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Collaborative Development of a Perioperative Thermal Care Bundle Using the Guideline Implementability Appraisal Tool

KEYWORDS

Perioperative inadvertent hypothermia; knowledge translation; care bundle

ABSTRACT

Background: Perioperative hypothermia significantly increases a patient's risk of adverse complications such as surgical site infection; morbid cardiac events; and surgical bleeding. Although guideline recommendations are relatively simple and inexpensive they are often not adhered to in clinical practice. Knowledge tools are tangible resources that assist clinicians to provide evidence-based care. **Purpose:** This paper reports the collaborative development of a knowledge tool - a perioperative thermal care bundle. **Method:** A multidisciplinary panel of experts used the online GuideLine Implementability Appraisal tool to prioritise and select recommendations for inclusion in the care bundle. **Findings:** Through a consensus process the expert panel selected three main bundle elements: Assess patient's risk of hypothermia and contraindications to active warming; record temperature frequently pre, intra, and postoperatively; and actively warm, intraoperatively, if they are at high risk, or anytime they are hypothermic. **Conclusions:** The eGLIA tool was a simple yet comprehensive tool that enabled the development of a care bundle by expert clinicians.

INTRODUCTION

It is widely accepted by clinicians, the community, and regulatory agencies that clinical care should be evidence-based; however, there are many factors that impede the application of research into practice. Evidence-based guidelines (guidelines) have become internationally recognised as an essential element for translation of evidence into practice; yet despite their

availability, patients are still failing to consistently receive treatments of proven effectiveness.¹

² It has become abundantly apparent that guidelines alone are not enough to significantly improve quality of care and patient outcomes and more effort is needed to bridge the gap between guidelines and practice.^{2, 3}

The Knowledge to Action framework (Figure 1) - used to facilitate the uptake of research evidence in practice- recognizes that knowledge creation is composed of three phases: knowledge inquiry, knowledge synthesis, and knowledge tools.⁴ Knowledge tools, as described by the framework, are tangible evidence-based resources that are used to facilitate the implementation of evidence into practice.⁵ Examples include patient and provider decision aids, care pathways, mobile apps, and care bundles.

The aim of this paper is to report the collaborative development of an evidence-based knowledge tool (a perioperative thermal care bundle) by an expert panel of clinicians and academics using the eGLIA tool. A future paper will report the results of a knowledge translation study evaluating the impact of the care bundle on the quality of perioperative thermal care and patients outcomes at four leading Australian hospitals.

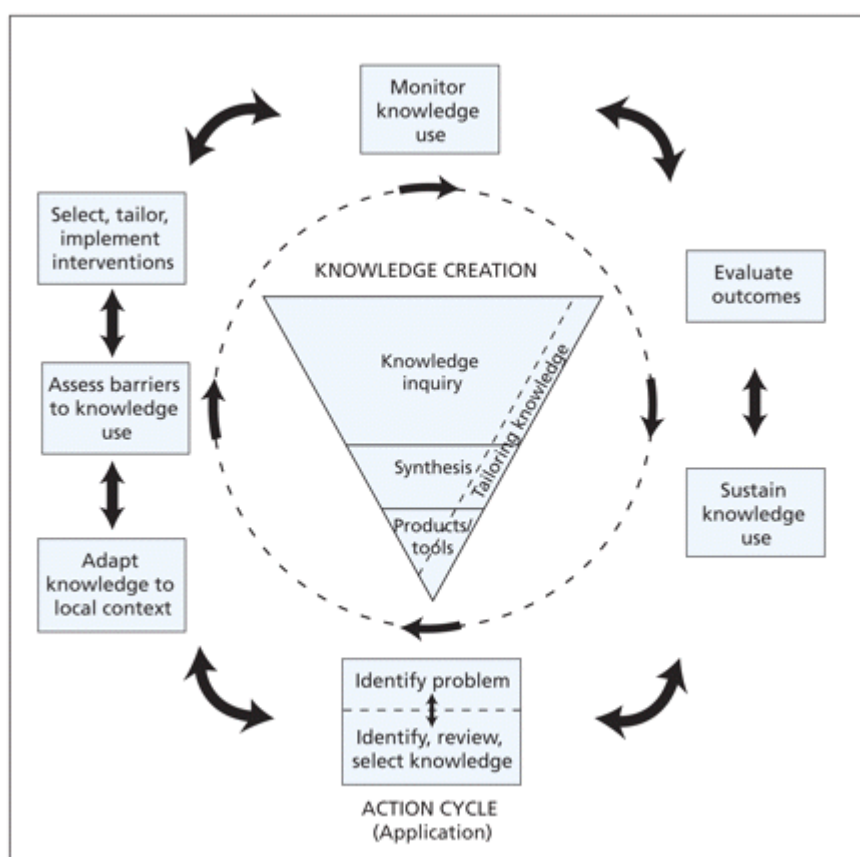


Figure 1: The knowledge-to-action cycle.

BACKGROUND

It is well established that keeping patients warm and preventing hypothermia before, during and after surgery leads to better outcomes. Perioperative hypothermia has been shown to quadruple the risk of surgical site infection,⁶ double the risk of morbid cardiac events,⁷ and significantly increase the risk of surgical bleeding.⁸ Thermal comfort is also an integral component of a patient's overall perception of well-being and memories of thermal discomfort during the perioperative period are known to adversely affect a patient's overall surgical experience.⁹ Together, the physiological and psychological adverse effects of hypothermia result in prolonged recovery times, lengthier hospital stays, and increased resource use which translate into greater overall healthcare costs.¹⁰

Perioperative hypothermia is preventable and guidelines exist which synthesise research findings into evidence-based recommendations. The guideline widely used and endorsed in Australia is from the UK National Institute for Health and Care Excellence (NICE).¹¹ The guideline, first published in 2008 and reviewed without change in 2012, consists of 24 evidence-based recommendations based on a comprehensive systematic review, meta-analysis, and cost benefit report. The key recommendations common to all perioperative hypothermia prevention guidelines are the monitoring of patient temperature and the provision of active warming devices. Although these interventions are relatively simple and inexpensive, there is good evidence that they are often not adhered to in clinical practice. As a result, the published incidence of perioperative hypothermia ranging from 40% to 70%.^{12, 13} The repeated failure to successfully address this evidence practice gap has led to calls for implementation researchers to identify effective ways for translating the guideline recommendations into clinical practice.^{11, 14}

One effective approach for facilitating guideline implementation involves the use of care bundles which comprises a set of high impact recommendations from guidelines that, when implemented together with a high degree of fidelity, are expected to significantly improve patient outcomes.¹⁵ There is currently no published care bundle for the prevention of perioperative hypothermia although a number exist for similarly common, yet severe, iatrogenic medical conditions (ventilator associated pneumonia, central line associated bacteraemia, and catheter associated urinary tract infections) and they have demonstrated significant improvements in quality of care and clinical outcomes.¹⁶ Although care bundles are becoming more common in clinical practice there is no agreed method for their development. The Institute for Healthcare Improvement- that first championed the approach- recommends they be developed by a multidisciplinary team using the best available evidence but they do not provide any detail on an optimal method.¹⁷

The online GuideLine Implementability Appraisal (eGLIA) tool is a method that has previously been used by clinicians and researchers to help select guideline recommendations for implementation.¹⁸⁻²¹ The tool has been rigorously developed and validated by researchers at the Yale School of Medicine.²² It contains 26 criteria arranged into eight domains (global, executability, decidability, validity, flexibility, effect on process of care, measurability, and novelty/innovation). The criteria from the first ‘global’ domain are applied to the guideline as a whole (Table 1); while the criteria from the other seven domains are applied to each individual recommendation of the guideline (Table 2). eGLIA is one of a growing number of instruments and frameworks developed to assist clinicians and researchers prioritise, adapted, contextualise, and implement evidence-based guidelines. Other well known tools include AGREE II^{23, 24}, ADAPT²⁵, and IMPLEMENT²⁶.

METHOD

Ethics

The study was approved by the Tasmanian Social Sciences Human Research Ethics Committee (reference number H13843).

Participant recruitment and training

An expert panel of clinicians and academics was assembled to select the recommendations for inclusion in the care bundle using the eGLIA tool. The professional colleges of the clinicians primarily responsible for perioperative thermal care (Perioperative Nurses, Surgeons, and Anaesthetists) were contacted and invited to nominate two representatives for the panel. Nominees were required to be an experienced clinician or academic with an interest in perioperative hypothermia and an understanding of the Australian healthcare sector. Participants attended a brief (30 minute) training webinar which outlined the appraisal process

and provided practical instructions on accessing the eGLIA website. The training was complemented by printed instructions and email support from the research team.

Appraisal

Each panellist independently appraised the overall implementability of the guideline using the nine global criteria (Table 1). Each individual recommendation was then appraised against the 17 recommendation specific implementability criteria (Table 2). Appraisers answered the criteria questions with either a yes, meets this criterion fully; no, does not meet this criterion; unknown, the rater is unable to address this question because of insufficient knowledge or experience in this area; or n/a, the criterion is not applicable.

Table 1: Global guideline appraisal.

Global Domain Criteria	Appraisal
1. Does the guideline clearly define the target patient population?	✓
2. Does the guideline clearly define its intended audience (i.e., types of providers)?	✓
3. Are the settings in which the guideline is to be used clearly described?	✓
4. Do the organisation(s) and author(s) who developed the guideline have credibility with the intended audience of the guideline?	✓
5. Does the guideline suggest strategies for implementation or tools for application e.g. a summary document, a quick reference guide, educational tools, patients' leaflets, online resources or computer software?	✓
6. Is the guideline internally consistent i.e. without contradictions between recommendations or between text recommendations and flowcharts, summaries, patient education materials etc.?	✓
7. Is it clear in what sequence the recommendations should be applied?	✓
8. Are all recommendations easily identifiable e.g. summarised in a box, bold text, underlined etc.?	✓
9. Are all recommendations (and their discussions) concise?	✓

✓= Agreement that the recommendation meets criterion fully; X= agreement that the recommendation does not meet criterion; ⊖= unable to reach agreement either way.

Table 2: Implementability dimensions and criteria.

Domain	Individual Recommendation Criteria
Executability	<p>10. Is the recommended action (what to do) stated specifically and unambiguously?</p> <p>11. Is sufficient detail provided to allow the intended audience to perform the recommended action?</p>
Decidability	<p>12. Are all reasonable combinations of conditions addressed?</p> <p>13. Would the guideline's intended audience consistently determine whether each condition in the recommendation has been satisfied?</p> <p>14. If this recommendation contains more than one condition, is the logical relationship (ANDs and ORs) between conditions clear?</p>
Validity	<p>15. Is the justification for the recommendation stated explicitly?</p> <p>16. Is the quality of evidence that supports each recommendation stated explicitly?</p> <p>17. Is the strength of each recommendation stated explicitly?</p>
Flexibility	<p>18. Does the recommendation specify patient characteristics (such as emergency cases or cases requiring therapeutic hypothermia) that permit individualisation?</p> <p>19. Does the recommendation specify practice characteristics (such as location and availability of equipment or support services) that require or permit modification?</p>
Effect on process of care	<p>20. Can the recommendation be carried out without substantial disruption in workflow?</p> <p>21. Can the recommendation be pilot tested without substantial resource commitment?</p>
Measurability	<p>22. Can adherence to this recommendation be measured?</p> <p>23. Can outcomes of this recommendation be measured?</p>
Novelty/innovation	<p>24. Can the recommendation be performed by the guideline's intended users without acquisition of new knowledge or skills?</p> <p>25. Is the recommendation consistent with existing attitudes and beliefs of the guideline's intended audience?</p> <p>26. Is the recommendation consistent with patient expectations?</p>

Reconciliation and interpretation of results

The experts entered their responses and their rationale for them into the eGLIA online platform from which summary reports were generated. The summary appraisal report was shared with the panellists and divergent responses were discussed in an attempt to achieve consensus (whether each recommendation did or did not fully meet all criterion within a given domain). The results of this deliberation were used by the panel to select the recommendations for inclusion in the care bundle.

RESULTS

Participants

The expert panel consisted of six members representing the perioperative professions (two anaesthetists; two surgeons; two operating room nurses) and two improvement researchers. The group contained a mix of professionals working in clinical, academic, and management roles (three academic; three clinical; one management; and one combined academic/clinical). All participants had an insight into the Australian healthcare system and an interest or expertise in the prevention of perioperative hypothermia.

Guideline appraisal

The results of the global guideline appraisal are presented in Table 1 and the appraisal of the 24 specific guideline recommendations are summarised in Table 3. A tick denotes agreement that the recommendation did fully meet all criteria within that domain; while a cross denotes it did not fully meet all criteria. The circle with backward slash signifies agreement could not be reached either way. Note that the recommendations in Table 3 have been abridged for presentation.

Table 3: Recommendation specific appraisal.

Guideline Recommendation*	Implementability Domains						
	Executability	Decidability	Validity	Flexibility	Effect	Measurability	Novelty
Patient education	✓	✓	⊖	✓	✓	X	✓
Use thermometers correctly	⊖	✓	✓	✓	✓	⊖	✓
Assess hypothermia risk	✓	✓	✓	✓	✓	✓	✓
Cotton blankets preoperatively	✓	✓	X	✓	✓	X	✓
Special care after premedication	X	✓	⊖	✓	✓	X	✓
Record temp preoperatively	✓	✓	✓	✓	✓	✓	✓
Actively warm preoperative if <36°C	✓	✓	✓	✓	✓	✓	✓
Keep comfortably warm on transfer to OR	X	✓	✓	✓	✓	X	✓
Incident report for patients arriving <36°C	✓	✓	X	⊖	✓	✓	⊖
Record temp prior to induction	✓	✓	✓	✓	✓	✓	✓
Do not anaesthetise if <36°C	✓	✓	✓	⊖	X	✓	✓
Record temp regularly throughout case	✓	✓	✓	✓	✓	✓	✓
Maintain ambient OR temp >21°C if exposed	✓	✓	✓	✓	✓	X	✓
Do not expose until necessary	✓	✓	✓	✓	✓	X	✓
Warm IV fluids >500ml and blood products	✓	✓	✓	⊖	✓	✓	⊖
Actively warm intraoperatively if high-risk	✓	✓	✓	✓	✓	✓	✓
Actively warm intraop if case >30min	✓	✓	✓	✓	✓	✓	✓
Set forced air warming to max then titrate	✓	✓	✓	✓	✓	X	✓
Warm intraoperative irrigation fluid	✓	✓	✓	✓	⊖	✓	⊖
Record temp on admission to PARU	✓	✓	✓	✓	✓	✓	✓
Record temp regularly until PARU discharge	✓	✓	✓	✓	✓	✓	✓
Actively warm in PARU if <36°C	✓	✓	✓	✓	✓	✓	✓
Do not discharge from PARU until >36°C	✓	✓	✓	⊖	⊖	✓	✓
Actively warm on ward if <36°C	✓	✓	✓	✓	X	✓	✓

✓= Agreement that the recommendation does meet all criterion fully; X= agreement that the recommendation does not meet all criterion; ⊖= unable to reach agreement either way. *Guideline recommendations have been abridged; OR= Operating Room; PARU= Post Anaesthetic Recovery Unit; IV= Intravenous.

Global implementability criteria

The panel agreed that the guideline met all nine global implementability criteria. The scope of the guideline was clearly limited to adult surgical patients and the target audience was clinicians working in the perioperative environment (criteria 1 to 3). It was agreed by all that the National Institute for Health and Care Excellence (NICE) was a highly credible organisation (question 4). It was noted that the guideline contained a summary document, flow chart, and audit tool to aid with implementation (question 5) and these were internally consistent with the recommendations in the body of the document (question 6). It is clear from the document the sequence the recommendations are to follow pre, intra, and postoperatively (question 7). The panel agreed that the recommendations were appropriately concise and clearly identifiable (criteria 8 and 9)

Recommendation specific implementability criteria

Executability (criteria 10 and 11) is focused on the action within a recommendation and whether there is sufficient detail provided to allow the intended audience to perform the recommended action, given their likely baseline knowledge and skills. The panel agreed that there was significant ambiguity or uncertainty with a number of recommendations; namely, the recommendations to provide ‘special care after premedication’ and ‘keep comfortably warm on transfer to the operating room’. Consensus could not be reached on the executability of the recommendation to ‘use thermometers correctly’.

Decidability (criteria 12 to 14) applies specifically to conditional recommendation where an action is only performed if one or more stated conditions are fulfilled. For example, conditions may include patient descriptors (e.g. age, gender), clinical observations and laboratory results. This dimension seeks to identify if each and every condition is described clearly enough in order for a reasonable practitioner to identify when the recommendation should be applied. All

recommendations that contained conditions in this guideline were found to be reasonable and logical by the expert panel.

Validity (criteria 15 to 17) denotes the degree to which the recommendation reflects the intent of the developer and the strength of evidence. It prompts the review of the strength and quality of evidence that supports the stated recommendation. The strength or quality of the supporting evidence was questioned by the panel for the recommendations to provide 'cotton blankets preoperatively' and to submit an 'incident report for patients arriving to the operating room <36°C'. Consensus could not be reached on the validity of the recommendations to 'use thermometers correctly' or to provide 'patient education'.

Flexibility (criteria 18 and 19) focuses on whether or not the recommendation permits interpretation and allows for alternatives in its execution. This domain highlights the need for individualisation based on patient or practice characteristics. The expert panel identified issues regarding lack of individualisation and modification of a number of recommendations but could not reach consensus either way. The recommendations in question included submit an 'incident report for patients arriving to the operating room <36°C'; 'do not anaesthetise if <36°C'; 'warm IV fluids >500ml and blood products'; and 'do not discharge from the Post Anaesthetic Recovery Unit until >36°C'.

Effect on process of care (criteria 20 and 21) is concerned with the impact of the recommendation on usual workflow. It ascertains whether the recommendation can be carried out by current non-performers without substantial increases in provider time, staff, or equipment. Two recommendations were thought to potentially impact on workflow or resources and they were 'do not anaesthetise if <36°C' and 'actively warm on ward if <36°C'. 'Warm intraoperative irrigation fluid' and 'do not discharge from PARU until >36°C' were questioned but agreement could not be reached.

Measurability (criteria 22 and 23) judges if the recommendation has identifiable markers or endpoints that will enable the effect of the implementation to be tracked. A significant number of recommendations did not meet all the criteria of this dimension including provide ‘patient education’; ‘cotton blankets preoperatively’; ‘special care after premedication’; ‘keep comfortably warm on transfer to OR’; ‘maintain ambient OR temp >21°C if exposed’; do not expose until necessary’; and ‘set forced air warming to max then titrate’. Agreement could not be reached on the measurability of the recommendation to ‘use thermometers correctly’.

Novelty/innovation (questions 24 to 26) ascertains the degree to which the recommendation proposes behaviours considered unconventional or inconsistent with the current beliefs and attitudes of clinicians or patients. The alignment of three recommendations with current practitioner attitudes and beliefs was queried but agreement could not be reached either way. The recommendations were to submit an ‘incident report for patients arriving to OR <36°C’; ‘warm all IV fluids >500ml and blood products’; and ‘warm all intraoperative irrigation fluid’.

Perioperative thermal care bundle

Ten recommendations were identified as fully meeting each of the 17 criteria making up the seven implementability dimensions (Table 3). Through a process of discussion, challenge, and eventual consensus the expert panel collapsed the 10 recommendations into three main elements (assess risk, record temperature, and actively warm) with subparts per element (Figure 2).

1. Assess risk:
 - a. Risk of hypothermia;
 - b. Contraindications to active warming.
2. Record temperature:
 - a. In the hour before transfer to the operating room; and
 - b. Prior to induction and regularly throughout surgery; and
 - c. On admission to recovery and regularly thereafter until discharge.
3. Actively warm:
 - a. Intraoperatively, if at high risk of hypothermia (two risk factors or estimated surgery time > 30min); and
 - b. Anytime the temperature is below 36.0°C.

Figure 2: Perioperative thermal care bundle.

DISCUSSION

Many guidelines have been criticised for not being implementable by end-users and this is generally accepted to be related to the poor quality of the recommendations.²⁷ The guideline used in this study was of a relatively high standard based on the appraisal of the expert panel as all of the recommendations met the decidability domain criteria and only two recommendation failed to meet the executability criteria. The eGLIA tool places the highest priority on executability and decidability (exactly what to do and when to do it) and if these two domains are not fully met the recommendation is considered to be fatally flawed and non-implementable.²² The two recommendations that failed to meet the executability criteria – ‘provide special care after premedication’ and ‘keep comfortably warm on transfer to the operating room’ - were considered by the panel to be too ambiguous to implement.

The development of knowledge tools has become increasingly important as researchers and clinicians continue to struggle to implement guidelines into practice. Care bundles are an example of a knowledge tool that has shown to be highly successful at operationalising a wide

variety of clinical guidelines.²⁸⁻³⁰ In an early example of the use of care bundles, one well regarded multi-centre study reported a reduction in ventilator associated pneumonia (VAP)- once the most common nosocomial infection in mechanical ventilated patients- by 59% post bundle implementation.³¹ Since this study, this care bundle has been widely implemented across the USA and other developed countries resulting in the dramatic reduction of VAP to the point that it is now considered a rare event.³²

There are three proposed mechanisms by which care bundle implementation produces improved outcomes.¹⁷ Firstly, they are thought to change the misconception that evidence-based care is being delivered reliably. This is done through the use of an ‘all-or-nothing’ measurement where bundle compliance is achieved only if every element is performed. It is common for clinicians to feel that evidence-based care is being reliably performed on their patients when in fact it is not. Figure 3 depicts the dramatic effect on compliance when an ‘all-or-nothing’ measure is used. This hypothetical audit of 5 patients illustrates how some bundle elements may be performed with relative high reliability, while very few patients receive every bundle element every time.

The second proposed mechanism is the promotion of team interdependence through raising of awareness that the entire team must work together to produce high reliability care. It has been demonstrated that to successfully implement a care bundle with a high degree of compliance teams need to learn to work together in new ways.¹⁷ This is related to the final proposed mechanism which is the emphasis on improvement methods to redesign processes (or ways of working) to facilitate care bundle compliance. Teams that have successfully implemented a care bundle only do so by learning to adapt and implement the bundle using systematic planned improvement approach.^{17, 33}

	Element 1	Element 2	Element 3	Total Bundle
Patient 1	✓	✓	✓	✓
Patient 2	✓	✓	x	x
Patient 3	✓	x	x	x
Patient 4	✓	✓	x	x
Patient 5	x	x	✓	x
Compliance %	80%	60%	40%	20%

X= not compliant with element of care bundle;
✓= compliant with element of care bundle.

Figure 3: Hypothetical example of ‘all-or-nothing’ compliance measure.

A detailed description of how care bundles should be developed is surprisingly hard to find in the literature. Published papers that do report care bundle implementation and development pay cursory attention to the development using phrases such as ‘the science was summarised and prioritised’ or ‘the bundle was developed by a multidisciplinary team’.³⁴ The IHI simply recommend following six principles when developing a care bundle: The bundle should include three to six recommendations (bundle elements); each element should be relatively independent; the bundle should be used with a defined patient population; the bundle should be developed with clinicians; bundle elements should be descriptive rather than prescriptive; and compliance should be measured with an all-or-nothing measurement.³⁵

The lack of a clear approach for care bundle development has led to some criticism in the literature of included and excluded elements in some care bundles. The Institute of Healthcare Improvement’s ventilator associated pneumonia prevention (VAP) care bundle is a good illustration of this point. Despite its impact on outcomes, much controversy surrounds the

evidence-based for the elements it contains.^{36, 37} Two strengths of this study are the use of a systematic, rigorous, yet relatively simple process for selecting recommendations for inclusion in the care bundle; and the use of a well-regarded and thoroughly developed guideline as the starting point.¹¹

One limitation of the eGLIA platform is that very little detail is collected concerning the rationale for each appraiser's selection; particularly when agreement is reached at the outset and no discussion was required. This makes results in a quicker and more convenient process for the participants but it does limit the amount we, as researchers, can potentially learn about clinicians' understanding of recommendation implementability.

CONCLUSION

The development of knowledge tools, such as the thermal care bundle, is an emerging area of innovation that has the potential to significantly enhance the uptake of evidence into practice. Despite their popularity, there is currently no agreed approach for developing care bundles. In this study, the eGLIA tool was found to be a simple, yet comprehensive method for a panel of experts to develop a care bundle.

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