A Guide to Writing a Qualitative Systematic Review Protocol to Enhance Evidence-Based Practice in Nursing and Health Care

Ashleigh Butler, MNurs, BNurs, RN • Helen Hall, PhD, MMid, RN, ND • Beverley Copnell, PhD, RN

ABSTRACT

Keywords
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Background: The qualitative systematic review is a rapidly developing area of nursing research. In order to present trustworthy, high-quality recommendations, such reviews should be based on a review protocol to minimize bias and enhance transparency and reproducibility. Although there are a number of resources available to guide researchers in developing a quantitative review protocol, very few resources exist for qualitative reviews.

Aims: To guide researchers through the process of developing a qualitative systematic review protocol, using an example review question.

Methodology: The key elements required in a systematic review protocol are discussed, with a focus on application to qualitative reviews: Development of a research question; formulation of key search terms and strategies; designing a multistage review process; critical appraisal of qualitative literature; development of data extraction techniques; and data synthesis. The paper highlights important considerations during the protocol development process, and uses a previously developed review question as a working example.

Implications for Research: This paper will assist novice researchers in developing a qualitative systematic review protocol. By providing a worked example of a protocol, the paper encourages the development of review protocols, enhancing the trustworthiness and value of the completed qualitative systematic review findings.

Linking Evidence to Action: Qualitative systematic reviews should be based on well planned, peer reviewed protocols to enhance the trustworthiness of results and thus their usefulness in clinical practice. Protocols should outline, in detail, the processes which will be used to undertake the review, including key search terms, inclusion and exclusion criteria, and the methods used for critical appraisal, data extraction and data analysis to facilitate transparency of the review process. Additionally, journals should encourage and support the publication of review protocols, and should require reference to a protocol prior to publication of the review results.

INTRODUCTION

The qualitative systematic review is a newly emerging area of health care research. Qualitative reviews differ from their quantitative counterparts in that they aim to present a comprehensive understanding of participant experiences and perceptions, rather than assess the effectiveness of an intervention (Stern, Jordan, & McArthur, 2014). However, their goal remains the same: to produce high-quality recommendations for patient care based on a scrupulous review of the best available evidence at the time (Aromataris & Pearson, 2014; Risenberg & Justice, 2014a). In order to achieve this, the review process must be well developed and preplanned to reduce researcher bias and eliminate irrelevant or low quality studies. Typically, a systematic review is planned by developing a protocol, which forms the foundation of the entire process.

Developing the protocol before undertaking the review ensures that all methodological decisions, from identifying search terms to data extraction and synthesis processes, are carefully considered and justified, enhancing the integrity and trustworthiness of the results (Moher et al., 2015; Risenberg & Justice, 2014a). Additionally, it encourages consistency between reviewers, reduces the ambiguity of what constitutes "data," and ensures the data extraction and synthesis processes are not arbitrary (Moher et al., 2015).

Although the processes used in quantitative systematic reviews are well developed, with many guidelines available to assist novice researchers, there are very few examples of a qualitative systematic review protocol available. This paper aims to guide readers through the process of developing a qualitative systematic review protocol, using a meta synthesis protocol

Table 1. Example SR: Modified PICO

Population	Parents, family, siblings (deceased child)
Context	Death of a child in PICU
Outcome	Family experiences

entitled "The family experience of the death of a child in the Pediatric Intensive Care Unit (PICU)" as an example.

Where to Start: Choose a Topic and Aim

Systematic reviews aim to answer a specific question, rather than provide a simple overview of the evidence (Aromataris & Pearson, 2014). It is important to have a well-developed question from the outset, as it will form the basis for the entire review protocol, guiding the formation of the search strategy, inclusion criteria, and data extraction (Bettany-Saltikov, 2012). However, developing a focused, answerable question for a review can be challenging for novice researchers. There are numerous frameworks to aid in designing a question for qualitative studies: Population, Exposure, Outcomes (PEO); Sample, Phenomena of Interest, Design, Evaluation, Research type (SPIDER); and Setting, Perspective, Intervention, Comparison, Evaluation (SPICE). The acronym PICO, (Population, Intervention, Comparison, Outcome) developed for quantitative review questions, (Bettany-Saltikov, 2012; Risenberg & Justice, 2014a; Stern et al., 2014) can also be modified to Population, Context, Outcome (PCO) or Population, Interest, Context (PICo), to more appropriately suit a qualitative methodology (Risenberg & Justice, 2014a; Stern et al., 2014). For example, the question "What is the experience of the family when a child dies in the PICU?" was designed using the modified PCO framework (see Table 1).

The review question is used to design the overall study aim. The aim should be a clear statement of the intention of the review, and is typically phrased as a statement. For the above example, the aim would be stated as follows: "The aim of this review is to synthesize the best available evidence exploring the experiences of the death of a child in the PICU, from the perspective of the child's family."

Locating the Literature

Once a focused question has been developed and the aim written, the search strategy must be designed. This is one of the most important parts of the systematic review protocol, because it outlines a priori the strategies reviewers will use to find, select, appraise and utilize the data. It is advisable to conduct a brief search of the literature before planning the review, to ensure it has not previously been done. Consulting an expert librarian at this stage may also provide valuable assistance in identifying keywords and appropriate databases, and developing a robust search strategy.

Stage One: Developing a Search Strategy

Keywords and search terms. The next step in writing a qualitative systematic review protocol is developing the keywords and search terms. The PICO framework can be used to identify the keywords in the review question. The example from Table 1 outlines five main keywords: Population-Family, Context-Death, Context-Child, Context-PICU, and Outcome-Experiences. Once the keywords are ascertained, a table listing all of the synonyms can be developed to guide the search, such as in Table 2. This table of synonyms will then form the basis of the search strategy. Examining some of the key studies on the topic can help to uncover commonly used synonyms and keywords in the literature and help to focus the search terms. Familiarity with the truncation or wildcard operators for each database will enable searching for all alternative spellings or endings to a word, ensuring all possibilities are captured. Plans to use relevant MeSH headings or similar should also be documented.

Determining inclusion and exclusion criteria. The inclusion criteria provide boundaries for the review, defining which studies will be potentially included, and which ones are irrelevant to the topic (Stern et al., 2014). Additionally, inclusion criteria help to mitigate any personal bias of the reviewer; they ensure that studies are selected only on the basis of predefined, justified criteria, rather than because they are of interest to the reviewer, fit into a preconceived framework, or match emerging findings (Aromataris & Pearson, 2014). The researcher must negotiate the fine balance between having too narrow or specific inclusion criteria, where there is a risk of eliminating relevant papers, and having too few or too broad criteria, capturing a large number of irrelevant papers. Commonly, inclusion criteria consist of aspects such as type of study, type of data (qualitative or quantitative), phenomena under study, date of study and age or sex of participants (Stern et al., 2014). Excluding papers based on language may introduce a language bias into the review, limiting the transferability of the results; however, this may be difficult to avoid as translating papers is often not possible. Whatever the inclusion criteria, they should be justifiable based on the requirements of the review, and clearly documented in the protocol. The inclusion criteria used for the example question are outlined in Table 3, and provide an illustration of the typical types of justifications used in a qualitative systematic review protocol.

Designing the search strategy. A systematic review requires a comprehensive search of multiple databases, using the same search strategy for each database. It is important that the protocol clearly outlines the planned search strategy; it ensures the search is undertaken in exactly the same way each time, and also allows the search to be replicated by other researchers in the future with the same results (Aromataris & Riitano, 2014). Ideally, the search will contain three parts: the

Table 2. Example SR PICO Search Terms

Population	Context-death	Context-child	Context-PICU	Outcome
Mother	Death	Child*	PICU	Experience
Father	Die	Daughter	P*ediatric ICU	Perception
Grandparent	Dead	Son	P*ediatric Intensive Care	Perspective
Grandmother	Deceased	P*ediatric	P*ediatric critical care	View
Grandfather	Dying		P*ediatric Intensive therapy unit	Need
Sibling	Loss			
Brother	'Passed away'			
Sister	Bereav*			
Famil*	'End of life'			
Parent*				

Note. The * is used as a truncation indicator.

Table 3. Example SR Question: Inclusion Criteria

Criteria	Justification
Conducted between 1990 and 2014	The development of a formal definition of family centred care in 1987 (Shelton, Jeppson, & Johnson, 1987) led to a change in the way pediatric departments recognize and incorporate parents and family members into a child's care delivery. Studies published before 1990 will be excluded, to ensure the review examines current practice and philosophical standpoints.
Examines family member experiences, perspectives or needs as a primary aim	Family experiences and needs surrounding child death in PICU must be a primary aim of each study. Studies examining family experiences of organ donation, bereavement follow up or family presence during resuscitation will be excluded, owing to the expansive number of reviews on each topic.
Relates to the death of a child aged less than 18 years in a PICU setting	The child's death must have occurred in a PICU setting. Any studies which focus on the death of a child in the neonatal ICU (NICU) will be excluded, due to the difference in the philosophy of care delivery. Studies which examine data from both NICU and PICU settings will be included if the data from PICU parents is reported separately.
Original qualitative data	The review will focus on the experiences, needs or perspectives of family members, which is most appropriately answered through qualitative research. Any study which utilizes survey data or statistical reporting of results will be excluded, as will commentaries or discussions on the subject. Qualitative data from a mixed methods study will be included.
Published in the English Language	Due to limited resources, studies published in languages other than English are unable to be translated and included into the review.

databases, the reference lists and hand searching, and the grey literature sources.

Identifying the most appropriate databases for the review topic is crucial. Searching inappropriate databases leads to inappropriate results, which may impact on the overall review findings. Librarians are often well positioned to identify the most useful databases for the area under study. Typical nursing databases include CINAHL Plus, PubMed, OVID Medline, and Scopus. These databases, alongside PsychINFO and EMBASE, were proposed in the example review protocol, due to their relevance to the review question.

Once the databases are identified, the search strategy should be developed. The protocol should document who will undertake the search, how the search terms will be combined and used, and whether any limits will be applied.

The search strategy used to answer the example question is outlined in Figure 1, and was based on the recommendations given by Bettany-Saltikov (2012) and Aromataris and Riitano

Each database will be searched by the research student, in consultation with an expert librarian, based on the following strategy. Each column in **Table 2** contains a set of synonyms for the key search terms. Each term in the column will be entered into the database and will be truncated where appropriate. All individual searches for that column will be combined using the "OR" Boolean operator into a single group. Each overall group will then be combined using the "AND" function to produce a final list of citations, which will be saved into Endnote, and screened for duplicates. Records of all searches in each database will be maintained.

Figure 1. Example SR question: search strategy.

(2014). It provides a systematic way to search each database, minimizing the impact of the researcher on the outcome of the search.

It is important that thorough records of all searches are maintained for future reference, as this provides an audit trail and enhances trustworthiness of the review findings. Additionally, use of a PRISMA flowchart is recommended as a pictorial representation of the search process (Moher, Liberati, Tetzlaff, & Altman, 2009).

Another common search strategy is examination of reference lists, or hand searching key journals in the area of interest. The reference lists of relevant papers, especially other literature reviews on the topic, may identify citations which did not appear during a database search. The protocol should outline whether this type of search will be undertaken, and if key journals will be manually searched for potentially relevant articles, these should be identified as well.

Lastly, the protocol should also outline whether or not grey literature will be sourced, and which databases will be searched. Grey literature is the term given to unpublished studies, theses, conference proceedings, presentations, government documents, or any other relevant documents that are not published in journals and will not appear in a database search (Aromataris & Riitano, 2014; Bellefontaine & Lee, 2014). The inclusion of grey literature helps to reduce publication bias—the notion that studies with limited, negative, or neutral outcomes are less likely to be published (Aromataris & Riitano, 2014; Pappas & Williams, 2011). Grey literature can be obtained from government websites, Google scholar, these databases (such as trove.nla.gov.au; worldcat.org), or grey literature data bases (such as opengrey.eu; greylit.org).

Stage Two: Reviewing the Literature

In order to uncover the studies most relevant to the review, a multistage process for reviewing and selecting citations must be developed. The protocol should stipulate how many reviewers will undertake the review, how many stages there are, and what each stage will encompass.

How many reviewers? A systematic review requires at least two independent reviewers (Aromataris & Pearson, 2014; Porritt, Gomersall, & Lockwood, 2014; Risenberg & Justice, 2014b). Having more than one reviewer at each stage increases the trustworthiness of the review findings by removing personal bias from the review process, and minimizing the potential for error. The protocol should clearly stipulate what each reviewer's role will be in each stage of the review, such as in Figure 2.

How many stages? Typically, the review process is undertaken in a series of stages, with articles moving through screening based on title and abstract, and then full text review. Only those with titles and abstracts that meet inclusion criteria are retrieved and included for full text review (Aromataris & Pearson, 2014; Porritt et al., 2014). The protocol should outline how many review stages each article will undergo, what each stage involves, and how many reviewers will be included at each stage. The protocol should also clearly document what will occur if reviewers disagree. Generally, most reviewers tend to err on the side of caution and include any citations that are unclear when screening based on title and abstract, and then utilize a third reviewer if reviewers disagree during full text review (Porritt et al., 2014). The protocol should also discuss what will occur if there is insufficient or unclear information in an article. Many reviewers will attempt to contact the author for clarification; however, the protocol should stipulate a timeframe for reply before the article is excluded on the basis of insufficient information. An outline of the review process for the example SR question can be viewed in Figure 3.

The Critical Appraisal

The aim of critical appraisal in a systematic review is to assess the potential studies for rigour, and ensure they are free from significant methodological issues which may impact on the quality of the review findings (Bettany-Saltikov, 2012; Korhonen, Hakulinen-Viitanen, Jylha, & Holopainen, 2013). Whilst the more traditional qualitative literature provides ample guidance on what constitutes rigor in the various qualitative methodologies (Charmaz, 2006, 2014; Corbin & Stauss, 2008; Holloway & Wheeler, 2010; Lincoln & Guba, 1985; Polit & Beck, 2010; Sandelowski, 1986; Thomas & Magilvy, 2011; Whittemore, Chase, & Mandle, 2001), very few of these guidelines have been incorporated into critical appraisal tools. Thus, critical appraisal of qualitative studies remains a contentious issue, with little consensus on what makes a good study, whether critical appraisal should be undertaken at all, and if so, what

The review process will use four reviewers - one research student, and three supervisors. Articles will be distributed across the four reviewers in such as way that the research student reviews each citation, and the three supervisors independently review one third of the total citations at each stage.

Figure 2. Example SR question: reviewer roles.

All potential articles will undergo a two stage screening process based on the inclusion criteria, and undertaken by four reviewers, as outlined in **Figure 2.**

Stage 1: All citations will be screened based on title and abstract. Reviewers will meet to discuss results. All uncertain citations will be included for full text review.

Stage 2: Full text of each included citation will be obtained. Each study will be read in full and assessed for inclusion. Any discrepancies which cannot be resolved through discussion will be sent to a third reviewer for a decision. Authors will be contacted for missing or incomplete information. If there is no response within 2 weeks, the article may be excluded on the basis of missing information.

Figure 3. Example SR question: screening and review.

should be done with the findings (Dixon-Woods et al., 2006; Downe, 2008; Porritt et al., 2014; Thomas & Harden, 2008; Toye et al., 2014). To further complicate the issue, there are a number of different tools available to aid in the critical appraisal of qualitative research, with ongoing debate over which is most suitable for use in systematic reviews (Dixon-Woods et al., 2006; Downe, 2008; Toye et al., 2014).

In light of these issues, there are a number of aspects the protocol must consider and discuss in relation to critical appraisal:

- Whether critical appraisal will be carried out, and by whom. The protocol should provide justification if no appraisal will occur.

- Which appraisal tool will be used, and why. The protocol should also outline any information or instructions for reviewers when using the tool.

- Whether the papers will be scored or ranked, and how this will occur. Generally, most critical appraisal tools provide a checklist for reviewers, but do not provide any guidance as to what constitutes a high or low quality study. The protocol should therefore clearly document any scoring system which will be implemented, and what will happen if reviewers disagree during this process.

- How the results of the appraisal will be used. This decision will depend largely on the purpose of the review: those which aim to present an overview of findings may opt to include all studies, whilst those reviews which aim to inform practice or policy may omit lower quality studies to enhance trustworthiness.

The protocol should outline the definition of a low- or high-quality article, and discuss whether any studies will be excluded and why. It is wise to trial the tool and scoring system on a small sample of papers from the initial scoping literature review during this stage of protocol design, to examine the scores provided and inform development of an appropriate ranking system and cut-off point.

For the example systematic review, the researchers took the view that the use of critical appraisal was necessary to assess the extent to which the authors' findings represent the participants' experiences or views, and decided that studies would be excluded based on quality. The Critical Appraisal Skills Programme (CASP; CASP International Network, 2013) qualitative checklist was used for critical appraisal, which had been widely used in recent similar reviews. The tool allows for appraisal of all types of qualitative data, and the tool contains only 10 questions, facilitating rapid evaluation; however, it does not provide a scoring system. Based on previous experience, the scoring system outlined in Table 4 was designed, and was used without issue.

Data Extraction

The next step in developing a systematic review protocol is data extraction. Designing this stage of a qualitative review is often more difficult than for a quantitative review, because what constitutes data is often unclear. The protocol should clearly outline what "data" is before outlining how it will be extracted. Commonly, qualitative reviews define data as first order constructs (participants' quotes), or second order constructs (researcher interpretation, statements, assumptions and ideas; Toye et al., 2014). Extracting both forms of data allows the reviewers to

Table 4. Example SR Question: Reviewer Guidelines for Using the CASP Checklist

Item	Guidelines
Question 2: Appropriate for qualitative methodology	Exclude if inappropriate
Question 3: Research design	*Yes*- Specifically states research design, with justification
	Unsure- Outline of research design only
	No- Not discussed or inappropriate to research question
Question 5: Data collection	*Yes*- Addresses 4 or more items listed on the CASP checklist
	Unsure- Addresses 2–3 items listed on the CASP checklist
	No- Addresses less than 2 items
Question 7: Ethical considerations	Exclude if unclear or unstated ethical approval
Question 10: Recommendations	*Yes*- The following must be discussed: Contributions to existing knowledge, identifies areas for future research, makes recommendations based on results
	Unsure- only 2 items discussed
	No- only 1 item discussed
Scoring system:	
Yes: 1 point	High-quality paper: Scores 9–10
Unsure: 0.5 points	Moderate-quality paper: Scores 7.5-9
No: 0 points	Low-quality paper: Less than 7.5
	Exclude: Less than 6

view and work with the raw data (quotes) as well as the authors' interpretations, which we argue helps ensure the review findings are thoroughly grounded in the original experiences of the participants.

After the concept of data is well defined, the protocol should outline how it will be extracted, whether any other information will be gathered during the extraction process, and how many reviewers will be involved, similarly to the example provided in Figure 4. Generally, data is extracted using a data extraction tool, which also facilitates the extraction of bibliographic and methodological information about each study, and ensures that data extraction is consistent amongst all reviewers and across all studies (Aromataris & Pearson, 2014; Bettany-Saltikov, 2012; Risenberg & Justice, 2014b). The extraction tool should be designed by the reviewers based on the needs of the study, and should be attached as an appendix in the protocol. Additionally, the protocol should outline whether the tool will be piloted before use, and how any modifications will be managed and reported.

Data Synthesis

Developing a plan for data analysis is the final stage of writing a systematic review protocol. Generally speaking, the aim of data synthesis or analysis is to assemble the collective findings into

a meaning statement or set of statements which represent and explain the phenomena under study (Munn, Tufanaru, & Aromataris, 2014). The meta synthesis of qualitative data has long been a contentious issue. Many scholars argue that by interpreting an interpretation, qualitative synthesis risks losing the essence of the original studies (Korhonen et al., 2013; Thomas & Harden, 2008; Toye et al., 2014). However, a well-planned data synthesis process can help to ensure that the review findings remain firmly grounded in the original data, ensuring the results reflect the original participants' experiences.

Several methods exist to guide the synthesis and analysis of qualitative systematic review data, each with its own strengths and limitations (Dixon-Woods, Agarwal, Jones, Young, & Sutton, 2005). The chosen method will depend largely on the type and purpose of the review being undertaken; for example, a meta synthesis typically requires reviewers reinterpret the qualitative data into a higher level of abstraction and may use similar thematic analysis techniques to those used in original studies, whereas a meta summary may only require content analysis to provide an aggregation of the overall findings (Dixon-Woods et al., 2005; Korhonen et al., 2013; Sandelowski, 2006). Whatever the chosen method, each step should be clearly outlined in the protocol (see Figure 5 for an example), alongside who will undertake the analysis and whether the

A data extraction tool has been developed for the purpose of this review. The tool will be piloted on 2-4 articles prior to use, and will then be modified as required. Data extraction will be undertaken by 4 reviewers as per citation screening.

The following information will be extracted from each article: Bibliographic information; study aims; study design: methodological underpinnings; sample: strategy, size, inclusion/exclusion criteria and participant characteristics; data collection methods; data analysis techniques; ethical considerations and issues; results: themes, quotes, author interpretations or explanations; strengths and limitations; and reviewer comments.

Figure 4. Example SR question: data extraction.

The extracted data will be analyzed utilising thematic analysis techniques, allowing clear identification of themes arising from the data, and facilitating higher order abstraction and theory development. The thematic analysis and meta synthesis processes outlined by J. Thomas and Harden (2008) are outlined below, and will be used to enhance transparency in the review process. Data analysis will primarily be undertaken by the student reviewer, with findings continually discussed in team meetings to ensure they appropriately reflect the original data.

Stage 1: Coding text: Free line by line coding of the findings from the primary studies will occur. Data will be examined for meaning and content during the coding. The codes will then be entered into a code book. This process will allow the translation of codes and concepts between studies.

Stage 2: Developing descriptive themes: The codes will then be examined and analysed for their meanings, and reorganized into related categories. Each category will be analyzed for its properties.

Stage 3: Generating analytical themes: Each category will then be examined and compared to other categories, specifically looking for similarities and differences. Similar categories will be merged into higher level constructs and then themes, going beyond the findings of the original studies into a higher order abstraction of the phenomena.

Figure 5. Example SR question: data synthesis.

findings will be discussed with other reviewers. This not only allows the results to be reproduced by other researchers, but also enhances the transparency and overall trustworthiness of the review findings.

Publishing the Protocol

Once completed, the protocol should be made available to other researchers. Most commonly, this is achieved by registering the protocol with review databases such as the Joanna Briggs Institute, The Cochrane Collaboration, or PROSPERO, although there are also a limited number of nursing journals which will publish a review protocol (Booth et al., 2011; Moher et al., 2015). Publication encourages transparency of the review methodology and enables peer review and feedback prior to the review being undertaken, improving the quality and trustworthiness of the subsequent review findings and recommendations (Aromataris & Pearson, 2014; Booth et al.,

2011; Moher et al., 2015). It also ensures that reviewers adhere to the predefined review processes, as deviation from the protocol is easily identifiable and requires justification during publication of the review findings (Booth et al., 2011; Moher et al., 2015). Additionally, publication of the review protocol ensures other researchers are aware that the review is being undertaken, minimizing the amount of time and resources wasted on duplicate reviews (Booth et al., 2011). Overall, the publication or registration of review protocols increases the trustworthiness of the review findings, ensuring that the recommendations are based on high-quality review of the best available evidence at the time.

CONCLUSIONS

The qualitative systematic review remains relatively new to the discipline of nursing, providing greater insight into the needs

of participants than any one single study. The systematic review should be based on a predeveloped protocol which outlines the methods and processes which will be used in the review before it is undertaken, enhancing transparency and trustworthiness of the review findings. However, given that the techniques used to design and undertake the qualitative review itself are still developing, there are very few resources available to guide nurse researchers through the process of developing a review protocol. This paper highlights the importance of developing a systematic review protocol for qualitative reviews, and uses an example review question to guide researchers through the protocol development process. By learning to design and implement a systematic review protocol, researchers can help to ensure that their findings and recommendations are based on trustworthy, high-quality evidence, improving care delivery to patients and their families. **WVN**

LINKING EVIDENCE TO ACTION

- Develop a review protocol prior to undertaking the review to enhance rigor.

- Utilize a framework (such as PICO) to design an appropriate and answerable review question.

- Consult an expert librarian for assistance in developing keywords, identifying appropriate databases, and designing the search strategy.

- Use two or more reviewers at each stage of the review to reduce personal bias and minimize potential for error.

- Publish the protocol before undertaking the review to enhance transparency of the review process and trustworthiness of the findings.

Author information

Ashleigh Butler, PhD candidate, School of Nursing and Midwifey, Monash University, and Clinical Nurse Specialist, Adult and Pediatric Intensive Care Unit, Monash Health, Melbourne, Victoria, Australia; Helen Hall, Lecturer, School of Nursing and Midwifery, Monash University, Melbourne, Victoria, Australia; Beverley Copnell, Senior Lecturer, School of Nursing and Midwifery, Monash University, Melbourne, Victoria, Australia

Address correspondence to Ashleigh Butler, C/O Intensive Care Unit, Monash Medical Centre, 246 Clayton Rd., Clayton, Victoria, Australia, 3168; aebut2@student.monash.edu

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