NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review decision

Review of MTG31: HumiGard for preventing inadvertent perioperative hypothermia

This guidance was issued in February 2017.

NICE proposes an amendment of published guidance if there are no changes to the technology, clinical environment or evidence base which are likely to result in a change to the recommendations. However the recommendations may need revision to correct any inaccuracies, usually in relation to providing a more accurate estimate of the results of the cost modelling. The decision to consult on an amendment of published guidance depends on the impact of the proposed amendments and on NICE's perception of their likely acceptance with stakeholders. NICE proposes an update of published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance.

1. Review decision

NICE guidance on HumiGard for preventing inadvertent perioperative hypothermia guidance remains valid and does not need updating.

The external assessment centre's (EAC) review of the clinical evidence can be found in the review report.

2. Original objective of guidance

To assess the case for adoption of HumiGard for preventing inadvertent perioperative hypothermia.

3. Current guidance

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 using HumiGard to avoid important adverse outcomes and on how it affects resource use in open and laparoscopic surgery.*

1.2 *Research is recommended on HumiGard compared with standard insufflation gases in patients having laparoscopic or open surgery*

alongside general measures to reduce the risk of perioperative hypothermia described in section 2.5. Research should report on the comparative rate of surgical site infections and other complications associated with hypothermia and normothermia, as well as related resource use.

4. Rationale

There is no functional change to the technology, no change to the care pathway and no change to the cost of the technology since MTG31 was published. New published evidence is available on the use of HumiGard on core body temperature and the prevention of hypothermia in patients undergoing laparoscopic or open abdominal surgery. There is also new evidence on the use of HumiGard on peri- and post-surgical complications. However, none of the uncertainties identified by MTAC in the original guidance have been unequivocally addressed by the new data. There were no new data to satisfactorily update clinical effectiveness parameters of the economic model so uncertainties in the economic evidence remain due to gaps in the clinical evidence.

5. New evidence

The search strategy from the original assessment report was re-run. References from November 2015 onwards were reviewed. Additional searches of clinical trial registries were also carried out and relevant guidance from NICE and other professional bodies were reviewed to determine whether there have been any changes to the care pathways. The company was asked to submit all new literature references relevant to their technology along with updated costs and details of any changes to the technology itself or the CE marked indication for use for their technology. Searches were also conducted on the FDA Maude and MHRA websites. See Appendix 2 for further details of ongoing and unpublished studies.

5.1 Technology availability and changes

The technology is still available to the NHS. The company state that HumiGard has been used in over 30 NHS hospitals over the last 12 months. Current models (the SH870 Surgical Humidification System used with ST320 Humidified Insufflation kit) have superseded the MR860 Surgical Humidifier and ST310 kits, which are no longer available. There are no significant changes to the technology between the current and predecessor systems. The CE mark, indication and costs are unchanged.

5.2 Clinical practice

The NICE pathway is inadvertent perioperative hypothermia. The relevant NICE clinical guideline is called 'hypothermia: prevention and management in

adults having surgery (CG65)'. This guideline has not been updated since the publication of HumiGard guidance (last updated December 2016).

The guideline recommends using a mixture of methods to keep the patient warm prior to, during, and immediately after surgery to reduce the likelihood of discomfort and complications. Specifically, temperatures above 36.0°C should be maintained preoperatively; 36.5°C intra-operatively; and 36.0°C post-operatively. Methods to achieve this include regular temperature monitoring; adequate ambient temperature; use of warmed intravenous fluids and irrigation fluids; use of forced air warming devices; and use of actively warmed mattresses.

All 3 clinical experts contacted during guidance review said that there have been no substantial changes to the clinical pathway.

5.3 NICE facilitated research

Two projects have resulted from the MTEP research commissioning workstream. One of the projects was a technical evaluation which pre-dated MTG31. The other project was to design an RCT aimed at determining if the use of HumiGard alongside standard perioperative warming techniques can improve patient recovery including pain, surgical site infections, complications, and the use of analgesia compared with standard care alone. The protocol for this study has been published in *JMIR Research Protocols* (Ryczek et al. 2019). A pilot study of this RCT, the HumiGard Evaluation Study (HEAT; NCT04164706), intends to recruit 40 participants and randomise them to HumiGard or sham (HumiGard with no heating). This study was due for completion in October 2020, but no results have been published yet.

5.4 New studies

For the clinical evidence review, the EAC focused on how new evidence addressed the following 4 key issues:

- The impact of HumiGard on core body temperature and prevention of hypothermia in patients undergoing laparoscopic or open abdominal surgery.
- The use of HumiGard in children and high-risk patient groups.
- Direct evidence showing HumiGard reduces peri- and post-surgical complications.
- Direct evidence on the impact of HumiGard on healthcare resource use (such as length of stay).

The updated literature searches identified 11 new studies on the use of HumiGard published since MTG31. These studies consisted of 5 RCTs, 3 observational studies, 1 meta-analysis, 1 cost-utility study and 1 study protocol. The key findings are summarised below. For full details of the included studies and their results, please see sections 4.4 and 4.5 of the review report.

Two studies directly reported on the incidence of hypothermia (Mason et al. 2017; Wittenborn et al. 2019). Mason et al. (2017) reported that HumiGard was associated with statistically significantly reduced cases of hypothermia compared with the control group. Data from this study had been made available as CiC information at the time of guidance development and has already been considered by MTAC. Wittenborn et al. (2019) reported that in the HumiGard group, the proportion of patients with hypothermia reduced (from more than 54% at the start of surgery to 36% immediately after surgery) while the proportion in the control group increased (from 36% to 42%). The statistical significance of this however was not reported. Four RCTs reported on core body temperature. Some of the RCTs showed that HumiGard was associated with modest increases in core body temperature, while others reported non-significant increases (see Table B3 of the review report). Gaps remain in the clinical evidence concerning the efficacy of HumiGard in preserving temperature in patients undergoing open surgery.

None of the new studies identified focused specifically on children or high-risk subgroups or reported subgroup analyses in these groups.

There was little new direct evidence that HumiGard reduces the rate of post-surgical complications. The incidence of surgical site infections (SSIs) was reported in one primary comparative observational study in patients undergoing laparoscopic surgery (Mason et al. 2017). This study showed that HumiGard resulted in significantly less SSIs compared to the control group. Secondary evidence from a meta-analysis showed no significant difference in SSI incidence (Frey et al. 2016).

Three RCTs reported on total length of hospital stay (Oderda et al. 2019; Cheong et al. 2017; Matsuzaki et al. 2017). All 3 of which did not report any statistically significant differences between HumiGard and control groups. Mason et al. (2017) reported that people receiving HumiGard had a shorter median length of stay compared with those receiving control (6.4 versus 8.3 days), but this difference was not statistically significant ($p = 0.11$).

5.5 Cost update

There were no new data to satisfactorily update clinical effectiveness parameters in the economic model. The company confirmed that the costs of

the technology had not changed since MTG31 had published. The EAC updated the downstream costs on complications with the most up-to-date data available. The direction of cost savings for HumiGard was not impacted by these changes in either the laparoscopic or open surgery cohorts, with HumiGard remaining cost saving. For full details please see section 4.7 of the review report.

6. Summary of new information and implications for review

The new evidence is unlikely to have a material effect on the recommendations in the published guidance. New evidence was identified evaluating the use of HumiGard in people undergoing open or laparoscopic abdominal surgery. However, none of the areas of uncertainty which were identified by MTAC have been unequivocally addressed by the new evidence. The cost of the technology has not changed. Economic modelling using up-to-date costs for downstream complications showed HumiGard remains cost saving. However, uncertainty in the economic evidence remains due to gaps in the clinical evidence. The research recommendations made in the original guidance remain valid.

There were no reports on the MHRA or FDA Maude website.

7. Implementation

According to the company HumiGard has been used by at least 30 NHS Hospitals within the last 12 months.

8. Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were raised in the original guidance. No new equality issues were identified during guidance review.

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Appendix 1 – explanation of options

If the published Medical Technologies Guidance needs updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
Amend the guidance and consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Amend the guidance and do not consult on the review proposal	The guidance is amended but the factual changes proposed have no material effect on the recommendations.	No
Standard update of the guidance	A standard update of the Medical Technologies Guidance will be planned into NICE's work programme.	No
Update of the guidance within another piece of NICE guidance	The guidance is updated according to the processes and timetable of that programme.	No

If the published Medical Technologies Guidance does not need updating NICE must select one of the options in the table below:

Options	Consequences	Selected – 'Yes/No'
No change required	The guidance remains valid.	Yes
Defer the decision to review the guidance	NICE will reconsider whether a review is necessary at the specified date.	No
Withdraw the guidance	The Medical Technologies Guidance is no longer valid and is withdrawn.	No

Appendix 2 – supporting information

Relevant Institute work

Published

Hypothermia: prevention and management in adults having surgery (2008 updated 2016) NICE guideline CG65

Bair Hugger for measuring core temperature during perioperative care (2017) NICE medtech innovation briefing 99

Inditherm patient warming mattress for the prevention of inadvertent hypothermia (2011) NICE medical technologies guidance 7

In progress

None identified.

Registered and unpublished trials

A total of 6 study protocols of ongoing or unpublished trials were identified. Full details are provided in Appendix C of the review report.

Trial name and registration number	Details
HEAT HumiGard Evaluation Study NCT04164706	HEAT is a multicentre, blinded (patient, surgeon, and assessor), sham device-controlled, parallel RCT. NCT04164706 was a feasibility study aimed to highlight the most appropriate outcomes to be measured in a larger RCT. Recruitment Status: recruiting (last updated Jan 2020) Estimated study completion date: October 2020, results not published Estimated enrolment: 40 participants Location: UK Funder/sponsor: Cardiff and Vale University Health Board
Temperature and Pain in Laparoscopy (TePaLa) study NCT02781194	TePaLa was a prospective RCT investigating intraoperative temperature and postoperative pain course following gynaecological laparoscopy using Bair Hugger blanket (3M), HumiGard Surgical Humidification System or HumiGard plus Bair Hugger blanket. Recruitment Status: completed (last updated Feb 2019) Actual study completion date: September 2018, results not published Actual enrolment: 150 participants Location: Germany Funder/sponsor: RWTH Aachen University

Trial name and registration number	Details
Does utilisation of surgical humidification reduce surgical site infection in colorectal surgery patients? A randomised control trial ACTRN12620000269932	A single-centre, single blind, parallel RCT evaluating the use of HumiGard compared with standard care (in absence of HumiGard) in people undergoing elective or emergency open colorectal resection. Recruitment Status: not yet recruiting (last updated March 2020) Date of last data collection: April 2022 Estimated enrolment: 298 participants Location: Australia Funder/sponsor: Fisher and Paykel Ltd
Efficacy of warm humidified insufflation for reducing post-operative ileus in patients undergoing acute general surgical laparotomy: A randomised single-blind controlled trial. ACTRN12619001570178	A single blind, parallel RCT evaluating the efficacy of HumiGard compared with Insufflation with cool, dry CO_2 in people undergoing an elective, expedited, urgent, or emergency laparotomy lasting at least 60 minutes. Recruitment Status: submitted, not yet approved (last updated Nov 2019) Estimated enrolment: 226 participants Location: New Zealand Sponsor: Fisher and Paykel Ltd
Effect of warm humidified insufflated carbon dioxide on wound bacterial load in open elective gastrointestinal surgery: a pilot investigation ACTRN12617001558314	A single-blind, parallel RCT evaluating the efficacy of HumiGard compared with standard care (in absence of HumiGard) in people scheduled to undergo upper gastrointestinal surgical procedures longer than 120 minutes involving an open midline laparotomy incision. Recruitment status: recruiting (last updated July 2018) Date of last data collection: Feb 2019, results not published Estimated enrolment: 10 participants Location: New Zealand Sponsor: Fisher and Paykel Ltd

Trial name and registration number	Details
A randomised controlled trial investigating the effect of humidified warm carbon dioxide (CO2) insufflation during laparoscopic and open abdominal surgery. ACTRN12617000850370	Single-centre, single-blind RCT evaluating the efficacy of HumiGard in people undertaking elective Upper GI or hepatobiliary surgery of longer than 2 hours duration. HumiGard was compared with no intracorporeal warming during open abdominal surgery and Cool, dry room temperature CO_2 insufflation during laparoscopic surgery. Recruitment Status: recruiting (last updated Nov 2019) Date of last data collection: Dec 2020, results not published Estimated enrolment: 120 participants Location: Australia Sponsor: St Vincent's Hospital Melbourne

References

Cheong J, Oliphant R, Richardson G et al. (2017) The use of warmed, humidified CO2 during open abdominal surgery: a modified delivery technique. Techniques in Coloproctology, 21, 309-310.

Frey J, Holm M, Janson M et al. (2016) Relation of intraoperative temperature to postoperative mortality in open colon surgery—an analysis of two randomized controlled trials. International journal of colorectal disease, 31, 519-524.

Mason SE, Kinross JM, Hendricks J et al. (2017) Postoperative hypothermia and surgical site infection following peritoneal insufflation with warm, humidified carbon dioxide during laparoscopic colorectal surgery: a cohort study with cost-effectiveness analysis. Surgical Endoscopy, 31, 1923-1929.

Matsuzaki S, Vernis L, Bonnin M et al. (2017) Effects of low intraperitoneal pressure and a warmed, humidified carbon dioxide gas in laparoscopic surgery: a randomized clinical trial. Scientific reports, 7, 11287.

Oderda M, Cerutti E, Gontero P et al. (2019) The impact of warmed and humidified CO2 insufflation during robotic radical prostatectomy: results of a randomized controlled trial. Urologia, 86, 130-140.

Ryczek E, White J, Poole RL et al. (2019) Normothermic Insufflation to Prevent Perioperative Hypothermia and Improve Quality of Recovery in Elective Colectomy Patients: Protocol for a Randomized Controlled Trial. JMIR research protocols, 8, e14533.

Wittenborn J, Clausen A, Zeppernick F et al. (2019) Prevention of Intraoperative Hypothermia in Laparoscopy by the Use of Body-Temperature and Humidified CO2: A Pilot Study. Geburtshilfe und Frauenheilkunde, 79, 969-975.