
Theses

2020

Perceptions, impact and scope of medication errors with opioids in Australian specialist palliative care inpatient services: A mixed methods study (the PERISCOPE project)

Nicole Heneka

Follow this and additional works at: <https://researchonline.nd.edu.au/theses>



COMMONWEALTH OF AUSTRALIA
Copyright Regulations 1969

WARNING

The material in this communication may be subject to copyright under the Act. Any further copying or communication of this material by you may be the subject of copyright protection under the Act.

Do not remove this notice.

This dissertation/thesis is brought to you by ResearchOnline@ND. It has been accepted for inclusion in Theses by an authorized administrator of ResearchOnline@ND. For more information, please contact researchonline@nd.edu.au.



Chapter 3: Methods

3.1 Overview

As detailed in Chapter 2 there is a paucity of empirical literature reporting opioid errors in the palliative care setting (Heneka, Shaw, Rowett, & Phillips, 2015). This is despite palliative care clinicians' perceptions that opioid errors are common in specialist palliative care inpatient services, contribute to iatrogenic patient harm, and are a quality improvement priority (Heneka, Shaw, Azzi, & Phillips, 2018a). Reports of opioid error prevalence, opioid error characteristics beyond deviations from prescribing guidelines, and the impact of opioid errors on palliative care patients are notable gaps in the literature.

Given this reality, a detailed and systematic exploration of opioid errors in the specialist palliative care inpatient services context was considered essential to better understand the scope and factors contributing to opioid errors in this specialist setting. This doctoral research project was designed to identify the prevalence, patient impact and characteristics of opioid errors in specialist palliative care inpatient services, and determine how to best support safe opioid delivery practices in this clinical environment.

This chapter details the methodology underpinning this mixed methods doctoral research project. It highlights the rationale for choosing a mixed methods design, and explains why neither a purely qualitative or quantitative approach would have adequately answered the phenomena of interest. The two conceptual frameworks used to guide the project are also described. An overview of the research design and methods of each of the five studies that comprise the PERISCOPE project are presented in this chapter.

3.2 Objectives

The objectives of this two-phase, pragmatic, explanatory sequential mixed methods doctoral research project were to:

- i) Describe the prevalence, patient impact and characteristics of opioid errors in specialist palliative care inpatient services in NSW;

- ii) Identify and understand the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services;
- iii) Explore opioid error mitigating factors in specialist palliative care inpatient services; and
- iv) Integrate these data to determine how specialist palliative care inpatient services can best support and strengthen safe opioid delivery practices.

3.3 Research design

To answer the research questions, a pragmatic, explanatory sequential mixed methods design (Creswell & Plano Clark, 2018) was selected. This doctoral project comprises five discrete but inter-related studies, as summarised below:

- Study 1: A systematic review of opioid errors reported in palliative care and cancer services (Heneka et al., 2015) (reported in Chapter 2);
- Study 2: A retrospective review of clinical incidents involving opioids in palliative care and cancer services reported at a state-wide (NSW) level (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b) (reported in Chapter 4);
- Study 3: A retrospective review of clinical incidents involving opioids in local specialist palliative care inpatient services in metropolitan NSW (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018d) (reported in Chapter 4);
- Study 4: Multi-incident analysis of reported opioid error contributing factors in local specialist palliative care inpatient services in metropolitan NSW (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018c) (reported in Chapter 5); and
- Study 5: Semi-structured interviews and focus groups with palliative care clinicians and service managers (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2019a) (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2019b) (reported in Chapters 6 and 7).

The research was guided by a multi-incident analysis framework (Incident Analysis Collaborating Parties, 2012). The alignment of the project's research questions, study stages and research methods are presented in Table 3.1.

Table 3.1 Overview of PERISCOPE project research questions, alignment with the multi-incident analysis framework and study methods

Study Phase	Multi-incident analysis stage	Research questions	Method	Output	
Phase 1	Stage 1: Prepare for analysis	1. What is the prevalence, patient impact and characteristics of opioid errors in specialist palliative care inpatient services?	Study 1: Systematic review	(Heneka et al., 2015)	
	Stage 2: Understand what happened		Study 2: Retrospective review of clinical incidents with opioids reported by palliative care services through a state-wide clinical incident monitoring system	(Heneka et al., 2018b)	
				Study 3: Retrospective review of reported clinical incidents with opioids in local palliative care services	(Heneka et al., 2018d)
				Study 4: Retrospective review of reported opioid error contributing factors in local palliative care services	(Heneka et al., 2018c)
Phase 2	Stage 3: Determine how and why it happened	2. What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?	Study 5: Semi-structured interviews and focus groups	(Heneka et al., 2019a)	
		3. What are the opioid error mitigating factors in specialist palliative care inpatient services?		(Heneka et al., 2019b)	
Interpretation	Stage 4: Recommendations	4. What is required to support and strengthen safe opioid delivery practices in specialist palliative care inpatient services?	Data integration and meta-inference		

3.3.1 Defining mixed methods research

Mixed methods research explicitly integrates quantitative and qualitative research data, drawing on the inherent, yet complementary, differences and strengths of each method, to better understand complex research problems (Creswell, 2014; Plano Clark, 2017). Mixed methods research is now recognised as the third major research paradigm, positioned mid-way between the qualitative-quantitative research continuum (Johnson, Onwuegbuzie, & Turner, 2007; Teddlie & Tashakkori, 2009). Mixed methods are best suited to research problems where one data source may not adequately answer the research question(s), where initial results require further explanation and/or exploration, or when a research aim is best addressed with multiple studies (Creswell & Plano Clark, 2018). Central to the premise of mixed methods research is that the combination of quantitative and qualitative approaches provides a greater breadth and depth of understanding, than either approach alone (Creswell & Plano Clark, 2018).

As a methodology, mixed methods research encompasses many diverse viewpoints, and is defined by a core set of characteristics that combine methods, philosophy and research design orientation (Creswell & Plano Clark, 2018; Greene, 2006). These characteristics include: i) rigorous collection and analysis of both quantitative and qualitative data informed by the research questions; ii) integration of quantitative and qualitative data by combining/merging, sequentially building, or embedding one data set within the other; iii) prioritising one or both forms of data in accordance with the emphasis of the research; iv) applying the procedures in a single study, or in multiple phases of a program of study; v) framing the procedures within philosophical world views and/or theoretical lenses; and vi) combining the procedures into specific research designs that guide the study conduct (Creswell & Plano Clark, 2018).

As such, mixed methods research extends beyond an ad hoc combination of quantitative and qualitative methods and/or data in a study (Andrew & Halcomb, 2009b; Johnson et al., 2007). Rather, the mixed methods approach is informed by philosophical assumptions that guide the research design and methods of inquiry. Creswell and Plano Clark (2018) describe these philosophical assumptions as the 'worldview' (i.e., the beliefs and assumptions about knowledge) the researcher brings to their inquiry. The researchers' worldview, in turn, may inform the

theoretical lens (e.g., explanatory framework), which directs and shapes the direction of the research study, for example, guiding the development of the research questions and answers. The methodological approach to the study (e.g., mixed methods), and the methods of data collection (e.g., surveys, interviews) are then informed by the theoretical lens selected by the researcher (Creswell & Plano Clark, 2018; Crotty, 1998). Critically, the research methods in a mixed methods study should be selected to best, and most fully, answer the research question(s), and reflect the needs of the population for whom the research is conducted (Andrew & Halcomb, 2009b; Johnson & Onwuegbuzie, 2004)

3.3.2 Reporting a mixed methods study

The reporting of the PERISCOPE project is guided by the Good Reporting of A Mixed Methods Study (GAMMS) guidelines (O'Cathain, Murphy, & Nicholl, 2008). Accordingly, the following elements have been included in this thesis: i) the justification for using a mixed methods approach to answer the research questions; ii) description of the study design purpose, priority and sequence of the methods; iii) detailed description of each method including sampling strategies, data collection and analysis; iv) identifying and describing where and how data integration occurred; v) identifying the associated strengths and limitations of study methods; and vi) describing the insights gained from data integration (O'Cathain et al., 2008).

3.3.3 Rationale for mixed methods in the PERISCOPE project

Health services research is inherently complex as it seeks to better understand multifaceted and dynamic systems of care, service culture, a myriad of clinical processes, and individual clinician/patient behaviours and perceptions (Curry et al., 2013; Fetters, Curry, & Creswell, 2013). Accordingly, both quantitative and qualitative forms of data are often required to answer research questions posited in the health services research context (Creswell, Klassen, Plano Clark, & Smith, 2011). Combining both quantitative and qualitative methods allows for deeper insight into complex health services research problems, and facilitates a broader understanding of the issues at hand (Andrew & Halcomb, 2009a; Onwuegbuzie & Leech, 2005). As a result, mixed methods research is rapidly growing in health science and health services research (Creswell, 2014; Doyle, Brady, & Byrne, 2016; NIH Office of

Behavioral and Social Sciences, 2018), and has gained traction as a particularly useful approach for palliative care research specifically (Morag et al., 2013).

3.3.4 Contextualising the need for a mixed methods design

The PERISCOPE project sought to explore the phenomenon of opioid errors in the specialist palliative care inpatient service delivery context. Medication error research has been undertaken for over 50 years (Flynn & Barker, 2007) with several seminal studies published since 1990 (Allan & Barker, 1990; Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Leape et al., 1995; Leape et al., 1991). The goals of medication error research include: measuring rates of medication errors within a specific service(s); identifying error characteristics; identifying error causes/contributing factors; comparing the accuracy of medication administration rates associated with various drug distribution systems; and assessing the effectiveness of medication error detection and prevention techniques (Allan & Barker, 1990; Flynn & Barker, 2007).

There are numerous methods used to identify medication errors including review of clinical incident data, retrospective patient chart review, direct observation, and trigger tools (Flynn & Barker, 2007; McLeod, 2015). Direct observation, although a validated method for detecting administration errors (Flynn, Barker, Pepper, Bates, & Mikeal, 2002), is costly, and was beyond the scope of practice of the doctoral researcher (NH), who does not have a clinical background. Trigger tools (i.e., the identification of specific events to trigger a detailed incident review, such as the use of specific antidotes) (Resar, Rozich, & Classen, 2003) were deemed inappropriate as, in the context of opioid errors, would be limited to errors resulting in opioid overdose, which were treated with an opioid reversal agent, such as naloxone.

Thus, for the purposes of the PERISCOPE project, a combination of retrospective clinical incident and patient chart review was considered the most feasible approach given the constraints of a doctoral project and the medication errors of interest. Clinical incident data is routinely collected, in a standardised format, in the NSW public health system, and was readily accessible at a state-wide and local level. While access to patient charts was not possible for the state-wide data (Study 2), patient chart review was undertaken in the local participating services (Studies 3 and 4). Patient chart review in the PERISCOPE project encompassed a review of opioid

orders, clinician progress notes, and medication administration records (Flynn & Barker, 2007).

There is, however, a notable disadvantage to clinical incident review as an error detection method. Namely, medication errors are known to be widely under-reported across all healthcare settings (Flynn et al., 2002; Franklin et al., 2009; Levinson, 2012; Westbrook et al., 2015). In a recently published Australian study, comparing medication errors in the acute care setting identified by audit and/or observation to medication errors reported in internal incident management systems, there were only 1.2 incident reports per 1000 identified prescribing errors. Additionally, there were nil incident reports for over 2000 clinical administration errors identified during direct observation (Westbrook et al., 2015). The reasons for medication error under-reporting are multi-factorial, and include: lack of awareness an error has occurred, fear of disciplinary action or other repercussions, perceived or actual lack of time it takes to report an error, and perceived effectiveness of error reporting (Braithwaite, Westbrook, Travaglia, & Hughes, 2010; Lawton & Parker, 2002)

Hence, while clinical incident data would provide initial insights into opioid error characteristics and scope in the specialist palliative care inpatient setting, these data were unlikely to accurately reflect actual error prevalence. In order to better understand, and verify, clinical incident data, it was imperative that palliative care clinicians' perspectives were sought to answer the PERISCOPE project research questions.

3.3.5 Applying a mixed methods design

To answer the research questions the PERISCOPE project sought both complementarity and completeness by combining quantitative and qualitative methods (Bryman, 2006; Greene, Caracelli, & Graham, 1989). The PERISCOPE project sought to both quantify opioid errors in the palliative care service delivery context (clinical incident review) *and* understand why these errors are occurring (clinician's perceptions, qualitative data), which could not be determined using quantitative or qualitative data alone (*completeness*) (Bryman, 2006). While each of the five studies in the PERISCOPE project stand alone, the overall aim of the PERISCOPE project is addressed through data integration and meta-inference.

3.3.6 Philosophical assumptions

The PERISCOPE project was guided by an overarching pragmatist worldview. From a pragmatist worldview, research begins with a problem to be addressed or a question(s) to be answered (*purpose*). In turn, the research purpose must be connected with appropriate *procedures* that can adequately address the problem/question(s). Thus research guided by pragmatism is a process where purpose and procedures are actively combined and cannot be considered in the absence of one another (Morgan, 2014).

Pragmatism is typically associated with mixed methods research, as this stance privileges the research questions and consequences of the research rather than the methods, and supports the use of multiple data collection methods to inform the problems being studied (Creswell & Plano Clark, 2018; Teddlie & Tashakkori, 2009). Fundamental to pragmatism is the premise that the research question(s), not a method or paradigm, is the impetus for selecting the research design (Muncey, 2009).

Pragmatism is not aligned to any single system of philosophy and reality (Creswell & Creswell, 2017). Instead, pragmatism prioritises ‘what works’ (Creswell & Plano Clark, 2018), allowing researchers flexibility in their choice of research methods to answer the research question (Onwuegbuzie & Leech, 2005). As a result, research guided by a pragmatic worldview abandons both the use of concepts such as ‘truth’ and ‘reality’, and the forced-choice dichotomy between quantitative (post-positivism) or qualitative (constructivism) methods (Teddlie & Tashakkori, 2003). Rather, pragmatism purports that knowledge is about relationships between actions and consequences, and can only be acquired through the combination of action and reflection (Biesta, 2010). Importantly, the pragmatist worldview is real-world practice oriented (Creswell, 2009), making it well suited to exploring phenomena under investigation in health services research.

3.3.7 Theoretical lens

The theoretical lens used in the PERISCOPE project was grounded in quality and safety principles for healthcare, namely, that care is *consumer* centred, driven by *information*, and organised for *safety* (Australian Commission on Safety and Quality

in Health Care, 2010). These principles directed and shaped the direction of the PERISCOPE project which sought to collect and analyse safety and quality data (information) to understand and minimise opioid errors (safety) and improve palliative patient outcomes (consumer) (Australian Commission on Safety and Quality in Health Care, 2010). Informed by these quality and safety principles, two conceptual frameworks were employed to guide the project. Firstly, a multi-incident analysis framework (Incident Analysis Collaborating Parties, 2012) facilitated the systematic exploration of opioid errors from a patient safety perspective, in congruence with the PERISCOPE project research questions. Secondly, the Yorkshire Contributory Factors Framework (Lawton et al., 2012) was applied to categorise opioid error contributory and mitigating factors using a standardised taxonomy, and guide data analysis and interpretation. Both conceptual frameworks, and their application in the PERISCOPE project are described in detail in Section 3.4.

3.3.8 Explanatory sequential mixed methods design

A two-phase, pragmatic explanatory sequential mixed methods design was considered the ideal methodology for the PERISCOPE project given the nature of the research questions. The explanatory sequential mixed methods design commenced with a predominantly quantitative phase (Phase 1) (QUAN + qual). Classification of opioid error types and contributing factors in Phase 1 necessitated some thematic coding of clinical incident narratives; however, quantitative data was given priority in this phase. Phase 1 was followed by a qualitative phase (Phase 2) (QUAL), which allowed for key elements of the quantitative data to be explored in more depth (Creswell, Plano Clark, Gutmann, & Hanson, 2003; Creswell & Plano Clark, 2018).

As illustrated in Figure 3.1, the quantitative methods in Phase 1 and qualitative research methods in Phase 2 were given equal priority (QUANT → QUAL) in addressing the research problem. Figure 3.1 illustrates the study phases and points of data integration in the PERISCOPE project. This figure also outlines the study procedures ('procedures'), and the associated data ('product') for each study phase (Figure 3.1).

As reported earlier, the researchers were aware of the limitations of the quantitative clinical incident data to be collected in Phase 1 of the PERISCOPE project. Namely,

under-reporting of medication errors is widespread and unlikely to reflect the actual error prevalence or error characteristics (Westbrook et al., 2015). Despite these acknowledged limitations of the quantitative data, analysis of reported opioid errors was considered a critical first step in the PERISCOPE project. This was due to both the paucity of existing empirical literature (Heneka et al., 2015) and an absence of benchmarked opioid error data across palliative care services in NSW.

Secondly, data analysis from Phase 1 of the PERISCOPE project was used to inform the question route for the subsequent qualitative study planned for Phase 2. The qualitative phase of the PERISCOPE project provided opportunities to explore the quantitative data from the perspective of palliative care clinicians, and provide additional insights into error reporting practices and perceived error contributory and mitigating factors in the participating palliative care services. Participants in Phase 2 of the project (Study 5) were recruited from the same local palliative care services where quantitative data was collected in Phase 1. Given the paucity of data related to opioid errors in the palliative care service context, the explanatory sequential design lent itself to emergent approaches in the second phase, following analysis of quantitative data in Phase 1 (Creswell & Plano Clark, 2018).

3.3.9 Data integration

Data integration is a critical component of all mixed methods research (Creswell & Plano Clark, 2018; Teddlie & Tashakkori, 2009). The meaningful and deliberate integration of quantitative and qualitative data distinguishes mixed methods research from other research methodologies, providing insights beyond what is identified from the separate quantitative and qualitative results (Creswell & Plano Clark, 2018).

There are four key considerations for planning and implementing integrative analysis and interpretation in mixed methods research (Creswell & Plano Clark, 2018): i) the intent of the integration; ii) the primary data analysis procedure; iii) the representation of the integration results; and iv) the interpretation of the integration results, which are outlined below in the context of the PERISCOPE project.

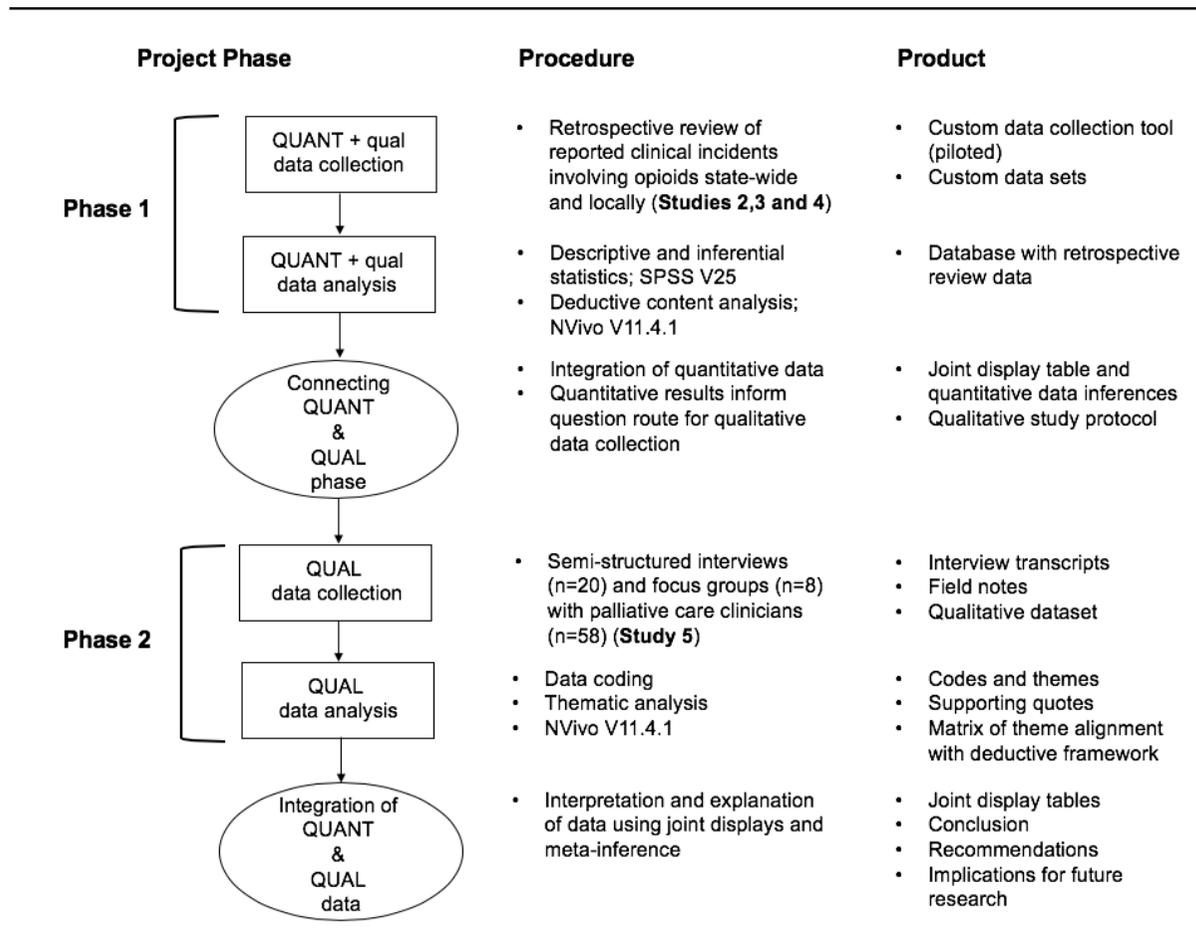


Figure 3.1 Visual model for the mixed methods sequential explanatory design procedures in the PERISCOPE project, adapted from Creswell and Plano Clark (2018) and Ivankova et al. (2006)

The *intent of the integration* was to connect the quantitative and qualitative phases of the PERISCOPE project, so that the qualitative data (Study 5) provided a strong explanation of the quantitative data (Studies 2, 3 and 4). The *primary data analysis procedures* unfolded over four phases. Firstly, quantitative state-wide data (Study 2) and local data (Study 3) were analysed to determine if local data were congruent with state-wide data. Secondly, all quantitative data (Studies 2, 3 and 4) were analysed to inform the qualitative study phase. Thirdly, the qualitative data (Study 5) were analysed and used to follow up on specific data identified in the quantitative phase. Finally, data integration of the quantitative results and qualitative findings was undertaken to answer the mixed methods research questions.

The connected, sequential, integration throughout the PERISCOPE project was *represented* using joint displays (Guetterman, Fetters, & Creswell, 2015). Joint displays are an increasingly common way of representing the data integration process in mixed methods research (Bazeley, 2017; Creswell & Plano Clark, 2018; Guetterman et al., 2015). In a joint display, quantitative and qualitative data are presented side-by-side, enabling researchers to visually display the process of drawing inferences from the integrated data (Guetterman et al., 2015; McCrudden & McTigue).

For the PERISCOPE project, each joint display comprised five columns representing the research question domain, quantitative and/or qualitative data relevant to each domain, the degree of data convergence, and the mixed methods inference for each domain. An exemplar is provided in Table 3.2. The joint displays visually represented the connection between the quantitative and qualitative data across all study question domains, and the degree of data convergence in each domain, i.e. whether quantitative and qualitative data confirmed (*'confirm'*), contradicted (*'contradict'*) or enhanced (*'enhance'*) each other (Fitzpatrick, 2016). They also showed how the quantitative results in the first phase of the PERISCOPE project were used to guide the development of the question route in the second (qualitative) phase of the project. Finally, the joint display tables presented the inferences generated through data integration to answer the research questions (Bazeley, 2017; Creswell & Plano Clark, 2018; Guetterman et al., 2015).

Interpretation of the integrated data was achieved through data consolidation (Caracelli & Greene, 1993) and meta-inference (Greene, 2007; Teddlie & Tashakkori, 2009). Inferences generated during data integration were thematically coded to create a new, consolidated, qualitative data set (Caracelli & Greene, 1993). Through multiple, sequenced phases of iterative analysis (Bazeley, 2017), this process of meta-inference enabled the elicitation of new understandings and explanations of factors required to support safe opioid delivery in specialist palliative care inpatient services (Teddlie & Tashakkori, 2009). Meta-inference enabled the development of a coherent conceptual framework to answer the project aim (Teddlie & Tashakkori, 2009) which is reported in Chapter 8.

3.3.10 Considerations for the explanatory sequential design

Although the explanatory sequential design is one of the most straightforward mixed methods designs, there are specific challenges that require consideration prior to the PERISCOPE project commencing: i) the two phase nature of the explanatory sequential design requires considerable time for implementation, and participants must be available over an extended time period; ii) the qualitative phase cannot be fully planned in advance as it is dependent on the results of the quantitative phase; iii) similarly, the quantitative results to follow up cannot be identified until quantitative data collection and analysis is complete; and iv) careful consideration must be given to sampling methods in the second phase in order to best explain/elaborate on the quantitative results (Creswell & Plano Clark, 2018; Ivankova, Creswell, & Stick, 2006).

These potential challenges were addressed in the PERISCOPE project as follows: i) a project plan was developed factoring in the potential time span for each study and project phase within the constraints of the doctoral candidature; participating services were advised of the extended time-frame of the study and committed to participation in both study phases; contingencies to extend the project if required were planned; ii) a protocol for the qualitative study was drafted early in the PERISCOPE project and updated as quantitative data analysis was completed; a separate ethics application, and corresponding timeline for the qualitative study, was pre-planned in the project plan; iii) a defined timeframe for identification of quantitative data for follow up was planned to ensure timely completion of the qualitative study protocol; and iv)

purposive sampling at participating study sites was selected as the most appropriate sampling strategy (described in Section 3.6.3).

Skills of the researcher

The skills of the researcher also need to be considered when undertaking mixed methods research in the context of a doctoral project, regardless of the design chosen (Halcomb & Andrew, 2009). The conduct of a mixed methods project requires a number of skills including project design, research management, and familiarity with both quantitative and qualitative data collection, analysis and integration from a mixed methods perspective (Halcomb & Andrew, 2009). Additionally, understanding the theories underpinning mixed methods research, and the nuances of mixed methods designs can prove challenging for the novice researcher (Creswell & Plano Clark, 2018; Halcomb & Andrew, 2009).

To address these challenges, the doctoral researcher (NH) was supported to attend academic workshops, seminars and conferences (e.g., mixed methods research, quality and safety methodologies, data management, statistical analysis, qualitative research). An interdisciplinary supervisory team with extensive expertise in mixed methods research methodology, health services and palliative care research, and patient safety was convened to guide and support the doctoral researcher throughout the project (Halcomb & Andrew, 2009).

3.3.11 Positioning of the researcher

In all interactions with site teams, potential and/or actual study participants, the researcher (NH) openly presented herself as a PhD candidate, with a non-clinical background, who was exploring medication errors with opioids in specialist palliative care inpatient services. This positioning was critical to establish an open and transparent relationship with service managers during site engagement and throughout the study, as the nature of data collection (both quantitative and qualitative) was sensitive and potentially damaging for participating services and individual clinicians.

At the start of each semi-structured interview or focus group, the researcher introduced herself to participants, provided an overview of the project and advised participants of the interview/focus group purpose. Participants were reassured they

would not be asked to disclose any medication errors they had been involved in, that they did not have to answer any questions they were not comfortable with, and that anything that was discussed in the context of the interview/focus group would remain strictly confidential. For focus groups specifically, the researcher asked that all discussions that took place remained confidential and requested participants did not share anything that was discussed with anyone outside the focus group. This initial rapport building was critical to creating an environment where participants felt safe to explore opioid errors in their service without fear of consequences. The effectiveness of the rapport building was evident in the depth of disclosure given by participants. Despite not ever being directly asked to disclose their personal experiences with opioid errors, participants readily shared examples of opioid errors they had made, and how that had impacted them.

There were no pre-existing relationships between the researcher and the study participants. This, and the fact the researcher was not a clinician, may have enabled the open disclosure of participants' experiences with opioid errors, as they may have felt more secure sharing their experiences with someone removed from their service and discipline. While the researcher had initial concerns that a lack of clinical background may be a barrier to effectively conducting the semi-structured interviews and focus groups with clinicians, this concern was unfounded. Clinicians welcomed the researcher's disclosure and suggested data collection and analysis would be less prone to clinical and/or confirmation biases in the absence of a clinical background.

Summary

Having described the rationale for the use of mixed methods and the selection of the explanatory sequential design in the PERISCOPE project in this section, the following section unpacks the conceptual frameworks used to guide the project's data collection and analysis.

3.4 Conceptual frameworks for the PERISCOPE project

Two complementary conceptual frameworks were used to guide the PERISCOPE project. An over-arching multi-incident analysis framework was used to inform project implementation, in alignment with accepted methods for clinical incident review in healthcare (Incident Analysis Collaborating Parties, 2012). In addition to

the multi-incident analysis framework, the Yorkshire Contributory Factors Framework was selected to guide classification and data analysis of opioid error contributing and mitigating factors (Lawton et al., 2012). Each conceptual framework is described in detail below.

3.4.1 Multi-incident analysis framework

Increasingly, patient safety incidents are being recognised as resulting from systems failures rather than human error alone (Institute of Medicine, 2007; Lawton et al., 2012; Reason, 2008). Hence, there is value in exploring common causes across multiple incidents of a similar nature, to identify system-level changes that are contributing to, or could prevent, these incident types in future (Percarpio, Watts, & Weeks, 2008). Multi-incident analysis is being increasingly implemented in healthcare to facilitate systems-level changes in patient safety (Incident Analysis Collaborating Parties, 2012).

Multi-incident analysis provides a structured process for concurrent review of clinical incidents grouped by pre-defined theme, facilitating organisational and system-wide learning that cannot be readily achieved through other methods, such as root cause analysis (Incident Analysis Collaborating Parties, 2012). Multi-incident analysis can also reveal the effectiveness, or ineffectiveness, of recommended actions undertaken following an incident (e.g., tailored education, policy change) (Incident Analysis Collaborating Parties, 2012).

The multi-incident analysis methodology is one component of the Canadian Incident Analysis Framework, which was developed by the Incident Analysis Collaborating Parties (2012) in response to the recognised limitations of root cause analysis in healthcare (Incident Analysis Collaborating Parties, 2012; Percarpio et al., 2008). Root cause analysis is typically used in healthcare to determine the characteristics, contributing factors and causes of serious safety incidents, such as medication errors (Burkhardt, Lee, Talyor, Williams, & Bagian, 2007). The process of root cause analysis yields recommendations to prevent the occurrence of similar incidents and rules out non-contributory factors (Burkhardt et al., 2007; NSW Health, 2014). However, root cause analysis is limited to the investigation of an individual, serious incident that has resulted in significant patient harm or death, and does not allow for

the concurrent analysis of multiple similar incidents, or incidents with less serious patient outcomes (NSW Health, 2014; Percarpio et al., 2008).

Multi-incident analysis has been widely used in Canada, including for patient safety incidents involving medications (Cheng, Yang, Chan, & Patel, 2017; Incident Analysis Collaborating Parties, 2012; Institute for Safe Medication Practices (ISMP) Canada, 2008). In Australia, the multi-incident analysis methodology underpins the best practice guide to clinical incident management in Queensland (Queensland Health, 2014).

The multi-incident analysis closely aligns with the explanatory sequential mixed methods design used in the PERISCOPE project. As illustrated in Figure 3.2, the multi-incident analysis framework, like the explanatory sequential design, comprises distinct, and sequential, quantitative and qualitative data collection stages, which are ultimately integrated to generate recommended actions.

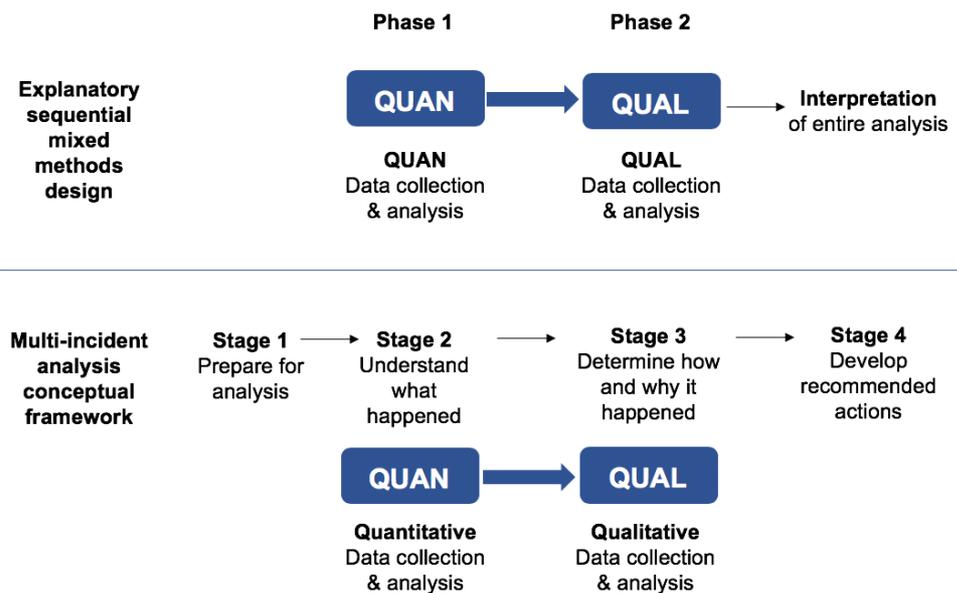


Figure 3.2 Alignment of the explanatory sequential mixed methods study design (Creswell & Plano Clark, 2018) with the multi-incident analysis framework (Incident Analysis Collaborating Parties, 2012) in the PERISCOPE project

3.4.2 Yorkshire Contributory Factors Framework

As previously mentioned, in addition to the multi-incident analysis, the Yorkshire Contributory Factors Framework (‘framework’) (Lawton et al., 2012) was applied throughout the PERISCOPE project to guide classification of opioid error contributory and mitigating factors. The framework is depicted in Figure 3.3.

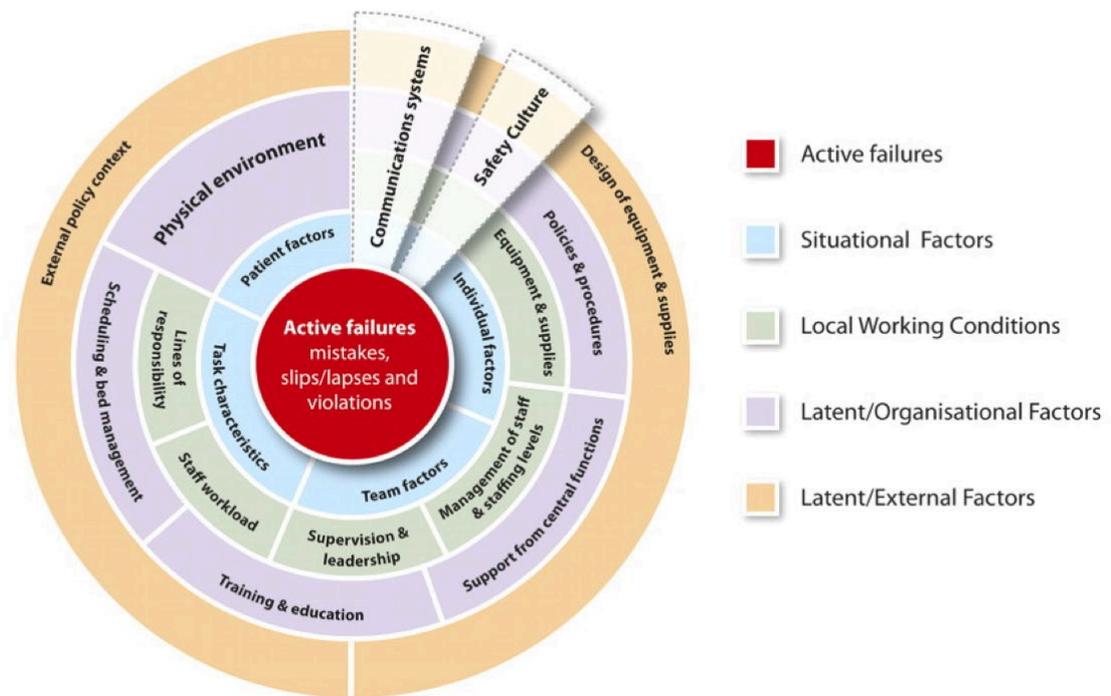


Figure 3.3 Yorkshire Contributory Factors Framework (Lawton et al., 2012)

Reproduced from: Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review, Lawton R, McEachan RETROSPECTIVE REVIEW, Giles SJ, Sirriyeh R, Watt IS and Wright J. 21:369-80 ©2012 with permission from BMJ Publishing Group Ltd. (Appendix 3)

This framework was specifically developed for application in the healthcare context, and identifies multiple levels of contributory factors to clinical incidents in accordance with a systems approach to patient safety (Kohn, Corrigan, & Donaldson, 2000; Lawton et al., 2012; Reason, 2000). The framework comprises 20 factor domains representing active failures (i.e. any failure in performance or behavior of the person in direct contact with the patient) (Reason, 1990), situational factors, (patient, individual, task or team) and latent factors (e.g., physical environment, training and education, policies and procedures) that influence patient safety (Lawton et al., 2012). Definitions of each factor domain are listed in Table 3.2.

Table 3.2 Definition of contributory factor domains, adapted from Lawton et al. (2012)

Factor	Definition
Active failures	Any failure in performance or behaviour of the health professional, including slips, lapses, mistakes and violations.
<i>Situational factors</i>	
Individual factors	Characteristics of the person delivering the care that may contribute in some way to active failures, e.g., inexperience, stress, attitudes.
Patient factors	Those features of the patients that make caring for them more difficult and therefore more prone to error, such as abnormal physiology, language difficulties, personality characteristics (e.g., aggressive attitude).
Task characteristics	Factors related to specific patient related tasks that may make individuals vulnerable to error.
Team factors	Any factor related to the working of different professionals within a group that they may be able to change to improve patient safety.
<i>Local working conditions</i>	
Equipment and supplies	Availability and functioning of equipment and supplies.
Lines of responsibility	Existence of clear lines of responsibility clarifying accountability of staff members and delineating the job role.
Management of staff and staffing levels	The appropriate management and allocation of staff to ensure adequate skill mix and staffing for the volume of work.
Staff workload	Level of activity and pressures on time during a shift.
Supervision and leadership	The availability and quality of direct and local supervision and leadership.
<i>Latent/organisational factors</i>	
Physical environment	Features of the physical environment that help or hinder safe practice, such as the layout of the unit, fixtures and fittings, level of noise, lighting, temperature, etc.
Policies and procedures	The existence of formal and written guidance for the appropriate conduct of work tasks and processes. This can also include situations where procedures are available but contradictory, incomprehensible or of otherwise poor quality.
Scheduling and bed management	Adequate scheduling to manage patient throughput, minimising delays and excessive workload.
Support from central functions	Availability and adequacy of central services to support the functioning of wards/units. This might include support from information technology, human resources, portering services, or clinically related services such as radiology, pharmacy.
Training and education	Access to correct, timely and appropriate training, both specific (e.g., task related) and general (e.g., organisation related).
<i>Latent external factors</i>	
Design of equipment and supplies	The design of equipment and supplies to overcome physical and performance limitations.
External policy context	Nationally driven policies/directives that impact on the level and quality of resources available to hospitals.
<i>General factors</i>	
Communication systems	Effectiveness of the processes and systems in place for the exchange and sharing of information between staff, patients, groups, departments and services, including both written (e.g., documentation) and verbal (e.g., handover) communication systems.
Safety culture	Organisational values, beliefs and practices surrounding the management of safety and learning from error.

To better understand the nature of incidents coded as ‘active failures’ (i.e., errors made by the clinician), these incident types were further categorised into slips, lapses, mistakes, and/or violations, in accordance with accepted human error taxonomies (Reason, 1990), namely:

- *Slip*: failure to execute an action due to misdirection of a routine behaviour (skill based, unintentional), e.g., drawing the wrong drug into an infusion.
- *Lapse*: failure to execute an action due to a lapse in memory, resulting in the omission of a routine behaviour (skill based, unintentional), e.g., forgetting to administer a dose of regular analgesia.
- *Mistake*: an error originating from an incorrect thought process or analysis (knowledge or rule based, unintentional), e.g., ordering morphine for a patient with a known allergy to morphine.
- *Violation*: a deliberate deviation from rules, protocols, policies/procedures etc., (behavioural choice), e.g., failing to undertake a second person check before administering a high-risk medicine.

Violations were considered in the context of compliance with the state medication handling policy (Ministry of Health NSW, 2013), which mandates general principles for medication charting/orders and safe medication administration, and additional requirements for the recording and safe delivery of scheduled/high-risk medications.

3.5 PERISCOPE project study settings and participants

The PERISCOPE project was undertaken in three specialist palliative care inpatient services in NSW, from to January 2015 to November 2017. The project’s study settings and participants are described below.

3.5.1 Study settings

The initial PERISCOPE project studies (Study 1 and Study 2) included both adult palliative and cancer care settings because opioids are widely used to manage cancer related pain (Australian Adult Cancer Pain Management Guideline Working Party, 2014; Therapeutic Guidelines Limited, 2016). Investigating opioid errors in both palliative and cancer care services provided an opportunity to identify similarities and differences in error characteristics and patient impact between services where

opioid delivery to manage cancer pain is routine (Australian Adult Cancer Pain Management Guideline Working Party, 2014; Australian Institute of Health and Welfare, 2018). Paediatric services were excluded because of the unique needs of paediatric patients, compared to adult patient populations, and ought to be the focus of a separate study (O'Leary, Flynn, MacCallion, Walsh, & McQuillan, 2006) (Hynson & Sawyer, 2001). The local retrospective review (Study 3) and the qualitative study (Study 5) involved three NSW specialist palliative care inpatient services.

All three participating specialist palliative care inpatient services ('local services') are situated in metropolitan NSW, Australia. They are all classified as Level 3 palliative care services, that is, highly resourced services providing for patients with complex end of life care issues, staffed by palliative medicine and palliative nursing specialists (NSW Ministry of Health, 2016). Services 1 and 2 are larger 40-bed palliative care units, while Service 3 is a smaller 20-bed palliative care unit.

These services were selected based upon existing professional relationships with the researcher and the researcher's doctoral supervisors, which supported the researcher's access. However, only two of the three specialist palliative care inpatient services (Service 1 and 3) were able to be involved in Study 4 (retrospective review of reported opioid error contributing factors). Service 1 and Service 3 had ready access to three years of reported clinical incidents involving opioids, including comprehensive incident narratives on opioid error contributing factors. However, Service 2 was unable to contribute as their electronic medication management system had undergone a substantial rebuild two years earlier. This rebuild limited access to two years of reported opioid incidents and narrative data pertaining to opioid error contributing factors was not available.

3.5.2 Study participants

Participants for the qualitative study (Study 5) were recruited from each of the three participating specialist palliative care services. These participants included clinicians (medical, nursing, pharmacy) and service managers (service/unit managers, quality and safety managers) involved in any step of the opioid delivery process or with

oversight of the opioid delivery process. Participant recruitment is described in detail in Section 3.6.3.

3.6 Data collection and analysis methods

In accordance with the multi-incident analysis framework, there are four defined stages that determine data collection and analysis methods:

- Stage 1 - Prepare for analysis;
- Stage 2 - Understand what happened;
- Stage 3 - Understand how and why it happened; and
- Stage 4 - Develop recommended actions (Incident Analysis Collaborating Parties, 2012).

Each of these stages, as they were applied in the PERISCOPE project and the corresponding studies, are summarised in Figure 3.4. A detailed description of data collection and analysis methods for each stage of the multi-incident analysis in the PERISCOPE project is provided below.

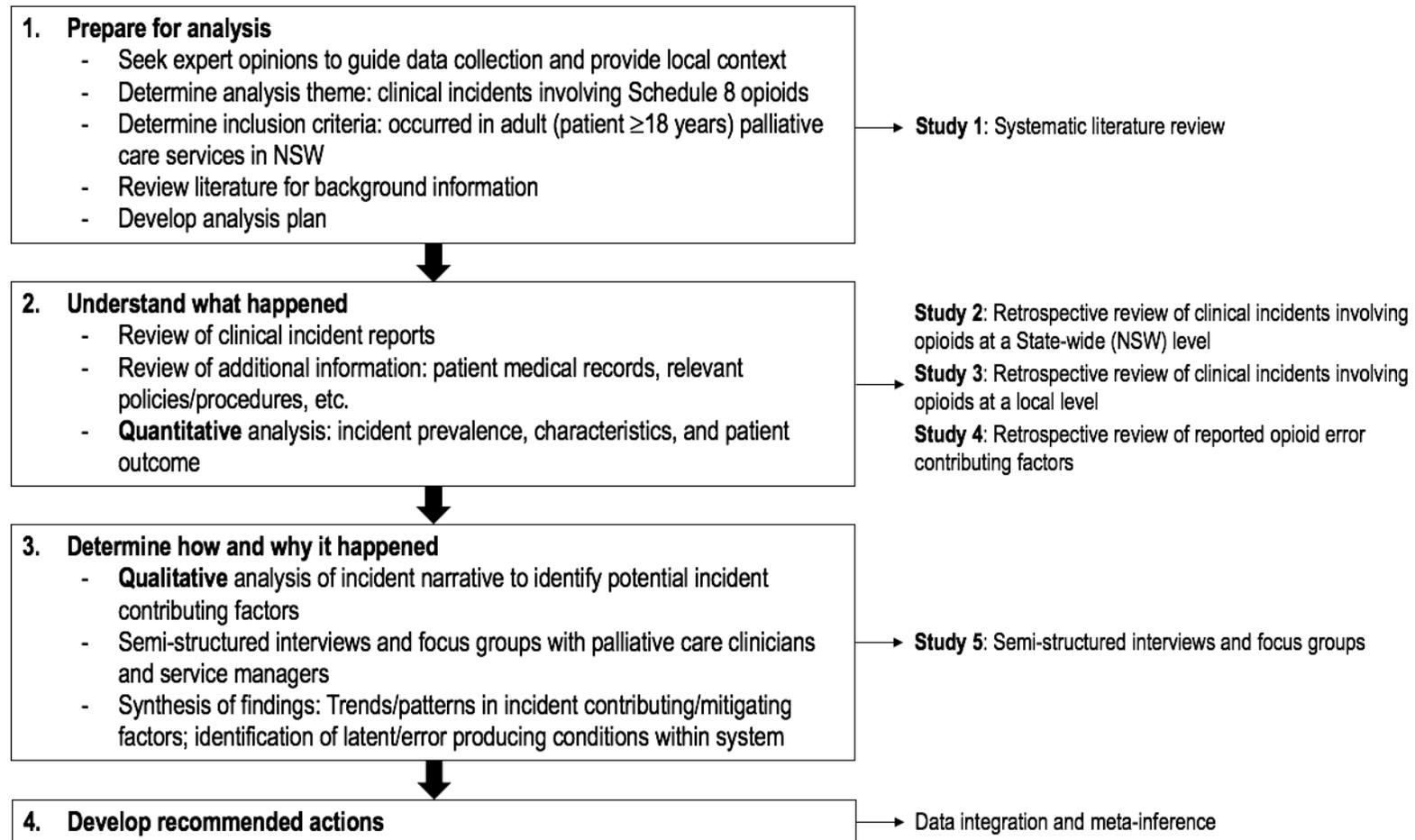


Figure 3.4 Stages of multi-incident analysis and corresponding studies in the PERISCOPE project, adapted from Incident Analysis Collaborating Parties (2012)

3.6.1 Stage 1: Prepare for analysis

Seek expert opinions to guide data collection and provide local context

Extensive consultation with service managers, palliative care clinicians (doctors, nurses, pharmacists), hospital pharmacists, and hospital quality and safety managers at participating services ('site team') was undertaken in preparation for the multi-incident analysis, and throughout the project, to provide local context and facilitate data collection.

Identify analysis theme and inclusion criteria

In the preparation for a multi-incident analysis, the analysis theme and inclusion criteria for clinical incidents are determined (Incident Analysis Collaborating Parties, 2012). Following consultation with the site teams, the selected theme for the PERISCOPE project was: *clinical incidents involving Schedule 8 opioids* ('opioids'). The analysis theme was restricted to Schedule 8 opioids (controlled drugs), versus opioids such as codeine (Schedule 4, prescription only), as Schedule 8 opioids are: i) the primary pharmaceutical treatment used in palliative care services to manage cancer and other pain, and symptoms such as coughing and dyspnoea towards the end of life (Australian Adult Cancer Pain Management Guideline Working Party, 2014; Therapeutic Guidelines Limited, 2016); and ii) the most frequently implicated drug class causing patient harm due to medication error (Colquhoun, Koczmara, & Greenall, 2006; National Patient Safety Agency, 2008; Prairie Research Association, 2014).

Inclusion criteria for the PERISCOPE project encompassed: i) all clinical incidents reported via the palliative care services' internal incident management system which involved opioids in adult (≥ 18 years) patients; and ii) occurred in the palliative care service during a pre-defined timeline.

Reported opioid incidents that did not directly involve a patient, (e.g., narcotic discrepancies, drug storage, wastage, and/or security incidents), or opioid incidents that occurred in an external service but were first identified and reported by the palliative care service, were excluded in the PERISCOPE project.

Review literature for background information

Prior to the PERISCOPE project commencing, consultation with palliative care clinicians suggested opioid errors were contributing to iatrogenic harm in specialist palliative care inpatient services, and reducing these errors was a quality improvement priority (Heneka et al., 2018a). As a result, a systematic literature review to determine the prevalence, types and patient impact of opioid errors reported in adult palliative and cancer care patient settings was undertaken at the outset of the PERISCOPE project (Heneka et al., 2015). The systematic review was guided by The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement (Liberati et al., 2009). The detailed methodology of the review process is reported in Chapter 2. The systematic review was critical to highlighting the paucity of empirical research reporting opioid errors in the palliative care service delivery context.

Develop analysis plan

A data analysis plan was developed *a priori* in conjunction with a biostatistician for each of the PERISCOPE project quantitative studies. Qualitative data were analysed using thematic content analysis (Braun & Clarke, 2006). Details of data analyses for each of the four studies are reported in the corresponding sections below.

3.6.2 Stage 2: Understand what happened

In order to understand what happened, Stage 2 of the multi-incident analysis focused on quantitative analysis of reported incidents involving opioids. In this stage of the multi-incident analysis, preliminary patterns and trends, including incident characteristics, reported contributing factors, and patient outcomes were identified.

Study 2: Retrospective review of state-wide clinical incident data

Study 2 combined a retrospective review of de-identified clinical incidents involving opioids, and analysis of opioid incident trends, reported to the Clinical Excellence Commission via the state-wide incident management system. The Clinical Excellence Commission has oversight over the NSW incident information management system and responsibility for identifying opportunities for statewide policies and strategies to improve health care (Clinical Excellence Commission, 2018). Incidents are classified into one of 19 ‘Principal Incident Types’ and rated in

accordance with a Severity Assessment Code (SAC) risk rating (Clinical Excellence Commission NSW Health, 2016).

Due to the paucity of published literature reporting medication errors with opioids in palliative and cancer care services, this retrospective review was designed to capture a snapshot of opioid incident reporting, characteristics of reported opioid incidents, incident contributing factors, and patient impact of opioid incidents in the NSW public hospital system ('NSW Health'). Retrospective research is a widely used methodology in health care that utilises existing health records and/or clinical data to answer research questions (Vassar & Holzmann, 2013). In medication error research, retrospective review of incident reports is used to determine the clinical significance and potential causes of medication errors (Flynn & Barker, 2007).

For this study, two custom, state-wide datasets were created in collaboration with the Clinical Excellence Commission. Both datasets were extracted from incidents notified under the principal incident type – 'medication/IV fluid' (Clinical Excellence Commission NSW Health, 2016). Data collection and analysis methods for each data set is detailed below.

Dataset 1 comprised a search of reported incidents involving opioids, for calendar years 2011 to 2014 inclusive.

Data collection: The trend search variables encompassed: i) service type (all hospital services), ii) opioid type; and iii) incident SAC. Sample size was limited by the Clinical Excellence Commission to four retrospective calendar years of data, commencing with the most recently available full data set at the time of the study (calendar year 2014).

Data analysis: Data analysis was undertaken using descriptive statistics and percentage analysis to quantify reported incidents by variable. Pearson's Chi-Square test was used to determine differences in frequency of errors by opioid type and service involved. Quantitative data analysis was undertaken with the IBM Statistical Package for the Social Sciences ('SPSS') V25 software package.

Dataset 2 comprised 500 consecutive, retrospective incident report summaries of incidents involving opioids reported in palliative care and cancer services.

Data collection: Sample size was limited by the Clinical Excellence Commission to a total of 500 consecutive retrospective incident reports commencing December 31, 2014, in accordance with the Commission's data release policy at the time of the study. Variables in this data set included incident by: problem type; incident SAC; incident time band; patient age band; and free text entries completed by the notifier at the time of reporting comprising: incident description; and incident contributing factors.

Data analysis: Data analysis of the incident reports was undertaken by firstly classifying opioid incidents by service (palliative care or cancer service) then problem type (Clinical Excellence Commission NSW Health, 2016), and then by error type (National Coordinating Council for Medication Error Reporting and Prevention, 1998). Patient harm was determined by deductive thematic content analysis of the incident narrative (Braun & Clarke, 2006) and categorised according to the National Coordinating Council for Medication Error Reporting and Prevention index (Hartwig, Denger, & Schneider, 1991). Similarly, incident contributing factors were identified by deductive thematic content analysis of the incident narrative (Braun & Clarke, 2006) and categorised according to the Yorkshire Contributory Factors Framework (Figure 3.4, Table 3.2) (Lawton et al., 2012). To ensure correct interpretation of error contributory factors, a second clinical reviewer independently identified and classified error contributory factors from the incident narrative. Where discrepancies between the candidate and clinical reviewer were identified, a third clinical reviewer was consulted. Descriptive statistics and percentage analysis were used to quantify reported incidents. Pearson's Chi-Square test was used to determine differences in error characteristics and patient impact between cancer and palliative care services. All quantitative data analysis was undertaken with the IBM Statistical Package for the Social Sciences ('SPSS') V25 software package. Qualitative data was managed using the NVivo software package V11.4.1.

Data from Study 2 served as a comparison measure for data collected at the local level (Study 3 and Study 4).

Study 3: Retrospective review of local clinical incident data

Study 3 commenced with a seven-day snapshot audit to quantify the frequency of opioid delivery in the specialist palliative care inpatient service delivery context.

This was followed by a retrospective review of consecutive clinical incidents with opioids reported by three specialist palliative care inpatient services in metropolitan NSW ('local services'). For ease of reporting, the seven-day snapshot audit is reported as Study 3a, and the local retrospective review as Study 3b.

Study 3a - Snapshot audit

Data collection - snapshot audit: A retrospective seven-day snapshot audit of all documented opioid orders and administrations was undertaken to quantify the number of opioids delivered in the three local participating specialist palliative care inpatient services. The medication charts of all patients admitted to the participating palliative care inpatient units, from February 12 to 18 (inclusive), 2015, were included in the snapshot audit. All regular, PRN and immediate ('STAT') opioid orders and administrations were recorded into an Excel spreadsheet (Appendix 4). The date and start time of each opioid order was documented and projected doses aligned with the patients' length of stay/time of discharge in the audit period. Where a dose had been ordered but not administered, the reason for non-administration was noted. Any doses not administered without a documented reason were categorised as omitted dose errors. The sum of all opioid doses ordered and all doses administered, was calculated. The sum of opioid administrations by opioid was also calculated. Service characteristics (i.e., number of available beds, number of patients, percentage occupancy, and patient length of stay in the snapshot audit period) were sought from the Clinical Information Team at each service.

Data analysis - snapshot audit: Descriptive statistics and percentages were used to quantify opioid delivery and administrations by opioid. All quantitative data analysis was undertaken with the SPSS V25 software package.

Study 3b - Local retrospective review

Data collection - local retrospective review: Custom datasets were created in consultation with the site teams to capture clinical incidents with opioids, extracted from the participating services' internal incident management system. Data was extracted by the services' Quality and Safety team and provided to the research team for analysis. A purpose-built data collection tool (Appendix 5) was developed and piloted for this project following consultation with senior palliative care clinicians,

hospital pharmacists, and service quality/safety managers. This data collection tool was designed to capture: patient demographics, problem type and opioid involved, incident characteristics, patient impact of the opioid incident, and action by service following incident. The local retrospective review period spanned March 1, 2013 to February 28, 2015, inclusive.

Data analysis - local retrospective review: Incidents were firstly classified by problem type (Clinical Excellence Commission NSW Health, 2016) then by error type (National Coordinating Council for Medication Error Reporting and Prevention, 1998). Patient harm was determined by deductive thematic content analysis of the incident narrative (Braun & Clarke, 2006) and categorised according to the National Coordinating Council for Medication Error Reporting and Prevention index (Hartwig et al., 1991). Sample size was determined by the number of opioid incidents identified. Descriptive statistics and percentages were used to quantify reported incidents. Pearson's Chi-Square test was used to determine differences in error characteristics between services. All quantitative data analysis was undertaken with the SPSS V25 software package. Qualitative data was managed using the NVivo software package V11.4.1.

Study 4: Retrospective review of reported opioid error contributing factors

In Study 4 a retrospective review of opioid error contributing factors documented in clinical incident reports involving opioids was undertaken in two specialist palliative care inpatient services in NSW.

Data collection: The retrospective review period for Study 4 spanned January 1, 2013 to December 31, 2015, inclusive. Data collection was undertaken using the same methods as described in Study 3b above. Additionally, the incident narrative of reported clinical incidents involving opioids in the audit period was recorded to identify documented opioid error contributing factors.

Data analysis: Incident classification and assessment of patient harm following an error was undertaken using the same data analysis methods as in Study 3b above. Differences in patient demographics between the two local specialist palliative care inpatient services were analysed using Chi-square tests, test of normality and homogeneity of variance, and univariate one-way analysis of variance (ANOVA) by

General Linear Model. Descriptive statistics and percentage analysis were used to identify incident characteristics. Pearsons' Chi Square and Correlation were applied to determine relationships between patient and opioid error characteristics. Deductive thematic content analysis of the incident narrative, (Braun & Clarke, 2006) in alignment with the Yorkshire Contributory Factors Framework (Figure 3.4, Table 3.2) (Lawton et al., 2012), was undertaken to classify and quantify opioid error contributing factors. Verbatim quotes from the incident narrative were reported to support contributory factor classifications. Quantitative data analysis was undertaken with the IBM SPSS Statistics V25 software package. Qualitative data was managed using the NVivo software package V11.4.1.

3.6.3 Stage 3: Determine how and why it happened

Stage 3 is the qualitative portion of the multi-incident analysis. The focus in this stage is to explore palliative care clinicians' and service managers' perceptions of opioid error prevalence, contributing and mitigating factors, to better understand how and why opioid errors are occurring in specialist palliative care inpatient services.

Study 5: Semi-structured interviews and focus groups

Study 5 was informed by the results of Study 2, 3 and 4 in accordance with an explanatory sequential mixed methods design (Creswell & Plano Clark, 2018).

Data collection - sampling: Purposive sampling was used to identify eligible participants at each service. This sampling technique is widely used in qualitative research to identify participants with in-depth knowledge and/or experience with the phenomenon of interest (Creswell & Plano Clark, 2018; Patton, 2015). The purposive sampling strategy was selected for the PERISCOPE project based on the sampling strategy guidelines developed by Curtis and colleagues (2000), as described below.

The sampling strategy stemmed logically from the multi-incident analysis and Yorkshire Contributory Factors conceptual frameworks, and the project's research questions. Palliative care clinicians and service managers involved in opioid delivery or oversight were well positioned to provide insights into opioid error reporting practices, characteristics, contributory and/or mitigating factors in the PERISCOPE project. A critical stage in the multi-incident analysis (conceptual framework) is the

qualitative exploration of opioid errors to understand how and why errors occurred (Stage 3) (Curtis et al., 2000).

Participants in the PERISCOPE project were able to generate a comprehensive dataset on opioid errors in the palliative care context as they represented three clinical disciplines, across multiple levels of management, with a wide range of years of experience in palliative care. These participants were specifically recruited for the PERISCOPE project, to provide sufficient data to answer the research questions and confirm or refute the quantitative data results. Throughout the semi-structured interviews and focus groups, the researcher (NH) fed-back their interpretation of the data and asked study participants to assess whether these interpretations were accurate. Hence, the PERISCOPE project participants enabled the drawing of clear inferences and credible explanations from the data (Curtis et al., 2000).

The sampling strategy was ethical in that all participants provided informed consent prior to attending a semi-structured interviews or focus group (refer Section 3.6.3); and the sampling plan was feasible, as purposive sampling was congruent with the abilities of the researcher, who had prior qualitative interviewing experience (Curtis et al., 2000).

Data collection: A combination of focus groups and semi-structured interviews were used in the PERISCOPE project to explore and better understand the quantitative data from Stage 2 of the multi-incident analysis. Data were collected between March and November 2017.

Rationale for focus groups and semi-structured interviews

Both focus groups and semi-structured interviews are commonly used data collection methods in qualitative and mixed methods research (Creswell & Plano Clark, 2018; Teddlie & Tashakkori, 2009) (Kitzinger, 2005). In the PERISCOPE project, both methods were used in order to maximise the number of participants in Phase 2 of the project. The researchers were highly cognisant of palliative care clinicians' busy schedules. Hence, giving clinicians the option of attending either a pre-scheduled focus group or having them nominate a preferred time for a semi-structured interview, was considered the best approach to accommodating clinicians' schedules.

Focus groups are a planned series of discussions designed to explore participants' thoughts or feelings about an issue, based on their personal experience (Kitzinger, 1994; Krueger, 2014). They are typically composed of five to eight participants with common characteristics, based on the purpose of the study. In the PERISCOPE project, we sought perceptions and experiences of opioid errors in specialist palliative care inpatient services from the perspective of clinicians and service managers who were involved in opioid delivery or oversight. These characteristics formed the basis for recruitment (Krueger, 2014).

Focus groups are an ideal way of collecting qualitative data of interest to the researcher in a timely manner and assist with identifying a range of opinions across multiple groups. In the PERISCOPE project, focus group questions were pre-determined and open-ended, starting with more general questions at the beginning of the group and becoming more focussed as the group progressed. The researcher moderated the focus group, acting as listener, observer, and ultimately data analyst. The purpose of a focus groups was not to reach consensus, rather, the moderator focussed on understanding the opinions, perceptions and thought processes of participants as the opioid errors in the specialist palliative care inpatient setting were discussed (Krueger, 2014).

However, as focus groups are often difficult for busy clinician to participate in, interested clinicians in the PERISCOPE project were also provided with the option to participate in a semi-structured interview. Semi-structured interviews provided an opportunity to explore the phenomenon of opioid errors from the perspective of the different disciplines that are involved in key stages of opioid delivery (nursing, medical, pharmacy) in more depth than afforded in a focus group. Open-ended questions were developed in a manner that allowed question prompts to be introduced (Table 3.4) to encourage participants to reflect more deeply on different question elements (Teddlie & Tashakkori, 2009).

Throughout both the focus groups and semi-structured interviews the researcher (NH) sought to further explore the results of the preceding quantitative studies (Creswell & Plano Clark, 2018; Teddlie & Tashakkori, 2009). To assist the researcher to better understand the results from the retrospective reviews, a summary of the retrospective review data for each local service (Study 3) was

provided to participants, once their perceptions of opioid error prevalence, patient impact and characteristics had been explored (Appendix 6). Participants were asked to comment on the results, giving the researcher an opportunity to explore the congruences and differences between the quantitative and qualitative data in the PERISCOPE project.

Recruitment

Eligible clinicians received an email invitation to attend a focus group or semi-structured interview from the unit/service manager. Included in the email invitation was a participant information and consent form (Appendix 7), which clearly described what taking part in the study would involve. Participants could attend either an onsite focus group or semi-structured interview, or a semi-structured telephone interview. The focus group schedule at each participating service was arranged with the unit managers. Interested clinicians contacted the researcher (NH) directly if they: had any questions prior to consenting to the study, wished to attend a scheduled focus group, or wanted to arrange a time for an interview. Written informed consent was obtained from eligible participants prior to the focus groups or interviews.

A question route, informed by the literature (Heneka et al., 2015) and piloted with palliative care service managers and medication safety experts, guided the focus groups and semi-structured interviews (Table 3.3).

All focus groups and semi-structured interviews were conducted by a researcher (NH) with qualitative interviewing expertise and were audio recorded and professionally transcribed by an external transcription service. A dedicated scribe (PB) took detailed focus group field notes. Immediately following each focus group, the researcher and scribe individually reflected on the focus group content, then compared and discussed their reflections, noting any differences in the field note observations. The researcher (NH) summarised the key points and insights and noted any questions or concepts for follow-up after each focus group and semi-structured

Table 3.3 Question route for semi-structured interviews and focus groups

Semi-structured interviews only

- Just so I understand how it works in this unit, I am wondering if you could walk me through a typical opioid order (doctor); administration (nurse); dispensing (pharmacist) scenario?
- Is there anywhere in this (opioid delivery) process where you think the risk of making error is high?

Semi-structured interviews and focus groups

1. Opioid error prevalence, characteristics and patient harm

- What do you define as an opioid error?
- How often do you think opioid errors occur in this unit?
- What are the main types of opioid errors that occur in this unit?
- Do you think all opioid errors that occur are reported?
 - *Question prompts: Why or why not? What would/wouldn't you report?*
- Can you tell me how you think opioid errors impact on:
 - patients?
 - other members of the team?

A summary of the retrospective review data for each local service (Study 3) was shown to participants at this point in the question route, and participants were asked:

- Do you have any comments about the results of this review?
 - *Question prompts: Is there anything in the review you find surprising/not surprising?*

2. Opioid error risk and contributing factors

- Is there anywhere in the opioid delivery process, from the time the patient is first admitted to the unit, until the opioid has been administered to the patient, where the risk of opioid error is greater?
- Are there any factors that you think contribute to opioid errors in this unit?
 - *Question prompts: Are there any systems factors that contribute to opioid errors in this unit?*
- Is there anything you think could be done in this service to better support safe opioid delivery in this unit?

3. Opioid error mitigating factors

- What are the strategies (current and/or previous) used in this unit to prevent/reduce opioid errors?
 - Is there anything else you think helps support safe opioid delivery in this unit?
-

interview. The qualitative data collection continued until no new insights were generated.

Data analysis: All transcriptions were read in conjunction with the original audio recording (NH) to check for accuracy. Data familiarisation was achieved through multiple readings of the transcripts and field notes (NH). Confirmation of contributory and descriptive themes was reached through collaborative analysis (NH and JP). A combination of inductive and deductive thematic data analysis (Braun & Clarke, 2006) was used in Study 5.

Inductive thematic analysis: Initial data coding was guided by the focus group/semi-structured interview questions, with codes and collated data examined for potential themes. To ensure rigour, the preliminary themes were identified independently (NH and JP) and refined through collaborative analysis until the final themes and sub-themes were confirmed.

Deductive thematic analysis: opioid error contributing factors were categorised using the domains of the Yorkshire Contributory Factors Framework (Lawton et al., 2012) as initial coding categories.

Trustworthiness of the data and findings: Development and reporting of this study was guided by the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist (Tong, Sainsbury, & Craig, 2007). The procedures used to generate the findings were guided by the four general types of trustworthiness in qualitative research, namely: credibility, transferability, dependability and confirmability (Lincoln, Guba, & Guba, 1985).

Credibility was achieved by using purposive sampling targeting palliative care clinicians. Participants were assured that their identities would be protected on all transcripts, reports and publications that resulted from the interviews. Open-ended questions, probes and prompts were utilised throughout the interview process to encourage participants to share their experiences. A combination of semi-structured interviews, focus groups and field notes were used to enhance the reliability, validity, and veracity of qualitative data collection (Taylor, Bogdan, & DeVault, 2015). Member checking was undertaken within and across semi-structured interviews and focus groups to check interpretation of the data, and data collection was undertaken

until data saturation was reached. Validation and discussions among co-researchers was used to enhance the trustworthiness of the data analysis (Lincoln et al., 1985).

To enhance the *transferability* of the PERISCOPE project findings, the participants, study settings, impetus for the study, and specific contexts of the study were described in detail, allowing other researchers to determine the potential for applying the project's findings to other contexts and/or participants (Braun & Clarke, 2013; Lincoln et al., 1985). Data analysis was congruent with the accepted standards of the mixed methods explanatory sequential design, the conceptual frameworks used to guide the PERISCOPE project, and qualitative research reporting criteria (Tong et al., 2007) ensuring *dependability* of the project findings (Korstjens & Moser, 2018). Finally, each of the research steps taken, from study conception to development and reporting of the findings, were transparently described to lend *confirmability* to the findings. The voices of the participants were widely represented in the quotes provided to support the themes and show transparency in the confirmability of the data interpretation.

3.6.4 Stage 4: Develop recommended actions

Data integration and meta-inference is undertaken in this stage in order to generate recommendations to support safe opioid delivery in specialist palliative care inpatient services. Details of data integration methods for the PERISCOPE project have been described in Section 3.3.9. All inferences drawn from the integrated PERISCOPE project data were entered into a matrix and thematically analysed to arrive at a new, consolidated, qualitative data set (Braun & Clarke, 2013; Caracelli & Greene, 1993). A conceptual framework based on the primary themes generated during analysis was created to identify relationships within and between themes and subthemes, and to answer the project aim. Chapter 8 reports the inferences reached at each stage of data integration in the PERISCOPE project, as well as the meta-inferences drawn from the project as a whole. Recommended actions generated from the meta-inference are also reported in Chapter 8.

3.7 Ethical considerations in the PERISCOPE project

3.7.1 Values

The PERISCOPE project was undertaken in accordance with the National Statement on Ethical Conduct in Human Research ('National Statement') (The National Health and Medical Research Council, 2007) and the Australian Code for Responsible Conduct of Research (National Health and Medical Research Council, 2018).

Accordingly, the PERISCOPE project addresses and reflects each of the following values.

Research merit

The PERISCOPE project sought to make a substantial contribution to the body of knowledge pertaining to medication safety with opioids in specialist palliative care inpatient services. Prior to submission for ethical review the project underwent peer review at the: Improving Palliative Care through Clinical Trials (ImPaCCT) Concept Development Workshop (August 11, 2014); and the Sacred Heart Health Services, St Vincent's Hospital, New Studies Meeting (November 11, 2014), to ensure the research merit of the project, and the appropriateness of the research design. Collectively, the project research team (NH, JP, TS, DR, SL) had appropriate qualifications and extensive experience in palliative care services research, medication safety research, and mixed methods research methodology.

Research integrity

The PERISCOPE project was undertaken following the principles of research integrity, namely: seeking new knowledge and understanding; following recognised principles of research conduct, and local codes of conduct as participating services; and, conducting the research with honesty and transparency (National Health and Medical Research Council, Australian Research Council, & Universities Australia, 2007). Study results/findings were shared with participating services for feedback prior to submission for publication. Study results were communicated through written reports (Appendix 8) and presentations at participating services, as well as through peer reviewed oral and poster presentations and invited presentations (refer Research Outputs Associated with Thesis in front matter).

Justice

The participant inclusion criteria for the PERISCOPE project was broad, encompassing all palliative care clinicians and personnel who were involved with, or had oversight of, the opioid delivery process. Participation was voluntary and participants were made aware of the time burden and what the research activities would entail, prior to consenting to the study. The conduct of the study was the same at all sites, ensuring there was no unfair burden of participation in particular groups.

Research outcomes were made accessible to participants through written reports and presentations at all participating services in a timely manner, following completion of each study (Appendix 8).

Beneficence

The likely benefit of the project extended to: i) participants, who had an opportunity to reflect on their clinical practice in relation to opioid delivery, risk factors for opioid error, and exploration of safety culture in the service; ii) specialist palliative care inpatient services, who were provided with analyses of opioid errors both within their unit and benchmarked against local and state-wide data; as well as analysis of systems factors contributing to or mitigating opioid errors; and iii) palliative inpatients, who may benefit from a reduction in opioid errors and resultant patient harm.

Respect

Throughout the PERISCOPE project, there was a high level of engagement with participating services, including clinicians, service managers and support staff (e.g., clinical information teams, quality and safety personnel) to ensure the research was conducted in a respectful manner, with due regard for the welfare of participants. All research activities were negotiated with senior management at participating sites and conducted in a way to minimise disruption of unit workflow. Semi-structured interviews and focus group times were negotiated with Nurse Unit Managers and Clinical Nurse Educators, and scheduled at the site at a time that suited the workflow of the unit. The dates, venues and times for the focus groups and interviews were negotiated to minimise inconvenience for the participants. Participants were also assured they did not need to answer any questions they were not comfortable with

and were made aware of support options if the semi-structured interviews/focus groups raised any issues for them.

Risk and benefit

All studies in the PERISCOPE project were assessed as low/negligible risk by the relevant Human Research Ethics Committees. The only foreseeable risk for participants was one of discomfort and/or inconvenience related to participation in the focus groups and/or semi-structured interviews. Participants were asked about their perceptions of opioid errors within the service. Whilst they were not specifically asked to disclose any personal involvement in regard to opioid errors that they may have been directly or indirectly involved in, raising the possibilities of errors may cause participants to reflect on their practice or to recall an error that could cause them discomfort and/or distress especially if there was an adverse outcome. As such, being asked to reflect on opioid errors, and their impact on patients and staff, may raise feelings of discomfort related to participants' professional practice. To minimise these potential study procedure risks, the researchers outlined support services that were available to participants and are free of charge, offered by participating sites, as well as other relevant local/national support services. This information was included in the participant information sheet and given to participants again at the conclusion of the interview/focus group. Additionally, participants were advised that they were not obliged to answer interview or focus group questions and could end the interview or focus group at any time without giving a reason, and with no consequence to their current employment. Participants were also given the option of attending a one-on-one interview following the focus group if they wished to further discuss opioid errors, but were not comfortable sharing this in the context of a focus group.

3.7.2 Consent

Eligible participants were provided with a study information form (Appendix 7), which provided detailed information about study procedures and participant involvement. Participants were advised that taking part in the study was voluntary, and that they were free to decline participation without any consequences. Written informed consent was collected from all participants prior to study enrolment, and any study activities being undertaken.

3.7.3 Ethical and site specific approval

Ethical approval, ratification and cross-institutional recognition

Ethical approval was sought from three Human Research Ethics Committees (HREC) for the PERISCOPE project: i) NSW Population and Health Services Research Ethics Approval, ii) St Vincent's Hospital HREC, and iii) University of Notre Dame Australia HREC.

Study 2 required access to a data collection owned by NSW Health, via the Clinical Excellence Commission. As such, ethical approval for this study was sought from the NSW Population and Health Services Research Ethics Committee, which is jointly convened by the NSW Ministry of Health and the Cancer Institute NSW. Prior to submitting Study 2 for ethical approval to the NSW Population and Health Services Research Ethics Committee, a study protocol review was requested from the Cancer Institute NSW, who confirmed the study would be of benefit to the NSW Health system. Subsequent in-principle support of the data request was then offered by the Clinical Excellence Commission, subject to ethics approval. Low and negligible risk ethical approval was also sought, and granted, by the University of Notre Dame Australia HREC.

Ethical approval for Studies 3, 4 and 5 was obtained from St Vincent's Hospital HREC [EC00140]. Cross-institutional recognition of ethics approval was then obtained from the University of Notre Dame Australia HREC (Appendix 9).

Site specific/governance approval

Site specific assessment (SSA) authorisation was obtained from the relevant Research Governance Office at participating sites (Appendix 9). As Study 3 and Study 4 required access to hospital incident reports and patient medical records by the researcher, who was external to participating services, an Honorary Research Appointment was sought where required.

3.7.4 Data storage and security

All data arising from the PERISCOPE project were stored on a secured, password protected research drive, or in a locked filing cabinet in a secure office, at the Centre for Improving Palliative, Aged and Chronic Care through Clinical Research and

Translation (IMPACCT), University of Technology Sydney, where the candidate's primary supervisor is based. A copy of the de-identified project data is also stored on a secured, password protected research drive at the University of Notre Dame School of Nursing per University requirements. De-identified data were also stored on an encrypted repository on the researcher's password-protected computer while the study was in progress.

Participant confidentiality, privacy and anonymity were ensured through the allocation of site codes and de-identified participant codes that were used throughout data analysis. Signed consent forms were securely stored separately from other study data. Participant names were removed from all data transcripts and digital files were saved using participants codes only. The electronic list of study codes with participant details was stored in the secure, password protected IMPACCT research drive, with an additional level of password protection. Only the researcher (NH) and primary supervisor (JP) have access to study data (electronic and/or hard copy). All publications associated with the project reported global, de-identified data only.

All study data will be stored for a period of five years from the date of any associated publications in accordance with national requirements (National Health and Medical Research Council, 2018; National Health and Medical Research Council et al., 2007). At the completion of the study, all data collection forms and study materials (both hard copy and electronic) will be prepared for collation and archiving consistent with the jurisdictional regulations regarding the retention and disposal of research data, as advised by the National Statement (National Health and Medical Research Council et al., 2007).

3.8 Summary

This chapter has outlined the rationale for a mixed methods design, conceptual frameworks, data collection and analysis methods, and ethical considerations of the PERISCOPE project. The following chapters report, in detail, the individual studies that comprise PERISCOPE project, the project conclusions and recommendations.

The following chapter reports the results of the retrospective review of reported clinical incidents with opioids undertaken in palliative care services across NSW (Study 2), and in three local specialist palliative care inpatient services (Study 3).

3.9 References

- Allan, E. L., & Barker, K. N. (1990). Fundamentals of medication error research. *American Journal of Hospital Pharmacy*, 47(3), 555-571.
- Andrew, S., & Halcomb, E. J. (2009a). *Introduction to mixed methods research for nursing and the health sciences*. Chichester, West Sussex: Wiley and Blackwell.
- Andrew, S., & Halcomb, E. J. (2009b). *Mixed Methods Research for Nursing and the Health Sciences*. Chichester, West Sussex: Wiley.
- Australian Adult Cancer Pain Management Guideline Working Party. (2014). Cancer pain management in adults. Retrieved from <http://wiki.cancer.org.au/australiawiki/index.php?oldid=89991>
- Australian Commission on Safety and Quality in Health Care. (2010). Australian Safety and Quality Framework for Health Care. Retrieved from <https://www.safetyandquality.gov.au/wp-content/uploads/2012/01/32296-Australian-SandQ-Framework1.pdf>
- Australian Institute of Health and Welfare. (2018). Palliative care services in Australia. Retrieved from <https://www.aihw.gov.au/reports/palliative-care-services/palliative-care-services-in-australia/contents/summary>
- Barker, K. N., Flynn, E. A., Pepper, G. A., Bates, D. W., & Mikeal, R. L. (2002). Medication errors observed in 36 health care facilities. *Archives of Internal Medicine*, 162(16), 1897-1903. doi:10.1001/archinte.162.16.1897
- Bazeley, P. (2017). *Integrating Analyses in Mixed Methods Research*: SAGE Publications.
- Biesta, G. (2010). Pragmatism and the Philosophical Foundations of Mixed Methods Research. In Tashakkori, A. & Teddlie, C. (Eds.), *SAGE Handbook of Mixed Methods in Social & Behavioral Research* (pp. 95-118): SAGE Publications.
- Braithwaite, J., Westbrook, M. T., Travaglia, J. F., & Hughes, C. (2010). Cultural and associated enablers of, and barriers to, adverse incident reporting. *Quality and Safety in Health Care*, 19, 229-233.
- Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3(2), 77-101. doi:10.1191/1478088706qp063oa
- Braun, V., & Clarke, V. (2013). *Successful Qualitative Research: A Practical Guide for Beginners*: SAGE Publications.
- Bryman, A. (2006). Integrating quantitative and qualitative research: how is it done? *Qualitative Research*, 6(1), 97-113. doi:10.1177/1468794106058877
- Burkhardt, M., Lee, C., Talyor, L., Williams, R., & Bagian, J. (2007). Root cause analysis of medication errors. In Cohen, M. R. (Ed.), *Medication errors* (2nd ed., pp. 67-86). Washington DC: American Pharmaceutical Association.
- Caracelli, V. J., & Greene, J. C. (1993). Data Analysis Strategies for Mixed-Method Evaluation Designs. *Educational Evaluation and Policy Analysis*, 15(2), 195-207. doi:10.2307/1164421

- Cheng, R., Yang, Y., Chan, M., & Patel, T. (2017). Medication Incidents Involving Antiepileptic Drugs in Canadian Hospitals: A Multi-Incident Analysis. *Healthcare quarterly (Toronto, Ont.)*, 20(2), 54-62.
- Clinical Excellence Commission NSW Health. (2016). Clinical Incident Management in the NSW public health system. Retrieved from <http://www.cec.health.nsw.gov.au/clinical-incident-management>
- Colquhoun, M., Koczmara, C., & Greenall, J. (2006). Implementing system safeguards to prevent error-induced injury with opioids (narcotics): an ISMP Canada collaborative. *Healthcare quarterly (Toronto, Ont.)*, 9 Spec No, 36-42.
- Creswell, J. W. (2009). *Research Design: Qualitative, quantitative, and mixed methods approaches* (3rd ed.). Thousand Oaks: Sage Publications, Inc.
- Creswell, J. W. (2014). *A Concise Introduction to Mixed Methods Research*: SAGE Publications.
- Creswell, J. W., & Creswell, J. D. (2017). *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*: SAGE Publications.
- Creswell, J. W., Klassen, A. C., Plano Clark, V. L., & Smith, K. C. (2011). Best practices for mixed methods research in the health sciences. *Bethesda (Maryland): National Institutes of Health, 2013*, 541-545.
- Creswell, J. W., Plano Clark, V., Gutmann, M., & Hanson, W. (2003). Advanced mixed methods research designs. In Tashakkori, A. & Teddle, C. (Eds.), *Handbook of mixed methods in social and behavioral research* (pp. 209-240). Thousand Oaks, CA: Sage.
- Creswell, J. W., & Plano Clark, V. L. (2018). *Designing and conducting mixed methods research* (3rd ed.). California, USA: SAGE Publications.
- Crotty, M. (1998). *The Foundations of Social Research: Meaning and Perspective in the Research Process*: SAGE Publications.
- Curry, L. A., Krumholz, H. M., O'Cathain, A., Plano Clark, V. L., Cherlin, E., & Bradley, E. H. (2013). Mixed methods in biomedical and health services research. *Circulation. Cardiovascular Quality And Outcomes*, 6(1), 119-123. doi:10.1161/CIRCOUTCOMES.112.967885
- Curtis, S., Gesler, W., Smith, G., & Washburn, S. (2000). Approaches to sampling and case selection in qualitative research: examples in the geography of health. *Social Science and Medicine*, 50(7-8), 1001-1014.
- Doyle, L., Brady, A.-M., & Byrne, G. (2016). An overview of mixed methods research – revisited. *Journal of Research in Nursing*, 21(8), 623-635. doi:10.1177/1744987116674257
- Fetters, M. D., Curry, L. A., & Creswell, J. W. (2013). Achieving integration in mixed methods designs-principles and practices. *Health Services Research*, 48(6 Pt 2), 2134-2156. doi:10.1111/1475-6773.12117
- Fitzpatrick, K. R. (2016). Points of Convergence in Music Education: The Use of Data Labels as a Strategy for Mixed Methods Integration. *Journal of Mixed Methods Research*, 10(3), 273-291. doi:10.1177/1558689814560264

- Flynn, E. A., & Barker, K. N. (2007). Research on errors in dispensing and medication administration. In Cohen, M. R. (Ed.), *Medication errors* (2nd ed., pp. 15-41). Washington DC: American Pharmaceutical Association.
- Flynn, E. A., Barker, K. N., Pepper, G. A., Bates, D. W., & Mikeal, R. L. (2002). Comparison of methods for detecting medication errors in 36 hospitals and skilled-nursing facilities. *American Journal Of Health-System Pharmacy*, 59(5), 436-446.
- Franklin, B. D., Birch, S., Savage, I., Wong, I., Woloshynowych, M., Jacklin, A., & Barber, N. (2009). Methodological variability in detecting prescribing errors and consequences for the evaluation of interventions. *Pharmacoepidemiology and Drug Safety*, 18(11), 992-999. doi:10.1002/pds.1811
- Greene, J. C. (2006). Toward a methodology of mixed methods social inquiry. *Research in the Schools*, 13(1), 93-98.
- Greene, J. C. (2007). *Mixed methods in social inquiry*. San Francisco: Wiley.
- Greene, J. C., Caracelli, V. J., & Graham, W. F. (1989). Toward a Conceptual Framework for Mixed-Method Evaluation Designs. *Educational Evaluation and Policy Analysis*, 11(3), 255-274. doi:10.3102/01623737011003255
- Guetterman, T. C., Fetters, M. D., & Creswell, J. W. (2015). Integrating Quantitative and Qualitative Results in Health Science Mixed Methods Research Through Joint Displays. *Annals of Family Medicine*, 13(6), 554-561. doi:10.1370/afm.1865
- Halcomb, E. J., & Andrew, S. (2009). Practical considerations for higher degree research students undertaking mixed methods projects. *International Journal of Multiple Research Approaches*, 3(2), 153-162. doi:10.5172/mra.3.2.153
- Hartwig, S. C., Denger, S. D., & Schneider, P. J. (1991). Severity-indexed, incident report-based medication error-reporting program. *American Journal of Hospital Pharmacy*, 48(12), 2611-2616.
- Heneka, N., Shaw, T., Azzi, C., & Phillips, J. L. (2018a). Clinicians' perceptions of medication errors with opioids in cancer and palliative care services: a priority setting report. *Supportive Care in Cancer*, 26(10), 3315-3318. doi:10.1007/s00520-018-4231-0
- Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. (2018b). *Characteristics of reported incidents with opioids in adult palliative and cancer care services in New South Wales, Australia: Analysis of incidents reported to the Clinical Excellence Commission [2011-2014]*. Unpublished report prepared for the Clinical Excellence Commission.
- Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018c). Exploring factors contributing to medication errors with opioids in Australian specialist palliative care inpatient services: a multi-incident analysis. *Journal of Palliative Medicine*, 21(6), 825-835. doi:10.1089/jpm.2017.0578
- Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018d). Opioid errors in inpatient palliative care services: a retrospective review. *BMJ Supportive and Palliative Care*, 8(2), 175-179. doi:10.1136/bmjspcare-2017-001417
- Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2019a). Clinicians' perceptions of opioid error contributing factors in inpatient palliative care

- services: A qualitative study. *Palliative Medicine*, Advanced online publication. doi:10.1177/0269216319832799
- Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2019b). Exploring opioid error mitigating factors in specialist palliative care inpatient services: A qualitative study. *Collegian*, (Under consideration). doi:10.1177/0269216319832799
- Heneka, N., Shaw, T., Rowett, D., & Phillips, J. (2015). Quantifying the burden of opioid medication errors in adult oncology and palliative care settings: a systematic review. *Palliative Medicine*, 30(6), 520-532. doi:10.1177/0269216315615002
- Hynson, J. L., & Sawyer, S. M. (2001). Paediatric palliative care: distinctive needs and emerging issues. *Journal of Paediatrics and Child Health*, 37(4), 323-325.
- Incident Analysis Collaborating Parties. (2012). *Canadian Incident Analysis Framework*. Retrieved from: <http://www.patientsafetyinstitute.ca/en/toolsResources/IncidentAnalysis/Documents/Canadian%20Incident%20Analysis%20Framework.PDF>
- Institute for Safe Medication Practices (ISMP) Canada. (2008). Analysis of a cluster of medication incidents in community pharmacy. *ISMP Canada Safety Bulletin*, 8(8), 1-2.
- Institute of Medicine. (2007). *Preventing Medication Errors: Quality Chasm Series* (9780309101479). Retrieved from Washington DC: http://www.nap.edu/openbook.php?record_id=11623
- Ivankova, N. V., Creswell, J. W., & Stick, S. L. (2006). Using Mixed-Methods Sequential Explanatory Design: From Theory to Practice. *Field Methods*, 18(1), 3-20. doi:10.1177/1525822X05282260
- Johnson, R. B., & Onwuegbuzie, A. J. (2004). Mixed Methods Research: A Research Paradigm Whose Time Has Come. *Educational Researcher*, 33(7), 14-26. doi:10.3102/0013189x033007014
- Johnson, R. B., Onwuegbuzie, A. J., & Turner, L. A. (2007). Toward a Definition of Mixed Methods Research. *Journal of Mixed Methods Research*, 1(2), 112-133. doi:10.1177/1558689806298224
- Kitzinger, J. (1994). The methodology of Focus Groups: the importance of interaction between research participants. *Sociology of Health and Illness*, 16(1), 103-121. doi:doi:10.1111/1467-9566.ep11347023
- Kitzinger, J. (2005). Focus group research: using group dynamics to explore perceptions, experiences and understandings. In Holloway, I. (Ed.), *Qualitative Research In Health Care*. Berkshire, UK: Open University Press.
- Kohn, L. T., Corrigan, J. M., & Donaldson, M. S. (2000). *To Err Is Human: Building a Safer Health System*. Retrieved from Washington, DC: https://www.ncbi.nlm.nih.gov/books/NBK225182/pdf/Bookshelf_NBK225182.pdf
- Korstjens, I., & Moser, A. (2018). Series: Practical guidance to qualitative research. Part 4: trustworthiness and publishing. *European Journal of General Practice*, 24(1), 120-124.

- Krueger, R. A. (2014). *Focus Groups: A Practical Guide for Applied Research*: SAGE Publications.
- Lawton, R., McEachan, R. R., Giles, S. J., Sirriyeh, R., Watt, I. S., & Wright, J. (2012). Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. *BMJ Quality & Safety*, *21*(5), 369-380. doi:10.1136/bmjqs-2011-000443
- Lawton, R., & Parker, D. (2002). Barriers to incident reporting in a healthcare system. *Quality and Safety in Health Care*, *11*, 15-18.
- Leape, L. L., Bates, D. W., Cullen, D. J., Cooper, J., Demonaco, H. J., Gallivan, T., . . . et al. (1995). Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA*, *274*(1), 35-43.
- Leape, L. L., Brennan, T. A., Laird, N., Lawthers, A. G., Localio, A. R., Barnes, B. A., . . . Hiatt, H. (1991). The nature of adverse events in hospitalized patients: results of the Harvard Medical Practice Study II. *New England Journal of Medicine*, *324*(6), 377-384.
- Levinson, D. (2012). *Hospital incident reporting systems do not capture most patient harm, Report OEI-06-09-00091*. Retrieved from Dallas: <https://oig.hhs.gov/oei/reports/oei-06-09-00091.pdf>
- Liberati, A., Altman, D. G., Tetzlaff, J., Mulrow, C., Gøtzsche, P. C., Ioannidis, J. P. A., . . . Moher, D. (2009). The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. *Annals of Internal Medicine*, *151*(4), W65-W94.
- Lincoln, Y. S., Guba, Y. S. L. E. G., & Guba, E. G. (1985). *Naturalistic Inquiry*: SAGE Publications.
- McCrudden, M. T., & McTigue, E. M. Implementing Integration in an Explanatory Sequential Mixed Methods Study of Belief Bias About Climate Change With High School Students. *Journal of Mixed Methods Research*, *0*(0), 1558689818762576. doi:10.1177/1558689818762576
- McLeod, M. (2015). Measuring Medication Errors. In Tully, M. P. & Franklin, B. D. (Eds.), *Safety in Medication Use* (pp. 61-72): CRC Press.
- Ministry of Health NSW. (2013). *NSW Health Policy Directive: Medication Handling in NSW Public Health Facilities - PD2013_043*. Retrieved from http://www0.health.nsw.gov.au/policies/pd/2013/pdf/PD2013_043.pdf.
- Morag, F., Nancy, P., J., E. C., Gunn, G., Vicky, S., Hamid, B., . . . Todd, o. b. o. M. C. (2013). Mixed Methods Research in the Development and Evaluation of Complex Interventions in Palliative and End-of-Life Care: Report on the MORECare Consensus Exercise. *Journal of Palliative Medicine*, *16*(12), 1550-1560. doi:10.1089/jpm.2012.0572
- Morgan, D. L. (2014). Pragmatism as a Paradigm for Social Research. *Qualitative Inquiry*, *20*(8), 1045-1053. doi:10.1177/1077800413513733
- Muncey, T. (2009). Does Mixed Methods Constitute a Change in Paradigm? In Andrew, S. & Halcomb, E. J. (Eds.), *Mixed Methods Research for Nursing and the Health Sciences*. Chichester: Wiley-Blackwell.

- National Coordinating Council for Medication Error Reporting and Prevention. (1998). *Taxonomy of Medication Errors*. Retrieved from <http://www.nccmerp.org/sites/default/files/taxonomy2001-07-31.pdf>
- National Health and Medical Research Council. (2018). *Australian Code for Responsible Conduct of Research*. Retrieved from <https://nhmrc.gov.au/guidelines/publications/r41>
- National Health and Medical Research Council, Australian Research Council, & Universities Australia. (2007). Retrieved from: <https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>
- National Patient Safety Agency. (2008). *Rapid Response Report Supporting Information: NPSA/2008/RRR05. Safety in Doses: Improving the use of medicines in the NHS*. Retrieved from <http://www.nrls.npsa.nhs.uk/resources/?entryid45=59888>
- NIH Office of Behavioral and Social Sciences. (2018). *Best practices for mixed methods research in the health sciences (2nd ed)*. Retrieved from <https://www.obsr.od.nih.gov/wp-content/uploads/2018/01/Best-Practices-for-Mixed-Methods-Research-in-the-Health-Sciences-2018-01-25.pdf>
- NSW Health. (2014). Incident Management Policy PD2014_004. Retrieved from http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014_004.pdf
- NSW Ministry of Health. (2016). *NSW Health Guide to the Role Delineation of Clinical Services*. Retrieved from <http://www.health.nsw.gov.au/services/Publications/role-delineation-of-clinical-services.PDF>
- O'Cathain, A., Murphy, E., & Nicholl, J. (2008). The quality of mixed methods studies in health services research. *Journal of Health Services Research and Policy*, 13(2), 92-98. doi:10.1258/jhsrp.2007.007074
- O'Leary, N., Flynn, J., MacCallion, A., Walsh, E., & McQuillan, R. (2006). Paediatric palliative care delivered by an adult palliative care service. *Palliative Medicine*, 20(4), 433-437.
- Onwuegbuzie, A. J., & Leech, N. L. (2005). On Becoming a Pragmatic Researcher: The Importance of Combining Quantitative and Qualitative Research Methodologies. *International Journal of Social Research Methodology*, 8(5), 375-387. doi:10.1080/13645570500402447
- Patton, M. Q. (2015). *Qualitative Research & Evaluation Methods* (4th ed.): SAGE Publications.
- Percarpio, K. B., Watts, B. V., & Weeks, W. B. (2008). The Effectiveness of Root Cause Analysis: What Does the Literature Tell Us? *The Joint Commission Journal on Quality and Patient Safety*, 34(7), 391-398. doi:[https://doi.org/10.1016/S1553-7250\(08\)34049-5](https://doi.org/10.1016/S1553-7250(08)34049-5)
- Plano Clark, V. L. (2017). Mixed methods research. *The Journal of Positive Psychology*, 12(3), 305-306. doi:10.1080/17439760.2016.1262619
- Prairie Research Association. (2014). *Case Study of the Institute for Safe Medication Practices Canada's Work on HYDRORmorphine and Other Opioids. Final*

- Report*. Retrieved from https://www.ismp-canada.org/download/cmiprps/rptISMPC_casestudy_hydromorphone.pdf
- Queensland Health. (2014). *Best Practice Guide to Clinical Incident Management. First edition - June 2014*. Retrieved from <https://clinicalexcellence.qld.gov.au/sites/default/files/2018-01/clinicalincidentguide.pdf>
- Reason, J. (1990). *Human Error*: Cambridge University Press.
- Reason, J. (2000). Human error: models and management. *BMJ*, 320(7237), 768-770.
- Reason, J. T. (2008). *The Human Contribution: Unsafe Acts, Accidents and Heroic Recoveries*: Ashgate.
- Resar, R. K., Rozich, J. D., & Classen, D. (2003). Methodology and rationale for the measurement of harm with trigger tools. *Quality & Safety in Health Care*, 12 Suppl 2, ii39-45.
- Taylor, S. J., Bogdan, R., & DeVault, M. (2015). *Introduction to Qualitative Research Methods: A Guidebook and Resource*. USA:Wiley.
- Teddlie, C., & Tashakkori, A. (2003). Major issues and controversies in the use of mixed methods in the social and behavioural sciences. In Tashakkori, A. & Teddlie, C. (Eds.), *Handbook of mixed methods in social and behavioural research*. Thousand Oaks: Sage Publications, Inc.
- Teddlie, C., & Tashakkori, A. (2009). *Foundations of Mixed Methods Research: Integrating Quantitative and Qualitative Approaches in the Social and Behavioral Sciences*: SAGE Publications.
- The National Health and Medical Research Council, (2007). *National Statement on Ethical Conduct in Human Research 2007 (Updated 2018)*. Retrieved from https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#section_1__values_and_principles_of_ethical_conduct
- Therapeutic Guidelines Limited. (2016). Pain: opioid therapy in palliative care. In: eTG complete [Internet]. Melbourne: Therapeutic Guidelines Limited; 2018 Jul. Retrieved from <https://tgldcdp.tg.org.au/etgcomplete>
- Tong, A., Sainsbury, P., & Craig, J. (2007). Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*, 19(6), 349-357. doi:10.1093/intqhc/mzm042
- Vassar, M., & Holzmann, M. (2013). The retrospective chart review: important methodological considerations. *Journal of Education & Evaluation in Health Professions*, 10, 12. doi:10.3352/jeehp.2013.10.12
- Westbrook, J. I., Li, L., Lehnbohm, E. C., Baysari, M. T., Braithwaite, J., Burke, R., . . . Day, R. O. (2015). What are incident reports telling us? A comparative study at two Australian hospitals of medication errors identified at audit, detected by staff and reported to an incident system. *International Journal for Quality in Health Care*, 27(1), 1-9. doi:10.1093/intqhc/mzu098