NICE National Institute for Health and Care Excellence

NICE guidance

Inditherm patient warming mattress for the prevention of inadvertent hypothermia

Medical technology guidance

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nice.org.uk/guidance/mtg7

Contents

1 Recommendations

NICE medical technologies guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

NICE clinical guideline 65 (Inadvertent perioperative hypothermia: the management of inadvertent perioperative hypothermia in adults, published April 2008) recommends that each patient undergoing anaesthesia should be assessed for risk of inadvertent perioperative hypothermia, and forced air warming used where indicated to keep patients warm. This medical technology guidance does not supersede the clinical guideline but addresses the case for adoption of the Inditherm patient warming mattress as an alternative to forced air warming.

1.1 The case for adopting the Inditherm patient warming mattress in the NHS is supported by the evidence. The clinical evidence suggests that the effectiveness of the Inditherm patient warming mattress in maintaining patient core body temperature above 36°C is similar to that of forced air warming, and that the Inditherm mattress may have practical advantages.

1.2 The Inditherm patient warming mattress should be considered for use in patients undergoing operations that carry a risk of inadvertent hypothermia.

1.3 The annual cost saving when the Inditherm patient warming system is compared with forced air warming is estimated to be £9800 per operating theatre (assuming that all eligible patients are warmed). This is based on an annual cost of £1300 for an Inditherm patient warming system comprising one full-length and one half-length mattress, two blankets and three controllers, and including maintenance costs.

2 The technology

Description of the technology

2.1 The Inditherm patient warming mattress (Inditherm plc) uses flexible, carbon-based conductive polymer technology that aims to generate a uniform, direct heating surface. It is a low voltage, reusable device that does not require disposable products. The temperature of the mattress is maintained by a control unit and is user-selectable where appropriate. To prevent over-heating, there is an alarm and an automatic over-temperature shut-off. The control unit can be mounted on an intravenous infusion pole or an anaesthetic trolley.

2.2 The mattress polymer is combined with a viscoelastic foam pad which is designed to mould itself to the shape of the patient. Pressure-relieving pads are integrated under the heating surface. The mattress is covered in a latex-free, nylon fabric cover with non-microporous polyurethane coating and welded seams.

2.3 The Inditherm mattress has been tested and certified as compliant with the relevant international standard on safety and performance requirements for heating devices using blankets, pads or mattresses that are intended for warming in medical use. This standard requires that the mattress is tested to ingress protection specification IPX2 (ingress limit is dripping water: 15° tilt).

2.4 The Inditherm polymer technology is used to make a range of warming mattresses and blankets. These can be used in different combinations (the Inditherm patient warming system) to achieve the desired warming effect. In this evaluation clinical effects were considered for use of the mattress alone, but the cost model was based on an Inditherm warming system with mattresses and blankets of various sizes and controller units.

2.5 The Inditherm mattress can be used on its own, with additional Inditherm blankets or with other warming methods such as forced air warming.

Current management

2.6 NICE clinical guideline 65 Inadvertent perioperative hypothermia recommends forced air warming should be used for all patients undergoing anaesthesia for

longer than 30 minutes and for patients at higher risk of inadvertent perioperative hypothermia undergoing anaesthesia for less than 30 minutes.

3 Clinical evidence

Summary of clinical evidence

3.1 The clinical effectiveness of the Inditherm mattress has been assessed by the maintenance of patient core body temperature above 36°C (NICE clinical guideline 65 defines hypothermia as a core body temperature of below 36°C).

3.2 The clinical effectiveness of the Inditherm mattress was examined in five studies: one randomised controlled trial (RCT; Wong et al. 2007), two unpublished RCTs (Satheesan et al: conference abstract 2006; Baxendale et al. 2000), one pilot RCT (Harper and Crook 2010) and one non-randomised comparative study (Engelen et al. 2007). Data from 14 summary reports of audits carried out in 10 UK hospitals were also assessed.

3.3 The one published RCT (Wong et al. 2007) compared combined use of the Inditherm mattress and forced air warming (intervention group) against forced air warming (with an Inditherm mattress in place but not switched on – control group) for patients undergoing elective major abdominal surgery. In the intervention group (n = 47), the Inditherm mattress was switched on 2 hours before surgery and was used throughout the procedure and for up to 2 hours afterwards. In the control group (n = 56), the Inditherm mattress was not switched on at any time. Both groups received forced air warming during surgery. Core body temperature was monitored using a tympanic thermometer. After preoperative warming, core body temperature was higher in the intervention group (median 36.4°C, range 35.1–37.4°C) than in the control group (median 36.0°C, range 35.1–36.9°C). Postoperative core body temperatures were above 36°C for both groups and not significantly different.

3.4 A conference abstract reported preliminary results (n = 21) from an RCT that compared the use of the Inditherm warming system (intervention group) with no warming (control group) for surgical patients during the initial admission phase in A&E (Satheesan et al. 2006). The patient inclusion criteria for the RCT were surgical patients considered at risk of inadvertent perioperative hypothermia: adults presenting to A&E with abdominal pain or with a suspected fractured neck or femur, and older adults (> 65 years) presenting to A&E with falls. After the patients were randomised, both the intervention group (n = 11) and the control group (n = 10) included seven patients who were hypothermic

on arrival at A&E. On transfer from A&E, none of the patients in the intervention group were hypothermic compared with one patient in the control group. After transfer from A&E to the admission ward, none of the patients in the intervention group were hypothermic compared with four patients in the control group. The authors concluded that systemic warming of 'at risk' surgical patients during their initial admission phase in the A&E department appeared to increase their core body temperature and prevent hypothermia.

3.5 One abstract reported results from an unpublished RCT (n = 80) that compared the Inditherm mattress with forced air warming during major abdominal or orthopaedic surgery (Baxendale et al. 2000). Core body temperature was monitored using an oesophageal temperature probe. Apart from an initial drop in core body temperature, a graph showing the change in temperature at 15-minute intervals during surgery indicated that the two groups were comparable throughout the study period.

3.6 A pilot RCT (n = 40) compared the Inditherm mattress with forced air warming in patients undergoing surgery in the supine position under general anaesthetic (Harper and Crook 2010). Core body temperature was monitored using a temporal artery thermometer throughout the operation and an oesophageal probe during anaesthesia. Of 19 patients warmed with the Inditherm mattress, one (5.3%) was hypothermic on arrival at the recovery room compared with 1 of 21 (4.8%) patients who received forced air warming. The authors concluded that there was no evidence of a difference in effectiveness between the two methods of warming, but stated that they are conducting further studies comparing the Inditherm mattress with forced air warming.

3.7 A randomised, non-comparative study compared the combined use of forced air warming and the Inditherm mattress against forced air warming alone in patients undergoing off-pump coronary artery bypass (OPCAB) surgery (Engelen et al. 2007). Core body temperature was monitored by measuring nasopharyngeal and rectal temperatures. A cohort of ten patients who received additional warming with the Inditherm mattress during surgery (intervention group) had higher core body temperatures than the cohort of ten patients who received forced air warming alone (control group). At the end of the 4-hour study period, mean rectal temperatures were 36.1 ± 0.6°C and 34.9 ± 0.6°C ($p < 0.01$) for the intervention and control groups respectively. The authors of this study concluded that the combined use of the Inditherm mattress and

forced air warming resulted in higher patient core body temperatures during OPCAB surgery than forced air warming alone.

3.8 The 14 audit studies covered a range of surgical specialties including gynaecology, orthopaedics, urology and general surgery. The number of patients included in each study ranged from 5 to 146 (total number of patients in all the studies was 398). Core body temperature was measured using tympanic membrane, nasopharyngeal or oesophageal probes. The mean final temperature in all 14 audit studies using the Inditherm mattress was above 36°C. Six of the audit studies, which included a total of 116 patients, recorded a lowest final temperature above 36°C, indicating that no cases of hypothermia were recorded. In the other eight audit studies, which included a total of 282 patients, the lowest final temperature fell below 36°C in 19 patients by the end of surgery or in the recovery room.

Committee considerations

3.9 The Committee considered that the clinical evidence supported the effectiveness of the Inditherm mattress in maintaining patient body core temperature above 36°C for patients undergoing operations. In particular, the evidence suggested that the effectiveness of the Inditherm mattress was similar to that of forced air warming

3.10 The Committee considered expert advice that no single warming device is effective at warming all patients.

3.11 Based on description of the technology, expert advice and audit data, the Committee considered that the Inditherm mattress (and Inditherm patient warming system) was likely to offer practical advantages compared with forced air warming.

3.12 The Committee considered that more research relating clinical outcomes of inadvertent hypothermia to observed variation in core body temperature would be valuable to determine critical temperature thresholds.

3.13 The Committee noted that evidence on rewarming patients (which is distinct from preventing inadvertent hypothermia) was outside the scope of this guidance. Evidence on rewarming was not considered.

4 NHS considerations

System impact

4.1 Avoidance of inadvertent hypothermia has been demonstrated to reduce the incidence of postoperative infections, with consequent savings in cost to the NHS.

4.2 The Inditherm mattress can be left in place on an operating table throughout a theatre operating list with low running costs. This may allow faster turnaround times for patients compared with the use of forced air warming.

4.3 The Inditherm mattress is a reusable device and no consumables are needed. This limits the need for disposal of consumables and any impact that might have on the environment.

4.4 The Inditherm mattress is silent, has low energy consumption and specifically warms the patient without inadvertently warming the surgical team.

Committee considerations

4.5 The Committee considered that the clinical evidence supported the effectiveness of the Inditherm mattress in maintaining core body temperature and therefore, preventing inadvertent hypothermia. The Committee was advised by clinical experts that it was reasonable to assume that the prevention of inadvertent hypothermia would result in a decrease in surgical site infections, as demonstrated for forced air warming. Direct evidence showing that the use of the Inditherm mattress reduces the incidence of surgical site infections, compared with not warming, was not available. It is unlikely that such research would now be conducted, because the advantages of keeping patients warm are known.

4.6 The Committee considered the claims for practical advantages of the Inditherm mattress compared with forced air warming to be plausible and likely to be realised in clinical practice.

4.7 The Committee recognised that availability of the Inditherm warming mattress would be likely to result in more patients being warmed during surgery than in

current practice. It noted that the mattress can be left switched on, so that increased use would not require increased staff or time.

4.8 Mindful of possible transmission of infection, the Committee asked the expert advisers and the manufacturer about cleaning the Inditherm mattress between patients. It was told that the mattress is cleaned in the same way as the normal operating table mattress. The Committee also enquired in detail about the durability of the mattress and the possibility that damage to mattresses might allow fluid ingress. It was sufficiently reassured on all these points.

4.9 The Committee questioned whether warming areas of the body with poor perfusion (for example, warming the legs when arterial perfusion is reduced during vascular procedures) might lead to thermal injury. It was advised that mattresses of different sizes are available which means that warming poorly perfused areas can be avoided. The Committee recognised that clinical judgement is required to select Inditherm mattresses and blankets of appropriate size for individual patients.

4.10 The Committee considered that there was no evidence to suggest that the use of the Inditherm patient warming mattress had caused harm to patients, although it noted expert advice that thermal injury was a theoretical risk (for example, as a result of pooling of surgical antiseptic preparations).

4.11 The Committee considered that the Inditherm mattress offers a practical means of maintaining core body temperature during procedures done under X-ray guidance, including endovascular aneurysm repair. It noted that testing showed that image quality was not significantly affected when the Inditherm mattress was used, and was advised that a potential 15% increase in radiation dose associated with use of the warming blanket was not clinically significant.

4.12 The Committee was advised that the connection rails, sensors and wiring down the sides of the mattress could interfere with imaging if X-rays were used at certain oblique angles.

5 Cost considerations

Cost evidence

5.1 The annual cost of the Inditherm patient warming system in the cost model was approximately £1300 per operating theatre. The cost of the patient warming system includes one full-length mattress, one half-length mattress, two blankets and three controllers. This combination represents the maximum number of components in an Inditherm patient warming system, which can consist of a combination of Inditherm mattresses, patient warming blankets and control units. The maintenance cost and likely costs of repairs are also included in the annual cost.

5.2 The cost of the Inditherm patient warming system used in the initial cost model was based on the cost of an 'average' system (as proposed by the manufacturer) calculated using the proportions and list prices of the different-sized mattresses, blankets and control units purchased in the NHS in a recent 6-month period. Additional analyses were undertaken by the External Assessment Centre to calculate the overall costs of the Inditherm system using the minimum and maximum number of mattresses, blankets and controllers needed for an operating theatre. These revised costs were used to calculate the annual cost per theatre and cost savings associated with use of the Inditherm patient warming system.

5.3 The economic evidence comprised the costing report for Inadvertent perioperative hypothermia (NICE clinical guideline 65), which modelled the costs and consequences of using forced air warming versus no warming, and a new cost model assessing the costs and savings to the NHS of using the Inditherm patient warming system.

5.4 The cost model compared the Inditherm patient warming system with forced air warming using data from the costing report for NICE clinical guideline 65 and capital, maintenance and repair costs for the Inditherm patient warming system. The cost model assumed equivalence of clinical outcomes.

5.5 The initial cost model was based on a unit cost of forced air warming of £15 (as stated in the costing report for NICE clinical guideline 65). The External Assessment Centre updated the unit cost to allow for 10% wastage of

consumables because of damage, which resulted in an increased unit cost of £17. The cost of forced air warming per theatre was calculated using the annual number of surgical procedures undertaken in England that involved general anaesthetic for longer than 30 minutes; this was estimated to be 2 million procedures based on 2006/07 Hospital Episodes Statistics data. The annual total cost of forced air warming was divided by the number of operating theatres in England (3030) to calculate an average annual cost per theatre.

5.6 In the cost model it is assumed that the Inditherm patient warming system is used in place of forced air warming in the 2 million surgical procedures. The average annual cost saving associated with use of the Inditherm patient warming system is estimated to be £9800 per theatre, assuming all eligible patients are warmed. This is based on the average annual cost of £1300 for the Inditherm patient warming system and an average annual cost of forced air warming of £11,100.

5.7 The cost of using the Inditherm system in surgical settings with no warming was calculated using data from NICE clinical guideline 65. This calculation assumed that 3% of surgical patients without warming will develop a surgical site infection, the base case annual cost of treating surgical site infections is approximately £12,350 per theatre and the estimated reduction in surgical site infections by warming surgical patients is 25%. Therefore, the estimated net annual cost saving of using the Inditherm patient warming system versus no warming is £7250 per theatre. This is based on the average annual cost of £1300 for the Inditherm patient warming system and an annual cost of fluid warming of £3800 per theatre. It is assumed that fluid warming is performed in conjunction with all patient warming methods as outlined for forced air warming in NICE clinical guideline 65.

5.8 The cost of ordering, transporting, processing and stocking consumables was not included in the cost analysis for the Inditherm patient warming system or for forced air warming. Energy costs and the cost of disposal of consumables were not included. No additional staff or other NHS resources are needed for the use of the Inditherm patient warming system compared with forced air warming.

5.9 The sensitivity analysis found the cost savings to be robust to fluctuations in the price of forced air warming. The unit cost of forced air warming would need an

eight-fold reduction for the use of the Inditherm system to no longer be cost saving.

Committee considerations

5.10 The Committee considered that the predictions of cost saving from the use of the Inditherm patient warming system compared with the use of forced air warming were credible and were likely to be achieved in practice.

5.11 The Committee noted that the cost model included purchase of a number of components of the Inditherm patient warming system in addition to the mattress, and so considered that cost savings predicted by the model might be an underestimate.

5.12 The Committee was advised that the Inditherm mattress might be used in combination with forced air warming, with the aim of additional patient benefit. However, the costs of that combined approach were not available.

6 Conclusions

6.1 The Committee concluded that the available clinical and cost evidence supported the case for adopting the Inditherm patient warming mattress in the NHS for patients undergoing operations which carry risk of inadvertent hypothermia.

7 Implementation

7.1 NICE has developed tools to help organisations put this guidance into practice (listed below).

- Slides highlighting key messages for local discussion.
- Costing template and report to estimate the national and local savings and costs associated with implementation.
- Podcast with Dr Mark Harper (Lead Expert Adviser for the Medical Technologies Advisory Committee) discussing use of the Inditherm mattress in practice.
- Factsheet with information on the practical and technical considerations when using the Inditherm mattress.

8 Related NICE guidance

Published

- Perioperative hypothermia (inadvertent): management of inadvertent perioperative hypothermia in adults. NICE clinical guideline 65 (2008).
- Surgical site infection: prevention and treatment of surgical site infection. NICE clinical guideline 74 (2008).

Andrew Dillon
Chief Executive
August 2011

Appendix A. Committee members and NICE lead team

A Medical Technologies Advisory Committee members

The Medical Technologies Advisory Committee is a standing advisory committee of NICE. A list of the Committee members who took part in the discussions for this guidance appears below.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each Medical Technologies Advisory Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Professor Bruce Campbell (Chair) Consultant Vascular Surgeon, Exeter

Dr Peter Groves (Vice Chair) Consultant Cardiologist, Cardiff and Vale NHS Trust

Dr Dilly Anumba Senior Clinical Lecturer/Honorary Consultant Obstetrician and Gynaecologist, University of Sheffield

Ms Susan Bennett Lay member

Professor Bipin Bhakta Charterhouse Professor in Rehabilitation Medicine and NHS Consultant Physician, University of Leeds

Dr Keith Blanshard Consultant Radiologist, Leicester Royal Infirmary

Dr Martyn Bracewell Senior Lecturer in Neurology and Neuroscience, Bangor University

Dr Daniel Clark Head of Clinical Engineering, Nottingham University Hospitals NHS Trust

Professor Karl Claxton Professor of Economics, University of York

Mrs Gail Coster Radiography Manager, Strategy, Planning and Governance, Yorkshire NHS Trust

Dr Craig Dobson General Practitioner and Senior Lecturer in Medical Education and General Practice, Hull York Medical School

Dr Alex Faulkner Senior Research Fellow, Centre for Biomedicine & Society, King's College London

Professor Tony Freemont Professor of Osteoarticular Pathology, University of Manchester

Professor Peter Gaines Consultant Interventional Radiologist, Sheffield, Vascular Institute and Sheffield Hallam University

Mr Harry Golby Head of Commissioning, Acute, Access and Diagnostics, Salford NHS

Mr Matthew Hill Lay member

Dr Paul Knox Reader in Vision Science, University of Liverpool

Ms Catherine Leonard Reimbursement Manager, Medtronic UK

Dr Susanne Ludgate Clinical Director, Devices Medicines and Healthcare Products Regulatory Agency

Professor Christopher McCabe Professor of Health Economics, Institute of Health Sciences, University of Leeds

Mrs Jacqui Nettleton Programme Director, Long Term Conditions, West Sussex PCT

Professor Sharon Peacock Professor of Clinical Microbiology, University of Cambridge

Dr Allan Swift Director of Quality and Regulatory Affairs, Gen-Probe Life Sciences

Professor Stephen Westaby Consultant Cardiac Surgeon, John Radcliffe Hospital, Oxford

Dr Janelle York Lecturer and Researcher in Nursing, University of Salford

B NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a non-expert member of the Medical Technologies Advisory Committee and a representative of the External Assessment Centre.

Sarah Baggaley Technical Analyst

Lizzy Latimer Technical Adviser

Dr Mark Harper Lead Expert Adviser

Dr Keith Blanshard Non-Expert MTAC Member

Ms Rebecca Gossage-Worrall External Assessment Centre Representative

Appendix B: Sources of evidence considered by the Committee

A The External Assessment Centre report for this assessment was prepared by Healthcare Innovation and Technology Evaluation Centre (HITEC):

- Gossage-Worrall R, Craven M, Clift M, et al. Inditherm patient warming mattresses. October 2010.

B Submissions from the following sponsor:

- Inditherm plc

C The following individuals gave their expert personal view on Inditherm patient warming mattress for the prevention of inadvertent hypothermia by providing their expert comments on the draft scope and assessment report.

- Dr Mark Harper, nominated/ratified by Royal College of Anaesthetists – clinical expert
- Dr John Andrzejowski, nominated/ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert

D The following individuals gave their expert personal view on Inditherm patient warming mattress in writing by completing a patient questionnaire or expert adviser questionnaire provided to the Committee.

- Dr Mark Harper, nominated/ratified by Royal College of Anaesthetists – clinical expert
- Dr John Andrzejowski, nominated/ratified by Association of Anaesthetists of Great Britain and Ireland – clinical expert

About this guidance

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This 'case' is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

This guidance was developed using the NICE medical technologies guidance process.

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes after publication
April 2015: minor maintenance

February 2013: minor maintenance.

April 2012: minor maintenance.

Your responsibility
This guidance represents the views of NICE and was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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