 years old is at best unhelpful and at worst, a total disregard for out-of-control NHS spending. Why would an independent body recommend that something needs to be done (preventing IPH), recommend that everyone does it (CG65) and then tell them that it will cost an extra £20 million without offering a cheaper solution? The evidence is already there – the technology works and is 'not inferior' to FAW. It's time to offer patients, clinicians and NHS Trusts the benefit of alternative 21st Century technology.			
Royal College of Nursing (RCN)	Disagree	The original guideline was commissioned in 2003 and although published in 2008, there may be more recent studies worthy of inclusion.	There is a huge gap in evidence pertaining to pre-warming patients and		Thank you. The guideline will be updated and new evidence will be considered. Consideration will also

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Perioperative Forum Steering Committee			the impact of this on IPH		be given to pre-warming during the scoping phase.
Royal College of Nursing (RCN) Perioperative Forum Steering Committee		While inclusion and exclusion criteria are clearly stated within the current guideline, a detailed methodology for sifting the evidence is not apparent.			It is not clear if your comment relates to the existing guideline or this review. In the existing guideline the methods used for sifting the evidence are clearly stated and are also given in detail in the methods manual. If your comment relates to the review of this guideline, the process and methods for guideline reviews is currently being evaluated as part of the guideline manual review. The process and methods will be out for public consultation as part of the Guideline Manual Update in January 2012. We would welcome your comments on this matter during the consultation.
Royal College of Nursing (RCN)		The NICE GDG consensus was that patients with a temperature <36°C should not be operated on until this was raised. The guideline is not explicit on what			This issue will be considered in the update of the guideline.

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Perioperative Forum Steering Committee		an acceptable rise is.			
Royal College of Nursing (RCN) Perioperative Forum Steering Committee		NICE included combined regional and general anaesthesia as a risk factor for hypothermia. Only the included Kongsayreepong study analysed the combined effect of these.			In areas where there is limited evidence, the GDG will develop recommendations based on their expert opinions. Any new evidence relating to combined regional and general anaesthesia will be considered in the update of the guideline.
3M /Arizant Healthcare	Agree	We agree there is no sufficient or significant evidence on warming methods, other than forced air warming, that warrant an update to CG65.			Thank you. In light of new evidence and issues raised by stakeholders, the original guideline will be updated.
3M /Arizant Healthcare		The benefits of pre-warming are numerous and known through clinical practice, although we agree that current evidence does not meet the Cochrane analysis standard.			Evidence relating to pre-warming will be considered in the update of the guideline.
3M /Arizant Healthcare		We have concerns about confusion that may be caused when the MTA guidance on the use of the Inditherm warming system is published (should the recommendations remain the same as the draft). The discrepancy between the decision not to review CG65, due to a lack of sufficient evidence, and a positive statement about the use of Inditherm, may be confusing for the NHS. We would welcome			The guideline will be updated and any discrepancies between the guideline and other guidance issued by NICE will be addressed.

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		clarification on how NICE will communicate this apparent discrepancy to the NHS.			
Medicines and Healthcare products Regulatory Agency (MHRA)	AGREE	Having read and discussed CG65, Dr Nicola Lennard and I agree no update is required.	None	None	Thank you. In light of new evidence and issues raised by stakeholders, the original guideline will be updated.
GDG member	Agree	I have recently returned from holiday and have not had sufficient time to view the studies listed and to assess the methodology and quality. Hence I have drawn my conclusions from the consultation document. The original Guideline states: "***It is important to prevent inadvertent perioperative hypothermia. Although there are several different types of patient warming devices available that can be used for prevention, the evidence for many of these was too limited for recommendations to be made, and further research in this area is required. There was sufficient evidence of clinical effectiveness and cost effectiveness for recommendations to be made on the use of forced air warming to prevent perioperative hypothermia and treat perioperative***			Thank you. In light of new evidence and issues raised by stakeholders, the original guideline will be updated.

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		hypothermia" A number of recent studies (including comparative studies) have been quoted on other warming systems, but the conclusions stated are inconsistent. However there is evidence of clinical effectiveness. I agree that with regard to warming devices/mechanisms the evidence does not mandate any change to the Guideline recommendations. Further research, especially comparative trials, is still needed to define which systems (Both singly and in combination) are the most clinically and cost effective work for pre, peri, and post operative applications and for particular procedures.			
GDG member		One concern is that there is very little consideration of resistive warming. Furthermore there are studies that haven't apparently been considered. For example: " Anesth Analg. 2008 Nov;107(5):1621-6. Resistive polymer versus forced-air warming: comparable heat transfer and core rewarming rates in volunteers. Kimberger O, Held C, Stadelmann K, Mayer N, Hunkeler C, Sessler DI, Kurz A." I find this particularly odd given the positive outcome of the recent NICE technology review of the Inditherm resistive warming device.			Thank you for your comments. Resistive heating was considered in this review, and at least 4 studies were identified. The studies examining resistive heating devices compared them to forced air warming devices, and so their results were summarised in the forced air warming section of the consultation paper. This may appear unclear and that little consideration has been given to

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					resistive warming, but this is in part due to the brevity of the consultation document that precludes a more in depth description of the studies, and partly because the review was based on examination of abstracts, where only a high level overview of the study's results were reported. This issue will be addressed in the update of the guideline, where systematic reviews using full text papers will extract the information that is necessary in order to give adequate consideration to all relevant warming devices. The resistive heating study that you refer to focused on healthy volunteers, rather than patients, and was therefore excluded from the review in line with the original guideline protocol which also only considered studies from a patient population.
GDG member		Although a bit pedantic I think, especially given the Inditherm assessment, that a distinction should be made between blankets and mattresses as there are			The terminology used to refer to the various warming devices was the terminology used by the study

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		potentially significant differences in their performance (I have recruited around 120 patients to a study comparing FAW and Inditherm mattress but still need another 40). And I think it is important that this comes out in the text. For example, the resistive device in reference 17 is referred to as a blanket but in fact is an 'under-patient blanket' which is, of course, a mattress.			authors. Any potentially confusing terminology will be addressed during the update of the guideline
GDG member		Regarding heated fluids, there is an inaccuracy in the text: "that pre-warmed fluid is effective at preventing perioperative hypothermia regardless of whether it is heated to room temperature through a warming cabinet or whether it is delivered at room temperature through an inline warming system (29)." Fluids are not heated to room temperature because that is the temperature they are stored at. They are heated to around 37-40˚C before administration.			Thank you for pointing out the inaccuracy in the text. This will be corrected in any subsequent references to the study in the update of the guideline.
GDG member		There is another inaccuracy in this section as well (it seems that only the abstracts have been read): "that the warming of intravenous fluids by using the Hotline system prevents decreases in systemic temperatures during off pump coronary bypass surgery (27) " This article actually shows that the hotline prevents			Thank you for pointing out the inaccuracy. The review process only assesses abs tracts without conducting a full systematic review. The process and methods of guidelines review are being evaluated and will be out for public consultation as part of the

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		hypothermia ***in combination with a high (25˚C) ambient operating room temperature and a circulating water mattress.***			Guideline Manual Update in January 2012. We would welcome any comments on these methods during the consultation.
GDG member		You mention an ongoing study that is one of mine: Carbon Polymer Blankets to Prevent Incidence Of Perioperative Hypothermia (IPH) in the DSU (anticipated end date: unknown) Its anticipated end date is January 2012.			Thank you.
GDG member		I think the document misses a vital point in that, even if alternative devices are no better than forced-air warming, individual circumstances and financial considerations may mean that they work better in some institutions. Thus they should not, as they broadly are, be dismissed. Even if the evidence is not yet conclusive, I think it would be reasonable to point out that there is an increasing evidence base that suggests alternatives may be equally effective and could therefore be considered. This, and the fact that there are studies that, as far as I can see, should have been included have been completely missed, are my main concerns with this document. I am also very concerned that there has been an inaccurate reading of at least two papers: has a clinician with experience in this area been involved in the review at all?			The issues that you raise will be addressed in the update of the guideline. Part of the review process is to discuss the conclusions with either the GDG chair, clinical advisor or relevant GDG member as appropriate.