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Evidence Brief
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OREGON HEALTH AND SCIENCE UNIVERSITY
OFFICE OF CLINICAL INTEGRATION AND EVIDENCE-BASED PRACTICE

Evidence-Based Practice Summary
Forced air warming devices effect on patient outcomes

BACKGROUND AND RATIONALE

Maintaining intraoperative normothermia has been shown to reduce perioperative complications including surgical site infection (SSI).[1] Forced-air warming (FAW) represents one of the most widely used methods to prevent hypothermia and maintain intraoperative normothermia. Intraoperative hypothermia has been linked to increased mortalities and morbidities, longer hospital stays, increased requirements for blood transfusion, and increased SSI rates. [1] However, patient warming systems also release excess heat into the operating theatre that may generate convention currents even within a laminar flow system. [2] Multiple factors contribute to patient heat loss in the operating room, (OR) including room temperature, degree of cutaneous exposure, the planned procedure, the opening of large body cavities and cold intravenous fluids. The largest amount of heat loss occurs within the first hour of anesthesia with a 1 to 1.5°C drop in core temperature. The gradient is affected by elements such as the OR temperature, the patient's body composition of adipose tissue, the use of volatile agents, intravenous induction agents and neuraxiial anesthesia.[3] The use of anesthesia itself attenuates the patient's thermoregulation capabilities, allowing the opening of arterio-venous shunts and impairing the vasoconstriction threshold of blood vessels.[4] In neuraxial anesthesia, heat redistribution results from peripheral versus central inhibition; however, the lower extremity mass is adequate enough to contribute to core hypothermia. Overall, the major mechanisms of heat loss during the perioperative period is through the skin surface via radiation and convection, and to a much lesser degree through evaporation and conduction.[3] The purpose of evidence brief is to identify the best available evidence to determine if FAW devices effect patient outcomes in surgical areas.

ASK THE QUESTION

Do Forced Air Warming devices affect patient outcomes by disturbing air flow in surgical areas?

SEARCH FOR EVIDENCE

Appendix C

CRITICALLY ANALYZE THE EVIDENCE

348 research articles were found mentioning FAW Devices. Four guidelines, two systematic reviews, one cohort study, one retrospective study, and two experimental studies were found including information on how FAW devices affected patient outcomes. None of the four guidelines that were identified recommended against the use of FAW devices, although each had varying recommendations on its use. In 2019, The International Consensus on Orthopedic Infections concluded the following:[1]

> "There is a lack of strong evidence linking FAW to increased risks of SSIs. In light of this, while we recognize the theoretical risk posed by FAW, we cannot recommend discontinuing the use of these devices at this time. We do however recommend following the manufacturer's instructions and frequently changing the filters, making sure the devices are calibrated and most importantly using the devices only with the appropriate perforated blanket. Other alternative warming methods can be used."

Additionally, the Association of periOperative Registered Nurses (AORN) recommended using FAW systems when indicated for hypothermia, among other warming methods. The systematic review used to inform their recommendations failed to identify conclusive evidence for an increased risk of SSI with the use of FAW.[5] In 2016, the UK's National Institute for Health and Clinical Excellence (NICE) found there was sufficient evidence of clinical effectiveness and cost effectiveness for recommendations made on the use of FAW to prevent and treat perioperative hypothermia. NICE's review found that FAW vs. usual care for general anesthesia had significantly higher core temperatures at 30, 60, and 120 minutes intraoperatively and at the end of surgery in the ICU.[7] Lastly, the American Society of Anesthesiologists consultants and ASA members agreed that (1) the perioperative maintenance of normothermia and (2) the use of FAW reduce shivering and improve patient comfort and satisfaction.[7]

Recent Systematic Review:
Haeberle et al (Haeberle) conducted a systematic review that evaluated the infection risk of using FAW devices in the orthopedic population. The authors reviewed eight studies consisting of three RCTs, one of which involved canines; two laboratory studies; two quasi-experimental studies; and one retrospective study. The review authors concluded that there is no evidence in the current orthopedic literature that establishes a link between FAW devices and an increase in surgical site infections. One low quality study found a decrease in the number of periprosthetic infections after changing from a FAW system to a conductive fabric warming system.

Haeberle Systematic Review Evidence Table:

Table I
Summary of literature review

Study	Year	Design	Procedure	Experimental Group	Control Group	Primary Outcome Measure	Statistical Significance	Summary	Study Limitations
Tumia[36]	2002	Prospective non-randomized trial	THA, shoulder operation	FAW (n=4)	Empty OR (n=4) and before warming system turned on (n=4)	Bacterial counts	No	Non-significant increase in bacterial count with FAW as compared to empty OR and before FAW initiated	Small sample size with no SSIs noted in any group. Any increases in bacterial count may be attributed to OR personnel traffic.
Leaper[38]	2006	Randomized prospective trial	Orthopedic, general, and urologic surgery	FAW (n=161)	No warming device (n=163)	Incidence of pressure sores	No	Decreased, although not significant, rate of pressure sores in FAW (5.6%) versus no warming device (10.4%), with relative risk reduction of 46%.	Incidence of pressure sores measured as a proxy for cutaneous tissue viability. SSIs not measured. Orthopaedic surgeries grouped with other surgery types.
Moretti[34]	2009	Prospective non-randomized trial	THA	FAW (n=20)	No warming device (n=10)	Bacterial counts	Yes	No clinically significant difference in bacterial count with FAW compared to no warming device (significant decrease with FAW for 1 sample point, no difference at 2 other sample points)	Small sample size with no SSIs in either group.
McGovern[24]	2011	Retrospective study	THA, TKA	FAW (n=1066)	CWB (n=371)	Infection within 60 days of operation	Yes	Significantly increased chance of developing deep joint infection for FAW (3.1%) versus CWB (0.8%) (OR 3.8, p=0.024)	Did not control for patient demographics or changes to infection control and thromboprophylaxis protocols during study period. Causality cannot be determined. Did not consider other SSI risk factors such as blood transfusion, general health, incontinence, or obesity.
Legg[26]	2012	Laboratory study	Simulated TKA	FAW (n=1)	CWB (n=1) and no warming device (n=1)	Surgical site temperature and particle count	Yes	Significantly higher surgical site temperature and particle count with FAW than CWB or no warming device	Small sample size. Temperature and particle count measured as proxies for infection risk. Healthy volunteer used as subject and only one surgical personnel present.
Legg[27]	2013	Laboratory study	Simulated TKA	FAW (n=1)	CWB (n=1) and no warming device (n=1)	Particle count and drape temperature	Yes	Significant increased particle count and drape temperature with FAW as compared to CWB and no warming device	Small sample size. Temperature and particle count measured as proxies for infection risk. Mannequin used as subject and only one surgical personnel present.
Occhipinti[37]	2013	Prospective randomized study	Orthopaedic procedures in canines	FAW (n=46)	Circulating water blanket (n=30)	Bacterial contamination on surgical drape	No	No significant difference in contamination of surgical drapes with the use of FAW	Small sample size of canine subjects. SSIs not measured. High threshold of detection for bacterial contamination.
Oguz[35]	2017	Prospective randomized trial	5 orthopaedic procedures: arthroscopy, osteosynthesis, metal implant removal, ligament and soft tissue surgery, TKA	FAW (n=40)	CWB (n=40)	Bacterial counts	No	Increased, although not significant, bacterial counts on all plates with FAW	Small sample size, no surgical site infections occurred in either group, did not match for surgical type or duration.

FAW=forced-air warming, CWB=conductive warming blanket, THA=total hip arthroplasty, TKA=total knee arthroplasty, SSI=surgical site infection, OR=operating room

Studies not included in systematic review:
**Studies included in guideline and systematic review were not appraised individually in this brief.*
One large multicenter retrospective center study (Augustine 2017) investigated periprosthetic joint infection (PJI) rates while using FAW compared with air-free conductive fabric electric warming (CFW). The pooled data showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW (n=2034; P=0.002).

A systematic review (Alderson 2014) assessed the effects of pre- or intraoperative thermal insulation, or both, in preventing perioperative hypothermia and its complications during surgery in adults. There is some evidence that using FAW increases a person's temperature compared with what happens when using reflective blankets or clothing. The temperature increase was between 0.5 °C and 1 °C. It is unclear how this temperature difference would reduce the consequences of coldness, with uncertain effects on blood loss, shivering and time spent in recovery. Authors were unable to find sufficient information to look at adverse effects of insulation or warming, or major events affecting the heart or circulatory system. A cohort study (Sandoval 2017) compared the capabilities of patient warming between two different devices that use different mechanisms of warming: FAW and non-air warming. FAW and non-air warming achieved similar results in maintaining the core temperature of patients undergoing total knee or hip arthroplasty. No adverse events were reported in either group. Operating room staff observed that the non-air warming device was less noisy and appreciated the disposable covers that could be changed after each surgical case.

Additional experimental studies not included in Haeberle systematic review raised a concern for the possibility of intraoperative contamination caused by FAW. Dasari et al (Dasari 2012) conducted an experiment in which mannequin was used as a patient, and the temperature was measured at multiple different heights and locations with the use of FAW, a conductive blanket, or a resistive mattress. They found significantly greater temperature increases caused by FAW at patient height locations, whereas, temperatures measured at other heights (floor, head, and ceiling) were similar among the three warming devices. Additionally, Belani et al (Belani 2013) conducted a study with a mannequin draped for a TKA in an orthopedic room and a bubble generator placed at the head to visualize air currents. The direct mass-flow exhaust from FAW generated hot air convection currents that mobilized bubbles over the anesthesia drape and into the surgical site, resulting in a significant increase in bubble counts for the factor of patient warming device ($P < 0.001$). Forced air had an average count of 132.5 versus 0.48 for conductive fabric ($P = 0.003$) and 0.01 for control conditions ($P = 0.008$) across both drape heights.

Conclusion
There is low quality evidence that using FAW increases a person's temperature compared with what happens when using reflective blankets or clothing. Evidence on SSIs is not consistent, but currently there is no evidence to support that FAW increases SSIs. One very low quality study found that use of FAW increased PJI rates.

In summary, the evidence is clearer on FAWs benefits to preventing perioperative hypothermia, but is conflicting when examining SSIs. The majority of studies linking FAWs to SSI were experimental studies done on mannequins, dummies or case studies. Current studies conducted in the clinical setting have not demonstrated a link between FAWs and SSIs. Although, one cohort study did find a link between FAWs and PJIs. Therefore, clinicians should weigh risks and benefits when contaminating of the surgical field is deemed critical.

Guideline Recommendations:

General Assembly, Prevention, Operating Room Environment: Proceedings of International Consensus on Orthopedic Infections, 2019

- There is no evidence to definitively link forced air warming to an increased risk of SSIs/PJIs. Alternative methods of warming can be effective and may be used. (**Level of Evidence: Limited**)

Association of periOperative Registered Nurses (AORN): Guideline for Prevention of Hypothermia, 2019

- When indicated, warm the patient with one or more of the following active warming methods during all phases of perioperative care:
  - **Forced-air warming systems (eg, over- and under-body blankets, warm-arm gowns) may be used. *(Conditional Recommendation)***
  - Warm water-circulating devices may be used. *(Conditional Recommendation)*
  - Conductive/resistive warming devices (eg, electric heating pads, carbon-fiber resistive-heating blankets, conductive warming mattresses, self-warming blankets) may be used. *(Conditional Recommendation)*
  - Warmed anesthesia gases may be used to warm the patient as an adjunct to other active warming or passive insulation methods. *(Conditional Recommendation)*
  - Warmed IV fluids may be used as an adjunct to other active warming methods. *(Conditional Recommendation)*
  - Warmed irrigation solutions (33° C to 40° C [91.4° F to 104° F]) may be used. *(Conditional Recommendation)*
  - Radiant warming devices may be used. *(Conditional Recommendation)*
  - Warm insufflation gases may be used as an adjunct to other active warming methods. *(Conditional Recommendation)*
  - Ambient room temperatures may be increased as an adjunct to other active warming methods. *(Conditional Recommendation)*
  - Document measures taken to maintain patient normothermia in the patient's medical record, including the warming method used, warming device identifier, and temperature settings when applicable. *(Recommendation)*

The UK's **National Collaborating Centre for Nursing and Supportive Care and National Institute for Health and Clinical Excellence (NICE)**, 2016 – the management of inadvertent perioperative hypothermia in adults.

Evidence Review

- Sufficient evidence of clinical effectiveness and cost effectiveness for recommendations to be made on the use of forced air warming to prevent and treat perioperative hypothermia.
  - Forced air warming vs usual care for general anesthesia had significantly higher core temperatures at 30, 60, and 120 minutes intraoperatively and at the end of surgery in the ICU.
  - Forced air warming versus reflective blanket for regional anesthesia had significantly higher core temperatures at 60 and 120 minutes intraoperatively but there was no statistically significant difference at 30 minutes.

- Forced air warming versus warmed cotton blankets for general anesthesia had a significantly lower incidence of IPH in PACU and significantly higher core temperatures at 120 minutes intraoperatively.
- Forced air warming versus electric heating pad for general anesthesia had significantly higher core temperatures at 120 minutes intraoperatively but there was no statistically significant difference at 30 or 60 minutes intraoperatively.
- Forced air warming plus warmed fluids (2.97 litres) versus Forced air warming plus unwarmed fluids (1.77 litres) for general anesthesia had significantly higher core temperatures at 30 and 120 minutes intraoperatively but there was no statistically significant difference at 60 minutes and we note that the amount of fluids was significantly different between the two groups.
- Forced air warming aggressive versus forced air warming conventional for regional anesthesia had significantly higher average core temperatures and at the end of surgery.
- Forced air warming plus warmed fluids (1.1 litre) versus usual care for general anesthesia had significantly higher core temperatures at the end of surgery (56 min) and the lowest core temperatures (at 25 and 35 minutes) were significantly higher. Forced air warming also significantly decreased the incidence of IPH at the end of surgery (RR 0.32).
    - We note that, of the patients receiving usual care, 29% of patients assigned to the routine care arm received forced air warming and 9% received warmed fluids at the discretion of the anesthetist. This is likely to underestimate the size of the effect.
- Forced air warming versus warmed cotton blankets for general anesthesia had a significantly lower incidence of IPH in PACU and a higher core temperature in PACU.

Recommendations

Preoperative phase

- If the patient's temperature is below 36.0°C:
    - forced air warming should be started preoperatively on the ward or in the emergency department (unless there is a need to expedite surgery because of clinical urgency, for example bleeding or critical limb ischemia)
    - forced air warming should be maintained throughout the intraoperative phase

Intraoperative phase

- Patients who are at higher risk of inadvertent perioperative hypothermia and who are having anesthesia for less than 30 minutes should be warmed intraoperatively from induction of anesthesia using a forced air warming device.
- All patients who are having anesthesia for longer than 30 minutes should be warmed intraoperatively from induction of anesthesia using a forced air warming device.

Postoperative phase

- If the patient's temperature is below 36.0°C, they should be actively warmed using forced air warming until they are discharged from the recovery room or until they are comfortably warm.

The **American Society of Anesthesiologists** Task Force on Postanesthetic Care, 2013

Normalizing Patient Temperature

- The consultants and ASA members agree that: (1) the perioperative maintenance of normothermia and (2) the use of forced-air warming reduce shivering and improve patient comfort and satisfaction.
- The original Guidelines indicated that active patient warming is associated with normalizing patient temperature (Category A2-B evidence); new literature is insufficient to further evaluate these findings. The original Guidelines indicated that the use of a forced air warming device normalizes patient temperature and reduces shivering (Category A1-B evidence); one new RCT corroborates these findings for the normalization of patient temperature (Category A3-B evidence) but is equivocal for the reduction of shivering (Category A3-E evidence).
- Normothermia should be the goal during emergency and recovery. When available, forced air warming systems should be used for treating hypothermia.

Table 1. Meta-Analysis Summary—Original Guidelines

Interventions/ Outcomes	No. Studies	Fisher Chi-square	*P* Value	Weighted Stouffer Zc	*P* Value	Effect Size	Mantel-Haenszel Chi-Square	*P* Value	Odds Ratio	Heterogeneity Significance	Heterogeneity Effect Size
Forced-air warming											
Temperature	8	107.43	< 0.001	17.67	< 0.001	0.99	—	—	—	< 0.001	< 0.001
Shivering	5	—	—	—	—	—	14.11	< 0.001	3.75	—	> 0.70 (NS)

Guideline References:

1. Aalirezaie, A., et al. (2019). "General Assembly, Prevention, Operating Room Environment: Proceedings of International Consensus on Orthopedic Infections." The Journal of Arthroplasty 34(2, Supplement): S105-S115.
2. Association of periOperative Registered Nurses. (2019) Guideline for Prevention of Hypothermia. Accessed on January 7, 2020. https://aornguidelines.org/guidelines/content?sectionid=173732053&view=book.
3. National Collaborating Centre for Nursing and Supportive Care and National Institute for Health and Clinical Excellence (2016). The management of inadvertent perioperative hypothermia in adults. Accessed on January 7, 2020. https://www.nice.org.uk/guidance/cg65/evidence/full-guideline-pdf-196802751.
4. The American Society of Anesthesiologists Task Force on Postanesthetic Care. (2013). Practice Guidelines for Postanesthetic Care: An Updated Report by the American Society of Anesthesiologists Task Force on Postanesthetic Care. Accessed January 7, 2020. https://anesthesiology.pubs.asahq.org/article.aspx?articleid=1918686.

Guideline Ratings

Guideline Issuer and Date	General Assembly 2019	AORN 2019	NICE 2016	ASA 2013
1. Transparency	B	A	A	A
2. Conflict of interest	B	A	A	B
3. Development group	B	A	A	B
4. Systematic Review	B	A	A	B
5. Supporting evidence	A	A	A	B
6. Recommendations	A	A	B	B
7. External Review	B	A	A	B
8. Currency and updates	A	A	A	B

See appendix B for full description of the Trustworthy Guideline grading system.

Primary Literature

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Modality: Forced-air warming device
Outcome: Infection Risk

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:
☐ High
☒ Medium
☐ Low

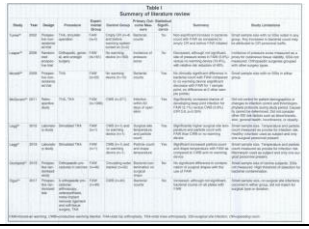
Lower Quality Rating if:
☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)

☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)*

☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*

Other Considerations:
Lower Quality Rating if:
☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

Increase Quality Rating if:
☐ Large effect
☐ Dose-response gradient
☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Haeberle, H. S., et al. Year Published: 2017 Location: Baylor College of Medicine, Houston, TX Journal: *Surgical Technology International*	To systematically review and evaluate if forced-air warming devices presented potential risks for surgical site infections.	**Size:** 7 trials **Inclusion Criteria:** Studies examining forced-air warming devices and infection risk, or bacterial load **Exclusion Criteria**: Studies that were not related to infections related to orthopedic surgeries with intraoperative forced-air warming devices and review articles	**Methods**: systematic Review	**Results:** There is no current evidence in the orthopedic literature that forced-air warming devices translate to increased SSIs. Authors concluded that these devices should continue to be used for the maintenance of intraoperative normothermia. 	**Study Limitations:** ☐ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☒ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

References:

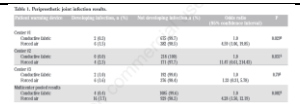
1. Haeberle, H. S., et al. (2017). "No Evidence of Increased Infection Risk with Forced-Air Warming Devices: A Systematic Review." Surgical Technology International **31**: 295-301.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Modality: Forced-air warming device
Outcome: Joint Infection

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☐ Low
☒ Very Low

Risk of Bias across studies:	**Lower Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) - ***Unknown*** ☐ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Augustine, S.D. Year Published: 2017 Location: USA Journal: *Orthop Rev*	To investigate periprosthetic joint infection (PJI) rates while using FAW compared with air-free conductive fabric electric warming (CFW)	**Size:** 2014 (conductive fabric = 1085; Forced air = 929)	**Type:** Multicenter retrospective outcome study **Methods**: Compared PJI rates during a period of FAW to a period of air-free CFW at three hospitals.	**Results:** The pooled data showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW (n=2034; P=0.002).	**Study Limitations:** ☐ None ***Non-Randomized Studies*** ☒ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome

					☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Augustine, S. D. (2017). "Forced-Air Warming Discontinued: Periprosthetic Joint Infection Rates Drop." Orthop Rev (Pavia) **9**(2): 6998.

BODY OF EVIDENCE APPRAISAL TABLE FOR:
Modality: Forced-air warming device
Outcome: Perioperative Hypothermia

Quality (certainty) of evidence for: (outcome)
☐ High
☐ Moderate
☒ Low
☐ Very Low

Risk of Bias across studies:	**Lower Quality Rating if:**	**Other Considerations:**
☐ High ☒ Medium ☐ Low	☐ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*) ☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☐ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*	Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)* Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect

Study Acronym; Author; Year Published; Location	Aim of Study	Patient Population	Study Methods	Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)	Design Limitations
Author: Alderson, P. et al. Year Published: 2014 Location: National Institute for Health and Care Excellence, Manchester, UK Journal: *Cochrane*	To assess the effects of pre- or intraoperative thermal insulation, or both, in preventing perioperative hypothermia and its complications during surgery in adults.	**Size:** 16 trials **Inclusion Criteria**: Randomized controlled trials of thermal insulation compared to standard care or other interventions aiming to maintain normothermia	**Type:** Systematic Review	**Results:** There is some evidence that using forced air warming increases a person's temperature compared with what happens when using reflective blankets or clothing. The temperature increase was between 0.5 °C and 1 °C. It is unclear how this temperature difference would reduce the consequences of coldness, with uncertain	**Study Limitations:** ☒ None ***Systematic Review*** ☐ Review did not address focused clinical question ☐ Search was not detailed or exhaustive ☐ Quality of the studies was not appraised ☐ Inappropriate pooled analysis

				effects on blood loss, shivering and time spent in recovery. Authors were unable to find sufficient information to look at adverse effects of insulation or warming, or major events affecting the heart or circulatory system.	
Author: Sandoval, M. F., et al Year Published: 2017 Location: USA Journal: *Patient Safety in Surgery*	To compare the capabilities of patient warming between two different devices that use different mechanisms of warming: forced-air warming and non-air warming.	**Size:** 120 (60 vs 60)	**Type:** Cohort Study **Methods**: One hundred twenty patients undergoing total hip or total knee arthroplasty received patient warming via a forced warming device or non-air warming fabric conductive material. The project was part of a quality improvement initiative to identify warming devices effective in maintaining normothermic patient core temperatures during orthopedic surgery.	**Results:** Forced-air warming and non-air warming achieved similar results in maintaining the core temperature of patients undergoing total knee or hip arthroplasty. No adverse events were reported in either group. Operating room staff observed that the non-air warming device was less noisy and appreciated the disposable covers that could be changed after each surgical case.	**Study Limitations:** ☐ None ***Non-Randomized Studies*** ☐ Failure to develop and apply appropriate eligibility criteria ☐ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☐ Incomplete or inadequately short follow-up

References:

1. Alderson, P., et al. (2014). "Thermal insulation for preventing inadvertent perioperative hypothermia." Cochrane Database of Systematic Reviews(6): CD009908.
2. Sandoval, M. F., et al. (2017). "Safety and efficacy of resistive polymer versus forced air warming in total joint surgery." Patient Safety in Surgery **11**(1): 11.

BODY OF EVIDENCE APPRAISAL TABLE FOR: Modality: Experimental Studies - Forced air warming devices Outcome: Infection		
Quality (certainty) of evidence for: (outcome) ☐ High ☐ Moderate ☐ Low ☒ Very Low		
Risk of Bias across studies: ☒ High ☐ Medium ☐ Low	**Lower Quality Rating if:** ☒ Studies inconsistent (*wide variation of treatment effect across studies, population, interventions, or outcomes varied*)	**Other Considerations:** Lower Quality Rating if: ☐ Publication Bias (*e.g. pharmaceutical company sponsors study on effectiveness of drug only small, positive studies found)*

		☒ Studies are indirect (*PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome)* ☒ Studies are imprecise (*when studies include few patients and few events, and thus have wide confidence intervals, and the results are uncertain)*		Increase Quality Rating if: ☐ Large effect ☐ Dose-response gradient ☐ Plausible confounders or other biases increase certainty of effect	
Study Acronym; Author; Year Published; Location	**Aim of Study**	**Patient Population**	**Study Methods**	**Endpoint Results / Outcome (Absolute Event Rates, P values; OR or RR; & 95% CI)**	**Design Limitations**
Author: Dasari, K.B., et al. Year Published: 2012 Location: UK Journal: *Anaesthesia*	To investigate whether the floor-to-ceiling temperatures around a draped manikin in a laminar-flow theatre differed when using three types of warming devices: a forced-air warming blanket; an over-body conductive blanket, and an under-body resistive mattress.	**Size:** None – study used mannequin **Inclusion Criteria**: None **Exclusion Criteria**: None	**Type:** Experimental Study **Methods**: Experiments were conducted in a partial-walled ultra-clean operating theatre (ExFlow 90, Howorth, UK; Validation certification QA ref AA719/1/SM) used for orthopaedic surgery (Royal Sussex County Hospital, UK). A manikin was placed in the supine position and a general surgical drape applied with the head end tented to form an anaesthesia screen. The foot end of the drape was raised and folded over to create an air channel that directed the forced-air warming exhaust out of the ventilation field. A lower-body patient warming device (either the Bair Hugger, Hot Dog or Inditherm) was introduced under the drape.	**Results:** With forced-air warming, mean (SD) temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7) °C; $p < 0.001$) or resistive mattress (+3.63 (0.7) °C; $p < 0.001$). Air temperature differences were insignificant between devices at floor ($p = 0.339$), knee ($p = 0.799$) and head height levels ($p = 0.573$).	**Study Limitations:** ☐ None ***Non-Randomized Studies*** ☒ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome ☒ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up
Author: Belani, K., et al. Year Published: 2012 Location: University of Minnesota Journal: *Anesthesia and analgesia*	To study the effects of two population patient warming technologies, forced air and conductive fabric, versus control conditions on ventilation performance in an orthopedic operating room	**Size:** None – study used mannequin **Inclusion Criteria**: None **Exclusion Criteria**: None	**Type:** Experimental Study **Methods**: Ventilation performance was assessed by releasing neutrally buoyant detergent bubbles ("bubbles") into the nonsterile region under the head-side of the	**Results:** The direct mass-flow exhaust from forced air warming generated hot air convection currents that mobilized bubbles over the anesthesia drape and into the surgical site, resulting in a significant increase in bubble	Study Limitations: ☐ None Non-Randomized Studies ☒ Failure to develop and apply appropriate eligibility criteria ☒ Flawed measurement of both exposure and outcome

	with a mannequin draped for total knee replacement		anesthesia drape. Excess heat from upper body patient warming was tracked from "bubbles" into the surgical site. Formally, a randomized replicated design assessed the effect of device (forced air, conductive fabric, control) and anesthesia drape height (low-drape, high-drape) on the number of bubbles photographed over the surgical site.	counts for the factor of patient warming device (P < 0.001). Forced air had an average count of 132.5 versus 0.48 for conductive fabric (P = 0.003) and 0.01 for control conditions (P = 0.008) across both drape heights. Differences in average bubble counts across both drape heights were insignificant between conductive fabric and control conditions (P = 0.87). The factor of drape height had no significant effect (P = 0.94) on bubble counts.	☒ Failure to adequately control confounding ☒ Incomplete or inadequately short follow-up

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1. Belani, K., et al. (2012). "Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance." Anesthesia and analgesia **117**.
2. Dasari, K. B., et al. (2012). "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation*." **67**(3): 244-249.

The GRADE criteria were used to evaluate the quality of evidence presented in research articles reviewed during the development of this guideline. For more detailed information, see Appendix A.

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17. Dasari, K. B., et al. (2012). "Effect of forced-air warming on the performance of operating theatre laminar flow ventilation*." 67(3): 244-249.

Appendix A. GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

Grades and interpretations:

High: Further research is very unlikely to change our confidence in the estimate of effect. Moderate: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. Low: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. Very low: Any estimate of effect is very uncertain.

Type of evidence and starting level

Randomized trial–high Observational study–low Any other evidence–very low

Criteria for increasing or decreasing level

Reductions Study quality has serious (–1) or very serious (–2) problems Important inconsistency in evidence (–1) Directness is somewhat (–1) or seriously (–2) uncertain Sparse or imprecise data (–1) Reporting bias highly probable (–1) **Increases** Evidence of association† strong (+1) or very strong (+2) †Strong association defined as significant relative risk (factor of 2) based on consistent evidence from two or more studies with no plausible confounders Very strong association defined as significant relative risk (factor of 5) based on direct evidence with no threats to validity.

Appendix B. Trustworthy Guideline rating scale

The University of Pennsylvania's Center for Evidence-Based Practice Trustworthy Guideline rating scale is based on the Institute of Medicine's "Standards for Developing Trustworthy Clinical Practice Guidelines" (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains.

The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guide-line does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated). Current quality scales like AGREE emphasize documentation. They are important checklists for developers of new guidelines, but are less useful for grading existing guidelines. These scales also are harder for clinicians and other persons who are not methodology experts to apply, and their length discourages their use outside formal technology assessment reports. This new scale is brief, balanced, and easy and consistent to apply.

We do not attempt to convert the results of this assessment into a numeric score. Instead we present a table listing the guidelines and how they are rated on each standard. This facilitates qualitative understanding by the reader, who can see for what areas the guideline base as a whole is weak or strong as well as which guidelines are weaker or stronger.

1. Transparency

A	Guideline development methods are fully disclosed.
B	Guideline development methods are partially disclosed.
C	Guideline development methods are not disclosed.

The grader must refer to any cited methods supplements or other supporting material when evaluating the guideline. Methods should include:

Who wrote the initial draft
How the committee voted on or otherwise approved recommendations

Evidence review, external review and methods used for updating are not addressed in this standard.

2. Conflict of interest

A	Funding of the guideline project is disclosed, disclosures are made for each individual panelist, and financial or other conflicts do not apply to key authors of the guideline or to more than 1 in 10 panel members).
B	Guideline states that there were no conflicts (or fewer than 1 in 10 panel members), but does not disclose funding source.

C	Lead author, senior author, or guideline panel members (at least 1 in 10) have conflict of interest, or guideline project was funded by industry sponsor with no assurance of independence.
NR	Guideline does not report on potential conflict of interests.

For purposes of this checklist, conflicts of interest include employment by, consulting for, or holding stock in companies doing business in fields affected by the guideline, as well as related financial conflicts. This definition should not be considered exclusive. As much as anything, this is a surrogate marker for thorough reporting, since it may be assumed that guideline projects are funded by the sponsoring organization and many authors think it unnecessary to report a non-conflict.

3. Guideline development group

A	Guideline development group includes 1) methodological experts and clinicians and 2) representatives of multiple specialties.
B	Guideline development group includes one of the above, but not both.
C	Guideline developers all from one specialty or organization, and no methodologists.
NR	Affiliations of guideline developers not reported

The purpose of this standard is to ensure that supporters of competing procedures, or clinicians with no vested interest in utilization of one procedure or another, are involved in development of the guideline. Both AGREE II and IOM call for patient or public involvement: very few guideline panels have done so to date, so this is not necessary for guidelines to be rated A. Involvement of methodologists or HTA specialists in the systematic review is sufficient involvement in the guideline development group for our purposes. In the absence of any description of the guideline group, assume the named authors are the guideline group.

4. Systematic review

A	Guideline includes a systematic review of the evidence or links to a current review.
B	Guideline is based on a review which may or may not meet systematic review criteria.
C	Guideline is not based on a review of the evidence.

In order to qualify as a systematic review, the review must do all of the following:

Describe itself as systematic or report search strategies using multiple databases
Define the scope of the review (including key questions and the applicable population)
Either include quantitative or qualitative synthesis of the data or explain why it is not indicated

Note: this element does not address the quality of the systematic review: simply whether or not it exists. Concerns about quality or bias of the review will be discussed in text, where the analyst will explain whether the weaknesses of the review weaken the validity or reliability of the guideline.

Note: a guideline may be rated B on this domain even if the review on which it is based is not available to us. This potential weakness of the guideline should be discussed in text of the report.

5. Grading the supporting evidence

A	Specific supporting evidence (or lack thereof) for each recommendation is cited and graded
B	Specific supporting evidence (or lack thereof) for each recommendation is cited but the recommendation is not graded.
C	Recommendations are not supported by specific evidence.

To score a B on this domain there should be specific citations to evidence tables or individual references for each relevant recommendation in the guideline, or an indication that no evidence was available. Any standardized grading system is acceptable for purposes of this rating. If a guideline reports that there is no evidence available despite a thorough literature search, it may be scored B on this domain, or even A if evidence for other recommendations is cited and graded.

6. Recommendations

A	Considerations for each recommendation are documented (i.e. benefits and harms of a particular action, and/or strength of the evidence); and recommendations are presented in an actionable form.
B	Either one or the other of the above criteria is met.
C	Neither of the above criteria are met

In order to be actionable, the guideline should specify the specific population to which the guideline applies, the specific intervention in question, and the circumstances under which it should be carried out (or not carried out). The language used in the recommendations should also be consistent with the strength of the recommendation (e.g. directive and active language like “should” or “should not” for strong recommendations, and passive language like “consider” for weak recommendations). A figure or algorithm is considered actionable as long as it is complete enough to incorporate all the applicable patients and interventions. Please see the forthcoming NICE manual (24) for a good discussion of actionability in guidelines.

7. External review

A	Guideline was made available to external groups for review.
B	Guideline was reviewed by members of the sponsoring body only.
C	Guideline was not externally reviewed.
NR	No external review process is described.

8. Updating and currency of guideline

A	Guideline is current and an expiration date or update process is specified.
B	Guideline is current but no expiration date or update process is specified.
C	Guideline is outdated.

A guideline is considered current if it is within the developers' stated validity period, or if no period or expiration data is stated, the guideline was published in the past three years (NOTE: the specific period may be changed at the analyst's discretion, based on whether the technology is mature and whether there is a significant amount of recent evidence). A guideline must address new evidence when it is updated. A guideline which is simply re-endorsed by the panel without searching for new evidence must be considered outdated

Appendix C. Search Strategy

Database: Ovid MEDLINE(R) ALL <1946 to December 04, 2019>
Search Strategy:

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1 forced air warmer*.ti. (9)
2 ((blow* or forc*) adj3 air* adj7 (heat* or hot or warm*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (555)
3 (air adj5 (flow* or circulat*)).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (7444)
4 2 and 3 (39)
5 (air adj5 (flow* or circulat* or pattern* or move* or moving or qualit* or contaminat* or steril*)).mp. (26005)
6 ventilat*.mp. (180435)
7 2 and 6 (38)
8 2 and 5 (65)
9 7 or 8 (91)
10 exp Operating Rooms/ (13386)
11 2 and 10 (34)
12 9 or 11 (109)
13 exp Postoperative Complications/ (530472)
14 exp body temperature changes/ (55469)
15 13 or 14 (583728)
16 2 and 15 (280)
17 exp Infection Control/ (61964)
18 exp Iatrogenic Disease/ (71279)
19 exp Cross Infection/ (57933)
20 (nosocom* or iatrogen*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms] (68828)
21 17 or 18 or 19 or 20 (159399)
22 2 and 21 (10)
23 12 or 16 or 22 (342)
24 exp "Outcome and Process Assessment (Health Care)"/ (1069824)
25 2 and 24 (38)
26 23 or 25 (348)