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Effect of a thermal care bundle on the prevention, detection and treatment of perioperative inadvertent hypothermia

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Preoperative phase

1. Patients should be assessed for their risk of inadvertent perioperative hypothermia and potential adverse consequences before transfer to the perioperative unit;
2. Patients' temperature should be measured and documented in the hour before they are transferred to the perioperative unit;
3. Patients whose temperature is $<36.0^{\circ}\text{C}$ should have active warming started preoperatively before transfer to the perioperative unit.

Intraoperative phase

4. Patients' temperature should be measured and documented before induction of anaesthesia and then every 30 minutes until the end of surgery;
5. Patients' temperature should be $\geq 36^{\circ}\text{C}$ before induction of anaesthesia;
6. The following patients should be actively warmed intraoperatively from induction of anaesthesia:
 - those at higher risk of inadvertent perioperative hypothermia
 - those having anaesthesia for >30 minutes;
7. Intravenous fluids intake $\geq 500\text{ml}$ and blood products should be warmed to 37°C using a fluid warming device.

Postoperative phase

8. Patient's temperature should be measured and documented on admission to the recovery room and then at 15-minute intervals;
9. Patients whose temperature is $<36.0^{\circ}\text{C}$ postoperatively should be actively warmed until they are transferred or discharged from the recovery room;
10. Transfer or discharge should not occur unless the patient's temperature is $\geq 36.0^{\circ}\text{C}$.

Figure 1: Sample of recommendations from the NICE guideline for the prevention of inadvertent perioperative hypothermia in adults

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1. Assess risk
 - a) Risk of hypothermia (ASA grade II-V, preoperative temperature $<36.0^{\circ}\text{C}$, combined general and regional anaesthesia, intermediate or major surgery, at risk of cardiac complications; estimated surgery $>30\text{min}$); and
 - b) Contraindications to active warming (therapeutic hypothermia, impaired thermoregulatory control).
2. Record temperature
 - a) In the hour before transfer to the operating room; and
 - b) Prior to induction and every 30 minutes during surgery; and
 - c) On admission to recovery and every 15 minutes thereafter until discharge.
3. Actively warm (forced air warming)
 - a) Intraoperatively, if at-risk of hypothermia; and
 - b) Anytime temperature is $<36.0^{\circ}\text{C}$.

Figure 2: Perioperative Thermal Care Bundle

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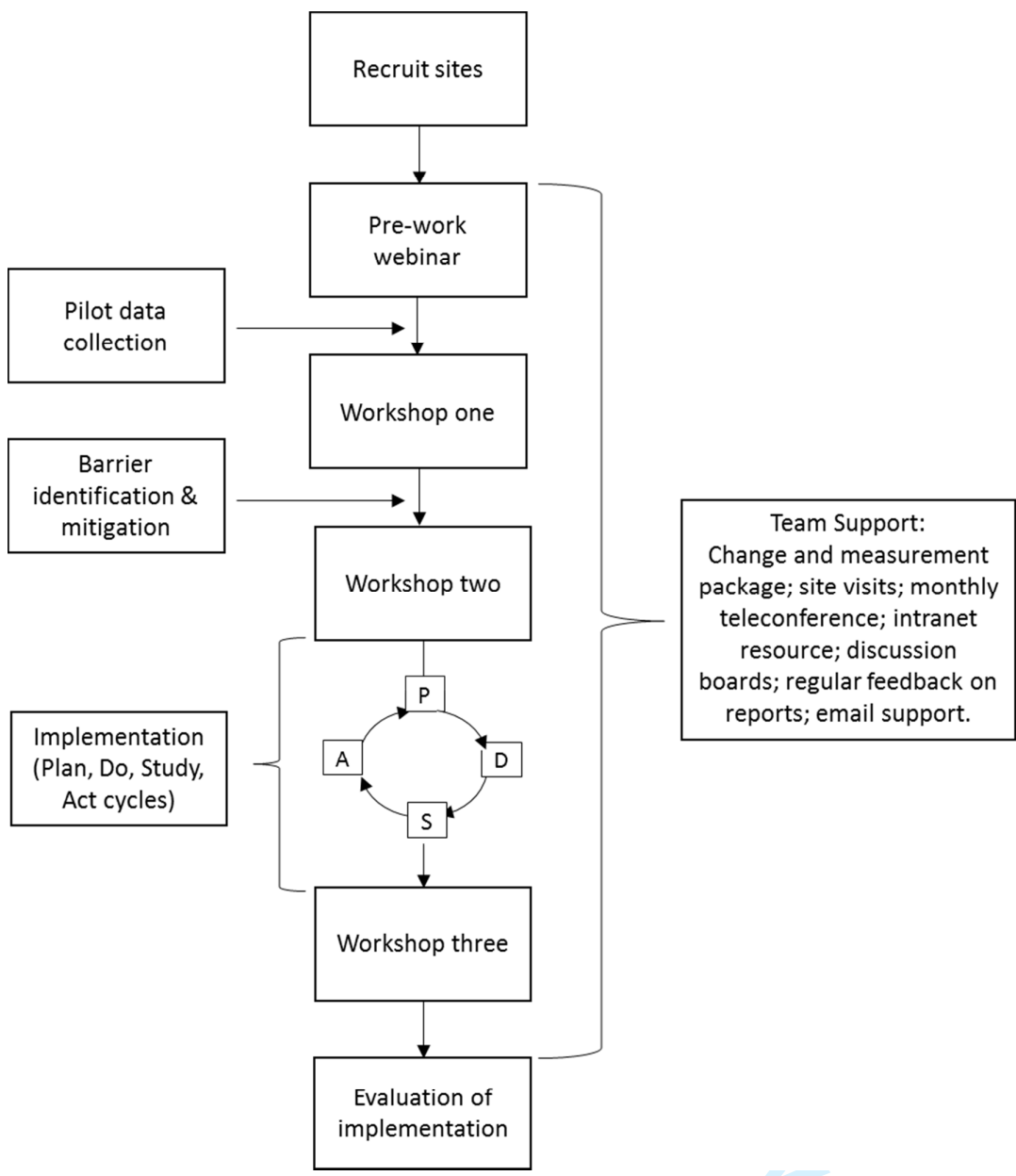


Figure 3: Collaborative model

Impact Statement

- Perioperative Inadvertent Hypothermia (PIH) is a significant health concern associated with known adverse surgical outcomes
- Care bundles are widely used to facilitate improvements to health service delivery
- This study reports on the first known care bundle for managing PIH for patients undergoing surgery
- The Thermal Care Bundle improved detection of PIH through increased temperature recording frequency but did not reduce the incidence of PIH overall
- Further research is needed to improve full bundle compliance with evidence-based perioperative thermal care management

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Table 1: Characteristics of participating sites

Sector	Beds	Admissions	Surgical admissions
Public	504	56,100	12,000
Private	502	62,400	38,500
Public	379	42,700	8,000
Private	270	25,000	6,500

For Peer Review

Table 2: Patient and surgical characteristics

Characteristic	Pre-implementation (n=351)	Post-implementation (n=378)
	n (valid %) or mean (SD)	n (valid %) or mean (SD)
Age (years)	55.8 (19.3)	53.5 (18.9)
Male	221 (54.2%)	215 (54.3%)
Female	187 (45.8%)	181 (45.7%)
BMI (kg/m ²)	27.5 (5.42)	28.1 (10.1)
Risk Factors:		
ASA grade II-IV	227 (64.9%)	271 (77.4%)
Preoperative hypothermia	22 (6.4%)	38 (13.7%)
Combined anaesthesia	40 (11.4%)	39 (13.0%)
Major or intermediate surgery	280 (80%)	331 (90.9%)
At-risk of cardiac complications	77 (21.9%)	127 (41.1%)
Surgery time >30min	281 (80.1%)	348 (92.1%)
At-risk (2 or more risk factors)	220 (62.7%)	259 (68.5%)
Surgical Specialties (top 5):		
Orthopaedic	98 (27.9%)	73 (19.3%)
General	47 (13.4%)	34 (9.0%)
Urology	40 (11.4%)	40 (10.6%)
Plastic and Reconstructive	37 (10.5%)	40 (10.6%)
Neurosurgery	33 (9.4%)	57 (15.1%)
Anaesthetic:		
General	293 (83.5%)	283 (75.3%)
Regional	18 (5.1%)	20 (5.3%)
Combined	40 (11.4%)	73 (19.4%)
Postoperative destination:		
Home	78 (22.3%)	24 (6.4%)
ICU [#] /HDU [*]	24 (6.9%)	43 (11.4%)
Ward	247 (70.8%)	309 (82.2%)
[#] ICU = Intensive Care Unit; [*] High Dependency Unit		

Table 3: Difference in evidence-based management of PIH following the care bundle implementation

Bundle element	Pre-implementation	Post-implementation	% difference (95% CI)	P value
	n/total (valid %)	n/total (valid%)		
Assess Risk	1/351 (0.3)	91/378 (24.1)	23.8 (19.4 to 28.1)	<0.001
Record Temperature:				
In the hour before transfer to the OR	191/251 (54.4)	201/378 (53.2)	-1.24 (-8.4 to 6.0)	0.73
Prior to induction	31/351 (8.8)	130/378 (34.4)	25.5 (19.9 to 31.2)	<0.001
Every 30 minutes in surgery	43/351 (12.3)	82/378 (21.7)	9.44 (4.0 to 14.8)	0.001
On arrival to PACU	308/351 (87.7)	367/378 (97.1)	9.34 (5.5 to 13.2)	<0.001
Every 15 minutes to PACU until discharge	42/351 (12)	78/378 (20.7)	8.6 (3.3 to 14.0)	0.002
All time points [#]	2/351 (0.6)	15/378 (4.0)	3.4 (1.28 to 5.51)	0.002
Actively warm:				
Active warm when at-risk	84/220 (38.2)	136/259 (52.5)	14.3 (5.4 to 23.2)	0.002
No active warming when not at-risk	64/131 (48.9)	63/119 (53.9)	5.0 (-0.07 to 0.17)	0.42
Appropriate [^] active warming	151/351 (43.0)	192/378 (50.8)	7.8 (0.55 to 15.0)	0.03
[#] At least one temperature at each listed time point. [^] Active warming for at-risk patients and no active warming for those not at-risk. OR = Operating Room, PACU= Post Anaesthetic Care Unit.				

Perioperative phase	Pre- implementation	Post- implementation	% difference (95 %CI)	P Value
	n/total (valid %)	n/total (valid %)		
Preoperative	20/204 (9.8)	40/254 (15.7)	5.9 (-0.3 to 12.1)	0.06
Intraoperative	34/70 (48.6)	58/106 (54.7)	6.1 (-8.9 to 21.1)	0.42
Postoperative	62/276 (22.4)	104/337 (30.9)	8.5 (1.4 to 15.5)	0.01
Total perioperative	101/351 (28.8)	159/378 (42)	13.2 (6.0 to 20.1)	<0.001

Numerators represent patients with a documented temperature reading at given Time point.

Table 4: Incidence of perioperative inadvertent hypothermia

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Legend of Figures and Tables

Figure 1: Sample of recommendations from the NICE guideline for the prevention of inadvertent perioperative hypothermia in adults

Figure 2: Perioperative Thermal Care Bundle

Figure 3. Collaborative model

Table 1: Characteristics of participating sites

Table 2: Patient and surgical characteristics

Table 3: Difference in evidence-based management of PIH following the care bundle implementation

Table 4: Incidence of perioperative inadvertent hypothermia

Pre Peer Review

**EFFECT OF A THERMAL CARE BUNDLE ON THE PREVENTION, DETECTION,
AND TREATMENT OF PERIOPERATIVE INADVERTENT HYPOTHERMIA**

ABSTRACT

Aims and Objectives: To improve the prevention, detection, and treatment of perioperative inadvertent hypothermia (PIH) in adult surgical patients by implementing a Thermal Care Bundle.

Background: Keeping patients normothermic perioperatively prevents adverse surgical outcomes. Hypothermia leads to serious complications including increased risk of surgical bleeding, surgical site infections, and morbid cardiac events. The Thermal Care Bundle consists of three elements: 1) assess risk; 2) record temperature; and (3) actively warm.

Design: A pre-post implementation study was conducted to determine the impact of the Thermal Care Bundle on the prevention, detection and treatment of PIH.

Methods: The Thermal Care Bundle was implemented using an adapted version of the Institute of Healthcare Improvement's Breakthrough Series Collaborative Model. Data were collected from auditing medical records.

Results: Data from 729 patients (pre-implementation: n=351; post-implementation: n=378) at four sites were collected between December 2014 to January 2016. Improvements were recorded in the percentage of patients with a risk assessment; at least one documented temperature recording per perioperative stage; and appropriate active warming. Despite this, the overall incidence of PIH increased post-implementation.

Conclusion: The Thermal Care Bundle facilitated improved management of PIH through increased risk assessment, temperature recording, and active warming but did not impact on

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3 PIH incidence. Increased temperature recording may have more accurately revealed the true
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5 extent of PIH in this population.
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8 **Relevance to clinical practice:** This study showed that a collaborative, context specific
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10 implementation method, such as the IHI Breakthrough Series Model, is effective at
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12 improving practices which can improve thermal care.
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16 **What does this paper contribute to the wider global clinical community?**
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20 • Perioperative Inadvertent Hypothermia (PIH) is a significant health concern
21
22 associated with known adverse surgical outcomes and there is a paucity of research
23
24 related to implementation strategies to improve evidence-based PIH management.
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27 • The Thermal Care Bundle can improve evidence-based management of PIH including
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29 increased hypothermia risk assessment, temperature recording, and active warming.
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32 • The increase in temperature readings associated with the implementation of the care
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34 bundle more accurately revealed the true extent of PIH.
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3 **EFFECT OF A THERMAL CARE BUNDLE ON THE PREVENTION, DETECTION,**
4 **AND TREATMENT OF PERIOPERATIVE INADVERTENT HYPOTHERMIA**
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7 **INTRODUCTION**
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10 Perioperative Inadvertent Hypothermia (PIH) – defined as a core temperature below 36°C - is
11 associated with serious adverse surgical outcomes including increased infection rates; morbid
12 cardiac events; and surgical bleeding (D. I. Sessler, 2016). Although evidence-based
13 recommendations for preventing and managing PIH are relatively simple and inexpensive;
14 such as identifying risk, recording temperature, and actively warming at-risk and
15 hypothermic patients, they are often not well adhered to in clinical practice. This study
16 evaluated the impact of an evidence-based care bundle on the prevention, detection, and
17 treatment of PIH in adult surgical patients at four Australian hospitals.
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29 **BACKGROUND**
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32 On average, patients experience a reduction in core temperature of between 2°C and 4°C
33 during surgery (D. Sessler, 2000). Patients experience heat loss due to several influences
34 including: 1) diminished thermoregulation caused by the redistribution of heat from the body
35 core to body peripheries after anaesthetic induction; 2) reduced metabolic heat production
36 caused by anaesthetic agents; and 3) heat loss from body surface exposure and cold
37 environment (Kurz, 2008). Certain individual and surgical characteristics are also known to
38 increase the risk of PIH in adult surgical patients including: an American Society of
39 Anaesthesiologists (ASA) score between >II (more than mild systemic disease); preoperative
40 hypothermia (<36°C one hour or < prior to induction); receiving both general and central
41 neuraxial blocks (such as spinal or epidural anaesthesia); undergoing intermediate (e.g.
42 inguinal hernia repair) or major surgery (e.g. neurosurgery); estimated surgery time >30
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3 minutes; and being at-risk of cardiac complications (National Collaborating Centre for
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5 Nursing and Supportive Care, 2008).

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PIH is a common occurrence in patients undergoing surgery with reported prevalence ranging from 20% to 90% (Moola & Lockwood, 2011). Serious consequences of PIH include an increased risk of surgical site infection; morbid cardiac events; and surgical bleeding (A. Kurz, D. I. Sessler, & R. Lenhardt, 1996; Rajagopalan, Mascha, Na, & Sessler, 2008). The patient's experience of surgery may also be affected by PIH as thermal comfort can impact overall perceptions of care (Fossum, Hays, & Henson, 2001; Kolcaba & Wilson, 2002; Wagner, Byrne, & Kolcaba, 2006). Complications associated with PIH can lead to prolonged postoperative recovery; poorer patient experience; prolonged length of stay; increased resourcing requirements; and higher healthcare related costs (Billeter, Hohmann, Druen, Cannon, & Polk, 2014; Nieh & Su, 2016; Sun et al., 2016).

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PIH is preventable with evidence-based clinical guidelines available for staff to apply to patient care. For instance, the National Institute for Health and Clinical Excellence (NICE Guideline 65) on the management of PIH in adults is based on a comprehensive systematic review which includes both meta-analysis and cost-effectiveness analysis (National Collaborating Centre for Nursing and Supportive Care, 2008). Recommendations from the guideline include the requirement for preoperative hypothermia risk assessment; regular temperature monitoring; and active and passive warming strategies (Figure 1). However, compliance to recommendations in clinical practice is poor despite their relative simplicity and cost-effectiveness. For example, results from a large European multi-site observational study (n=8083) conducted prior to the NICE guideline found that temperature monitoring was not appropriately undertaken in 81% of patients (A Torossian, 2007).

Insert Figure 1 here

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3 One common approach for facilitating guideline uptake involves the use of care bundles.
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5 Care bundles are made up of three to six high impact evidence-based recommendations that -
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7 when implemented together with a high degree of fidelity - are expected to significantly
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9 improve the quality of care and patient outcomes (Resar, Griffin, Haraden & Nolan, 2012). A
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11 variety of care bundles have been developed to address common iatrogenic medical
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13 conditions which, when studied, have demonstrated significant improvements in both
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15 processes of care and clinical outcomes (Aboelela, Stone, & Larson, 2007; Entesari-Tatafi et
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17 al., 2015; Tanner et al., 2015). One of the first published studies of care bundle effectiveness
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19 was the landmark keystone central line-associated bloodstream infection study conducted
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21 across 76 intensive care units in Michigan (P. Pronovost et al., 2006). This large multi-centre
22
23 study reported a large reduction (up to 66%) in rates of catheter-related bloodstream infection
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25 that was maintained throughout the 18-month study. A recent follow up study has shown that
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27 this improvement has been sustained 10 years post implementation (Peter J Pronovost,
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29 Watson, Goeschel, Hyzy, & Berenholtz, 2016).
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34 35 **THE STUDY**

36 37 38 **Aim**

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41 To improve the prevention, detection, and treatment of perioperative inadvertent hypothermia
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43 (PIH) in adult surgical patients by implementing an evidence-based Thermal Care Bundle.
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46 47 **Design**

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50 A pre and post implementation study was conducted to determine the impact of the Thermal
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52 Care Bundle on the prevention, detection, and treatment of PIH. The bundle was
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54 implemented using an adapted version of the Institute of Healthcare Improvement's
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56 Breakthrough Series Collaborative Model (Kilo, 1998).
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Care Bundle

The Perioperative Thermal Care Bundle (Figure 2) was developed by a panel of expert clinicians and researchers. The bundle elements were selected by the experts from the National Institute for Health and Clinical Excellence guideline on the management of PIH in adults (National Collaborating Centre for Nursing and Supportive Care, 2008) with the aid of the electronic GuideLine Implementability Appraisal (eGLIA) online tool (Shiffman et al., 2005). A full description of the care bundle development process has been previously published (Duff, Walker, & Edward, 2017).

The Thermal Care Bundle was designed to promote high reliability in care delivery. Each bundle element was to be delivered to every patient, every time. Exactly how the bundle should be operationalised (i.e. who provided the care, when, and with what equipment) was left to the discretion of the clinicians at each site. Thus, temperatures were recorded using a range of oral, tympanic and indwelling devices at the clinician's discretion and different brands and models of forced-air warming devices were used to actively warm patients along with various adjunct passive warming techniques.

Insert Figure 2 here

Implementation

The study used a collaborative implementation method based on the Institute of Healthcare Improvement's (IHI) Breakthrough Series model (Kilo, 1998) and the John Hopkins quality and safety research group's Translating Research into Practice (TRiP) model (Peter J. Pronovost, Berenholtz, & Needham, 2008) (Figure 3).

Insert Figure 3 here

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3 **Participants**
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6 Sites were asked to nominate a core team of project participants that included a clinical leader
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8 who had authority to test and implement change; a local content expert with an understanding
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10 of the current care process; a project leader to run the project day to day; and a project
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12 sponsor with executive authority
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16 *Team support*
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19 Participants were supported with monthly group conference calls; access to a hospital intranet
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21 site with printed resources and group discussion boards; regular feedback on clinical indicator
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23 data, plus email and telephone support as needed.
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27 *Pre-workshop webinar and pilot data collection*
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30 During a pre-workshop webinar participants were introduced to the method and instructed
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32 how to conduct and report the clinical indicator data.
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36 *Workshops*
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39 Participants came together for three one-day workshops. Agenda items included project
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41 background; protocol overview; readiness for change assessment; stakeholder management;
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43 marketing and education approaches; quality improvement methods; dissemination strategies;
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45 sustaining gains; evaluation and reflection.
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49 *Barrier identification and mitigation*
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52 Participants used a structured barrier identification and mitigation tool (Gurses, Murphy,
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54 Martinez, Berenholtz, & Pronovost, 2009) to identify local barriers to the successful
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3 implementation of the Thermal Care Bundle. This feedback then informed the site-specific
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5 mitigation strategies.
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8 *Implementation (PDSA cycles)*

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11 Participants implement the bundle at their site using the quality improvement methods (Plan-
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13 Do-Study-Act cycles) that were taught to them during the first two workshops (Langley et al.,
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15 2009).
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18 **Setting**

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21 The study was conducted at four leading metropolitan Australian hospitals. Two of the
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23 facilities are publicly funded and two are private hospitals. Two of the hospitals are in
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25 Melbourne (one public and one private hospital) and two are in Sydney.
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30 **Insert Table 1 here**

31 **Data collection**

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34 A random sample of 800 patient charts were audited (400 pre and 400 post implementation)
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36 by a registered nurse trained in the use of the audit tool. Cases were included if they involved
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38 elective or emergency surgery (inpatient or same day only) with general, regional or
39
40 combined anaesthesia. Cases were excluded if the patient was under 18 years, had impaired
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42 thermoregulatory control (e.g., acute head injury, hypothyroidism, ingestion of sedatives or
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44 psychoactive drugs); or required therapeutic hypothermia.
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50 *Audit tool*

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53 The researchers developed the audit tool based on the NICE Guideline (National Institute for
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55 Health and Clinical Excellence, 2008b). The tool collected data on temperature; patient
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3 characteristics (age, sex, body mass index, presence of known risk factors); surgical
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5 characteristics (type of surgery, grade of surgery, type of anaesthetic, length of surgery,
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7 recovery time); and compliance with guideline recommendations (Figure 1). Four
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9 experienced perioperative clinicians independent of the project reviewed the audit tool for
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11 utility and content validity. Two clinicians then independently audited the same five charts
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13 with the tool to establish inter-rater reliability (Kappa= 0.64, 95%CI 0.55 to 0.78, p<0.001).
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16 17 *Sample size*

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20 Based on the design and analysis plan, it was identified that an audit of 680 patients (pre and
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22 post implementation) was required to identify a 10% improvement in care-bundle compliance
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24 with an alpha of 0.5 and a beta of 0.80.
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27 28 **Ethical Considerations**

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31 Ethics approval was obtained from the site institutional Human Research Ethics Committee
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33 (LNR/14/SVH/403). Site-specific approval was obtaining from hospital executives prior to
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35 commencing the study.
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38 39 **Data analysis**

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42 Data were analysed using SPSS version 20 (IBM Corp., 2011). Categorical data were
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44 summarised as number and percentage while continuous data were summarised as mean and
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46 standard deviation. For comparisons between groups, a Z-test for the equality of binomial
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48 proportions was used. This test, which is applicable in samples sufficiently large to justify the
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50 normal approximation to the binomial distribution, makes the assumption that the populations
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52 have proportions π_1 and π_2 with the same characteristic; and that random samples of size n_1
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54 and n_2 are taken, with respective proportions p_1 and p_2 calculated. The test statistic is
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$$Z = \frac{(p_1 - p_2)}{\left[P(1-P) \left(\frac{1}{n_1} + \frac{1}{n_2} \right) \right]^{\frac{1}{2}}}$$

$$\text{where } P = \frac{p_1 n_1 + p_2 n_2}{n_1 + n_2}$$

Under the null hypothesis that $\pi_1 = \pi_2$, Z is approximately distributed as a standard normal deviate.

The p value for statistical significance was set at <0.05 . The difference in proportions, the 95% confidence intervals, and the significance level are provided in table 3 and 4.

RESULTS

Characteristics of patients and surgical procedures

Insert Table 2 here

After exclusions, a total of 729 medical records were audited. Patients treated pre-implementation were similar to those treated post-implementation in terms of age, sex and BMI, but in general showed lower levels of risk factors. Orthopaedic or general surgical procedures were more frequent pre-implementation and neurosurgery, otolaryngology, and head and neck surgery were more frequent post-implementation. In the pre-implementation phase, surgical procedures were more likely to involve general, rather than combined anaesthetic; be classed as urgent; be shorter in duration; and more likely to lead to the patient being sent home than post-implementation procedures (see Table 2).

The change in evidence-based management and the incidence of PIH following the bundle implementation are described below and presented in Table 3 and 4.

Assessing risk

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3 Before implementation, one patient out of 351 (0.3%) was appropriately assessed for their
4 risk of perioperative hypothermia. After implementation, 91 patients out of 378 (24.1%) were
5 assessed for their risk of hypothermia. The difference in proportions pre and post-
6 implementation was 23.8% (95% CI 9.4 to 28.1) which is statistically significant at the 5%
7 significance level ($p<0.001$).
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10 11 12 13 14 15 **Recording temperature**

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18 There was a small but statistically significant improvement post-implementation in the
19 percentage of patients with a documented temperature at all perioperative time points (+3.4%,
20 95% CI 1.28 to 5.51, $p=0.002$) although the number of documented temperatures remains
21 very low (15 out of 378 patients, 4.0%). There was no statistically significant difference in
22 temperature recording before patients were transferred to the operating room (-1.24%, 95%
23 CI -8.4 to 6.0, $p<0.73$). However, all other time points had a statistically significant increase
24 which ranged from an 8.6% improvement (95% CI 3.3 to 14.0, $p=0.002$) in temperatures
25 taken in the Post Anaesthetic Care Unit (PACU) to a 25.5% improvement (95% CI 19.9 to
26 31.2, $p=0.001$) in temperatures taken in the immediate pre-anaesthetic period.
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39 **Insert Table 3 here**

40 41 42 43 **Active patient warming**

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45 Pre-implementation, 151 patients out of 351 (43.0%) were provided with appropriate active
46 warming (active warming for at-risk patients; no warming for patients not at-risk) compared
47 to 192 out of 378 (50.8%) post-implementation (+7.8%, 95% CI 0.55 to 15.0, $p=0.03$).
48 Considering at-risk patients only, the difference in the proportion appropriately given active
49 warming pre- and post-implementation was +14.3% (95% CI 5.48 to 23.2, $p=0.002$).
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57 58 59 60 **Perioperative hypothermia**

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3 The incidence of PIH was defined as a recorded temperature below 36°C, either
4 preoperatively, intraoperatively or postoperatively. Results shown in Table 4 demonstrate a
5 statistically significant increase in the proportion of patients with a documented temperature
6 below 36°C following the Thermal Care Bundle implemented. Prior to implementation, 101
7 patients out of 351 (28.8%) experienced PIH compared to 159 patients out of 378 (42.0%)
8 post-implementation (+13.2%, 95% CI 6.0 to 20.1, p=0.001)
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17 **Insert Table 4 here**

20 **DISCUSSION**

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23 The evidence demonstrating a causal link between perioperative hypothermia and serious
24 adverse outcomes like surgical site infection, morbid cardiac events, and bleeding is 20 years
25 old (Frank et al., 1997; Andrea Kurz, Daniel I Sessler, & Rainer Lenhardt, 1996; Schmied,
26 Schiferer, Sessler, & Meznik, 1998). This research and others has been synthesised in
27 evidence-based guidelines on the prevention and management of PIH which is nearly 10
28 years old (Forbes et al., 2009; Hooper et al., 2009; National Institute for Health and Clinical
29 Excellence, 2008a). Despite the weight of research evidence around the need to prevent PIH;
30 the presence of evidence-based guidelines; and the availability of safe, effective, and
31 relatively inexpensive methods for patient warming, rates of PIH remain unacceptably high.
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33 The repeated failure to successfully address this significant perioperative adverse event has
34 led to calls for implementation researchers to identify an effective way for translating clinical
35 guideline recommendations into practice (Cheng & Martin, 2011; Hooper et al., 2009; Hopf,
36 2015). This is the first published study evaluating the use of a care bundle to achieve
37 improvements in the management of PIH.
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3 The recommendation to assess each patient for their risk of PIH was universally supported
4 by the expert panel who developed the Thermal Care Bundle (Duff et al., 2017). Following
5 implementation, there was a significant improvement in the percentage of patients who
6 received a risk assessment (23.8%). On examination of the data, it is apparent that there was
7 no relationship between improvements in risk assessment and the provision of active
8 warming. After implementation of the bundle, 259 patients out of 378 (68.9%) were assessed
9 as being at-risk of PIH. Of these patients, 136 (52.5%) received active warming. However,
10 active warming was also provided to a similar proportion of patients who were deemed not to
11 be at-risk (63 patients out of 119, 52.9%). This finding is not novel; other research has found
12 no added benefit from risk assessment over clinical judgement in the prevention of pressure
13 areas (Webster et al., 2011); venous thromboembolism (Baysari et al., 2016); and falls
14 (Myers & Nikoletti, 2003). A recent German guideline on the prevention of inadvertent
15 perioperative hypothermia recommends that all surgical patients should be considered at risk
16 (Torossian et al., 2015). Our findings, together with this literature raises questions about the
17 benefit of a formal risk assessment process in the Thermal Care Bundle.
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37 Routine temperature monitoring is a fundamental component in the management and
38 prevention of PIH. It helps identify patients at-risk of hypothermia and those requiring active
39 treatment. In this study, we found a small improvement (+3.4%) in the percentage of patients
40 with a least one documented temperature at all perioperative time points. However, the
41 absolute number remains unacceptably low (4.0%). The percentage of patients receiving
42 appropriate intraoperative temperature monitoring increased by 9.44% from 12.3% to 21.7%.
43 This result is similar to other published findings. For example, a large multi-site European
44 audit (n=8083) found only 19% of patients received appropriate intraoperative temperature
45 monitoring (A. Torossian, 2007); while an Australian audit (n=142) identified 29% (Bull et
46 al., 2011).
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3 A growing body of literature points to thermometer inaccuracy as a major barrier to
4 delivering high-quality thermal care. The imprecision of various thermometer types is
5 increasingly being called into question with recording inconsistencies reported across a
6 number of studies (Berry, Wick, & Magons, 2008; Kimberger, Cohen, Illievich, & Lenhardt,
7 2007; Winslow et al., 2012). A systematic review and meta-analysis found that peripheral
8 thermometers did not have clinically acceptable accuracy and recommended that they should
9 not be used in practice (Niven et al., 2015). These findings have significant implications for
10 practice as temperature measurement is central to the effective prevention, detection, and
11 treatment of PIH. Given this finding, any attempt by clinicians or researchers to improve
12 perioperative temperature monitoring should include efforts to ensure the reliability of
13 measurement equipment.
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28 Compliance with intraoperative active warming increased following implementation of the
29 care bundle by 7.8% overall and 14.3% for patients identified as at-risk. In a recent Cochrane
30 Review on the effectiveness of active warming for preventing PIH, the authors concluded that
31 intraoperative forced-air warming was beneficial but added that the addition of preoperative
32 full-body warming for a minimum period of 30 minutes had an extra protective benefit
33 (Madrid et al., 2016). Several other studies highlight the role of preoperative warming for
34 preventing PIH (de Brito Poveda, Clark, & Galvao, 2013; Horn et al., 2016; Steelman,
35 Perkhounkova, & Lemke, 2015). The use of preoperative warming is currently not
36 recommended in the NICE guideline; therefore, it was not amongst the options available for
37 the expert panel to select for inclusion in the care bundle. The more recent German guideline
38 on the prevention of perioperative hypothermia recommends that patient receive active pre-
39 warming for 20–30 minutes before surgery to counteract the decline in temperature
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3 hypothermia rate of 15.7% in this study, consideration should be given to adding preoperative
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5 warming to the Thermal Care Bundle.
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9 Implementation of the care bundle resulted in increased hypothermia risk assessment,
10 temperature recording, and active warming. However, this improvement did not positively
11 impact on the incidence of PIH. Contra to expectation, the documented hypothermia
12 incidence rate increased by 13.2% from 28.8% pre-implementation to 42% post-
13 implementation. We attribute this to improved hypothermia detection related to increases in
14 temperature monitoring rather than an actual increase in the incidence of PIH. This
15 phenomena (improved detection) has been reported in other studies focused on temperature
16 management including one that implemented a care bundle to prevent and manage sepsis
17 (Westphal et al., 2011) and another infection prevention improvement project (Huang et al.,
18 2007). The post-implementation incidence of 42% also supports the theory that increased
19 monitoring uncovered the true rate as it is similar to the outcome in many other studies
20 observing PIH in adult surgical patients (Bull et al., 2011; Duff, Walker, Edward, Williams,
21 & Sutherland-Fraser, 2014; Karalapillai et al., 2011; Karalapillai et al., 2013).
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38 **Limitations**

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40 The before-and-after design used in this study made it difficult to capture the true impact of
41 the Thermal Care Bundle on the quality of care and patient outcomes. The difference in
42 patient and procedural characteristics between the pre and post implementation populations,
43 particularly in risk status and surgery type and time, may have influenced the results. Once
44 the essential elements for the bundle have been reconfirmed, a future RCT could be
45 undertaken to provide a rigorous evaluation of its impact.
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55 **Relevance to Practice**

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3 This study was an implementation research project with the aim of identifying whether a care
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5 bundle can improve the evidence-based management of PIH. Compliance with the bundle
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7 was the primary outcome; therefore, outcomes such as surgical bleeding, surgical site
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9 infection rates, or morbid cardiac events were not measured. However, in previous studies of
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11 care bundles that did include these outcomes it was noted that a reductions in adverse events
12
13 was directly related to complete bundle fidelity. In their study of a surgical site infection
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15 bundle, Stulberg et al. (2010) found that only when full compliance with all bundle elements
16
17 was achieved did the risk of infection lower in a statistically significant manner. This finding
18
19 was mirrored in another two published studies reporting surgical care improvement projects
20
21 (Edmiston Jr et al., 2011; Wang, Chen, Ward, & Bhattacharyya, 2012). These studies suggest
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23 that full compliance in practice with all elements of the Thermal Care Bundle must be
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25 achieved for it to translate to an overall reduction in PIH-related adverse events.
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30 CONCLUSION

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33 Implementing the Thermal Care Bundle did result in improvements in the percentage of
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35 patients with a risk assessment; at least one documented temperature recording per
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37 perioperative stage; and appropriate active warming but this did not impact on the incidence
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39 of PIH. We attribute this to improved hypothermia detection related to enhanced temperature
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41 monitoring. The findings show that the improvement in active warming was not related to
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43 increased risk assessment which calls in question its overall benefit. Consideration should
44
45 therefore be given to removing risk assessment from the Thermal Care Bundle and, in concert
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47 with the growing body of evidence, including preoperative active warming to the care bundle.
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