Inadvertent perioperative hypothermia (standing committee update)

Consultation on draft guideline - Stakeholder comments table
07/09/16 – 05/10/16

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12	3M Health Care UK	Short	5	8 - 27	Core temperature is a measurement *concept*, not an actual temperature measured at a body location. As such, core temperature may only be *estimated* from a measurement at a given anatomical location. The NICE guideline asserts that core temperature may actually be measured at some anatomical location which is erroneous as can only be estimated from any site. We recommend the phrase "estimate of core temperature" be used throughout.	Thank you for your comment. We have discussed this issue with our topic experts and have clarified the difference between direct measurement, direct estimate and indirect estimate. The recommendations have been changed to: Measure the patient's temperature using a site that produces either: • a direct measurement of core temperature, or • a direct estimate of core temperature that has been shown in research studies to be accurate to within 0.5ºC of direct measurement. At the time of publication these sites are: • pulmonary artery catheter • distal oesophagus • urinary bladder • zero heat-flux (deep forehead). • sublingual • axilla • rectum. [new 2016] Do not use indirect estimates of core temperature in adults having surgery. [new 2016] Appropriate definitions have been added in footnotes
13	3M Health Care UK	Short	5	8 - 23	Sections **1.1.4** and **1.1.5** conflate anatomical location with the technology for temperature	Thank you for your comment. In the review protocol it was specified that "This update will make

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					measurement. Nearly all clinical thermometers have an equivalent instrument accuracy, but they don't all have the same reliability of measurement, and not all anatomical locations provide an equivalent estimate of core temperature[1]. The guidance should separately recommend acceptable measurement technologies and their appropriate locations for use. The reliability of IR temporal (forehead with correction factor) or IR tympanic measurements has been shown repeatedly in the published evidence to be quite poor and this should be acknowledged in the guidance by their removal as techniques for estimates of core temperature. It has been demonstrated that the error between pulmonary artery temperature and forehead skin temperature is not constant, but is dependent on the absolute estimate of core temperature.[2] **1.** Taylor NAS, Tipton MJ, Kenny GP. Considerations for the measurement of core, skin and mean body temperatures. *Journal of Thermal Biology.* 2014;46:72-101. **2.** Eshraghi Y, Nasr V, Parra-Sanchez I, Van Duren A, Botham M, Santoscoy T, Sessler DI. An Evaluation of a Zero-Heat-Flux Cutaneous Thermometer in Cardiac Surgical Patients. *Anesth Analg.* 2014;119(3):543-549.	recommendations on the site of monitoring, not on the individual manufacturer devices involved." We have clarified the technologies used at each site, and the recommendation has been reworded thus: 1.1.5 Measure the patient's temperature using a site that produces either: • a direct measurement of core temperature, or • a direct estimate of core temperature that has been shown in research studies to be accurate to within 0.5ºC of direct measurement. At the time of publication these sites are: • pulmonary artery catheter • distal oesophagus • urinary bladder • zero heat-flux (deep forehead). • sublingual • axilla • rectum. [new 2016] 1.1.6 Do not use indirect estimates of core temperature in adults having surgery. [new 2016]

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14	3M Health Care UK	Short	5	18	It is not clear what is meant by the term, "deep forehead" temperature. We suspect that the authors mean to suggest the use of a zero-heat-flux thermometer here, but it is not clear and most clinician readers will not be able to interpret this recommendation as it is phrased in the draft. We recommend that the description "deep forehead" is replaced with "zero-heat flux" thermometry which is generically used to describe instruments from several manufacturers.	Thank you for your comment. We have changed this bullet point to "zero heat-flux (deep forehead)"
15	3M Health Care UK	Short	5	24 - 27	It is our view that this text should be changed to reflect the fact that there is little evidence to support any of the methods of temperature measurement (listed in 1.1.5) having an intraoperative agreement (accuracy?) within 0.5°C, so why should alternatives need to have such research results supporting their use?	Thank you for your comment. The committee considered that the evidence reviewed was sufficient to recommend some site of measurement where agreement was with 0.5 as documented in the output of the Bland-Altman analyses. The committee added this specific recommendation to ensure that, in the future, any new devices have at least the same level of agreement with these devices before they can be introduced into clinical practice.
16	3M Health Care UK	Short	6	5 - 15	Although section **1.2.1** is not eligible for review, its presence in the guidance complicates a simple matter and has the potential to lead to confusion regarding the risk of inadvertent hypothermia. **All** patients who receive either general or neuraxial anaesthesia undergo heat redistribution. This is the dominant cause of intraoperative hypothermia, especially in shorter cases and all	Thank you for your comment. This recommendation was outside the scope of the update and therefore no changes can be made to the recommendation.

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					should receive warming as sated in 1.2.2. Other than this factor, there should be no other factors involved in assessing the patient's risk of intraoperative hypothermia. The factors listed in 1.2.1 certainly increase the *extent* of hypothermia, but all patients undergoing central anaesthesia have essentially the same risk of developing clinically relevant hypothermia. The inclusion of 1.2.1 complicates a simple decision and therefore this section should be deleted from the final version.	
17	3M Health Care UK	Short	6	16 - 19	For the reason cited above, clinicians should insist on prewarming instead of simply offering it as suggested in **1.2.2**. New text for section 1.2.2: "Implement active warming for at least 30 minutes before induction of anaesthesia to all patients having general anaesthesia or central neural blockade for surgery, unless this will delay emergency surgery."	Thank you for your comment. We have considered your comment and have changed the wording of recommendation 1.2.4 to highlight that pre-warming should happen: "If the patient's temperature is 36.0°C or above, start active warming at least 30 minutes before induction of anaesthesia, unless this will delay emergency surgery. **[new 2016]"** Please note that while the recommendation has been amended to acknowledge that warming should be started, it is not possible to strengthen the recommendation further to state that it "must" be

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						performed as there are only specific instances when NICE uses that language. NICE has particular processes with regard to translating the strength of the evidence into recommendations as follows: Please see section 9.1 and 9.2 of the methods manual for more details about the strength of recommendations https://www.nice.org.uk/process/pmg20/chapter/developing-and-wording-recommendations-and-writing-the-guideline#interpreting-the-evidence-to-make-recommendations)..
18	3M Health Care UK	Short	6	20 - 21	While we would not question the need to pay particular attention to the care of patients with communication difficulties, and thermal comfort is a desirable condition, it is simply not possible to adequately prewarm patients if they remain thermally comfortable as suggested by the recommendation in **1.2.3**. Successful prewarming requires patients to experience at least a brief period of heat imbalance, which, by definition, produces thermal discomfort in normothermic patients.	Thank you for your comment. We accept that pre-warming may involve slight discomfort when there is an increase in temperature. However, it was highlighted in the Equalities impact assessment (which was available for consultation), that people with communication difficulties may be disadvantaged with regards to accessing appropriate pre-warming. This recommendation highlights the need for healthcare professionals to pay particular attention to the overall comfort of people with communication difficulties, not specifically thermal comfort..
19	3M Health Care UK	Short	8	12 - 18	Section **1.3.7** recommends the use of intraoperative warming for procedures anticipated to last more than 30 minutes. For procedures	Thank you for your comment. The study by Roder et al. (2011) was not included in our review as it assessed re-warming of hypothermic patient (the

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					lasting between 30 minutes and 1 hour, the use of intraoperative warming of any type will have virtually no effect on the patient's core temperature because redistribution is the dominant cause of hypothermia in this time frame. In a recent published trial by Roder et al, the overall heat transfer rate of the forced air system is twice that of the comparison system; however, neither system is powerful enough to overcome the dominance of temperature redistribution until around 1 hour of warming[3]. The initial decrease in core temperature caused by redistribution within the body cannot be quickly reversed or prevented by intraoperative warming; the **only** solution to this problem is comprehensive prewarming. As the results published by Roder suggest, the use of a resistive heating blanket is about half as effective as a good forced-air warming system and in this, does not support the recommendation to use this technology where "forced air warming is unsuitable". We find the term "where unsuitable" to be open to interpretation and should be and the circumstances where occurs, better defined or this advice completely removed from the guideline. 3. Röder G, Sessler D, Roth G, Schopper C, Mascha E, Plattner O. Intra-operative rewarming with Hot Dog® resistive heating and forced-air heating: a trial of	patients were randomised only when bladder temperature reached 35°C) and the review protocol excluded studies where hypothermia was induced Using the evidence that met the inclusion criteria, the committee discussed the relative effectiveness of the interventions and felt that a resistive heating blanket or mattress should be an option for people where forced air warming was not able to be used. The phrase "where unsuitable" is indeed open to interpretation and to allow healthcare professionals to apply their clinical judgement in situations where forced air warming may not be appropriate.

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					lower-body warming. Anaesthesia. 2011;66(8):667-674.	
20	3M Health Care UK	Short	General		Throughout the guideline there is a confusion with certain terms. There is a need to resolve the use of these particular terms: *accuracy*, *agreement* and *reliability*.	It has been difficult to identify where you feel there is confusion in use of the terms 'accuracy, agreement and reliability'. We feel we have used the terms appropriately within the specific contexts.
21	3M Health Care UK	Short	General		This guideline does not emphasise enough the dominant effect of redistribution of heat during anaesthesia as the dominant cause of intraoperative hypothermia and the strong need for patient pre-warming. The emphasis should be on pre-warming of all patients who will be anaesthetised. This is a "must" rather than to be "offered".	Thank you for your comment. NICE has particular processes with regard to translating the strength of the evidence into recommendations as follows We have considered your comment and have changed the wording of recommendation 1.2.4 to highlight that pre-warming should happen: "If the patient's temperature is 36.0°C or above, start active warming at least 30 minutes before induction of anaesthesia, unless this will delay emergency surgery. **[new 2016]"** We are unable to change to wording to "must", as the committee considered that there was not sufficient evidence to make a recommendation of this strength; a "must" recommendation, is only used when there is

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						a legal duty to apply a recommendation or the consequences are extremely severe. (Please see section 9.1 and 9.2 of the methods manual for more details of strength of recommendations https://www.nice.org.uk/process/pmg20/chapter/developing-and-wording-recommendations-and-writing-the-guideline#interpreting-the-evidence-to-make-recommendations)..
2	Department of Health	General	General		Thank you for the opportunity to comment on the draft addendum to the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you for your comment.
22	Fisher and Paykel Healthcare	Addendum	General		The following comments are related to a request by the stakeholder to have the updated guideline for CG65 to include an assessment of surgical humidification to prevent additional heat loss due to evaporative cooling during surgery. Exposure of tissues to cool dry insufflation gas in laparoscopic surgery and room air in open surgery results in evaporation subsequent cooling of the patient. The original 2008 guideline considered insufflation gases but did not separate heated dry gas from heated humidified gas.	Thank you for your comment. Humigard (humidified insufflation gas) was specified as an intervention in the protocol and studies regarding HumiGard were picked up in our searches. We were looking for any active warming mechanism (or combination of active warming) vs other active warming mechanisms. Heated humidified gas vs dry or unheated or unhumidified gas was not a valid comparison and

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					Heated dry gas is known to accelerate evaporation and heated humidified gas aims to prevent evaporation and subsequent heat loss. In addition, since the time of publication of the 2008 guideline, warm humidified insufflation is also used in open surgery which was not considered in the 2008 guideline. A randomized controlled trial which utilizes the pre and intra-operative warming methods recommended in the addendum show that 18% (1 in 5) patients are still hypothermic at end of surgery (as defined as <36 ° C) (10). None of the recommended warming methods compensate for evaporative heat loss. When warm humidified insufflation was added in addition to the recommended warming measures no patients was hypothermic (P = 0.005). Perioperative hypothermia results in significant clinical and economic consequences not considering evaporative cooling could result in significant cost burden to the NHS. The stakeholder requests that an evaluation of surgical humidification to prevent hypothermia be considered for both open and laparoscopic surgery.	studies comparing these interventions were excluded from the review. Please see comment 26 which addresses individual reasons for the exclusion of each study. , The use of HumiGard in preventing IPH is currently being assessed by the Medical technologies programme at NICE (MT257, due for publication February2017), and this guidance will be referred to in NICE pathways once the guidance is published. Please see the NICE website for details regarding the development of this guidance https://www.nice.org.uk/guidance/indevelopment/gid-mt257

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23	Fisher and Paykel Healthcare	Addendum	11: Section 2.1 Introduction	General	The addendum document details that body temperature is maintained by thermoregulatory mechanisms and that exposure of the skin and organs during the perioperative period can increase heat loss. The addendum does not further this discussion to consider the impact of evaporative cooling caused by exposure of the organs to cold and dry insufflation gases in laparoscopic surgery and cold room air in open surgery. When the abdomen is exposed to cool dry gas or cold room air the gas will reach equilibrium with abdominal conditions in the peritoneal cavity drawing both heat and moisture from the patient to reach this equilibrium. This process is energy consuming which consequently induces heat loss in the patient. Evaporative cooling is due primarily to the energy spent to humidify the dry gas (577 calories to vaporize 1g of water, compared to 0.00003 calories to heat 1 mL CO_2 by 1 °C) (2). This localized heat loss can be prevented with warm humidified insufflation. The therapy is intended to be used in conjunction with traditional warming techniques.	Thank you for your comment. Humigard (humidified insufflation gas) was specified as an intervention in the protocol and papers regarding HumiGard were picked up in our searches. We were looking for any active warming mechanism (or combination of active warming) vs other active warming mechanism. Heated humidified gas vs dry or unheated or unhumidified gas was not a valid comparison and studies comparing these interventions were excluded from the review. Please see comment 26 which addresses individual reasons for the exclusion of each study.

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					• The addendum document states that it is concerned with forced air warming compared with other active warming devices in the intraoperative phase. In this regard the stakeholder wishes CG65 to consider warming patients with heated humidified CO_2, in addition to forced-air warming to address heat loss as a result of localized evaporative cooling.	
24	Fisher and Paykel Healthcare	Addendum	12: Section 2.2 Review questions 1 & 2	General	• The addendum document states the question "Are warming devices/mechanisms effective in preventing inadvertent perioperative hypothermia in adults in the different phases of perioperative care, specifically comparing classes of active warming device?." • The stakeholder would like to have the review question expanded to include the updated literature assessing the use of heated humidified CO_2 to reduce intraoperative hypothermia in abdominal surgery.	Thank you for your comment. HumiGard (humidified insufflation gas) was specified as an intervention in the protocol and papers regarding HumiGard were picked up in our searches. We were looking for any active warming mechanism (or combination of active warming) vs other active warming mechanism. Heated humidified gas vs dry or unheated or unhumidified gas was not a valid comparison and studies comparing these interventions were excluded from the review. Please see comment 26 which addresses individual reasons for the exclusion of each study. ,

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25	Fisher and Paykel Healthcare	Addendum	12: Section 2.3 Clinical evidence review	General	• The addendum document lists the systematic search conducted to appraise their aims. The stakeholder wishes to add the following (below) expansion to that search to encompass literature documenting randomised control trials (RCTs) that investigated heated humidified or heated dry insufflation gas.	Thank you for your comment. Our search included results for HumiGard; however, no evidence was identified that compared HumiGard to other active warming device/method and as such no studies were included in the systematic review.
26	Fisher and Paykel Healthcare	Addendum	12: Section 2.3.1 Methods	General	• Should now be updated to include "surgical humidification" (specifically heated, humidified CO_2 from heated, dry CO_2). • The following sections have been expanded by the stakeholder as per the CG65/CG65 addendum documents: **Characteristics of clinical studies included in the review:** (NEW MANUSCRIPTS to be added to the existing manuscripts in CG65 "heated gases" but updated to include surgical humidification) Update clinical studies section: New inclusions since 2008 (4): Klugsberger et al. 2014., Herrmann et al. 2015., Sammour et al. 2010., Agaev et al. 2015 (in Russian). Some that should have been included but were not in the previous CG65 document (Pubmed search from humidification/insufflation (3): Manwarring et al.	Thank you for your comment. Humigard (humidified insufflation gas) was specified as an intervention in the protocol and papers with HumiGard as an intervention were picked up in our searches. We were looking for any active warming mechanism (or combination of active warming) vs other active warming mechanism. Heated humidified gas vs dry or unheated or unhumidified gas was not a valid comparison and studies comparing these interventions were excluded from the review. Please see comment 26 which addresses individual reasons for the exclusion of each study. ,

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					2008., Davis et al. 2006, Kissler et al. 2004. Heated, dry insufflation (5): Nelskyla 1999, Puttick 1999, Saad 2000, Wills 2001, Lee 2011. Additionally there were two open surgery RCTs investigating insufflated humidified CO_2: Frey et al. 2012a., Frey et al. 2012b. Patient numbers: For heated humidified - (new 4) n=477; (additional 3) n= 118. Open studies n= 153, group size 30+. For heated dry – (5 additional) n=215, group size 11-20. NOTE: These studies are additive to the already mentioned studies in the CG65 document: Champion et al. 2006, Ott et al. 1998, Farley et al. 2004, Hamza et al. 2005, Nguyen et al. 2002 and Savel et al. 2005. All of these studies will be used for the analysis and justification of heated, humidified CO_2 as a therapy for intraoperative hypothermia (below). **Studies (new)** Agaev 2013 (3) RCT. Laparoscopic Cholecystectomy/fundoplication, N=170. General anesthesia. Warm, humidified CO_2 (intervention) versus unheated, dry CO_2 (comparator). Outcomes: Intra-operative and post-operative core body temperature, Postoperative pain and analgesic use, Recovery time.	We have checked the studies referenced in your comment and we would have excluded them for the following reasons:

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					Davis 2006 (4) RCT. Laparoscopic Gastric bypass, N=22. General anesthesia. Warm, humidified CO_2 (intervention 1) versus Heated, dry CO_2 (Intervention 2) versus Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature, Postoperative pain and analgesic use, Recovery time and Length of hospital stay. Herrmann 2015 (5) RCT. Laparoscopic Gynecological, N=97. General anesthesia– Propofol, esmoron and fentanyl. Warm, humidified CO_2 (intervention) versus Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature, Postoperative pain and analgesic use, Length of hospital stay. Kissler 2004 (6) RCT. Laparoscopic Gynecological, N=36. General anesthetics – propofol and alfentanil. Warm, humidified CO_2 (intervention 1) versus Heated, dry CO_2 (Intervention 2) versus Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature. Klugsberger 2014 (7) RCT. Laparoscopic cholecystectomy, N=148. General anesthesia. Warm, humidified CO_2 (intervention) versus	Agaev 2013 - Non-English language article. No active warming comparator. Davis 2006 – study did not compare insufflated gases with another active warming methods Herrmann 2015 - study did not compare insufflated gases with another active warming method Kissler 2004 - study did not compare insufflated gases with another active warming method Klugsberger 2014 - study did not compare insufflated gases with another active warming method

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					Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature, Postoperative pain. Manwaring 2008 (8) RCT. Laparoscopic gynecological, N=60. General anesthesia. Warm, humidified CO_2 (intervention) versus Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature, Postoperative pain and analgesic use, Recovery time. Sammour 2010 (9) RCT. Laparoscopic colonic resection, N=82. General anesthesia. Warm, humidified CO_2 (intervention) versus Unheated, dry CO_2 (comparator). Outcomes: Intra-operative core body temperature, Postoperative pain and analgesic use, Length of hospital stay. Frey 2012 A (10) RCT. Open colorectal, N=74. General Anesthesia. Warm, humidified CO_2 (intervention) versus ambient air (comparator). Outcomes: Intra-operative core body temperature Length of hospital stay. Frey 2012 B (11) RCT. Open colorectal, N=79. General Anesthesia. Warm, humidified CO_2	Mainwaring 2008 - study did not compare insufflated gases with another active warming method Sammour 2010 - study did not compare insufflated gases with another active warming method. Frey 2012 A - Study compared HumiGard to no insufflation gas. Both groups received usual/ supportive care: warming from a combination of methods (forced air warming, warm fluids and limb insulation). Usual/ supportive care was not only active warming, excluded as included fluid warming and insulation. Frey 2012 B - Study did not include HumiGard as an intervention. Netyla 1999 - study did not compare insufflated gases with other active warming methods

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					(intervention) versus ambient air (comparator). Outcomes: Intra-operative core body temperature Length of hospital stay. Nelskyla 1999 (12), RCT. Laparoscopic hysterectomy, N=37. General anesthesia – propofol. Heated dry CO_2 (intervention) versus Unheated dry CO_2 (comparator). Outcomes: Intraoperative core body temperature, Heart rate variability. Puttick 1999 (13), RCT. Laparoscopic cholecystectomy, N=30. General anesthesia. Heated dry CO_2 (intervention) versus Unheated dry CO_2 (comparator). Outcomes: Intraoperative and postoperative core body temperature, Postoperative pain, Peritoneal fluid cytokine concentrations. Saad 2000 (14), RCT. Laparoscopic cholecystectomy, N=20. General anesthesia. Heated dry CO_2 (intervention) versus Unheated dry CO_2 (comparator). Outcomes: Intraoperative core body and intra-abdominal temperature, Postoperative pain.	Puttick 1999 - study did not compare insufflated gases with another active warming method Saad 2000 - study did not compare insufflated gases with another active warming method Wills 2001 - study did not compare insufflated gases with another active warming method Lee 2011 - study did not compare insufflated gases with another active warming method

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					Wills 2001 (15), RCT. Laparoscopic fundoplication, N=40. General anesthesia. Heated dry CO_2 (intervention) versus Unheated dry CO_2 (comparator). Outcomes: Intraoperative core body temperature, Postoperative pain, Recovery. Lee 2011 (16), RCT. Laparoscopic major abdominal surgery (gastrectomy, colectomy or low anterior resection), N=30. General anesthesia. Heated dry CO_2 (intervention) versus Unheated dry CO_2 (comparator). Outcomes: Intraoperative core body temperature, Intraoperative acid-base parameters.	
27	Fisher and Paykel Healthcare	Addendum	12: Section 2.3.1 Methods	General	**Participants:** Age range as per previous CG65 (18-74). One study identified, Yu et al. 2013, was not included as the RCT was on pediatric patients and children were not considered in this review. Surgical humidification studies were conducted in Austria, Germany, New Zealand, Russia, Australia, USA and Germany (respectively). Both open surgical procedure RCTs were done in Sweden. Heated dry studies were done in Finland, UK, Germany, Australia and Korea. **ASA status:** Sammour et al. reported ASA scores of patients. 3-6% of patients had an ASA score I,	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.

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					21-23% ASA score II and 8-13% an ASA score III in the study and control groups. Saad et al. 2000 reported 9/20 patients to have an ASA I score and the remaining 11/20 to have an ASA II score. In the remainder of the studies ASA scores were not mentioned or reported higher than ASAII to be excluded (Puttick 1999). **Types of surgery:** laparoscopic cholecystectomy/fundoplication (Agaev et al. 2015); laparoscopic cholecystectomy (Klugsberger et al. 2014, Puttick 1999, Saad 2000); laparoscopic gastric bypass (Davis et al. 2006); laparoscopic gynaecological procedures (Harrmann et al. 2015, Kissler et al. 2004, Manwaring et al. 2008); laparoscopic colonic resection (Sammour et al. 2010); laparoscopic hysterectomy (Nelskyla 1999); Laparoscopic fundoplication (Wills 2001). Gastrectomy, colectomy or low anterior resection (Lee 2011). Elective open colon surgery (Frey et al. 2012a, Frey et al. 2012b): these include Ileocoloic resection, total colectomy, right hemicolectomy, left hemocolectomy, sigmoid colectomy, high anterior resection, colostomy, rectal amputation.	

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					Durations of surgeries recorded: Ageav et al: 42-56 minutes. Operating room time recorded: 78-86mins Davis, 45-62 (Kissler), 46-50 (Manwaring), 82-86 (Herrmann, 176-185 (Sammour), 181-217 (Frey et al, 2012a), 205-219 (Frey et al, 2012b), 31-33 (Puttick 1999), 42-78 (Saad 2000), 150-297 (Lee 2011). Operating room time or duration of surgery not listed in remaining studies. **Anesthesia:** General anesthesia administered to patients in Sammour et al., Herrmann et al., Agaev et al., Manwaring et al., Kissler et al., Davis et al., Klugsberger et al, Frey et al. 2012a/b. Nelskyla 1999, Puttick 1999, Saad 2000, Wills 2001, Lee 2011. **Interventions:** - Core body temperature change (Klugsberger 2014, Herrmann 2015, Sammour 2010, Agaev 2015, Manwarring 2008, Davis 2006, Kissler 2004, Frey 2012a, Frey 2012b, Nelskyla 1999, Puttick 1999, Saad 2000, Wills 2001, Lee 2011). - Operating room time (Herrmann 2015, Sammour 2010, Davis 2006, Kissler 2004, Frey 2012a, Frey 2012b).	

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					- Recovery (PACU) (Manwarring 2008, Davis 2006, Wills 2001). - Length of stay in hospital (Herrmann 2015, Sammour 2010, Davis 2006, Frey 2012a, Frey 2012b). - Perception of pain (Klugsberger 2014, Herrmann 2015, Sammour 2010, Agaev 2015, Manwarring 2008, Davis 2006, Puttick 1999, Saad 2000, Wills 2001). - Fogging (Sammour 2010, Agaev 2015, Davis 2006). - Time to extubation (Frey 2012a, Frey 2012b). Core temperature was measured with: Tempanic membrane thermometer (Frey 2012a/b, Nelskyla 1999). Esophageal probe (Sammour 2010, Saad 2000, Lee 2011). Rectal probe (Klugsberger 2014). Intravesical probe (unknown) (Kissler 2004). Intranasal probe (Herrmann 2015). Foley catheter (location not detailed) (Davis 2006). Intraperitoneal (Puttick 1999, Saad 2000). Unknown (Manwaring 2008, Agaev 2013, Wills 2001). **Methodological quality of included studies** Randomisation: Envelopes (Frey 2012a, Frey 2012b, Klugsberger 2014, Puttick 1999, Wills	

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					2001, Lee 2011), Block fashion (Davis 2006, Herrmann 2015), Computerized (Kissler 2004, Sammour 2010), Random number generator (Manwaring 2008), Not stated (Agaev 2013). No specifics given (Nelskyla 1999, Saad 2000). Double blinding: Yes (Frey 2012a, Frey 2012b, Davis 2006, Herrmann 2015, Kissler 2004, Klugsberger 2014, Manwaring 2008, Sammour 2010, Nelskyla 1999, Puttick 1999, Wills 2001, Lee 2011).Not stated (Agaev 2013, Saad 2000). Dropouts: Eight (Sammour 2010): 6 due to complications/alterations to the surgery, 1 due to unblinding, 1 due to allergic reaction to anesthetic. Seven (Herrmann 2015): 5 complications, 1 to unblinding, 1 to allergic reaction. Four (Frey 2012a): 3 overheating, 1 insufficient data. Six (Frey 2012b). 2 complications, 2 insufficient data, 2 accidental overheating. Not detailed (Davis 2006, Kissler 2004, Manwaring 2008, Agaev 2013, Klugsberger 2014). Two (Nelskyla 1999): 1 surgical complication, 1 did not fulfill the study protocol). Two (Wills 2001): 1 withdrawn due to failure to record pain data properly, 1 due to conversion to open laparotomy. Baseline comparisons: All similar and comparable between studies.	

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					Volume of gas: Sammour 2010 noted gas use - 113.9L (110.1) study group versus 178.4L (170.4) control group. Saad 2000 – 131L (60) heated group versus 135L (51) unheated group. Wills 2001 – 96L (43) heated group versus 116L (66) unheated group. SUMMARY (comparisons) A. Heated dry insufflation gas versus standard care Heated dry CO_2 versus cold dry CO_2 (Nelskyla 1999, Puttick 1999, Saad 2000, Wills 2001, Lee 2011). B. Heated humidified insufflation gas versus standard care (with/without adjunctive patient warming in both groups) Heated humidified CO_2 (35°C, 95% RH) versus cold dry CO_2 (~21°C, 0-1%) versus heated dry CO_2 (35°C, 0%) vs cold humid (~21°C, 95% RH) (Davis 2006). Heated humidified CO_2 versus cold dry CO_2 versus heated dry CO_2 (Kissler 2004). Heated humidified CO_2 versus cold dry CO_2 (Agaev 2013). Heated humidified CO_2 versus cold dry CO_2 (Herrmann 2015).	

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					Heated humidified CO_2 (37°C, 98% RH) versus cold dry CO_2 (19°C, 0% RH) (Sammour 2010). Heated humidified CO_2 versus standard gas (Klugsberger 2014). Heated humidified CO_2 versus standard cold dry gas (Manwaring 2008). Open - Heated humidified CO_2 (37°C, 100% RH) versus ambient air (standard treatment) (Frey 2012a). Open - Heated humidified CO_2 (30°C, 93% RH) versus ambient air (standard treatment) (Frey 2012b).	
28	Fisher and Paykel Healthcare	Addendum	13: Section 2.3.2 Results – Intraoperative active warming	General	• The stakeholder added new studies to existing heated, humidified insufflation meta-analyses (CG65 2008). The following analyses are a total comparison of literature identified in the previous CG65 as well as new literature found by the stakeholder (above).	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.
29	Fisher and Paykel Healthcare	Addendum	13: Section 2.3.2 Results – Intraoperative active warming	General	A. HEATED DRY CO_2 VERSUS COLD DRY CO_2 **1. Intraoperative core body temperature** Seven RCT's recorded mean temperature change totaling 105 patients in the treatment group (heated dry CO_2) and 110 in the standard care group (cold dry CO_2). Due to heterogeneity (I^2=80%) a random effects model was used. No difference in core	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.

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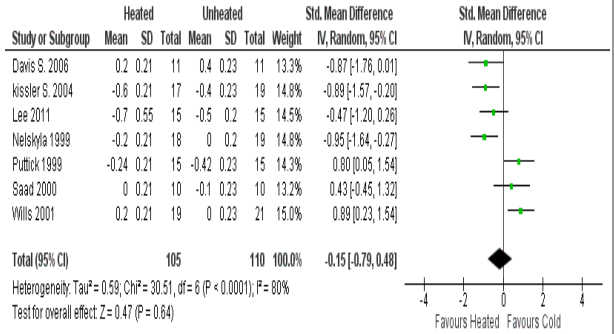
					temperature change between heated dry CO_2 and cold dry CO_2 was observed (p=0.64). It is worth noting that the prominent decrease in temperature (negative values) values in both treatment arms indicates a drop in temperature over surgery. In 5 out of the 7 studies core body temperature decreased throughout surgery with either heated dry CO_2 or cold dry CO_2 (Figure 1). Thus while the change in temperatures between the two therapies were similar, the average postoperative core body temperatures were lower at the end of surgery.  Figure 1: Intraoperative core temperature: heated dry CO_2 verses cold dry CO_2.	

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30	Fisher and Paykel Healthcare	General			B. HEATED HUMIDIFIED CO_2 VERSUS COLD DRY CO_2 (+/- adjunctive warming) **1. Intraoperative temperature** *Laparoscopic surgery* Fourteen RCT's recorded mean temperature change totaling 453 patients in the treatment group and 469 in the standard care group. Due to heterogeneity (I^2=77%/87%) a random effects model was used. Overall, a significant benefit in temperature maintenance was found in patients treated with heated humidified CO_2 (P<0.0001) (Figure 2). Sub-analysis of studies done with the use of adjunctive warming devices showed a significant benefit of temperature maintenance in patients receiving insufflation with heated humidified CO_2 (P<0.0001). Patients that did not receive adjunctive warming, or did not report the use of any adjunctive warming, showed a reduced but still significant difference in favor of surgical humidification (P=0.02). Collectively the RCTs report that heated humidified CO_2 significantly improves intraoperative core body temperature.	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.

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					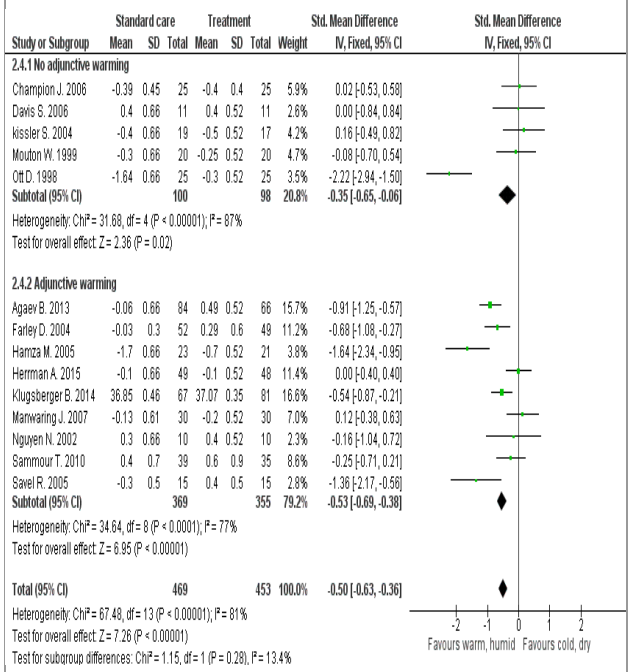 Figure 2: Laparoscopic intraoperative core temperature change: with and without adjunctive warming **Sub analysis: core temperature change by operation time**	

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					When sub-grouped by operation time (</> 80 minutes) studies with operating times averaging 80 minutes or greater showed a significant benefit in temperature maintenance for patients receiving heated humidified CO_2 compared with cold dry CO_2 (P=0.01). Surgeries with average operating times less than 80 minutes showed no difference (P=0.19) (Figure 3). This sub analysis should be interpreted with the fact that while it appears heated humidified gas is not as beneficial in shorter operations, the result may be due to the sensitivity of temperature recording devices. Core temperature changes will be greater in longer procedures compared to shorter ones and so the ability to accurately measure smaller changes is difficult with most intraoperative thermometers.	

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					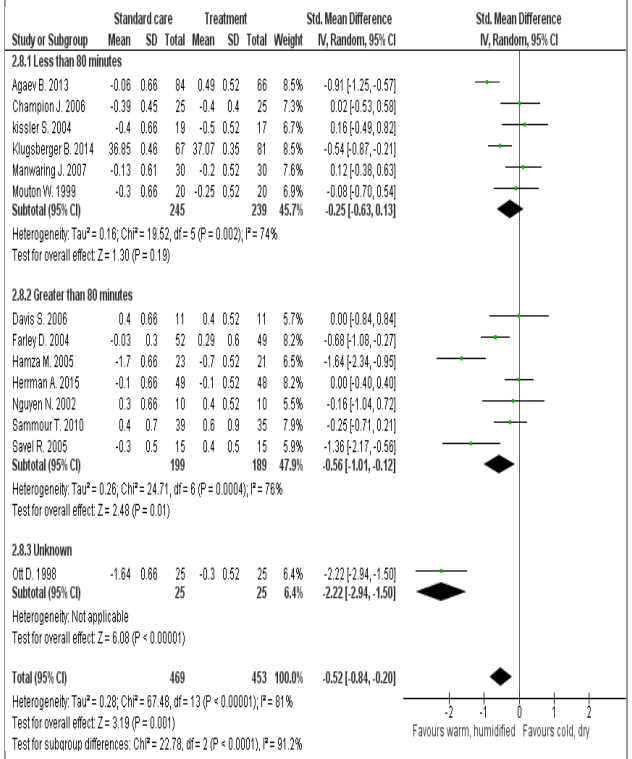 Figure 3: Core temperature change by operation time	

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					Post-operative temperature change In addition to operative core temperature changes, three studies reported post-operative temperature differences, that is, temperature change in the Intensive Care Unit (ICU) following surgery. Meta-analysis of three RCTs identified a significant benefit in core body temperature as recorded in the ICU in patients who received heated humidified CO_2 (P=0.009; Figure 4). The greatest difference was prominent at the 1hr post-surgery time point (p<0.00001).	

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					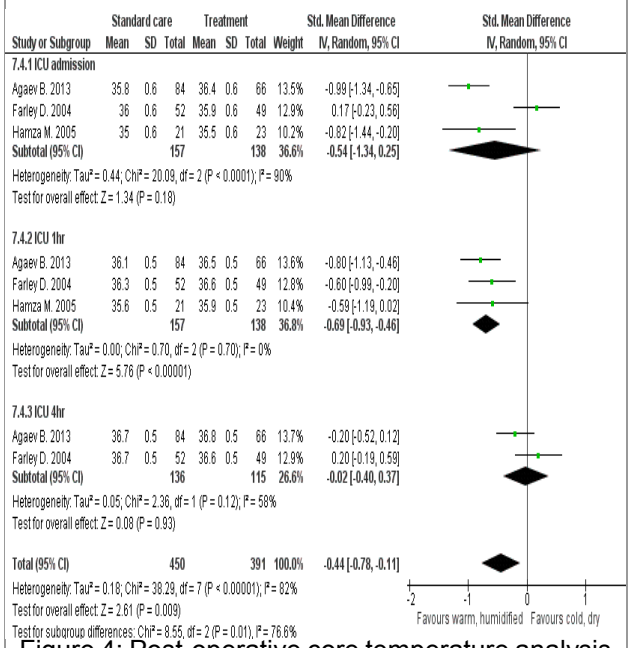 Figure 4: Post-operative core temperature analysis *Open surgery* Two randomized control trials were identified to investigate heated, humidified insufflation in open colorectal surgery. Both studies investigated	

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					colorectal patients and were published in 2012 (10, 11). Heterogeneity was low for all investigated objectives (I^2=0-4%) but a random effects model was employed to remain consistent with the data analysis used for laparoscopic studies. Both included studies received adjunctive warming in addition to the intervention. The meta-analysis showed that patients receiving heated humidified CO_2 insufflation into the open wound had significantly reduced *core temperature changes* during the procedure compared to patients receiving ambient air (no insufflation; standard care) (P<0.00001) (Figure 5).	

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					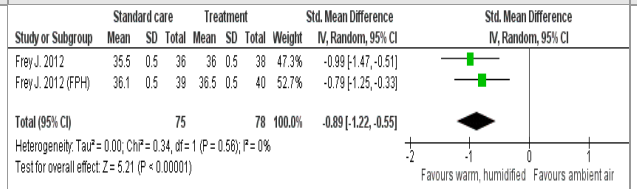 Figure 5: Core temperature change in open ery.	
31	Fisher and Paykel Healthcare	Addendum	38: Section 2.5 Evidence statements – Clinical evidence statements	General	As per the evidence above: • There is acceptable evidence comparing heated-dry insufflation gas with cold dry gas to show a no difference result in intraoperative core body temperature undergoing laparoscopic abdominal surgery. • There is strong evidence comparing heated-humidified gas with cold dry gas to show a statistically significant difference in patient intraoperative core temperature undergoing laparoscopic colorectal surgery, in favor of heated humidified CO_2. • There is strong evidence comparing heated-humidified gas with cold dry gas to show a small statistically significant difference in intraoperative core temperature in patients receiving adjunctive warming undergoing	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.

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					laparoscopic colorectal surgery, in favor of heated humidified CO_2. • There is weak evidence comparing heated-humidified gas with cold dry gas to show a small statistically significant difference in intraoperative core temperature in patients without adjunctive warming undergoing laparoscopic colorectal surgery, in favor of heated humidified CO_2. • There is acceptable evidence comparing heated-humidified gas with ambient air to show a statistically significant difference in patient core temperature undergoing open colorectal surgery, in favor of heated humidified CO_2.	
32	Fisher and Paykel Healthcare	Addendum	40: Section 2.6 Recommendations	General	**Update CG65 with heated humidified insufflation as a therapy to be administered during abdominal surgery to prevent hypothermia through evaporative heat loss**	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above.
33	Fisher and Paykel Healthcare	Addendum	68: Section 3 References (new)	General	1. Binda MM. Humidification during laparoscopic surgery: overview of the clinical benefits of using humidified gas during laparoscopic surgery. Archives of gynecology and obstetrics. 2015. 2. Binda MM, Molinas CR, Hansen P, Koninckx PR. Effect of desiccation and temperature during laparoscopy on adhesion	Thank you for submitting these references and details. These have now been considered and further details are outlined in the response to comment 26 above. For studies not mentioned in comment 26, the following reasons for exclusion are given:

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					formation in mice. Fertility and sterility. 2006;86(1):166-75. 3. Agaev BA, Muslimov GF, Ibragimov TR, Alieva GR. [The efficacy of the moisture and warmed CO(2) for laparoscopic surgery]. Khirurgiia (Mosk). 2013(11):35-9. 4. Davis SS, Mikami DJ, Newlin M, Needleman BJ, Barrett MS, Fries R, et al. Heating and humidifying of carbon dioxide during pneumoperitoneum is not indicated: a prospective randomized trial. Surgical endoscopy. 2006;20(1):153-8. 5. Herrmann A, De Wilde RL. Insufflation with humidified and heated carbon dioxide in short-term laparoscopy: a double-blinded randomized controlled trial. BioMed research international. 2015;2015:412618. 6. Kissler S, Haas M, Strohmeier R, Schmitt H, Rody A, Kaufmann M, et al. Effect of humidified and heated CO2 during gynecologic laparoscopic surgery on analgesic requirements and postoperative pain. The Journal of the American Association of Gynecologic Laparoscopists. 2004;11(4):473-7. 7. Klugsberger B, Schreiner M, Rothe A, Haas D, Oppelt P, Shamiyeh A. Warmed, humidified carbon dioxide insufflation versus standard carbon dioxide in laparoscopic cholecystectomy: a double-blinded randomized	Binda 2015 – Narrative review Binda 2006 – study in animals not humans

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					controlled trial. Surgical endoscopy. 2014;28(9):2656-60. 8. Manwaring JM, Readman E, Maher PJ. The effect of heated humidified carbon dioxide on postoperative pain, core temperature, and recovery times in patients having laparoscopic surgery: a randomized controlled trial. J Minim Invasive Gynecol. 2008;15(2):161-5. 9. Sammour T, Kahokehr A, Hayes J, Hulme-Moir M, Hill AG. Warming and humidification of insufflation carbon dioxide in laparoscopic colonic surgery: a double-blinded randomized controlled trial. Annals of surgery. 2010;251(6):1024-33. 10. Frey JM, Janson M, Svanfeldt M, Svenarud PK, van der Linden JA. Local insufflation of warm humidified CO(2)increases open wound and core temperature during open colon surgery: a randomized clinical trial. Anesthesia and analgesia. 2012;115(5):1204-11. 11. Frey JM, Janson M, Svanfeldt M, Svenarud PK, van der Linden JA. Intraoperative local insufflation of warmed humidified CO(2) increases open wound and core temperatures: a randomized clinical trial. World journal of surgery. 2012;36(11):2567-75. 12. Nelskyla K, Yli-Hankala A, Sjoberg J, Korhonen I, Korttila K. Warming of insufflation gas during laparoscopic hysterectomy: effect on body	

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					temperature and the autonomic nervous system. Acta Anaesthesiol Scand. 1999;43(10):974-8. 13. Puttick MI, Scott-Coombes DM, Dye J, Nduka CC, Menzies-Gow NM, Mansfield AO, et al. Comparison of immunologic and physiologic effects of CO2 pneumoperitoneum at room and body temperatures. Surgical endoscopy. 1999;13(6):572-5. 14. Saad S, Minor I, Mohri T, Nagelschmidt M. The clinical impact of warmed insufflation carbon dioxide gas for laparoscopic cholecystectomy. Surgical endoscopy. 2000;14(9):787-90. 15. Wills VL, Hunt DR, Armstrong A. A randomized controlled trial assessing the effect of heated carbon dioxide for insufflation on pain and recovery after laparoscopic fundoplication. Surgical endoscopy. 2001;15(2):166-70. 16. Lee KC, Kim JY, Kwak HJ, Lee HD, Kwon IW. The effect of heating insufflation gas on acid-base alterations and core temperature during laparoscopic major abdominal surgery. Korean J Anesthesiol. 2011;61(4):275-80.	
3	Royal College of Anaesthetists	Short	5	1.1.4	This statement would read better if it goes' where possible that direct measurement of core temperature is to be preferred and the following three routes will …….	Thank you for your comment. We have amended the wording of recommendation 1.1.5, which now reads:

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						Measure the patient's temperature using a site that produces either: • a direct measurement of core temperature, or • a direct estimate[1] of core temperature that has been shown in research studies to be accurate to within 0.5ºC of direct measurement. At the time of publication these sites are: • pulmonary artery catheter • distal oesophagus • urinary bladder • zero heat-flux (deep forehead). • sublingual[2] • axilla[2] • rectum.

[1] A direct estimate of core temperature is the reading produced by a thermometer with no correction factors applied.
[2] Be aware of possible inaccuracies in core temperature estimation when using peripheral sites, such as sublingual or axilla, in patients whose core temperature is outside the normothermic range (36.5°C to 37.5°C).

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						[new 2016]
4	Royal College of Anaesthetists	Short	6	1.2.2	The main change with significant implications is that we should use forced air warming for more or less all patients for half an hour before anaesthesia. Whist we agree with the overall premise of this statement, we are concerned that hospitals will find it challenging to offer all patients active warming for 30 minutes before induction. This recommendation will be difficult to implement in the prevailing fiscal climate. To give this some rough scale, in a large hospital this would cost about £500,000 per year in equipment/disposables. The net benefit in prevented hypothermia and its consequences is £2-40M. So obviously a good thing to do. The question is to whom does this benefit accrue? The cost will come out of the theatres budget, but the benefit will be spread out over a whole range of budgets, mostly not theatres but rather surgery, primary care etc. Would it therefore, not be better to offer it to patients found to be hypothermic pre-operatively?	Thank you for your comment. Pre-warming was found to be a cost effective use of NHS resources for all the subgroups (age, magnitude of surgery) examined in the economic analysis. When discussing the implementation of this guidance the committee considered that the kit is often available free of charge to NHS providers and that the marginal (per use) cost is low. The greatest cost savings, which contribute to the cost-effectiveness, were from avoiding cases of hypothermia were from reduced length of stay, reduction in infections and reduction in morbid cardiac events. The assumptions behind these costs were taken from the model conducted for the original guideline. A full discussion of these assumptions is available in Appendix H of the full guideline document, which is available on the NICE website. The costs in the model that have a probability of occurring (and therefore being avoided) are detailed in Table 4 in the economic discussion of this addendum. These cost savings may fall across different budgets depending on current local and national commissioning arrangements.

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						Commissioners and providers should work together to meet the challenges of implementing this guidance.
5	Royal College of Anaesthetists	Short	6	1.2.3	This statement needs rewording as it implies that one should ignore all other phases of treatment!	Thank you for your comment. We have taken your comments into account and have now moved this recommendation to section 1.1 Perioperative care, recommendation 1.1.2, , and the wording has been changed to: "Pay particular attention to the comfort of patients with communication difficulties before, during and after surgery. [new 2016]"
6	Royal College of Anaesthetists	Short	6	1.2.4	Should nefopam get a mention at all? Most clinicians never knowingly prescribe this medication to patients in the perioperative period.	Thank you for your comment. We have discussed this with the committee and it has been agreed to remove recommendation 1.2.4.
7	Royal College of Anaesthetists	Short	7	1.2.7	We agree with the statement but it should include a clause that allows patients, be it elective or emergency, to be released from the wards if the clinicians involved in their care judge that the patient will not benefit from the delay.	Thank you for your comment. This recommendation was outside the scope of the update and therefore no changes can be made to the recommendation.
8	Royal College of Anaesthetists	Short	7	1.3.1	This statement implies that the patient's temperature must be measured in the anaesthetic room. It may not be necessary as their temperature would be recorded just before leaving the ward.	Thank you for your comment. This recommendation was outside the scope of the update and therefore no changes can be made to the recommendation.

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9	Royal College of Anaesthetists	Short	7	1.3.3	As for 1.2.7	Thank you for your comment. This recommendation was outside the scope of the update and therefore no changes can be made to the recommendation.
10	Royal College of Anaesthetists	Short	7	1.3.4	This recommendation may be a challenge to implement as 21° C may not always be possible to attain, resulting in undue delays to operating lists. We feel that it perhaps better to re-word the statement without using absolute numbers.	Thank you for your comment. This recommendation was outside the scope of the update and therefore no changes can be made to the recommendation.
11	Royal College of Anaesthetists	Short	General		Overall it is a good document but it needs tighter wording which will help minimise confusion.	Thank you for your comment.
1	Royal College of Nursing	General	General		This is just to let you know that there is no comments to submit on behalf of the Royal College of Nursing for consultation on the NICE draft addendum on Inadvertent Perioperative Hypothermia. Thank you for the opportunity to review.	Thank you for your comment.

**There were no links to, or funding from, the tobacco industry disclosed by commenters.*

Registered stakeholders