NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

HumiGard for preventing inadvertent perioperative hypothermia

The National Institute for Health and Care Excellence (NICE) is producing guidance on using HumiGard for preventing inadvertent perioperative hypothermia in the NHS in England. The medical technologies advisory committee has considered the evidence submitted and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the draft recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence base (see Sources of evidence considered by the committee).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

Note that this document is not NICE's final guidance on HumiGard for preventing inadvertent perioperative hypothermia**. The recommendations in section 1 may change after consultation.** After consultation the committee will meet again to consider the evidence, this document and comments from public consultation. After considering these comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the Medical Technologies Evaluation Programme process guide and Medical Technologies Evaluation Programme methods guide.

Key dates:

- Closing time and date for comments: 09:00 Tuesday 04 October 2016
- Third medical technologies advisory committee meeting: 21 October 2016

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. 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. The medical technology guidance on 'HumiGard for preventing inadvertent perioperative hypothermia' recommends further research. This recommendation is not intended to preclude the use of the technology in the NHS but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Provisional recommendations

1.1 HumiGard shows promise for preventing hypothermia during abdominal surgery. There is, however, insufficient robust evidence to support the case for routine adoption, particularly on how using HumiGard may avoid important adverse outcomes and its impact on resource use in open and laparoscopic surgery.

1.2 Research is recommended on HumiGard compared with standard approaches to insufflated gases in patients having laparoscopic and open surgery and who also receive general measures to reduce the risk of perioperative hypothermia (see section 2.5). This should report on the comparative rate of surgical site infections and other complications associated with hypothermia and normothermia, as well as related resource use.

2 The technology

Description of the technology

2.1 HumiGard (Fisher and Paykel Healthcare) is designed to humidify and heat carbon dioxide (CO_2) gas, which is routinely used to fill the peritoneal cavity during laparoscopic abdominal surgery. The intention is to reduce the negative effects associated with the use of dry, unwarmed CO_2 gas, namely tissue desiccation and intra-operative hypothermia. HumiGard is designed to be used both independently and in addition to other warming measures that are

applied to the external body surfaces and extremities, such as forced air warming. HumiGard comprises a humidifier and consumable tubing set. It humidifies and warms the CO_2 by passing the gas over a reservoir of water. The heated, humidified gas is then passed along a sterile tube for delivery into the abdominal cavity through a needle cannula. HumiGard can also be applied to open surgical wounds using a bespoke patient interface diffuser to effectively immerse the open surgical wound cavity in warmed, humidified CO_2 gas.

2.2 HumiGard received a class IIa CE mark in April 2013. It is indicated for use in laparoscopic or open abdominal surgery where CO_2 insufflation gas is used.

2.3 The list prices (excluding VAT) for the components of HumiGard are as follows.

- Capital costs:
  - MR860AEU humidifier: £895
- Consumables:
  - For laparoscopic surgery: ST310 humidified and heated tubing kit: £75 per patient.
  - For open surgery: ST310 humidified and heated tubing kit plus VITA diffuser (ST300 DF): £99 per patient.

2.4 The claimed benefits of HumiGard in the case for adoption presented by the company are:

- Decreased incidence of intra-operative and post-operative hypothermia through less evaporative cooling.
- Decreased incidence of surgical site infections because of improved intra-operative temperature maintenance.
- Improved post-operative recovery and faster discharge.

- Reduced overall costs as a result of better patient outcomes including fewer surgical site infections, less time spent in hospital for surgery, and less time in post-operative recovery.

Current management

2.5 The NICE guideline on inadvertent perioperative hypothermia recommends that all patients intended for surgery be assessed for risk of perioperative hypothermia. All patients should receive warmed intravenous fluids and blood products; patients identified as being at higher risk should be warmed intraoperatively using a forced air warming device, as should any patient having anaesthesia for more than 30 minutes. Regular temperature measurement is recommended before, during and after surgery, and forced air warming is recommended for any patient whose core temperature drops below 36°C.

2.6 NICE's inadvertent perioperative hypothermia guideline relates to the general prevention of hypothermia during surgery and does not make any specific recommendations about the warming of insufflation gas. Unwarmed, dry insufflant gas is used routinely in laparoscopic surgery.

2.7 NICE medical technologies guidance on the Inditherm patient warming mattress recommends this device as a cost-effective alternative to forced air warming.

3 Clinical evidence

Summary of clinical evidence

3.1 The key clinical outcomes for HumiGard presented in the decision problem were:

- incidence of hypothermia during and after surgery (defined as a core body temperature of less than 36^{o}C)
- incidence of surgical site infections

- length of stay in post-operative recovery
- total length of hospital stay
- device-related adverse events
- patient-reported pain.

3.2 The company carried out separate literature searches for laparoscopic and open surgery, encompassing both published and unpublished studies. Its submission included 24 studies, 20 involving laparoscopic surgery and 4 involving open surgery. The company used a checklist to determine if studies were generalisable and presented 16 (of the total 24) involving other humidification devices. The external assessment centre (EAC) considered that humidification systems other than HumiGard were beyond the scope of the evaluation and that those 16 studies should be excluded. The EAC's independent literature searches did not identify any additional studies on HumiGard. It judged that 7 studies provided relevant evidence: 5 on laparoscopic surgery (Herrmann and De Wilde 2015, Manwaring et al. 2008, Sammour et al. 2010, Yu et al. 2013 and Mason et al. 2016) and 2 on open surgery (Frey et al. 2012 and Weinberg et al. 2014).

Laparoscopic surgery

3.3 Hermann and De Wilde (2015) reported on a double-blind randomised controlled trial that compared HumiGard with unwarmed, dry CO_2 gas in patients aged 18 years or over with benign uterine diseases having gynaecological laparoscopic surgery. Randomisation led to 52 patients receiving warm (35±2°C), humidified (98% humidity) CO_2 via HumiGard and 52 patients receiving standard room temperature, dry (0% humidity) CO_2. The primary outcome was post-operative pain at 2, 4, 6, 24 and 48 hours as measured by a visual analogue scale (VAS). Secondary outcome measures were morphine consumption, patient rejected boli postoperatively (because it was not needed), temperature change during surgery, length of time spent in the

recovery room and length of inpatient stay. The results showed a significant difference in total shoulder tip pain (p=0.037) but no statistically significant difference in any of the other outcome measures specified in the scope.

3.4 Manwaring et al. (2008) reported on a randomised controlled trial that compared HumiGard with unwarmed, dry CO_2 gas in women aged 18 to 55 years having gynaecologic laparoscopic surgery. Randomisation led to 30 patients receiving warmed, humidified CO_2 with HumiGard, and 30 patients receiving standard room temperature, dry CO_2. The primary outcome was shoulder tip pain at 4 hours after surgery. Secondary outcome measures were time in recovery room, nausea, post-operative temperature and pelvic pain. The results showed a significant difference in change in core temperature from theatre to recovery (p=0.027) but no other statistically significant difference in the other outcome measures specified in the scope.

3.5 Sammour et al. (2010) reported a double-blind randomised controlled trial that compared HumiGard with unwarmed, dry CO_2 gas in patients aged 15 years or older having elective laparoscopic colonic resection. Randomisation led to 41 patients receiving warm (37^oC), humidified (98% humidity) CO_2 via HumiGard, and 41 patients receiving room temperature, dry CO_2. The primary outcome was total opiate analgesia used during inpatient stay. Secondary outcome measures were post-operative pain (measured on a VAS) at 2, 4, 8 and 12 hours and 1, 2, 3, 7, 14, 30 and 60 days after the operation. Other secondary outcome measures were intra-operative core temperature, cytokine response and length of inpatient stay. Six patients in the HumiGard group and 2 in the control group were excluded from the analysis with reasons given. The results showed that HumiGard had a significant effect on post-operative pain at rest on day 1 (p=0.01) and post-operative pain on moving on day 1 (p=0.018). The results showed no statistically

significant difference in the other outcome measures specified in the scope.

3.6 Yu et al. (2013) reported on a double-blind randomised controlled trial that compared HumiGard with unwarmed, dry CO_2 gas in children aged 8 to 14 years having an acute laparoscopic appendectomy. Randomisation led to 95 patients receiving warm (37^oC), humidified (98% humidity) CO_2 with HumiGard and 95 patients receiving room temperature, dry CO_2. The primary outcome was post-operative pain (analgesic use) in the recovery room and at days 1 and 2 after the operation. Secondary outcome measures were pain intensity scores, intra-operative core temperature and post-operative recovery and return to normal activities. Two patients in the HumiGard group and 3 in the control group were excluded from the analysis with reasons given. The authors provided only graphical data for pain perceived at rest and on moving (VAS), but no differences were reported between the groups at any of the time points studied (0, 2, 4, 6, 8, 10, 12, 24 and 48 hours). The results showed no statistically significant difference in the other outcome measures specified in the scope.

3.7 Mason et al. (2016) was described as a retrospective cohort trial undertaken in the UK, including patients having laparoscopic colorectal resections. The outcome measures include incidence of surgical site infections, perioperative hypothermia and cost. The study was submitted as an unpublished manuscript which was available to the committee as academic in confidence.

Open surgery

3.8 Frey et al. (2012) reported on a randomised controlled trial that compared HumiGard with no insufflation in patients over 18 years (mean age 63.5 years) having elective open colonic surgery. Randomisation led to 42 patients receiving warm (37^oC), humidified (100% humidity) CO_2 gas via HumiGard and 41 patients receiving

no insufflation. The primary outcome was intra-operative core and wound temperature and the secondary outcome measure was length of hospital stay. Two patients in the HumiGard group and 2 in the control group were excluded from the analysis with reasons given. The results showed significant benefits for the HumiGard group in terms of the proportion of patients with core temperature <36.0°C at end of surgery (p=0.005), the proportion of patients with core temperature <36.5°C at end of surgery (p=0.001), reduced core temperature at end of surgery (p=<0.001), reduced core temperature during surgery (p=<0.001), reduced wound area temperature during surgery (p=<0.001) and reduced wound edge temperature during surgery (p=<0.001). The results showed no statistically significant difference between the groups for length of stay.

3.9 Weinberg et al. (2014) reported on a prospective pilot randomised controlled trial published as an abstract that compared HumiGard and standard care (predetermined temperatures for infused fluid, ambient air and heating mattress temperature) with standard care alone in adult patients having primary orthotopic liver transplantation. No details were provided regarding number of patients in each group , but 22 patients were randomised to the intervention or control. The primary outcome was intra-operative core temperature before reperfusion and at completion of surgery. No secondary outcomes were reported. The core temperature immediately before reperfusion (°C, via nasopharyngeal probe) was significantly higher in the HumiGard group (p=0.02). No statistically significant differences were reported for core temperature on wound closure (°C, via nasopharyngeal probe), core temperature immediately before reperfusion (°C, via pulmonary artery catheter), core temperature on wound closure (°C, via pulmonary artery catheter), core temperature immediately before reperfusion (°C, via bladder probe) and core temperature on wound closure (°C, via bladder probe).

3.10 The EAC concluded that the clinical evidence on HumiGard for laparoscopic surgery was of relatively good quality: there are 4 randomised controlled trials and 1 retrospective cohort study in appropriate patients, all of which compared HumiGard with standard unwarmed, dry CO_2 gas. However, the EAC noted that the cohort study (Mason et al. 2016) should be interpreted with caution, because it was submitted as unpublished data.

3.11 The clinical evidence submitted for open surgery was based on 2 small randomised controlled trials, 1 of which was a small pilot study published in abstract form only.

Adverse events

3.12 Two randomised controlled trials involving laparoscopic abdominal surgery (Herrmann and De Wilde 2015, Sammour et al. 2010), included device-related adverse events as an outcome measure. Both studies reported no adverse events associated with the use of HumiGard. The other 3 studies on laparoscopic surgery did not report device-related adverse events. None of the studies on open abdominal surgery reported device-related adverse events.

Committee considerations

3.13 The committee noted that there is good evidence that perioperative hypothermia is associated with poor patient outcomes, such as surgical site infections. Experts were in agreement and advised the committee that maintaining perioperative normothermia is now an established aim of clinical practice.

3.14 The committee considered that the clinical evidence supported the effectiveness of HumiGard in reducing hypothermia during laparoscopic and open abdominal surgery, noting that the evidence base was more substantial for laparoscopic surgery than for open surgery. The committee also noted the lack of high quality direct evidence supporting the use of HumiGard in avoiding the adverse outcomes of hypothermia following surgery.

3.15 The committee noted that only 1 of the included studies involved children and that, in this study, outcomes were not improved. The clinical experts advised that heat loss is partly determined by the ratio of body surface area to body mass. Because this is larger in children, overheating through the use of warming strategies can also be a concern. The committee concluded that there was insufficient evidence to recommend the use of HumiGard in children.

3.16 The committee heard from the clinical experts that total length of hospital stay after abdominal surgery has been reduced through the implementation of enhanced recovery programmes. Historically, length of stay after colorectal surgery was 7 to 9 days but this has now been reduced to approximately 4 to 5 days through the use of such programmes. This change makes it difficult to demonstrate how a single technology such as HumiGard affects total length of stay but the committee accepted that interventions which reduce SSIs would be of benefit.

3.17 The committee heard from the clinical experts that wound orientation is unlikely to affect the use and effectiveness of HumiGard. The committee was also advised that the presence of intra-abdominal sepsis would not be a barrier to its safe use. The experts expressed concerns about the use of HumiGard in circumstances where thermogenesis may occur (such as in ablation surgery) or when cooling is needed (such as in neurosurgery).

3.18 The committee noted that the only evidence submitted showing a reduction in the incidence of surgical site infections using HumiGard was from a single observational study which was unpublished.

4 NHS considerations

System impact

4.1 During abdominal surgery, HumiGard is used in combination with other warming measures (such as forced air warming) in patients at high risk of developing hypothermia. This includes patients having surgical procedures with anaesthesia for more than 30 minutes. During laparoscopic surgery, HumiGard replaces standard insufflation equipment. For open surgery, HumiGard is connected to standard sources of theatre-piped gas. If piped gas is unavailable, the company is able to supply a stand that delivers CO_2 to HumiGard. Clinical experts with experience in the use of HumiGard stated that minimal training is needed to introduce it into clinical practice.

Committee considerations

4.2 The committee was informed by the clinical experts that HumiGard can be set up in approximately 1 minute.

4.3 The committee heard that HumiGard has become a well-accepted part of standard theatre practice in centres that use it. An expert adviser added that HumiGard has been introduced as a part of their enhanced recovery programme and subsequently adopted by every theatre in the hospital.

4.4 The committee heard from the clinical experts that they had experienced no safety issues with HumiGard.

5 Cost considerations

Cost evidence

5.1 The company identified 2 studies that incorporated a cost-effectiveness analysis. The external assessment centre (EAC) judged that the company's search strategy was highly sensitive and well-constructed, and that the selection criteria reflected the NICE

scope. The EAC carried out its own economic search and found no additional studies.

5.2 Both of the identified studies were published as conference abstracts and compared HumiGard with standard care in the UK. The company provided unpublished, academic-in-confidence draft manuscripts relating to both abstracts.

5.3 Jenks et al. (2015) reported on a cost-utility analysis using a decision analytic model of HumiGard compared with standard care open or laparoscopic colorectal surgery. This showed that HumiGard dominated standard care in both open and laparoscopic surgery (that is, it was both less costly and more effective than standard care). The full manuscript by Jenks et al. provided further detail on the study and was available to the EAC. Effectiveness data for open surgery were derived from Frey et al. (2012), a randomised controlled trial of HumiGard compared with standard care in 83 patients having open colon surgery in Sweden. Data on the probability of complications related to hypothermia were taken from a published retrospective study (Billeter et al. 2014) and linked to the data from Frey et al. (2012). The effectiveness data for laparoscopic surgery were taken from a retrospective cohort study reported in a conference abstract (Noor et al. 2015). The costs of myocardial infarction, stroke, sepsis and pneumonia were taken from NHS reference costs 2013/14. The cost of surgical site infections was derived from the NICE quality standard. The results presented in the full manuscript matched those reported in the abstract.

5.4 Mason et al. 2016 (see section 3.8) also reported a cost-benefit analysis of HumiGard compared with standard care in patients having laparoscopic colorectal surgery. The EAC were unable to replicate the cost analysis from this study.

Cost model

5.5 The company presented a de novo economic model adapted from Jenks et al. estimating mean cost savings per patient in open and laparoscopic colorectal surgery. The model assumed a 70:30 split for the use of HumiGard in laparoscopic and open surgery respectively. It comprised 2 decision trees incorporating complications associated with hypothermia and related NHS costs for each kind of surgery. The model runs over 1 year; horizons up to 5 years were reported in scenario analyses, but because these extend post-myocardial infarction and stroke costs they affect only open surgery. The model was based on 3 studies: Noor et al. 2015 (laparoscopic surgery: incidence of surgical site infections and pneumonia), Frey et al. 2012 (open surgery: proportion of patients with hypothermia at the end of surgery) and Billeter et al. 2014 (open surgery: incidence of myocardial infarction, stroke, sepsis, pneumonia, surgical site infection and mortality).

5.6 The company's scenario analyses included exploring the use of alternative sources of clinical effectiveness, a univariate deterministic sensitivity analysis and a probabilistic analysis of the base-case results. For open surgery, it used 3 alternative sources for the proportion of patients experiencing complications (Kurz et al. 1996, Flores-Maldonado et al. 2001, Anannamcharoen et al. 2012). For laparoscopic surgery, the company presented 2 scenario analyses that used data on the proportion of patients with hypothermia linked with complications associated with open surgery (Billeter et al. 2014). The first of these used data from Mason et al. 2016. While the second used data from Sammour et al. (2010). The analyses showed that the costs for treating stroke (£2,715 to £13,858) and surgical site infections (£2,100 to £10,500) had the largest effects on the results.

5.7 The company's base case showed that, overall, HumiGard costs £419 per patient compared with £724 per patient for standard care.

The company therefore estimated that using HumiGard would save £305 per patient. Most cost savings (69%) come from fewer surgical site infections after laparoscopic surgery (with cost savings of £20 per patient in open surgery and £428 per patient in laparoscopic surgery).

5.8 Sensitivity analyses showed that HumiGard becomes cost incurring when the absolute difference in infection risk is 0.3% (for example, 4.7% versus 5%). For open surgery, using data from Sammour et al. (2010), HumiGard was associated with a modest additional cost (using complication data from Billeter et al. 2014 or Flores-Maldonado et al. 2001).

5.9 The company's probabilistic sensitivity analysis found that HumiGard was cost saving in 97.4% of iterations and the average probabilistic cost savings were £302 per patient. The company noted that the results of its probabilistic sensitivity analysis have a skewed distribution and stated that this is because of the distribution of costs of complications within the model (which have a gamma distribution bounded by 0, but no upper limit).

Additional work by the external assessment centre

5.10 The EAC re-ran the company's base case and univariate sensitivity analyses for open and laparoscopic surgery separately, and conducted additional analyses using its preferred estimates. The main changes to the company's model were:

- including updated NHS reference costs for pneumonia, acute myocardial infarction and sepsis
- annuitizing the capital cost of HumiGard
- re-estimating the costs of 'post-myocardial infarction' to reflect current drug prices
- using alternative costs of treating stroke and surgical site infections

- using a 5-year time horizon and including data on hypothermia from the randomised control trial in laparoscopic surgery linked to data on complications from the retrospective cohort study (laparoscopic surgery only).

5.11 The EAC re-ran univariate sensitivity analyses for open and laparoscopic surgery, including updated costs for adverse events and a discount rate for HumiGard of 3.5% over 5 years. In addition to this for laparoscopic surgery, the EAC took hypothermia data from Sammour et al. (2010) and risk of complications data from Billeter et al. (2014). The EAC considered that because stroke and myocardial infarction have long-term resource implications, a longer time horizon was preferable. However, the model incorporates this by simply adding in additional costs to later years, so the EAC also conducted analyses using a 1-year time horizon. Additional EAC sensitivity analyses included an alternative estimate for the cost of treating surgical site infections (£5,164, based on Jenks et al. 2014) and laparoscopic surgery complication data from Noor et al. (2015).

5.12 For open surgery, the results of the EAC's analysis suggest that HumiGard is cost saving compared with standard care, with an average saving per patient of £209. This is a larger cost saving than that identified in the company's model because of the longer (5-year) time horizon. The probability that HumiGard is cost saving was 98% in the sensitivity analysis. The results for a 1-year time horizon were broadly similar to those reported by the company (an average cost saving of £28 per patient).

5.13 For laparoscopic surgery, the EAC concluded that savings were lower than in the company model (an average of £77 per patient) because the EAC used data from Sammour et al. (2010) rather than Mason et al. 2016. The probabilistic analysis found that HumiGard was cost saving in 67.5% of iterations. Using a 1-year

time horizon, HumiGard was associated with a small additional cost of £11 per patient.

5.14 The committee was uncertain about assumptions and parameters in the cost modelling which could not be addressed by the evidence presented. The committee noted that the effect of hypothermia on the risk of stroke during abdominal surgery, the incidence of surgical site infection and the cost of a surgical site infection to the NHS were parameters associated with most uncertainty. The EAC was asked to make further changes to the model to better inform the economic analysis (sections 5.15 to 5.19).

5.15 The committee was advised by clinical experts that the risk of stroke during abdominal surgery is very low. In the context of elective colorectal surgery, the experts estimated it to be less than 1%. Hospital Episode Statistics data were presented to the committee on perioperative stroke rates for England. The data represented selected abdominal procedures that were done in April 2014 and were followed by a primary diagnosis of a stroke at any time during the 2014/15 financial year. The relevant procedures were selected following expert advice. The stroke rates were 0.4% for laparoscopic surgery and 0.6% for open surgery.

5.16 The EAC reviewed the NICE guideline on hypothermia to identify additional data on the associated complications. The guideline cited a study by Frank et al. (1997), as well as 2 studies referenced in the EAC report: Kurz (1996) and Flores-Maldonado (2001). Nevertheless, following the review, the EAC re-affirmed its view that Billeter et al. (2014) was most relevant to the decision problem.

5.17 The EAC used 2 sources of clinical-effectiveness data for HumiGard to reduce uncertainty in the cost model: Sammour et al. 2010 and Mason et al. 2016. The EAC used data in a personal communication from Mason et al. (2016) to calculate adjusted risks

for hypothermia and surgical site infections, taking into account the population characteristics in each study arm.

5.18 The EAC used a range of additional analyses to assess how different stroke rates, surgical site infection costs and sources of effectiveness data affect HumiGard's potential cost savings.

5.19 For open surgery, HumiGard appears to be associated with a cost saving for scenarios where the difference in risk of stroke between hypothermic and normothermic patients is greater than 0.75% to 1.25% (depending on the cost of surgical site infections). At a stroke risk difference below this range, HumiGard is associated with a modest increase in mean cost per patient.

5.20 For laparoscopic surgery (using data from Billeter and Sammour), HumiGard is cost saving only if the difference in stroke risk between hypothermic and normothermic patients is greater than 1.75% to 2.25% (depending on the cost of surgical site infections). Additional analyses using the data from the unpublished study by Mason et al. 2016 (and the updated predicted risk data calculated by the EAC) suggest that HumiGard is cost saving regardless of the cost of surgical site infections and stroke risk when using a range of complications data from Billeter et al. (2014), but cost saving or cost neutral when using only direct data on surgical site infection complications. However, the EAC has been unable to fully appraise these models due to incomplete information from the unpublished Mason et al. (2016).

Committee considerations

5.21 The committee was informed by the clinical experts that the 5.5% stroke risk extrapolated from Billeter et al. (2014) in the company's cost model was an overestimate of the risk in current UK NHS practice, and that this is more likely to be less than 1%. The committee concluded that this distinction is likely to be very influential in the outcome of cost modelling. The committee were

informed by the EAC that reducing the stroke risk to 0% in the cost model would make the use of HumiGard cost incurring. The committee concluded that the use of HumiGard was unlikely to reduce stroke rates for patients in the NHS having abdominal surgery.

5.22 The committee was informed that the NHS costs associated with surgical site infections were uncertain and that published estimates vary. The committee noted that the average cost used in the EAC cost analysis was reflective of current practice. Expert advice stated that surgical site infection costs vary considerably in colorectal surgery.

6 Conclusions

6.1 The committee concluded that there is good evidence to support the use of measures to prevent hypothermia during abdominal surgery and that, in this regard, HumiGard shows promise. However, it considered that there is insufficient evidence to demonstrate that HumiGard has a substantial effect on reducing adverse outcomes for patients undergoing abdominal surgery.

6.2 The committee concluded that the cost consequences of using HumiGard in abdominal surgery are very uncertain, and that further research is needed on resource use.

6.3 The committee recommended conducting research in collaboration with the company and with clinical and academic partners. NICE will update this guidance if new and substantive evidence becomes available.

Peter Groves
Chairman, medical technologies advisory committee
September 2016

7 Committee members and NICE lead team

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.

Dr Peter Groves (Chair)
Consultant Cardiologist, Cardiff and Vale University Health Board

Ms Susan Bennett
Lay member

Mr Matthew Campbell-Hill
Lay member

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

Dr Fiona Denison
Reader/Honorary Consultant in Maternal and Fetal Health, University of Edinburgh

Professor Tony Freemont
Professor of Osteoarticular Pathology, University of Manchester

Professor Shaheen Hamdy
Professor of Neurogastroenterology, University of Manchester

Dr Cynthia Iglesias

Health Economist, University of York

Professor Mohammad Ilyas

Professor of Pathology, University of Nottingham

Dr Greg Irving

GP and Clinical Lecturer, University of Cambridge

Professor Eva Kaltenthaler

Professor of Health Technology Assessment, School of Health and Related Research (ScHARR), University of Sheffield

Dr Paul Knox

Reader in Vision Science, University of Liverpool

Dr Rory O'Connor

Senior Lecturer and Honorary Consultant Physician in Rehabilitation Medicine, University of Leeds

Dr Jai V Patel

Consultant Vascular Radiologist, Leeds Teaching Hospitals NHS Trust

Mr Brian Selman

Managing Director, Selman and Company Limited

Professor Wendy Tindale

Scientific Director, Sheffield Teaching Hospitals NHS Foundation Trust

Professor Allan Wailoo

Professor of Health Economics, School of Health and Related Research (ScHARR), University of Sheffield

Mr John Wilkinson

Director of Devices, Medicines and Healthcare Products Regulatory Agency

Professor Janelle Yorke

Lecturer and Researcher in Nursing, University of Manchester

Dr Amber Young

Consultant Paediatric Anaesthetist, Bristol Royal Hospital for Children

NICE lead team

Each medical technology assessment is assigned a lead team of a NICE technical analyst and technical adviser, an expert adviser, a technical expert, a patient expert, a non-expert member of the medical technologies advisory committee and a representative of the external assessment centre.

Liesl Millar

Technical Analyst

Paul Dimmock

Technical Analyst (evaluations)

Dr Amber Young

MTAC member

Carole Cummins

External Assessment Centre Representative

Louise Longworth

External Assessment Centre Representative

8 Sources of evidence considered by the committee

The external assessment centre report for this assessment was prepared by Birmingham and Brunel Consortium external assessment centre:

- Duarte, R., Liu, Z., Bramley, G., et al, HumiGard Surgical Humidification System for the prevention of inadvertent perioperative hypothermia (January, 2016)

Submissions from the following company:

- Fisher and Paykel Healthcare

The following individuals gave their expert personal view on HumiGard by providing their expert comments on the draft scope and assessment report.

- Mr Tan Arulampalam, General Surgeon, Association of Surgeons of Great Britain and Ireland
- Dr Jonathan M Cousins, Consultant Anaesthetist Intensivist, Royal College of Anaesthetists
- Dr Mark Harper, Consultant Anaesthetist, Association of Anaesthetists of Great Britain and Ireland
- Dr John Andrzejowski, Consultant Anaesthetist, Association of Anaesthetists of Great Britain and Ireland

The following individuals gave their expert personal view on HumiGard in writing by completing a patient questionnaire or expert adviser questionnaire provided to the committee.

- Mr Tan Arulampalam, General Surgeon, Association of Surgeons of Great Britain and Ireland
- Dr Jonathan M Cousins, Consultant Anaesthetist Intensivist, Royal College of Anaesthetists
- Ms Jane Hendricks, Laparoscopic nurse practitioner, Royal College of Nursing

- Dr Mark Harper, Consultant Anaesthetist, Association of Anaesthetists of Great Britain and Ireland
- Dr John Andrzejowski, Consultant Anaesthetist, Association of Anaesthetists of Great Britain and Ireland

About this guidance [NICE to complete on publication]

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

It updates and replaces NICE medical technology guidance XXX (published [month year]). [Amend as necessary. Delete if not relevant.]

It has been incorporated into the NICE pathway on XXX, along with other related guidance and products. [Amend as necessary. Hyperlink to pathway from pathway name. Delete if not relevant.]

We have produced a summary of this guidance for the public [add hyperlink to the UNG page]. Tools [add hyperlink to the guidance summary page] to help you put the guidance into practice and information about the evidence it is based on are also available. [delete any wording that isn't relevant]

Related NICE guidance

For related NICE guidance, please see the NICE website.

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 have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this

guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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