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**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

MHumNutr

Submitted in fulfilment of the requirements for the Degree of Doctor of
Philosophy



School of Nursing

Darlinghurst Campus

January, 2020

Declaration

To the best of the candidate's knowledge, this thesis contains no material previously published by another person, except where due acknowledgement has been made.

This thesis is the candidate's own work and contains no material which has been accepted for the award of any other degree or diploma in any institution.

Human Ethics: The research presented and reported in this thesis was conducted in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007, updated 2018). The proposed research study received human research ethics approval from the University Of Notre Dame Australia Human Research Ethics Committee (EC00418), Approval Number(s): 017390S; 015115S; 017042S.

Abstract

ABSTRACT

Background

Opioids are a high-risk medicine, and one of the most frequently reported drug classes causing patient harm. In specialist palliative care inpatient services opioids are widely used to manage cancer pain and other symptoms. Palliative care inpatients are vulnerable to both exposure to, and harm from, opioid errors due to a combination of their: advanced age, comorbidities which affect drug metabolism, polypharmacy, and the seriousness of their illness. Despite this potential for harm, and the frequency of opioid administration in this specialist setting, little is known about opioid errors in palliative care. Better understanding the prevalence, patient impact and error contributing factors in the specialist palliative care inpatient setting will help to strengthen and support safe opioid delivery and minimise opioid error harms for this vulnerable population.

Aim

The PERISCOPE project aims to identify the: i) burden and characteristics of opioid errors; and ii) actions required to support safe opioid delivery within specialist inpatient palliative care services.

Methods

Research design: The PERISCOPE research project is a two-phase, pragmatic, explanatory sequential mixed methods study. This doctoral research project is situated within a quality and safety agenda and guided by a multi-incident analysis framework, and the Yorkshire Contributory Factors Framework. The PERISCOPE Project employed five discreet but inter-related studies conducted over two-phases. During Phase one, a: systematic literature review of opioid errors in palliative care services (Study 1); two retrospective reviews of clinical incidents involving opioids in palliative care services, one at a jurisdictional level (Study 2) and the other within three local specialist palliative care inpatient services in New South Wales (NSW) (Study 3) was undertaken. A review of opioid error contributing factors documented in clinical incident reports in local specialist palliative care inpatient services was also completed (Study 4). Phase two involved a series of semi-structured interviews

and focus groups which sought palliative care clinicians' and service managers perceptions of opioid errors in their specialist palliative care inpatient services (Study 5). Data integration and meta-inference of these data were undertaken following the completion of the two study phases, and facilitated a series of individual and systems-level recommendations to strengthen safe opioid delivery in specialist palliative care inpatient services.

Results

Phase one: The systematic review revealed a paucity of empirical data, with the reported opioid errors limited to deviations from opioid prescribing, and no opioid administration errors in the palliative care clinical setting reported. These systematic review findings contrasted with the results of the NSW state-wide and local retrospective reviews, which found that opioid administration errors accounted for three-quarters of reported opioid related incidents. The majority of these opioid errors were due to omitted dose errors. While serious patient harm due to error was exceedingly rare in palliative care services, half of all palliative inpatients exposed to an opioid error experienced iatrogenic harms. Over half of these errors resulted in opioid under-dose for the patient, which adversely impacted on their pain management. Active failures (i.e., errors made by the palliative care clinician) were reported as contributing to two-thirds of these opioid errors, and one-fifth of errors were directly attributed to deficits in clinical communication.

Phase two: The qualitative study with palliative care clinicians confirmed these results and identified additional error contributory factors including: the complexity and frequency of opioid delivery in specialist palliative care inpatient services, sub-optimal skill mix, and the absence of a clinical pharmacist in the palliative care service. This study also highlighted that palliative care services' had substantially invested in creating and sustaining a positive safety culture, which drove the services' approach to error mitigation strategies.

Meta-inference of the integrated data across the five studies revealed four factors that are required to support safe opioid delivery in specialist palliative care inpatient services: i) embedding a positive opioid safety culture; ii) enabling optimal skill mix, staffing and resources; iii) privileging opioid education in the palliative care service; and iv) empowering clinicians to identify, challenge and report opioid errors.

Conclusion

Despite specialist palliative care inpatient services clinicians ordering and administering opioids in high frequency, the overall prevalence of opioid errors in this setting is low. However, the most prevalent opioid errors that were identified were omitted dose errors, which caused unnecessary pain and suffering for affected palliative care inpatients. These errors were largely due to human error as a result of high workload and sub-optimal skill mix, and the use of paper-based versus electronic medication management systems.

The PERISCOPE Project confirmed that the opioid error contributory and mitigating factors in specialist palliative care inpatient services are multifactorial, encompassing individual and systems factors. Accordingly, any strategies to reduce opioid errors must apply an integrated systems approach in order to be of impact. Pro-actively embedding and sustaining a culture of opioid safety is a core component of supporting safe opioid delivery and reducing opioid errors in specialist palliative care inpatient services. While the PERISCOPE Project identified an overarching positive safety culture which encouraged and supported error reporting and facilitated organisational learnings to minimise and prevent opioid errors, there are still opportunities to reduce the prevalence of opioid errors, particularly missed doses in this setting. These strategies include ensuring optimal skill mix and medical/nursing ratios each shift, prioritising the transition from paper-based to electronic medication management systems, and mandating a minimum ratio of palliative care pharmacist hours for all specialist palliative care inpatient services.

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Anthology of Publications Associated with Thesis

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

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). 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. (2018). 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. (2019). Clinicians' perceptions of opioid error contributing factors in inpatient palliative care services: A qualitative study. *Palliative Medicine* *33*(4) 430-444.

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2019). Mitigating opioid errors in inpatient palliative care: A qualitative study. *Collegian (In press)*
<https://doi.org/10.1016/j.colegn.2019.09.005>

Published manuscripts, and permissions regarding copyright obtained from publishers where required, can be found in Appendix 1.

Research Outputs Associated with Thesis

Peer Reviewed Conference (Oral) Presentations

1. **Heneka, N., Shaw, T., Rowett, D., Lapkin, S. & Phillips, J.L. (2019).** *Exploring Opioid Errors in Australian, Inpatient Palliative Care Services: A Mixed Methods Study. 16th Congress of the European Association of Palliative Care (EAPC) Berlin, Germany. May 23 - 25, 2019.*
2. **Heneka, N., Shaw, T., Rowett, D., Lapkin, S. & Phillips, J.L. (2018).** Factors Contributing to Opioid Errors in Specialist Palliative Care Services: A Multi-Incident Analysis. *International Conference on Cancer Nursing, Auckland, New Zealand. 23-25 September 2018.*
3. **Heneka, N., Shaw, T., Rowett, D., Lapkin, S. & Phillips, J.L. (2018).** Characteristics of Opioid Errors Reported in Palliative Care Inpatient Services. *International Conference on Cancer Nursing, Auckland, New Zealand. 23-25 September 2018.*
4. **Heneka, N., Shaw, T., Rowett, D., Lapkin, S. & Phillips, J.L. (2018).** Reducing medication errors with opioids in specialist palliative care services. *Palliative Care Nurses Australia Biennial Conference, Brisbane, Australia, 20-21 May 2018.*
5. **Heneka, N., Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2017).** Opioid incidents reported in specialist palliative care services: Results from a quality audit. *International Conference on Cancer Nursing (ICCN). California, USA, July 9-12 2017.*
6. **Heneka, N., Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2015).** Defining and Addressing Opioid Errors in Cancer and Palliative Care. *Honor Society of Nursing, Sigma Theta Tau International (STTI), Nursing and Midwifery: Transforming Leadership, Education, Practice and Research. University of Technology Sydney, 16-17 August 2016.*
7. **Heneka, N., Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2015).** Defining and identifying opioid errors in adult palliative care and oncology settings: The PERISCOPE Study. *13th Australian Palliative Care Conference, Melbourne, Australia, 1-4 September, 2015.*
8. **Heneka, N., Shaw, T., Rowett, D., Phillips J.L. (2015).** Identifying and quantifying opioid medication errors in adult palliative care and oncology

settings, a systematic review. *Australian Palliative Care Conference, Melbourne, VIC, 1-4 September 2015.*

Peer Reviewed Conference (Poster) Presentations

1. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin, S. & Phillips, J.L. (2018). Reducing medication errors with opioids in specialist palliative care services. *International Forum on Quality and Safety in Healthcare, Melbourne, Australia. 10-12 September 2018.* Poster presentation.
2. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2018). Characterisation of Opioid incidents in Australian palliative care services: An analysis of reported medication incidents. *10th World Research Congress of the EAPC, Bern, 24-26 May 2018.*
3. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2016). Identifying opioid error types and patient impact in specialist palliative care services - preliminary results from a multi-site quality audit. *Palliative Care NSW Conference; Broken Hill, October 13th-15th 2016.*
4. **Heneka, N.**, Shaw, T., Rowett, D. & Phillips, J.L. (2016). Identifying opioid medication error types, incidence and patient impact in adult palliative care and cancer services: a systematic review. *Palliative Care NSW Conference; Broken Hill, October 13th-15th 2016.*
5. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2016). Opioid error types in specialist palliative care services - preliminary results from a multi-site quality audit. *Palliative Care Nurses Association (PCNA) 6th Biennial Conference, Canberra, Australia, 11-12 September 2016. Awarded Best Conference Poster Presentation.*
6. **Heneka, N.**, Shaw, T., Rowett, D. & Phillips, J.L. (2016). Identifying and quantifying opioid medication error types, incidence and patient impact in adult palliative care and cancer services: a systematic review. *Palliative Care Nurses Association (PCNA) 6th Biennial Conference, Canberra, Australia, 11-12 September 2016.*
7. **Heneka, N.**, Shaw, T., Rowett, D. & Phillips, J.L. (2016). Identifying the scope and impact of opioid medication errors in adult palliative care and oncology settings: A systematic review. *9th World Research Congress of the European Association for Palliative Care (EAPC), Dublin, Ireland, 9-11 June 2016.*

8. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2015). Identifying opioid medication error types, incidence and patient impact in adult oncology and palliative care settings: a systematic review. *Clinical Oncology Society of Australia, Annual Scientific Meeting, Hobart, Australia, 17-19 November, 2015.*
9. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2015). Opioid medication error types, incidence and patient impact in adult oncology and palliative care settings: a systematic review. *Innovations in Cancer Treatment and Care Conference, Sydney Australia, 15 October, 2015.*
10. **Heneka, N.**, Shaw, T., Rowett, D., Lapkin S. & Phillips, J.L. (2015). Identifying and quantifying opioid medication errors in adult palliative care and oncology settings: a systematic review. *13th Australian Palliative Care Conference, Melbourne, Australia, 1-4 September, 2015.*
11. **Heneka, N.**, Shaw, T., Rowlett, D., & Phillips, J.L. (2015). Opioid errors in cancer and palliative care: Findings from a systematic review. *International Forum on Quality and Safety in Health Care, London, UK, 22-24 April 2015.*

Invited Presentations

1. **NSW Oncology and Haematology Pharmacists Interest Group.** *Medication Errors with Opioids in Cancer and Palliative care services.* 18 Oct, 2018.
2. **St Vincent's Health Australia, Nursing Research Institute.** *Exploring opioid errors in inpatient palliative care services: The PERISCOPE Project.* 1 August, 2018.
3. **Concord Repatriation General Hospital.** *Drug errors with opioids in palliative care services.* 20 February, 2018.
4. **Sacred Heart Health Service – Palliative Care Seminar Series.** *Opioid errors in palliative care: A potentially hidden problem.* 8 November, 2017
5. **Calvary Health Care Sydney Research Forum.** *The PERISCOPE Project - findings of a quality audit of medication errors with opioids, reported in three specialist palliative care services in NSW.* 23 March 2017.
6. **University of Technology Sydney, Centre for Cardiovascular and Chronic Care, HDR Summer School.** *Systematic review methodology – The PERISCOPE Project.* January 15, 2017.

7. **University of Technology Sydney, Centre for Cardiovascular and Chronic Care, HDR Summer School.** *The PERISCOPE Project – Mixed methods integration.* January 14, 2017.
8. **Institute for Health Research (IHR) Health Research Symposium.** *Exploring opioid medication errors in specialist palliative care services: The PERISCOPE Project.* Fremantle, December 8, 2016
9. **Johns Hopkins University, School of Nursing.** *Identifying and managing opioid errors in adult palliative care and oncology settings: The PERISCOPE Project.* Baltimore, USA, September 19, 2016.
10. **Institute for Safe Medication Practices (ISMP), Practitioner in Residence Program.** *The PERISCOPE Project: Identifying and managing opioid errors in adult palliative care services.* Philadelphia, USA, September 12-16, 2016.
11. **Calvary Health Care Sydney Research Forum.** *Defining and identifying opioid errors in adult palliative care and oncology settings: The PERISCOPE Project.* 10 September 2015.

Media (Appendix 1)

1. Australian Science Media Centre and Scimex (Scientific Media Exchange). **Missed opioid doses a palliative pain.**
<https://www.scimex.org/newsfeed/missed-opioid-doses-a-palliative-pain>
2. Fairfax Media. **Opioid errors add to patient suffering, study finds.**
<https://www.theage.com.au/national/victoria/opioid-errors-add-to-suffering-of-ill-patients-study-finds-20180107-p4yyan.html>
3. **ABC News Breakfast**, a national radio broadcast, interviewed the PhD Candidate (NH) on January 8, 2018 based on the Fairfax Media article above.
4. BMJ Supportive and Palliative Care. **The best article to read this month - Opioid errors in inpatient palliative care services: a retrospective review.**
5. Clinical Excellence Commission. 2016-17 Year in Review: **Scholarship improves approach to medication errors in palliative care (p27).**
http://www.cec.health.nsw.gov.au/_data/assets/pdf_file/0012/399936/CEC-Year-in-Review-2016-17-FINAL.pdf

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1. **Palliative Care Australia** (2019): National Palliative Care Awards - Emerging Researcher.
2. **Translational Research Network (TCRN) Conference and Professional Development Grant** (2018): Attendance at the International Forum on Quality and Safety in Healthcare, Melbourne, Australia. 10-12 September 2018.
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Related Research Outputs Pre-Thesis

1. **Heneka, N.**, Shaw, T., Azzi, C. & Phillips, J.L. (2018). 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.
2. **Heneka, N.**, Phillips, J.L., and Shaw, T. (2013). Opiate errors in the specialist cancer and palliative care setting: an exploratory study. *Palliative Care Australia Conference, 4-6 September 2013. (Oral presentation)*
3. **Heneka, N.**, Phillips, J.L., & Shaw, T. (2013). Opiate errors in the specialist cancer and palliative care setting: an exploratory study. *Clinical Oncology Society of Australia Annual Scientific Meeting Adelaide, Australia, 12-14 November 2013. (Poster presentation)*

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Abbreviations

CNC	Clinical Nurse Consultant
CNE	Clinical Nurse Educator
CNS	Clinical Nurse Specialist
CON	Consultant
EEN	Endorsed Enrolled Nurse
GM	Governance Manager
HREC	Human Research Ethics Committee
INT	Intern
NHMRC	National Health and Medical Research Council
NSW	New South Wales
NUM	Nurse Unit Manager
PRN	<i>Pro re nata</i>
REG	Registrar
RMO	Resident Medical Officer
RN	Registered Nurse
SSA	Site Specific Assessment
UK	United Kingdom
US	United States

Glossary of Terms

Clinical incident	Any unplanned event which causes, or has the potential to cause, harm to a patient, including when an incident is intercepted before causing harm ('near miss') (NSW Health, 2014).
Clinician	A healthcare professional that is directly involved in patient care, e.g., physician, nurse, pharmacist.
Contributing factors	Circumstances or actions that may have played a part in the origin or development of the incident (World Health Organisation, 2005).
Drug room	A dedicated room for the preparation of drugs prior to administration. Controlled drug registers and secure drug storage units are located in the drug room (Ministry of Health NSW, 2013).
Drug storage/ wastage/security	The incident involved a problem related to medication storage, wastage, or involved a security issue, e.g., incorrect storage, loss through leakage, unintentionally discarded, tampering, stolen (Clinical Excellence Commission, 2019).
Error type	Descriptive classification of error following categorisation by 'problem type'. e.g., wrong dose, wrong drug (National Coordinating Council for Medication Error Reporting and Prevention, 1998).
Independent double check	Clinicians separately check (alone and apart from each other, then comparing results) each component of prescribing, dispensing, and verifying the medicine before administering it to the patient (Ministry of Health NSW, 2013).
Local palliative care services	The three specialist palliative care inpatient services that participated in the PERISCOPE project.
Medication error	Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer (National Coordinating Council for Medication Error Reporting and Prevention, 2014).
Multi-incident analysis	A structures process that enables the simultaneous reviewing of multiple clinical incidents with a common theme, to identify previously unrecognised patterns and/or trends in incident characteristics and contributing factors, which may not be apparent when incidents are investigated in isolation (Incident Analysis Collaborating Parties, 2012).
Narcotic discrepancy	The incident involved a discrepancy with a narcotic or a controlled drug count, e.g., discrepancy in stock count,

	incorrect documentation of count (Clinical Excellence Commission, 2019).
Near miss	A clinical incident that is intercepted before reaching the patient and/or causing patient harm (Ministry of Health, 2014).
Opioid delivery	The process encompassing opioid prescribing, dispensing, preparation for administration, and administering the opioid to the patient (Leape et al., 1995)
Opioid handling policy	Mandated medication handling policy which encompasses opioid procurement, storage, supplying, dispensing and administration (Ministry of Health NSW, 2013).
<i>Pro re nata</i> (PRN)	Medication administered ‘as required’.
Problem type (medication error)	Initial categorisation of opioid errors according to where in the opioid delivery process the error occurred, e.g., prescribing, administration (Clinical Excellence Commission, 2019).
Problem type: Administration problem	The incident occurred during the administration process, e.g., omission or suspected omission, problem with checking procedure, "signing off" or technique, wrong medication, dose, timing, route, patient etc. (Clinical Excellence Commission, 2019).
Problem type: Dispensing problem	There was a problem during the dispensing process (pharmacy), e.g., problem with labelling, no or delayed dispensing, wrong medication, wrong dose/volume (Clinical Excellence Commission, 2019).
Problem type: Prescribing problem	The incident involved a problem with the prescribing of a medication, e.g., not prescribed or transcribed when indicated, unclear prescription or transcription, wrong medication, dose, rate, patient etc. (Clinical Excellence Commission, 2019).
Problem type: Presentation problem	The incident involved a problem with the appearance of a medication, e.g., similar colour, size, shape or similarity between names (Clinical Excellence Commission, 2019).
Problem type: Supply/ordering problem	The incident occurred during the supply or ordering process, e.g., stock not ordered or not supplied, incorrect stock ordered, insufficient stock ordered or supplied (Clinical Excellence Commission, 2019).
Schedule 8 drug register	A dedicated register where all Schedule 8 medication transactions must be recorded, including disposal/destruction of expired, unusable or unwanted medications (Ministry of Health NSW, 2013).

Schedule 8 medication storage unit	A separate medication storage unit for Schedule 8 drugs that is kept locked when not in immediate use (Ministry of Health NSW, 2013).
Schedule 8 (S8) opioid(s)	Buprenorphine, fentanyl, hydromorphone, methadone, morphine, and oxycodone (Ministry of Health NSW, 2013).
Severity Assessment Code (SAC)	<p>A Severity Assessment Code (SAC) is assigned to all reported clinical incidents to direct the level of incident investigation and action required, and is informed by the consequence of the incident. SAC ratings range from SAC 1 to SAC 4:</p> <ul style="list-style-type: none"> • SAC 1: serious clinical consequence, e.g., death of a patient; extreme risk, must be reported to Ministry of Health within 24 hours, triggers root cause analysis investigation; • SAC 2: moderate to major clinical consequences, e.g., patient suffering permanent loss of function unrelated to the natural course of their illness; high risk, senior management notified, detailed investigation required; • SAC 3: minor clinical consequences, e.g., patient required increased level of care; medium risk, management responsibility specified, practice improvement project undertaken; and • SAC 4: minimum clinical consequences, e.g., no patient injury or increased level of care required as a result of incident; low risk, manage by routine procedure, practice improvement project undertaken (NSW Health, 2014).

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Dedication

For Walter, my Dad.

Chapter 1: Introduction to the PERISCOPE project

1.1 Overview

Almost two decades ago, in the seminal report *To err is human: Building a safer health system*, the Institute of Medicine (2000) brought to light the extent of patient harm from medication errors in healthcare. Medication errors continue to be one of the leading causes of preventable patient harm across all healthcare systems, and occur at all steps of the medication delivery process (Australian Commission on Safety and Quality in Health Care, 2013; Institute of Medicine, 2007). At least one quarter of medication error related harms are thought to be preventable (Institute of Medicine, 2007).

In the hospital inpatient setting medication errors occur in approximately one out of every five medication doses (Barker, Flynn, Pepper, Bates, & Mikeal, 2002). It is estimated that hospital inpatients, on average, experience at least one medication error for every admission day, with considerable variations in error rates between healthcare facilities (Institute of Medicine, 2007). To date, medication errors remain one of the most frequently reported clinical incidents in healthcare in Australia (Clinical Excellence Commission, 2019b).

Research into medication error characteristics, contributing factors, and patient harm resulting from medication errors, continues to grow both nationally (Roughead & Semple, 2009; Roughead, Semple, & Rosenfeld, 2016), and internationally (Barker et al., 2002; Institute of Medicine, 2007; Keers, Williams, Cooke, & Ashcroft, 2013), spanning many disciplines and healthcare settings. However, medication error research in the palliative care setting continues to be sparse (Currow et al., 2011; Dietz, Borasio, Schneider, & Jox, 2010; Dy, 2016), despite the significant polypharmacy that is known to occur in this population (Currow, Stevenson, Abernethy, Plummer, & Shelby-James, 2007).

1.1.2 Palliative care in Australia

Palliative care is defined as:

...an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual (World Health Organisation, 2019, para. 1).

In Australia, palliative care is provided in all health care settings, including acute hospitals, residential aged care and the community (Australian Institute of Health and Welfare, 2018). Despite the plethora of settings in which palliative care can be provided, a distinction is often made between palliative care provided in hospitals and that provided in the community or in residential aged care (Australian Institute of Health and Welfare, 2018; Palliative Care Australia, 2018). Palliative care in the acute care setting includes care provided in designated hospices, dedicated palliative care wards within acute hospitals, and/or outpatient services (Australian Institute of Health and Welfare, 2018; Palliative Care Australia, 2018).

Patients with palliative care needs requiring management in the acute care setting are often cared for by their usual care team (generalist palliative care providers). Whereas patients with more complex needs and persistent symptoms that are not effectively managed by standard therapies (e.g., pain, swallowing, breathing difficulties), are managed by specialist palliative care teams (Palliative Care Australia, 2018). The workforce profile of specialist palliative care services differs to generalist palliative care services in that care is provided by multidisciplinary teams, including medical practitioners, nurse and allied health professionals with specialist qualifications and/or skills and experience in palliative care, rather than individual medical practitioners. This type of specialist care often takes place within a designated specialist inpatient palliative care service (Palliative Care Australia, 2018).

1.1.3 Medication errors in specialist palliative care inpatient services

Inpatients cared for within a specialist palliative care service are particularly vulnerable to exposure to, and harm from, medication errors primarily because they are likely to: be older (Australian Institute of Health and Welfare, 2018), have multiple co-morbidities (Kemp, Narula, McPherson, & Zuckerman, 2009; Myers & Lynn, 2001), be living with an advanced illness (Australian Institute of Health and Welfare, 2018), and be receiving numerous medications (Currow et al., 2007; Raijmakers et al., 2013). Additionally, the average length of stay for palliative inpatients is almost four times longer than for other hospitalisations (Australian Institute of Health and Welfare, 2018), which also increases their risk of exposure to medication errors (Institute of Medicine, 2007).

Compounding the risk of harm from medication errors in palliative inpatients is the routine use of opioids to manage pain and other symptoms, such as chronic breathlessness and cough (Australian Adult Cancer Pain Management Working Group, 2013; Australian Institute of Health and Welfare, 2018). Opioids are on the World Health Organisation's Model List of Essential Medicines (2017) as they are considered the most efficacious, safe and cost-effective medicines for pain and palliative care. In Australia, opioids are the cornerstone of pharmacological cancer pain management and widely used in the palliative care setting (Australian Adult Cancer Pain Management Working Group, 2013; Therapeutic Guidelines Limited, 2016; World Health Organisation, 2018). Approximately half of Australian palliative patients have a diagnosis of cancer (Australian Institute of Health and Welfare, 2018) and will experience pain during their disease trajectory, including as the disease progresses to the terminal phase (van den Beuken-van Everdingen et al., 2007). Half the Australian palliative patient population is aged 75 years and over (Australian Institute of Health and Welfare, 2018), placing them at increased risk of medication error related harms by virtue of their age alone (Australian Commission on Safety and Quality in Health Care, 2017; Myers & Lynn, 2001).

Opioids are classified as 'high-risk' medicines as they have a narrow therapeutic index and margin of safety (Clinical Excellence Commission, 2019d; Cohen, Smetzer, Tuohy, & Kilo, 2007). The error rate of high-risk medicines is not necessarily higher than with other medicines; however, the patient consequences of a

high-risk medicine error can be catastrophic if these medicines are prescribed or administered incorrectly (Clinical Excellence Commission, 2019d; Institute for Safe Medication Practices, 2012). Opioids are one of the most frequently reported drug classes involved in medication errors causing patient harm (Colquhoun, Koczmara, & Greenall, 2006; Dy, Shore, Hicks, & Morlock, 2007; Prairie Research Association, 2014), including fatal and serious non-fatal outcomes (Moore, Cohen, & Furberg, 2007; National Patient Safety Agency, 2008; Phillips et al., 2001).

Despite the considerable potential for harm with high-risk opioids, in an already vulnerable patient population, very little is known about the scope and patient impact of opioid errors in specialist palliative care inpatient services. The *Perceptions, Impact and Scope of medication errors with Opioids in Australian specialist palliative care inpatient services project* ('PERISCOPE project') sought to explore opioid errors in this specialist inpatient setting, to address this knowledge gap. This chapter describes the impetus for the PERISCOPE project, outlines the structure of this thesis, and the key concepts used throughout the thesis.

1.2 Impetus for the PERISCOPE project

The PERISCOPE project emerged from the concerns of senior palliative and cancer care clinicians (doctors, nurses and pharmacists) from one Australian cancer research network in New South Wales (NSW). As part of a larger study (Phillips, Heneka, Hickman, Lam, & Shaw, 2017) palliative and cancer care clinicians identified reducing opioid errors as a quality improvement priority within their inpatient services. Clinicians from within this cancer research network were subsequently invited to attend a series of priority setting workshops ('workshops') (Sibbald, Singer, Upshur, & Martin, 2009) to explore the scope of opioid errors in their respective services. This process was undertaken as part of the planning phase for a future palliative and cancer care quality improvement project across the cancer research network (Heneka, Shaw, Azzi, & Phillips, 2018a).

These palliative and cancer care clinicians' perceived that opioid errors were occurring regularly in their services and contributed to iatrogenic patient harm, warranting targeted quality improvement strategies. However, clinicians acknowledged that characterising and quantifying opioid errors was challenging, and

suggested that it was unlikely all opioid errors were reported, particularly if the error did not reach the patient (Heneka et al., 2018a).

Clinicians suggested that opioid conversion errors were potentially the most prevalent opioid error type, particularly conversions between different routes of administration, or between long acting and short acting opioids. Human error, and gaps in clinicians' skills and knowledge were perceived to be key error contributory factors. The time consuming nature of opioid delivery itself, (i.e., independent double checking, documentation), compared to other non-high risk medicines, was also considered an error contributory factor (Heneka et al., 2018a). The priority setting exercise highlighted the need for a more in-depth exploration of opioid errors in palliative and cancer care services to better understand the magnitude of the problem, and to identify areas for targeted interventions to reduce opioid errors in these settings.

While the impetus for the PERISCOPE project was driven by both palliative and cancer care clinicians, a pragmatic decision was made to focus on palliative care services in the PERISCOPE project.

Opioid errors in palliative care services

While a small number of studies have explored medication errors in palliative care services, these studies were limited to reporting of medication error rates generally, and did not differentiate between the drugs involved in the error (Boyer, McPherson, Deshpande, & Smith, 2009; Gibbs, 2007; MacLeod, Fletcher, & Ogles, 2011; Taylor, Fisher, & Butler, 2010). At the commencement of the PERISCOPE project, there were no systematic reviews examining opioid errors specifically in palliative and/or cancer care settings.

Given the paucity of research in opioid errors in the palliative care context, and the insights from clinicians following the priority setting workshops, there was a need to: identify opioid error prevalence, patient impact and characteristics; understand the individual and systems factors that may be contributing to opioid errors; and determine opioid error mitigating factors in this clinical setting. The PERISCOPE Project's program of doctoral research was designed to explore each of these factors,

and to develop a series of recommendations to support safe opioid delivery in Australian specialist palliative care inpatient services.

1.3 Project aim

The PERISCOPE project aimed to identify the: i) burden and characteristics of opioid errors, and ii) actions required to support safe opioid delivery within specialist inpatient palliative care services.

1.4 Research questions

To answer the research aim, the following research questions were employed in the PERISCOPE project:

- i) What is the prevalence, patient impact and characteristics of opioid errors reported in specialist palliative care inpatient services?
- ii) What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?
- iii) What are the opioid error mitigating factors in specialist palliative care inpatient services?; and
- iv) How can specialist palliative care inpatient services support and strengthen safe opioid delivery practices?

1.5 Thesis outline

To answer the research questions, this doctoral research project employed a two-phase, pragmatic, sequential explanatory mixed methods research design (Creswell & Plano Clark, 2018), guided by a multi-incident analysis conceptual framework (Incident Analysis Collaborating Parties, 2012) and the Yorkshire Contributory Factors framework (Lawton et al., 2012).

The PERISCOPE project comprised five discrete but inter-related studies, and to date has generated five peer-reviewed journal publications (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018c, 2018d, 2019a, 2019b; Heneka, Shaw, Rowett, & Phillips, 2015) and one unpublished report (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b). Studies 1 and 4 are presented within the thesis as stand-alone chapters; Studies 2 and 3 are reported in a single chapter; Study 5 is presented in two chapters. Chapters containing the published studies have been lightly edited to minimise

repetition and provide a logical flow across the thesis. The structure and content of the thesis is presented in Table 1.1.

Table 1.1 Thesis outline

Sequence	Content	Chapter
Preliminary	Introduction to the PERISCOPE project	One
Phase 1	Study 1: Systematic literature review of opioid error prevalence, patient impact and characteristics in palliative care and cancer services	Two
	Research design, conceptual frameworks and methods	Three
	Study 2: Retrospective review of clinical incidents with opioids reported by palliative and cancer care services through a state-wide clinical incident monitoring system	Four
	Study 3: Retrospective review of reported clinical incidents with opioids in local palliative care services	Four
	Study 4: Retrospective review of reported opioid error contributory factors in local palliative care services	Five
Phase 2	Study 5: Semi-structured interviews and focus groups exploring palliative care clinicians' perceptions of opioid error contributory factors	Six
	Study 5: Semi-structured interviews and focus groups exploring palliative care clinicians' perceptions of opioid error mitigating factors	Seven
Conclusion and recommendations	Data integration and synthesis	Eight
	Recommendations to support safe opioid delivery in specialist palliative care inpatient services	

1.6 Key concepts

This section outlines key concepts used throughout the PERISCOPE project related to opioid prescribing and administration.

1.6.1 Opioids

The opioids of interest in the PERISCOPE project were those categorised as Schedule 8 medicines (Ministry of Health NSW, 2013), also labelled as strong opioids by the World Health Organisation (1996). In Australia these Schedule 8 opioids ('opioids') include: buprenorphine, fentanyl, hydromorphone, methadone, morphine, and oxycodone, all of which are classified as high risk medicines (Clinical Excellence Commission, 2019d; Institute for Safe Medication Practices, 2012).

1.6.2 Medication handling in NSW Public Health Facilities

All Australian public health facilities, including NSW palliative care inpatient services, must adhere to the mandated medication handling policy, which encompass medication procurement, storage, supplying, dispensing and administration (Ministry of Health NSW, 2013). There are specific, additional requirements for all Schedule 8 medicines including opioids (Ministry of Health NSW, 2013, 2015). These requirements include:

- a record of all Schedule 8 medication transactions must be kept in a drug register, including disposal/destruction of expired, unusable or unwanted medications;
- all Schedule 8 medications must be stored in a separate Schedule 8 medication storage unit that is kept locked when not in immediate use;
- balance checks of the Schedule 8 drug register against the physical balance in the Schedule 8 medication storage units must be undertaken at least once every 24 hours;
- a witness to all steps in the Schedule 8 medication transaction (i.e., removal of the medication from the S8 storage unit, preparation, discarding, recording in the S8 drug register, transfer and administration to the patient) is required;
- a second person check prior to administration (i.e., confirming patient identity, correct drug, dose, device settings and countersigning administration on the medication chart), using independent double check principles is required;
- where a second person check or witness is required, the check should be undertaken using independent double check principles, i.e., the clinicians separately check (alone and apart from each other, then comparing results)

each component of prescribing, dispensing, and verifying the medicine before administering it to the patient (Ministry of Health NSW, 2013).

1.6.3 Incident reporting in NSW

In the NSW public health system, policy mandates that all NSW health services staff are responsible for reporting any identified clinical incidents via the services incident management system (NSW Health, 2014). A clinical incident is defined as ‘*any unplanned event resulting in, or with the potential for, injury, damage or other loss*’ (NSW Health, 2014, p. 3) and includes ‘near misses’ (i.e., when an incident is intercepted before causing patient harm) (NSW Health, 2014).

Statewide clinical incident reporting was implemented in NSW in 2005, and is administered by the Clinical Excellence Commission (Clinical Excellence Commission, 2019c). The Clinical Excellence Commission is a board-governed statutory health corporation, established to promote and support improved clinical care, safety and quality in the NSW public health system (Clinical Excellence Commission, 2019a). A key role of the Clinical Excellence Commission is the provision of clinical incident management reports, based on analysis of incidents reported by NSW health services. Reports include the number of clinical incident notifications, incident severity and principal incident type. Analysis of incident information informs projects and programs developed in response to clinical incident reporting to improve patient care (Clinical Excellence Commission, 2019c).

At the time of this project, mandated incident reporting was undertaken using one of two electronic incident management/reporting systems in NSW: the Incident Information Management System (IIMS) or Riskman. Reported incidents are provided by the individual service to the Clinical Excellence Commission, where incidents are reviewed and analysed to identify significant issues, risks and trends relating to clinical care (Clinical Excellence Commission, 2019b; NSW Health, 2014).

Incidents are classified according to one of 19 Principal Incident Types (e.g., medication/IV fluid, clinical management, fall). Medication related incidents are further classified in the electronic system using a pre-defined drop-down ‘problem type’ (e.g., prescribing or administration problem). Additional incident details can

also be documented in the free-text incident description field at the time of reporting, including incident description, patient impact/outcome, error contributing factors, and actions taken by the service following the incident. However, apart from incident description, completion of the remaining fields is not compulsory (Clinical Excellence Commission, 2019b; NSW Health, 2014).

All incidents are also assigned a ‘Severity Assessment Code’ (‘SAC’) to direct the level of investigation and action required (Clinical Excellence Commission, 2019b). SAC ratings determine the level of incident investigation and action required, and are informed by the consequence of the incident (i.e., the degree of patient harm), and the action required following the incident:

- SAC 1: serious clinical consequence, e.g., death of a patient; extreme risk, must be reported to Ministry of Health within 24 hours, triggers root cause analysis investigation;
- SAC 2: moderate to major clinical consequences, e.g., patient suffering permanent loss of function unrelated to the natural course of their illness; high risk, senior management notified, detailed investigation required;
- SAC 3: minor clinical consequences, e.g., patient required increased level of care; medium risk, management responsibility specified, practice improvement project undertaken; and
- SAC 4: minimum clinical consequences, e.g., no patient injury or increased level of care required as a result of incident; low risk, manage by routine procedure, practice improvement project undertaken (NSW Health, 2014).

The tables used to determine SAC ratings in NSW Health can be found in Appendix 2.

1.7 Summary

Palliative inpatients are at heightened risk of exposure to, and harm from, opioid errors. Despite routine opioid use in specialist palliative care inpatient services to manage pain and other symptoms, little is known about opioid error prevalence, patient impact, or error contributing factors. The PERISCOPE project undertook a detailed and systematic examination of opioid errors in the specialist palliative care inpatient services context. This research aims to inform future strategies to support

safe opioid delivery in the palliative care service delivery context, and ultimately reduce the burden of iatrogenic harm for palliative patients.

As there are many terms used to define the range of medication errors and classify the patient consequences of error (Lisby, Nielsen, Brock, & Mainz, 2010) these definitions are described in detail at the start of Chapter 2. These definitions are described at the outset of the thesis as the PERISCOPE project sought to apply standardised definitions of medication error types and patient impact throughout the project to guide data collection and analysis (Allan & Barker, 1990; Lisby et al., 2010). Adopting a standardised definitions of medication error types was considered essential as inconsistency in error taxonomy is known to directly contribute to the substantial variations in the reported characteristics and patient outcomes of medication errors, and limits reliable comparisons of medications error findings across studies (Lisby et al., 2010).

Once these definitions have been presented, the remainder of Chapter 2 reports on the first study undertaken in the PERISCOPE project, a systematic review. This systematic review sought to quantify the prevalence and patient impact of opioid errors in the palliative care setting.

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Chapter 2: Prevalence, patient impact and characteristics of opioid errors in adult palliative and cancer care settings: A review of the evidence

2.1 Chapter preface

Chapter 2 details the standardised definitions used to classify opioid errors and patient harm in the PERISCOPE project data. This chapter also reports a systematic review of opioid errors in palliative and cancer care settings.

2.2 Applying standardised definitions of opioid errors and patient harm to the PERISCOPE project data

As noted in Chapter 1, the multiplicity of terms used to define medication errors and categorise patient harm following error, contributes to considerable variations in reporting practices (Lisby, Nielsen, Brock, & Mainz, 2010). Unlike other epidemiological fields in healthcare, no single agreed definition is currently used to classify medication errors globally; although, attempts have been made to standardise medication error classifications (e.g., the National Coordinating Council for Medication Error Reporting and Prevention (1998) Taxonomy of Medication Errors). As such, the PERISCOPE project sought to apply standardised medication error taxonomies and classifications of patient harms from error. Throughout the project, standardised definitions of: i) problem type, ii) error type, and iii) patient harm, were employed to guide data collection and analysis (Allan & Barker, 1990; Lisby et al., 2010). These definitions are described below.

2.2.1 Problem type

As detailed in Chapter 1, clinical incidents in NSW are classified into one of 19 ‘Principal Incident Types’ at the time of reporting (Clinical Excellence Commission, 2019a). For the purposes of the PERISCOPE project, clinical incident data were extracted from incidents notified under the principal incident type ‘*medication/IV fluid*’, under which any medication related incidents are reported. Incidents were then further categorised into *problem type*, according to where in the medication

delivery process the incident occurred (Clinical Excellence Commission, 2019a).

Definitions of problem types are described below:

- *Prescribing problem*: the incident involved a problem with the prescribing of a medication, e.g., not prescribed or transcribed when indicated, unclear prescription or transcription, wrong medication, dose, rate, patient etc.;
- *Dispensing problem*: there was a problem during the dispensing process (pharmacy), e.g., problem with labelling, no or delayed dispensing, wrong medication, wrong dose/volume;
- *Administration problem*: the incident occurred during the administration process, e.g., omission or suspected omission, problem with checking procedure, "signing off" or technique, wrong medication, dose, timing, route, patient etc.;
- *Supply/ordering problem*: the incident occurred during the supply or ordering process, e.g., stock not ordered or not supplied, incorrect stock ordered, insufficient stock ordered or supplied;
- *Near miss*: an incident of any problem type listed above, that is intercepted before reaching the patient (Clinical Excellence Commission, 2019a).

2.2.2 Error type

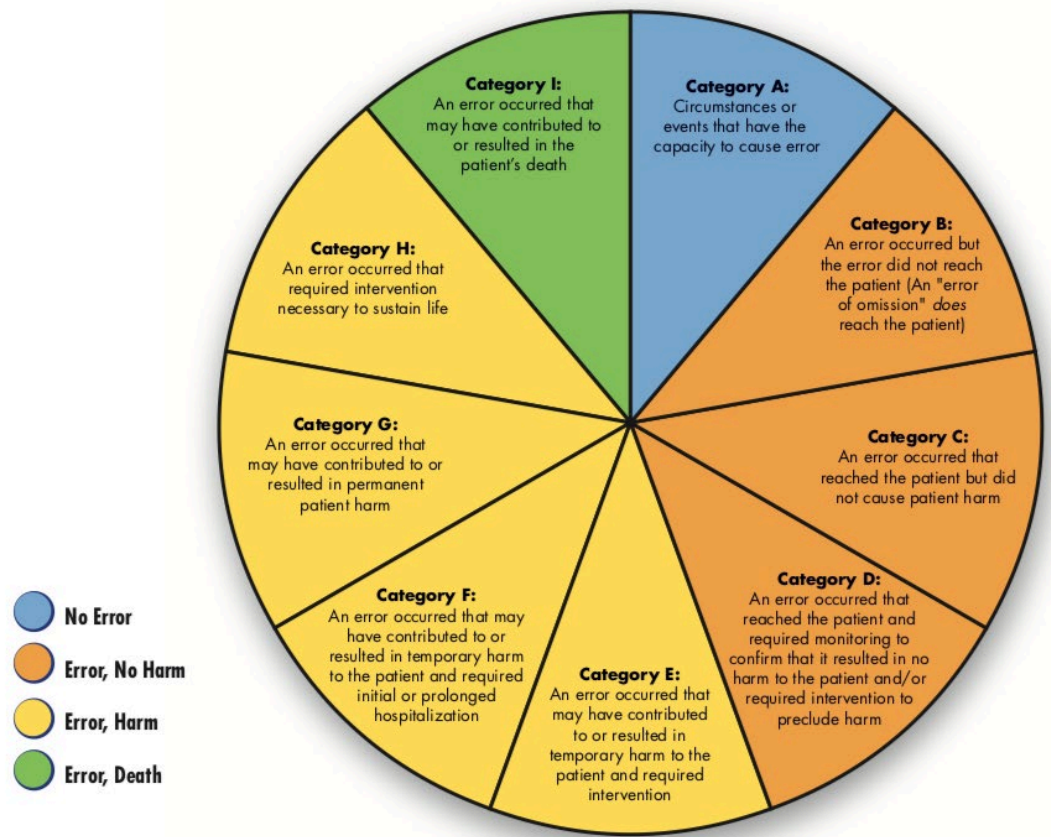
Following categorisation by problem type, a descriptive classification of the opioid incident ('error type') (e.g., wrong drug, omitted dose, etc.) was undertaken using the National Coordinating Council for Medication Error Reporting and Prevention taxonomy ('taxonomy') (National Coordinating Council for Medication Error Reporting and Prevention, 1998) as outlined in Table 2.1. This taxonomy was developed in the United States (US) in the late 1990s, in response to the need for a standardised language and structure for medication error reporting (National Coordinating Council for Medication Error Reporting and Prevention, 1998). As an equivalent Australian taxonomy could not be identified, this taxonomy was used throughout the PERISCOPE project.

Table 2.1 Classification of error type, adapted from the National Coordinating Council for Medication Error Reporting and Prevention taxonomy (1998)

1. Omitted dose (<i>the failure to administer an ordered dose to a patient before the next scheduled dose, if any; this excludes patients who refuse to take a medication or a decision not to administer</i>)
2. Wrong dose
2.1 Resulting in overdose
2.2 Resulting in under dose
2.3 Extra dose
3. Wrong strength/concentration
4. Wrong drug
5. Wrong dosage form
6. Wrong technique
7. Wrong route of administration
8. Wrong rate
8.1 Too fast
8.2 Too slow
9. Wrong duration
10. Wrong time (<i>administration outside a predefined time interval from its scheduled administration time, as defined by each health care facility</i>)
11. Wrong patient
12. Monitoring error (<i>includes contraindicated drugs</i>)
12.1 Drug-Drug Interaction
12.2 Drug-Food/Nutrient Interaction
12.3 Documented Allergy
12.4 Drug-Disease Interaction
12.5 Clinical
13. Deteriorated drug error (<i>dispensing drug which has expired</i>)
14. Other (<i>any medication error that does not fall into one of the above</i>)

2.2.3 Patient harm

As described in Chapter 1, all reported clinical incidents are assigned a SAC rating informed by the clinical consequence of the incident (Clinical Excellence Commission, 2019a). However, SAC ratings do not explicitly identify the nature of patient harm as a result of the incident (e.g., patient required monitoring to preclude harm from the incident). As a result, the patient impact of opioid errors identified in the PERISCOPE project was additionally categorised using the National Coordinating Council for Medication Error Reporting and Prevention Index for Categorising Medication Errors ('index') (Hartwig, Denger, & Schneider, 1991). This index categorises the degree of patient harm from medication errors specifically, using nine categories ranging from *circumstances that have the capacity to cause error* (Category A) to *an error occurred that may have contributed to or resulted in the patients' death* (Category I), and is illustrated in Figure 2.1.



Definitions

Harm

Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring

To observe or record relevant physiological or psychological signs.

Intervention

May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life

Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)

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Figure 2.1 The National Coordinating Council for Medication Error Reporting and Prevention Index for Categorising Medication Errors (Hartwig et al., 1991)

Summary

This section has described the standardised definitions used throughout the PERISCOPE project to classify opioid errors and patient harm. The following section reports the systematic literature review undertaken as the first study in the PERISCOPE project.

2.3 Systematic review of the literature

This systematic review was undertaken following the priority setting workshops with senior palliative and cancer care clinicians, reported in Chapter 1 (Heneka, Shaw, Azzi, & Phillips, 2018), to further explore opioid error prevalence, error type and patient harm in palliative and cancer care settings. Both palliative and cancer care settings were included in the systematic review as over three-quarters (78%) of Australian patients utilising palliative care service have a cancer diagnosis (Australian Institute of Health and Welfare, 2014). Additionally, opioids are the cornerstone of pharmaceutical cancer pain management and their use is common in cancer settings (World Health Organisation, 1996).

2.4 Publication reference and citations

This systematic review was published in 2015 in *Palliative Medicine*, a peer reviewed scholarly journal targeting palliative care clinical practice. This chapter contains an edited version of the published systematic review (Appendix 1).

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.

Palliative Medicine: Impact factor: 3.78; ISI JCR Ranking 2017: 15/94 (Health Care Sciences & Services), 24/154 (Medicine, General & Internal), 28/180 (Public, Environmental & Occupational Health).

This systematic review has been cited in the following publications/articles:

1. Yardley, I., Yardley, S., Williams, H., Carson-Stevens, A., & Donaldson, L. J. (2018). Patient safety in palliative care: A mixed-methods study of reports to a national database of serious incidents. *Palliative Medicine*, 32(8), 1353–1362.

2. Bicket, M. C., Kattail, D., Yaster, M., Wu, C. L., & Pronovost, P. (2017). An analysis of errors, discrepancies, and variation in opioid prescriptions for adult outpatients at a teaching hospital. *Journal of Opioid Management*, 13(1), 51.
3. O'Brien, H., Kiely, F., & Carmichael, A. (2017). Doctor-Related Medication Safety Incidents on a Specialist Palliative Medicine Inpatient Unit: A Retrospective Analysis of Three Years of Voluntary Reporting. *Journal of Pain & Palliative Care Pharmacotherapy*, 31(2), 105-112.
4. Müller-Busch, H. C. (2017). (Patient Safety and Critical Incidents in Palliative Care). *Zeitschrift für Palliativmedizin*, 18(04), 194-202.

2.5 Overview

Globally, medication errors are one of the leading patient safety risks and the most common type of health care error (Kohn, Corrigan, & Donaldson, 2000). Whilst there is great variation across healthcare services and facilities, reported medication errors account for approximately 20% of hospital errors (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Thomas & Brennan, 2000). This equates to, on average, at least one medication error per inpatient per day (Institute of Medicine, 2007). Although medication errors are more likely to result in serious patient harm and death than other incident types (Phillips et al., 2001), they are often under-reported (Levinson, 2012) or undetected by hospital staff, even in health care settings with established incident reporting systems (Westbrook et al., 2015). In a recently published study comparing medication errors in acute care, identified by audit versus errors reported to an incident system, only 1.2 incident reports per 1000 identified prescribing errors were identified (Westbrook et al., 2015). Additionally, there were nil incident reports by clinicians for over 2000 clinical administration errors identified during direct observation (Westbrook et al., 2015), suggesting the error rate above could be even higher than currently reported.

Medication administration may appear to be a relatively simple process; however, there is huge scope for error at each of the more than 30 individual steps involved in the delivery of a single dose of medication (Leape, 2006). Whilst there is no standardised definition of 'medication error' (Lisby et al., 2010), the National Coordinating Council for Medication Error Reporting and Prevention, on their website, defines a medication error as:

...any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use (2014, para. 1).

As previously described, medication error categories have also been developed to help standardise reporting and define the relationship between error type and harm (Hartwig et al., 1991; National Coordinating Council for Medication Error Reporting and Prevention, 1998). Error categories include errors of prescribing, dispensing, and administration (Clinical Excellence Commission, 2019a), with the relationship between error and harm ranging from potential for error (no harm to patient) to patient death as a result of an error (Hartwig et al., 1991).

2.5.1 Medication errors in palliative and cancer care settings

Numerous patient-related risk factors, such as advanced age, impaired hepatic or renal function, cognition, chronic comorbidities and polypharmacy are associated with an increased risk of medication error (Lesar, Briceland, & Stein, 1997; Myers & Lynn, 2001). Medication errors disproportionately affect patients receiving cancer treatments and those nearing the end of life due to frailty, the seriousness of their illnesses, the complexity of their treatment regimen(s), and the adverse impact of errors on vulnerable patient populations (Myers & Lynn, 2001; Thomas & Brennan, 2000).

Although several studies report medication errors in adult cancer care, the majority of these errors relate to chemotherapeutic agents, with few studies reporting errors due to other commonly used medications to manage cancer symptoms (Butts & Jatoi, 2011; Ford, Killebrew, Fugitt, Jacobsen, & Prystas, 2006; Muller, 2003; Walsh et al., 2009). Similarly, there is very little empirical research on medication errors in adult palliative care settings (Dietz, Borasio, Schneider, & Jox, 2010).

Data from 13 specialist palliative care units in the United Kingdom (UK) reported approximately two medication errors per occupied bed per annum across all services (Taylor, Fisher, & Butler, 2010). Another UK hospice calculated error rates based on estimated total drug administration, reporting an error rate of 0.03% (Gibbs, 2007). Medication error rates of 2.3 errors/month and 1.3 errors/month were reported in audits of two separate US hospice organisations over an 18 month audit period (Boyer, McPherson, Deshpande, & Smith, 2009). A palliative care inpatient facility in New Zealand, reported an average of 6.6 medication incidents (actual or perceived errors) per month over two years of voluntary reporting (MacLeod, Fletcher, & Ogles, 2011). These medication error rates are thought to reflect under-reporting in the palliative care setting (Currow et al., 2011; Sirriyeh, Armitage, Lawton, & Gardner, 2010), as, in contrast to the error rates reported in the literature, approximately two thirds of surveyed palliative care professionals' perceived medication errors to occur moderately often or frequently (Dietz et al., 2013).

2.5.2 Medication errors with opioids and the potential for patient harm

In addition to patient-related risk factors, several drug classes are associated with an increased risk of medication error. These drugs are classified as high risk and/or high alert medicines because of the heightened risk of causing patient injury or catastrophic harm if used in error (Clinical Excellence Commission, 2019b; Institute for Safe Medication Practices, 2012). Opioids are one example of high-risk medicines and are the most frequently reported drug classes in medication errors causing patient harm (Colquhoun, Koczmara, & Greenall, 2006; Hicks, 2005). Opioid errors have resulted in fatal and serious non-fatal outcomes (Moore, Cohen, & Furberg, 2007; National Patient Safety Agency, 2008; Phillips et al., 2001), and preventable adverse events leading to patient harm (Smith, 2004). A retrospective analysis of opioid errors from an anonymous national medication error reporting database identified 644 harmful errors over a seven year period on patient care units. Six of these opioid errors resulted in death, with more than half reported as administration errors resulting in opioid overdose (Dy, Shore, Hicks, & Morlock, 2007).

Opioids are widely used in palliative and cancer care, and are the primary pharmacological treatment for cancer pain (Australian Adult Cancer Pain

Management Guideline Working Party, 2014; Caraceni et al., 2012; World Health Organisation, 1996). In the palliative care setting, opioids are routinely used to manage a range of cancer and non-cancer pain and other symptoms, including dyspnoea and cough (National Collaborating Centre for Cancer, 2012; Palliative Care Expert Group, 2010). In high income countries the majority of patients utilising palliative care services have a primary diagnosis of cancer (Australian Institute of Health and Welfare, 2014; Kaasa, Torvik, Cherny, Hanks, & de Conno, 2007; National Hospice and Palliative Care Organisation, 2013). Consequently, these patients are likely to receive opioids for pain or symptom management during the course of their illness.

Increasingly, the adult palliative and cancer care populations are composed of older people (Australian Institute of Health and Welfare, 2014) with more than one chronic co-morbid disease, which may alter medication pharmacodynamics and pharmacokinetics (Kemp, Narula, McPherson, & Zuckerman, 2009; Myers & Lynn, 2001). This older population is also likely to be taking other medications for symptom control, particularly at the end of life (Currow, Stevenson, Abernethy, Plummer, & Shelby-James, 2007; Rajmakers et al., 2013). These factors all increase this vulnerable groups' risk of medication error and patient harm (Australian Commission on Safety and Quality in Health Care, 2017; Moore et al., 2007; Myers & Lynn, 2001).

The potential for opioid errors in palliative and cancer care populations may also be higher due to varying routes of administration (Institute of Medicine, 2007), numerous dosage forms with differing potencies, similar drug names (e.g., morphine/hydromorphone, oxycodone/OxyContin[®]/MS Contin[®]) and routine dose calculation and conversion in the clinical setting (Cohen, Smetzer, Tuohy, & Kilo, 2007; Dy et al., 2007; Institute for Safe Medication Practices, 2012). There is emerging evidence that the leading cause of medical error in palliative care is associated with drug treatment for symptom control, including opioid prescribing and administration (Currow et al., 2011; Dietz et al., 2013; Dietz et al., 2010). Notwithstanding the scope for opioid errors in cancer care, few studies report medication errors with opioids *per se* in cancer settings (Butts & Jatoi, 2011).

Despite these findings, and the widespread use of opioids, little is known about the degree of error reporting, or the prevalence and impact of medication errors with opioids ('opioid errors') in the palliative and cancer care settings (Currow et al., 2011; Dietz et al., 2010).

2.6 Objectives

The objectives of Study 1 were to:

- i) determine the reported prevalence of opioid errors in adult palliative and cancer care settings;
- ii) identify opioid error types reported in these settings; and
- iii) determine the patient impact of opioid errors reported in adult palliative and cancer care settings.

2.7 Method

Design: Systematic review.

Reporting of this systematic review was guided by The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement) (Liberati et al., 2009).

2.7.1 Eligibility criteria

Studies were included if they were published in English in a peer-reviewed journal and reported empirical data on opioid medication error prevalence, types or impact on patients within adult palliative care and/or cancer settings ('palliative and cancer care settings'), including inpatient, ambulatory or community care settings. All non-empirical studies, such as review articles and case reports were excluded from the review. The search was limited to studies published since 1980, reflecting the start of significant investment in specialist palliative and cancer care services (Wright, Wood, Lynch, & Clark, 2008).

2.7.2 Information sources and search strategy

A systematic search of the literature was undertaken between August 1 and August 31, 2014 using MEDLINE, Embase, Cumulative Index of Nursing and Allied Health Literature (CINAHL), the Cochrane Library and Scopus databases. The search strategy comprised three sets of terms. Set 1, was designed to capture literature

relating to opioid medications. As there is no single, standardised definition of “medication error” (Lisby et al., 2010), Set 2 aimed to capture terms relevant to ‘errors’. A range of search terms relating to medication error, patient safety and adverse medication events were employed to capture relevant citations. Set 3 limited the papers retrieved to palliative and/or cancer care populations, without limiting care settings (i.e., inpatient, ambulatory, community, and home care).

Terms within each set were combined using the Boolean ‘OR’ operator, and the sets were then combined using the ‘AND’ operator. Potential search terms were trialed on MEDLINE and mapped to indexed medical subject headings (MeSH). MeSH terms and keywords (.mp) identified in MEDLINE were adapted to each database. Consultation with a specialist research librarian and subject matter experts from palliative care, cancer care, pharmacy and quality and safety, was undertaken to ensure the search strategy was appropriate for the proposed review. A full electronic search strategy utilising the MEDLINE database is included in Table 2.2.

Grey literature was searched using Google Scholar, CareSearch Palliative Care Knowledge Network, PAIS (Public Affairs Information Service) International, The Grey Literature Report (New York Academy of Medicine), System for Information on Grey Literature in Europe, Health Management Information Consortium (HMIC), National Technical Information Service (NTIS), and PsycEXTRA. Additional search strategies included hand searching key journals and reference lists of identified articles for eligible papers, and searching conference abstracts.

2.7.3 Data collection process

A data extraction tool (Higgins & Deeks, 2008) was developed to capture data from potentially relevant studies and accommodate the varying methodologies and reported outcomes. Fields included: study design; setting; data source/participants; medication reported; error definition, measure, prevalence and type; and patient outcomes. Data extraction enabled a summary of both quantitative and qualitative data and informed the data analysis.

Table 2.2 Search strategy example (MEDLINE): conducted August 2014

1. opioid*.mp. or exp Analgesics, Opioid/ 2. opiate*.mp. or exp Morphine/ 3. medication*.mp.	Set 1
4. 1 or 2 or 3	
5. error*.mp. or exp Medication Errors/ 6. adverse event*.mp. 7. exp Patient Safety/ or safety.mp. or *Safety/	Set 2
8. 5 or 6 or 7	
9. exp Palliative Care/ or exp "Hospice and Palliative Care Nursing"/ or palliative.mp. 10. "palliative care".mp. 11. exp Hospice Care/ or hospice*.mp. 12. exp Terminal Care/ 13. exp Terminally Ill/ 14. dying.mp. 15. death.mp. or *Death/ 16. "end of life".mp. 17. cancer.mp. 18. oncology.mp. or exp Oncology Nursing/ or exp Medical Oncology/ or exp Radiation Oncology/ or exp Oncology Service, Hospital/	Set 3
19. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18	
20. 4 and 8 and 19	
21. limit 20 to yr="1980 -Current"	

2.7.4 Study selection

The titles and abstracts of all papers were examined by two authors (NH and JP) to determine if they met the inclusion criteria. Data from potentially relevant papers (n=158) was extracted by one author (NH).

2.7.5 Bias rating and synthesis of results

The methodological quality of included studies was assessed by the first author (NH) using the “QualSyst” systematic review tool (Kmet, Lee, & Cook, 2004). “QualSyst” incorporates two scoring systems to evaluate the quality of both quantitative and qualitative research studies. This tool was considered appropriate for critical appraisal of the included studies due to the varying study designs. The level of evidence for each study was determined using the Australian National Health and Medical Research Council (‘NHMRC’) evidence hierarchy (Coleman et al., 2009). Due to the range of study designs (quantitative and qualitative), synthesis of results was guided by the narrative synthesis method of Popay and colleagues (2006). This

method provides a framework to systematically and transparently conduct a narrative synthesis while minimising the inherent risk of bias inherent in systematic reviews which employ a narrative approach to synthesis (Higgins & Green, 2011).

2.8 Results

2.8.1 Study selection

The initial search of databases yielded 11,351 papers: MEDLINE (n=2970), Embase (n=7255), CINAHL (n=644), the Cochrane Library (n=6), Scopus (n=476). No papers meeting the inclusion criteria were identified in the grey literature. Removal of duplicates resulted in 9521 papers remaining for screening (Figure 2.2). On the basis of title or abstract, 9396 papers were excluded leaving 125 papers eligible for assessment. Eight additional papers were identified from the eligible papers following a hand search of reference lists. Upon further screening, 133 full text papers were identified for review, 128 papers were excluded as they did not meet the eligibility criteria, leaving five papers (Botterman & Criel, 2011; Dietz, Plog, Jox, & Schulz, 2014; Mayahara, Paice, Wilbur, Fogg, & Foreman, 2014; Shaheen et al., 2010; Turner, Clark, Root, & Hardy, 1994) that reported opioid medication error prevalence, type and/or impact in palliative care and/or cancer settings.

2.8.2 Study characteristics, design and quality

Five empirical studies reporting opioid errors in palliative care and/or cancer settings were included in this review. Methodological quality varied across the studies and the heterogeneity of the reported data precluded a meta-analysis from being undertaken (Table 2.3). All included studies met level IV evidence criteria as per the Australian National Health and Medical Research Council (NHMRC) Evidence Hierarchy (Coleman et al., 2009).

The majority (n=4) of the studies were published after 2010. All studies were undertaken in the Northern Hemisphere, with two studies undertaken in the US and one study each from Belgium, Germany and the UK (Table 2.3). These studies reported data from: two prospective surveys (Dietz et al., 2014; Shaheen et al., 2010); a prospective chart audit (Turner et al., 1994), a longitudinal study (Mayahara et al., 2014), and a retrospective case series (Botterman & Criel, 2011).

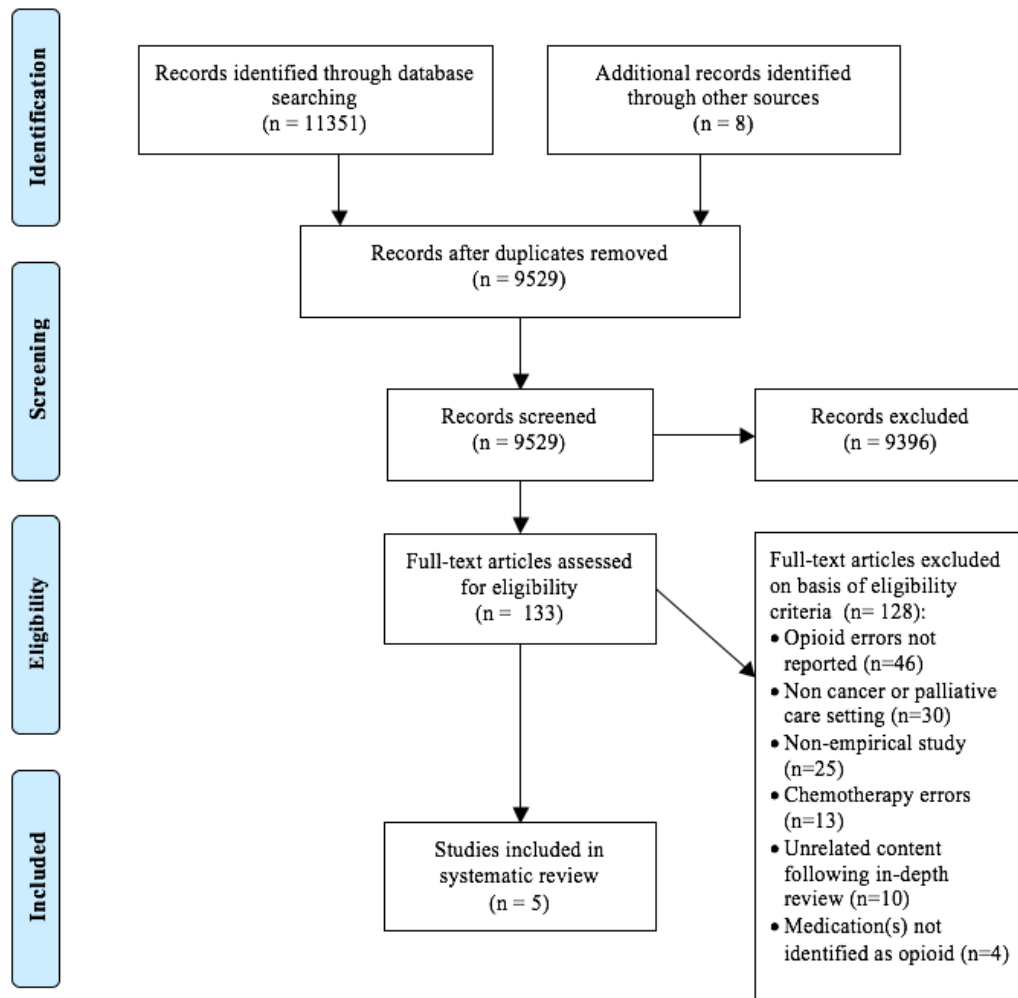


Figure 2.2 PRISMA flowchart of studies through the review process

Most studies reported patient data (Botterman & Criel, 2011; Mayahara et al., 2014; Shaheen et al., 2010; Turner et al., 1994) with one study reporting palliative care clinicians' perceptions and descriptions of medication error (Dietz et al., 2014). Three studies reported chart audit data, respectively assessing general opioid prescribing errors in palliative care inpatients and outpatients with cancer pain (Shaheen et al., 2010), morphine prescribing errors in cancer inpatients (Turner et al., 1994), and dosage errors with transdermal fentanyl in newly admitted palliative care inpatients (Botterman & Criel, 2011).

2.8.3 Settings, participants and opioid medication reported

Inpatient setting data was reported in the majority of studies (n=3) (Botterman & Criel, 2011; Dietz et al., 2014; Turner et al., 1994), with one study reporting both inpatient and outpatient data (Shaheen et al., 2010), and another study reporting data from the home care setting (Mayahara et al., 2014). Data from all but one study (Turner et al., 1994) was generated from the specialist palliative care setting (n=4).

The vast majority of patients admitted to the palliative care setting had a diagnosis of cancer (97%), all of whom had been ordered at least one opioid on or during their admission. The home care study (Mayahara et al., 2014) reported data from patient/caregiver dyads (n=46), with the majority of patients (63%) having a cancer diagnosis.

Medications were variously described as “opioids” (n=1), which encompassed morphine, hydromorphone, methadone, fentanyl and “other” (Shaheen et al., 2010), or “analgesic – mild/strong opioid” (n=1) (Mayahara et al., 2014). One study explicitly assessed morphine use (Turner et al., 1994), while another study identified morphine, diamorphine and fentanyl as opioids of interest, but primarily reported data on transdermal fentanyl (Botterman & Criel, 2011).

2.8.4 Definitions, identification and measure of error

There were various definitions of “error” employed across the studies, including deviations from: opioid dosing strategies from local practice (Botterman & Criel, 2011), local palliative care prescribing guidelines (Turner et al., 1994); US Agency for Health Care Policy and Research recommendations (Botterman & Criel, 2011; Shaheen et al., 2010), European Association of Palliative Care recommendations (Botterman & Criel, 2011; Shaheen et al., 2010), World Health Organisation guidelines (Botterman & Criel, 2011; Shaheen et al., 2010), and American Pain Society recommendations (Shaheen et al., 2010). In the home care setting, an “error” was defined as any deviation by the caregivers from the prescribed analgesic medication made by the patient’s health care provider when the analgesic was administered (Mayahara et al., 2014). One study examined perceptions of error types by palliative clinicians and, as such, did not explicitly define “error” (Dietz et al., 2014).

Table 2.3 Summary of included studies

Study, Year, Country	Design NHMRC level of evidence (Coleman et al., 2009)	Setting	Data source/ participants	Focus	Error definition	Error measure	Error prevalence (% of patients with at least one opioid error)	Quality of methods (QualSyst) (Kmet et al., 2004)
Dietz et al., (2014) Germany	Exploratory, cross-sectional survey IV	Specialist palliative care institutions	Palliative care professionals (n=46)	Incidents palliative care professionals perceive as typical errors in their practice, and descriptions of events	Described by participants	n/a – qualitative data only reported	n/a – qualitative data only reported	20/20 ^a
Mayahara et al., (2014) US	3-day, mixed methods longitudinal study: prospective survey and audit IV	Palliative care – home setting	Patient pain and medication diary Patient/caregiver dyads (n=46)	Analgesic errors by non-professional home-hospice caregivers	Deviations from prescribed analgesic medication when the analgesic was administered	% of patients where error identified	49	18/18 ^b
Botterman & Criel, (2011) Belgium	Retrospective chart audit IV	Specialist palliative care - inpatient	Patient charts (n=1154)	Patterns of transdermal fentanyl orders in patients admitted to a palliative care inpatient unit	Deviations from international guidelines; frank signs and symptoms of opioid toxicity	% of patients where error identified	63 (patients prescribed transdermal fentanyl only)	15/18 ^b

Table 2.3 Summary of included studies (cont.)

Study, Year, Country	Design NHMRC level of evidence (Coleman et al., 2009)	Setting	Data source/ participants	Focus	Error definition	Error measure	Error prevalence (% of patients with at least one opioid error)	Quality of methods (QualSyst) (Kmet et al., 2004)
Shaheen et al., (2010) US	Prospective survey IV	Palliative care – inpatient and outpatient	Patient charts - patients with cancer pain (n=117)	Identification of common errors in opioid use through assessment of clinicians' opioid prescribing practices	Deviations from local and international opioid dosing strategies	% of patients where error identified	70	18/18 ^b
Turner et al., (1994) UK	Prospective snapshot audit IV	Specialist cancer hospital	Patient charts containing morphine order (N=144) Pre audit (n=73); post audit (n=71)	Assessment of the quality and quantity of clinicians' morphine prescribing in accordance with local palliative care unit guidelines, pre and post guideline review	Deviations from local palliative care prescribing guidelines	% of patients where error identified	Not defined	7/18 ^b

^a Quantitative data scoring system /18; ^b Qualitative data scoring system /20

Three studies identified errors through patient chart audit, either retrospectively (Botterman & Criel, 2011) or prospectively (Shaheen et al., 2010; Turner et al., 1994). Comparisons of patients' medication diaries with the analgesic medication regimen prescribed by the patients' health care provider were used to identify errors in the home care setting (Mayahara et al., 2014). An anonymous survey asking palliative care clinicians' to describe a typical case in which an error occurred was used to identify error types and causes across palliative care institutions (n=168) in one state in Germany (Dietz et al., 2014). None of the studies included in this review utilised clinical incident reports as a method for opioid error identification or employed observations to detect opioid errors in the clinical setting.

The four studies reporting patient data, reported errors as a percentage of patients in which an error was deemed to have occurred, based on comparison to pre-established prescribing and dosing criteria. Each study examined differing aspects of opioid use, including: general opioid prescribing practices (Shaheen et al., 2010), morphine prescribing and administration practices (Turner et al., 1994), fentanyl dose on, and during, admission to the palliative care service (Botterman & Criel, 2011), and 'as-needed' ('PRN') opioid administration by non-professional caregivers (Mayahara et al., 2014).

2.8.5 Error prevalence

There was great variation in the reporting of opioid errors across the included studies (Table 2.4). One study examined prescribing patterns for patients with cancer pain (n=117), incorporating a range of opioids, (i.e., morphine, hydromorphone, methadone, fentanyl, oxycodone and "other opioids") to identify errors in opioid prescribing and dosing strategies (Shaheen et al., 2010). This study identified at least one incorrect opioid order in 70% of patients with cancer pain over an 80-day audit period (Shaheen et al., 2010). Dosage errors were identified in 63% of patients (n=199) prescribed transdermal fentanyl in a study examining patterns of strong opioid use in patients newly admitted to a specialist palliative care inpatient unit over a seven year period (n=1154) (Botterman & Criel, 2011). Two audits of morphine prescribing practices in a specialist cancer hospital were conducted over one day each, 13 months apart. The audits were undertaken at baseline (n=73) and following changes to the hospital based palliative care departments' prescribing guidelines

(n=71). Whilst the overall prevalence of opioid errors was not directly reported in this study, error prevalence by error type ranged from 5% to 81% across both audit days (Turner et al., 1994). For non-professional family caregivers in the home care setting, administering both strong and mild opioids, an administration error prevalence of 49% was reported in a longitudinal study conducted over three consecutive days (Mayahara et al., 2014).

2.8.6 Error type

The predominant error types in the clinical setting related to deviations from opioid prescribing guidelines (Table 2.4). Despite different local and national guidelines being utilised across the two studies that audited opioid prescribing strategies for patients with cancer (Shaheen et al., 2010; Turner et al., 1994), several common deviations from opioid prescribing guidelines were identified. These included no PRN analgesia ordered for patients with regular opioid orders (17-29% of patients), no pre-emptive prescribing of anti-emetics and/or laxatives to treat opioid side-effects (15-24% of patients), and incorrect opioid dosing intervals (11-81% of patients). One of these studies (Turner et al., 1994) also reported changes in the frequency of deviations from opioid prescribing guidelines following a review of local guidelines, including errors relating to regular analgesia orders (PRN oral morphine only ordered/nil regular analgesia ordered), ordering multiple PRN analgesics, and ordering multiple opioids from the same class (Turner et al., 1994).

A study examining transdermal fentanyl orders prior to admission to a specialist inpatient palliative care unit, found patients transferred from hospital or the home care setting had been ordered a three-fold higher median oral morphine equivalent dose than patients treated with oral, intravenous and subcutaneous morphine (Botterman & Criel, 2011). Nearly two thirds (63%) of these patients had signs and symptoms of opioid overdose or toxicity noted on or during their admission to the palliative care unit (Botterman & Criel, 2011). The majority (70%) of these patients had been transferred from hospital to the palliative care unit, and, prior to admission, were capable of taking oral analgesia as per opioid administration guidelines, yet had been inappropriately prescribed transdermal rather than oral opioids (Botterman & Criel, 2011).

Table 2.4 Reported opioid error type and prevalence as percentage of patients

Opioid error type	Dietz et al., (2014)	Mayahara et al., (2014)	Botterman & Criel, (2011)	Shaheen et al., (2010)	Turner et al., (1994)
Deviations from opioid prescribing guidelines	%	%	%	%	% Pre guideline change/ % post guideline change
1. No PRN analgesia ordered	*	*	*	17	26/29
2. PRN oral morphine only ordered/nil regular analgesia	*	*	*	*	43/5
3. Multiple PRN analgesics ordered	*	*	*	*	32/*
4. Opioid side effects not prescribed for	*	*	*	15	24/22
5. Incorrect dosing intervals	*	*	*	11	81/81
6. Multiple opioids from same class ordered	*	*	*	10	*
7. Incident pain not treated	*	*	*	8	*
8. Incorrect route/ formulation for pain type	a	*	b	8	*
9. Inadequate trial of initial opioid	*	*	*	5	*
10. More than one opioid changed at a time	*	*	*	2	*
11. Inappropriate dose ordered	a	*	63 ^c	*	*
Titration errors	%	%	%	%	%
1. Failure to titrate	*	*	*	9	*
2. Incorrect titration	a	*	*	*	*
Opioid conversion errors	%	%	%	%	%
1. Incorrect dose conversion for new route	a	*	*	3	*
2. Incorrect dose calculation for opioid rotation	*	*	*	2	*

Table 2.4 Reported opioid error type and prevalence as percentage of patients (cont.)

Opioid error type	Dietz et al., (2014)	Mayahara et al., (2014)	Botterman & Criel, (2011)	Shaheen et al., (2010)	Turner et al., (1994)
Administration errors	%	%	%	%	%
1. No analgesic administered	*	21	*	*	*
2. Too low a dose of prescribed analgesic administered	*	9	*	*	*
3. Over the counter medication instead of prescribed analgesic administered	*	6	*	*	*
4. Discontinued prescribed mild opioid administered	*	6	*	*	*
5. Sedative administered, not prescribed analgesic	*	6	*	*	*
6. Too high a dose of prescribed analgesic administered	*	3	*	*	*
7. Discontinued prescribed strong opioid administered	*	1	*	*	*
Perceptions of opioid errors	%	%	%	%	%
1. Incorrect titration and conversion of opioids	a	*	*	*	*
2. Over dosage of opioids caused by fear of the patient's pain	a	*	*	*	*
3. Inappropriate switch from oral to subcutaneous morphine	a	*	*	*	*
Adverse effects	%	%	%	%	%
1. "Appearance of adverse drug effects (from opioid over dosage)"	a	*	*	*	*
2. "Patient suffers from severe withdrawal symptoms (opioid switching)"	a	*	*	*	*
3. Higher pain intensity when analgesic regimen not adhered to	*	d	*	*	*
4. Signs and symptoms of opioid overdose or toxicity due to transdermal fentanyl	*	*	b	*	*

* Not reported

^a Qualitative example reported

^b "large majority" - actual numbers not reported

^c Transdermal fentanyl only

^d Non-professional caregivers' adherence to analgesic regimen correlated significantly with mean worst pain score: 0.37 (p≤.001)

Clinicians involved in a study exploring palliative care professionals' perceptions and experience of error types, acknowledged that wrong route and wrong dose errors were common in the palliative care setting; however, these perceived error types were not quantified in this study (Dietz et al., 2014). Opioid titration and conversion errors were reported in two studies (Dietz et al., 2014; Shaheen et al., 2010), accounting for nine percent and five percent of errors, respectively. In the home care setting, administration errors by non-professional caregivers were primarily due to caregivers withholding opioid analgesia even though it was indicated (21% of caregivers), or giving too low a dose of opioid analgesia (9%) (Mayahara et al., 2014). None of the included studies reported administration errors made by clinicians.

2.8.7 Patient impact

While patient impact was described in terms of opioid overdose/toxicity and pain intensity, none of the studies explicitly rated the degree of patient harm resulting from opioid errors. In one study, patients receiving inappropriately high doses of fentanyl on admission to a palliative care unit were observed to have frank signs and symptoms of opioid overdose or toxicity (details not specified); however, no deaths were reported as a result of opioid overdose (Botterman & Criel, 2011). In the home care setting, errors with opioid analgesia, administered by nonprofessional caregivers occurred in almost half (49%) of all administrations (n=422) over the three day study period, with 21% of patients receiving no analgesia when they reported pain (Mayahara et al., 2014). This study identified a significant correlation between nonprofessional caregiver administration error and mean worst pain score (0.37, $p \geq .001$) (Mayahara et al., 2014). Two other studies also noted the importance of timely and adequate pain management in patients with cancer pain and how effective pain management may be compromised if prescribing guidelines are not adhered to (Shaheen et al., 2010; Turner et al., 1994). A qualitative study described palliative care professionals' observations of adverse effects from opioid over dosage and the severe withdrawal symptoms caused by inappropriate opioid switching (Dietz et al., 2014).

2.9 Discussion

Despite the routine use of opioids in palliative and cancer care settings (Australian Adult Cancer Pain Management Working Group, 2013; Australian Institute of Health and Welfare, 2014), and the potential for patient harm due to opioid error (Dy et al., 2007), this review has identified that the scope and patient impact of opioid errors in palliative and cancer care settings is an under-explored area of patient safety.

Opioid error prevalence

Overall opioid error prevalence in palliative and cancer care settings was difficult to ascertain as audit periods in these studies varied, and each study focused on a single narrow area of error, such as deviations from local and national opioid prescribing guidelines (Shaheen et al., 2010; Turner et al., 1994), transdermal fentanyl dosage (Botterman & Criel, 2011), or non-professional caregiver opioid administration errors (Mayahara et al., 2014). Hence the prevalence of opioid errors in palliative and cancer care settings in this review ranged from 17% to 81% .

While there is also wide variation in reported opioid error prevalence in the acute care setting (Carson, Jacob, & McQuillan, 2009; Denison Davies et al., 2011; Humphries, Counsell, Pediani, & Close, 1997) these opioid error rates provide the best baseline for comparison with the error prevalence rates reported in palliative and cancer care settings. A retrospective audit in an acute general hospital in Ireland found opioid errors accounted for 12% of all reported medication errors (n=448) over a five-year period (Carson et al., 2009). In a 24-hour snapshot audit of medical and surgical patients in teaching hospital in the UK, 27% of patient charts with an opioid order (n=330) were found to have an opioid error (Denison Davies et al., 2011). In a large district general hospital, also in the UK, a prescribing audit of intramuscular opioid analgesics over a two week period identified errors in 60% of opioid prescriptions (n=120) (Humphries et al., 1997). Outside of acute care, 79% of reported analgesic medication errors (n=3949) over a two-year period in US nursing homes were related to opioid errors (Desai et al., 2013). Notably, the prevalence of opioid errors is often considerably higher in studies where audits of patient charts are undertaken (Denison Davies et al., 2011; Humphries et al., 1997) compared to when incident reports alone are utilised (Carson et al., 2009), reflecting the widespread

under-reporting of medication errors that is known to occur in the clinical setting (Levinson, 2012; Westbrook et al., 2015).

Opioid error types

The most common opioid errors identified in this review related to under prescribing of opioids for cancer pain (Shaheen et al., 2010; Turner et al., 1994), failure to order PRN analgesia for patients with regular opioid orders (Shaheen et al., 2010; Turner et al., 1994), incorrect dosing intervals (Shaheen et al., 2010; Turner et al., 1994), incorrect route or formulation for pain type (Botterman & Criel, 2011; Shaheen et al., 2010), and failure to pre-emptively prescribe for opioid side effects (Shaheen et al., 2010; Turner et al., 1994). Opioid prescribing strategy errors are also commonly reported in the acute care setting (Carson et al., 2009; Denison Davies et al., 2011; Dy et al., 2007; Humphries et al., 1997; Jenkins, Tuffin, Choo, & Schug, 2005), suggesting this is a widespread problem, and not unique to palliative and cancer care settings.

A notable absence in the empirical palliative and cancer care literature were reports of opioid administration errors in the clinical setting. A small number of case reports have described opioid administration errors in cancer and palliative care populations related to wrong route errors (Barrett & Sundaraj, 2003) and wrong dose errors (Blinderman, 2010; Butts & Jatoi, 2011). Given the routine use of opioids in palliative and cancer care settings, it is highly likely that opioid administration errors are prevalent in this setting, and this warrants further investigation.

Patient impact

The harm experienced by patients as a result of opioid errors was not specifically reported in any of the included studies in this review, rather patient impact was observed relative to pain intensity (Mayahara et al., 2014) and the immediate adverse effects from an opioid over dosage (Botterman & Criel, 2011; Dietz et al., 2014). The lack of detailed patient harm data resulting from opioid errors prevented an assessment of the relationship between error type and patient harm being undertaken.

2.9.1 Implications for future research

This review has highlighted the paucity of literature examining and reporting opioid error prevalence, type and patient harm in palliative and cancer care settings. As

identified in this review, the prevalence of opioid errors in these care settings is not readily identifiable, and, in the case of opioid administration errors, not reported at all.

There is scope for future research in the palliative and cancer care setting which quantifies and identifies opioid error types, in addition to those related to deviations from prescribing guidelines (e.g., opioid administration errors), and identifies the degree of patient harm from opioid errors. A comparison of opioid error prevalence, patient impact and characteristics in palliative and cancer care settings, relative to other acute care settings will be beneficial to better understand opioid errors in the palliative and cancer care service delivery context. Reviews of local, state-wide and national data on reported opioid errors, categorised by setting, may also be indicated. Additionally, exploring palliative care clinicians' perceptions of opioid error in their services, will provide valuable insights into the phenomena of opioid errors from the clinician's perspective.

2.9.2 Limitations

This review excluded papers not published in English, which may contribute to the risk of selection bias. Data extraction was undertaken by a single reviewer to assess eligibility of included studies; however, multiple independent reviewers rated study quality (NH, JP, TS). It is possible that some studies may not have been identified through database searching due to the multiplicity of terms used to describe medication errors (Lisby et al., 2010). Drug interactions with opioids and prescribing errors relating to adjuvant medications recommended for use with opioids (e.g., non-opioid analgesia, aperients, anti-emetics), were not explicitly identified as part of this review. The heterogeneity of the data reported in the included studies limits generalisability of this review in oncology and palliative care settings.

2.10 Summary

This systematic review examined the reported prevalence, types and impact of opioid medication errors in palliative and cancer care settings. Despite routine use of opioids for the management of cancer pain and end of life symptoms in a population already vulnerable to harm from medication errors, little remains known about the prevalence, patient impact and characteristics of opioid errors in palliative and cancer

care settings. There is a need to further explore opioid error types, other than those resulting from deviations from opioid prescribing guidelines, and the degree of patient harm resulting from these errors, from both patient data and the perspectives of palliative care clinicians, to better understand and address the patient safety issues in these vulnerable patient populations.

The following chapter (Chapter 3) reports the methodology used in the mixed methods PERISCOPE project to better understand the prevalence and patient impact of opioid errors in specialist palliative care inpatient services, and identify opioid error contributory and mitigating factors in this specialist setting.

2.11 References

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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.

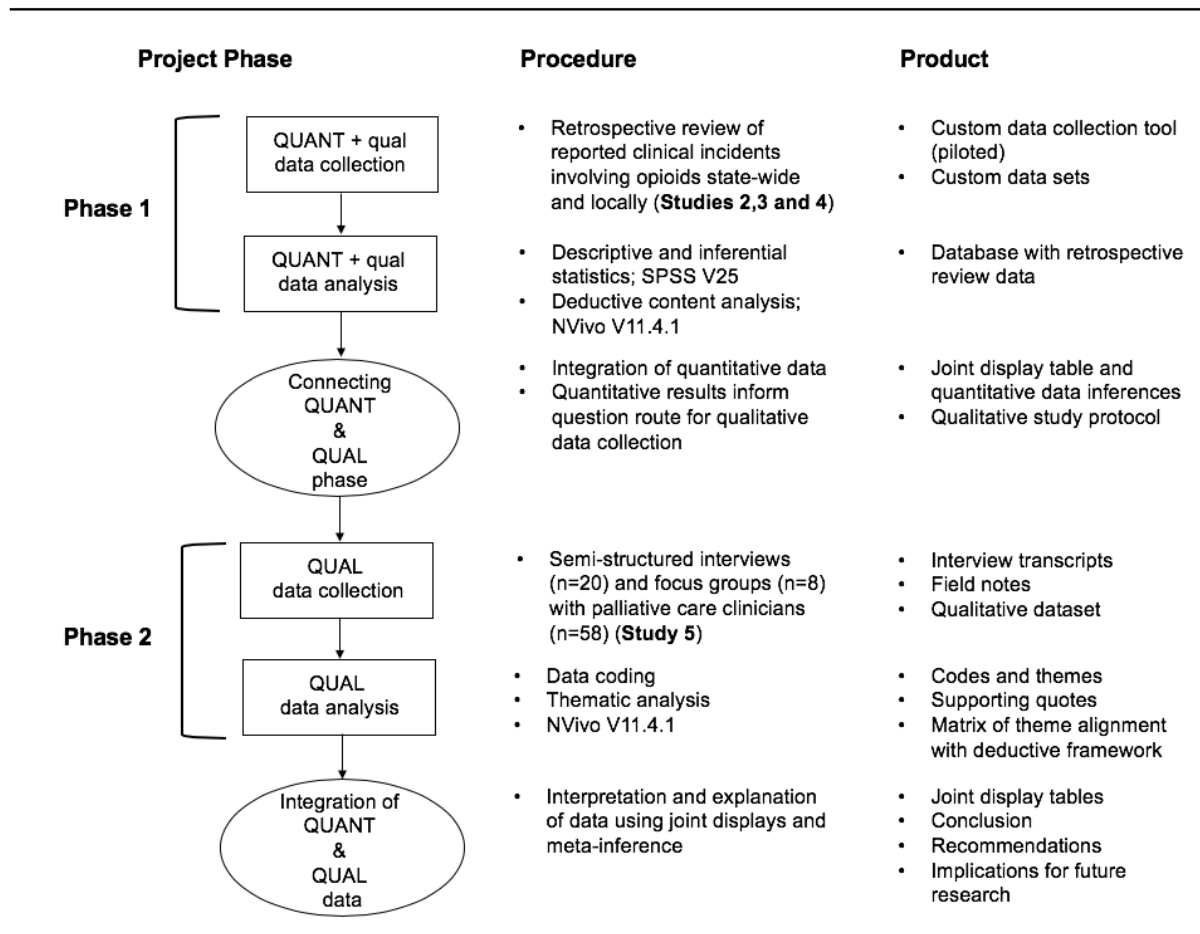


Figure 3.1 Visual model for the mixed methods sequential explanatory design procedures in the PERISCOPE project, adapted from Creswell and Plano Clark (2018) and Ivankova et al. (2006)

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.

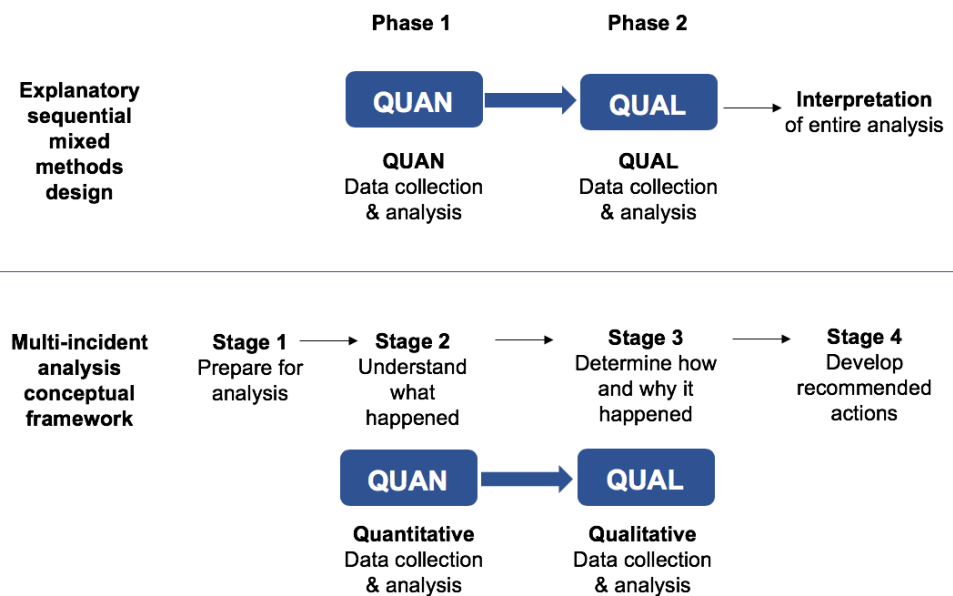


Figure 3.2 Alignment of the explanatory sequential mixed methods study design (Creswell & Plano Clark, 2018) with the multi-incident analysis framework (Incident Analysis Collaborating Parties, 2012) in the PERISCOPE project

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.

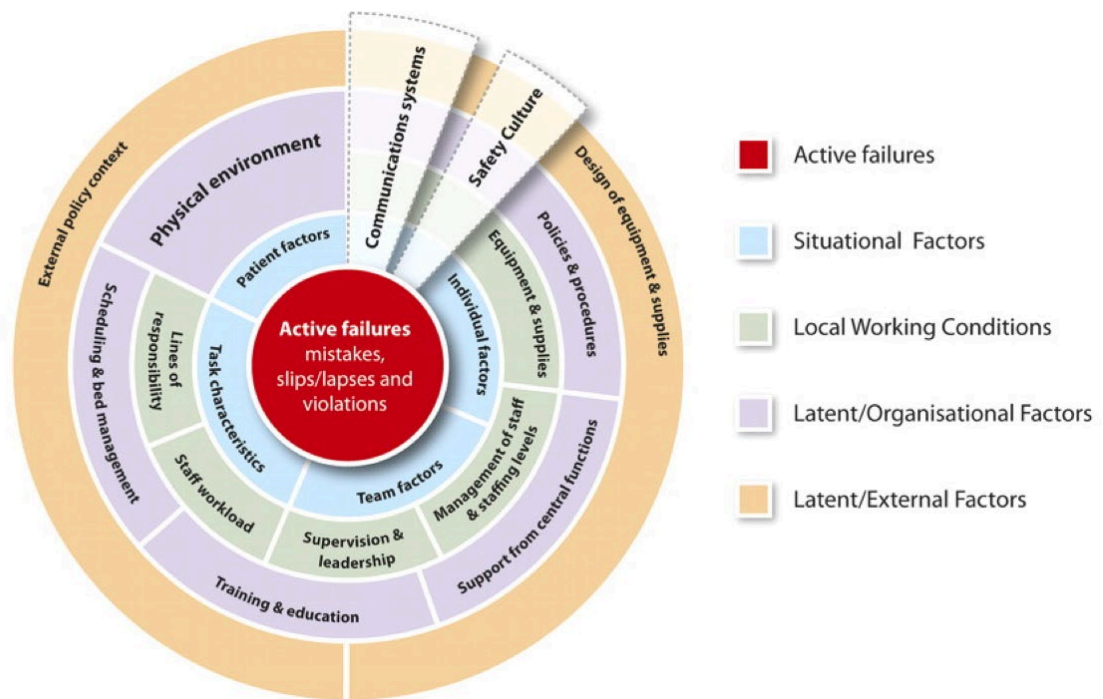


Figure 3.3 Yorkshire Contributory Factors Framework (Lawton et al., 2012)

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.

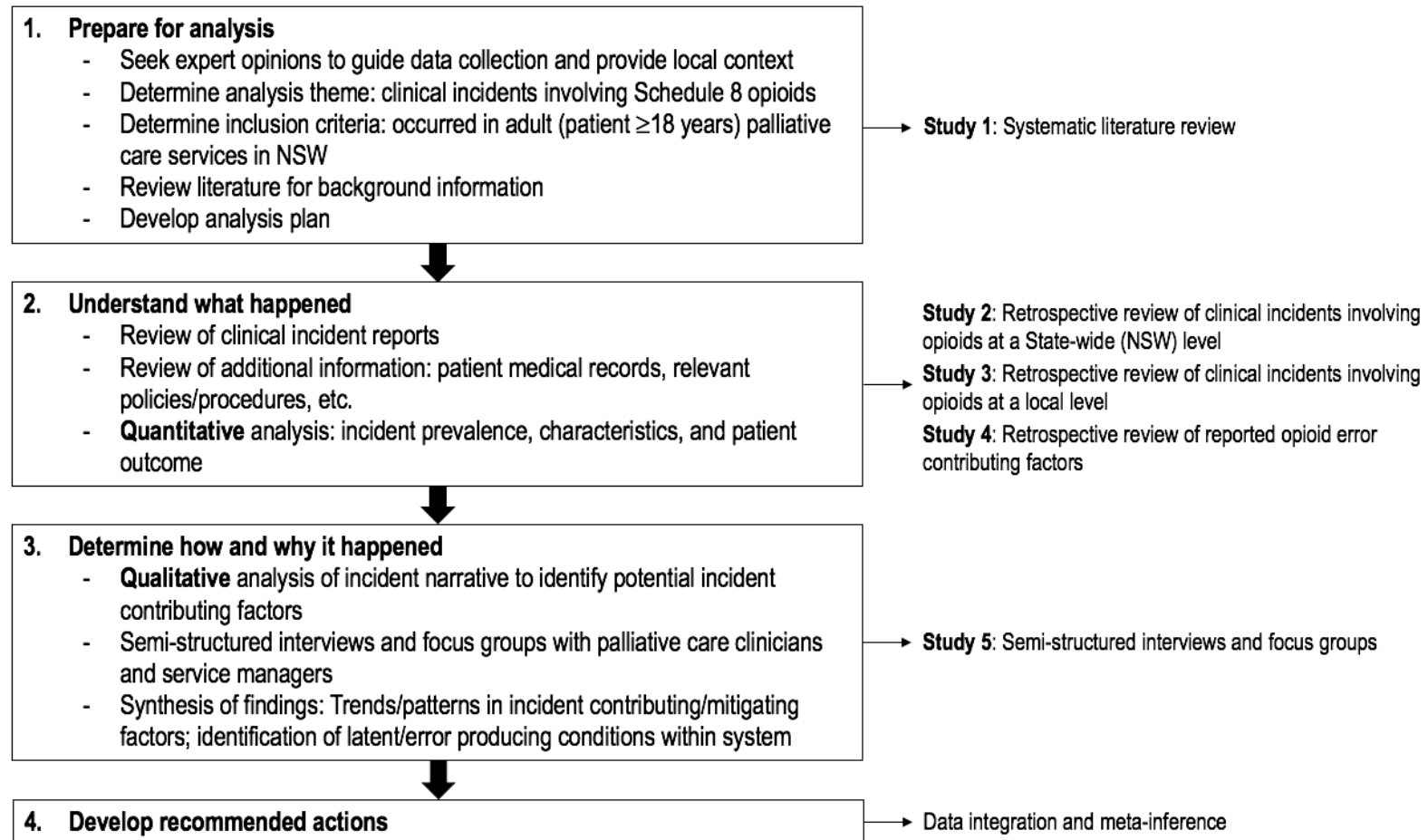


Figure 3.4 Stages of multi-incident analysis and corresponding studies in the PERISCOPE project, adapted from Incident Analysis Collaborating Parties (2012)

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).

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Chapter 4: Identifying opioid error prevalence, patient impact and characteristics in NSW and local palliative care services

4.1 Chapter preface

Despite the frequency in which opioids are used in palliative care services, the systematic review reported in Chapter 2 identified a dearth of empirical studies reporting opioid error prevalence, patient impact and characteristics in this setting (Heneka, Shaw, Rowett, & Phillips, 2015). Given these gaps in the literature, the second and third studies in the PERISCOPE project sought to undertake a retrospective review of opioid errors reported by palliative care services across the NSW public health system (Study 2) and in three local specialist palliative care inpatient services (Study 3). This chapter reports the individual results of Studies 2 and 3.

4.2 Context for Study 2

In Australia, opioids currently account for three of the top five medications involved in reported clinical incidents (Clinical Excellence Commission, 2019) and are widely used to manage cancer related pain. While a cohort of NSW palliative and cancer care clinicians had identified opioid errors as a patient safety priority (Heneka, Shaw, Azzi, & Phillips, 2018), little could be gleaned from the existing literature about the characteristics, contributory factors and patient impact of opioid errors in these care settings. In order to better understand opioid errors in palliative and cancer care services, it was decided to analyse clinical incidents involving opioids in palliative care and cancer services, reported through the NSW state-wide incident management system.

An unpublished report of study results from Study 2 was completed for the Clinical Excellence Commission (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018).

4.3 Objectives - Study 2

The objectives of Study 2 were to identify:

- i) the number of clinical incidents involving opioids reported in NSW via the incident management system [January 1, 2011 – December 31, 2014]; and
- ii) characteristics of opioid errors reported in NSW palliative and cancer care services, related to incident type, opioid involved and patient outcome.

4.4 Methods - Study 2

Study methods have been described in Chapter 3.

4.5 Results - Study 2

4.5.1 Dataset 1

Over four years, NSW public health services (N=220) reported 13,555 incidents involving opioids (Table 4.1). The majority (71%, n=9066) of opioid incidents were categorised as SAC 4 (Table 4.1). Palliative care services had the 7th highest opioid incident reporting rate by service type (3.4%, n=467), while cancer services reported a much smaller proportion of opioid incidents (1.9%, n=258) (Table 4.2).

Table 4.1 Reported opioid incidents by service and SAC [Jan 1, 2011 – Dec 31, 2014]

	Palliative Care		Cancer Care		All other services combined		Total	
2011-2014	N=467	(%)	N=258	(%)	N=12830	(%)	N=13555	(%)
Opioid incidents by year								
2011	104	(22.2)	55	(21.3)	2874	(22.4)	3033	(22.4)
2012	132	(28.3)	65	(25.2)	3104	(24.2)	3301	(24.3)
2013	109	(23.3)	71	(27.5)	3298	(25.7)	3478	(25.7)
2014	122	(26.1)	67	(26.0)	3554	(27.7)	3743	(27.6)
Opioid incidents by SAC								
SAC 1	0	(0)	2	(0.8)	5	(0.1)	7	(0.05)
SAC 2	4	(0.9)	1	(0.4)	48	(0.4)	53	(0.4)
SAC 3	133	(28.5)	68	(26.4)	3553	(27.7)	3754	(27.7)
SAC 4	314	(67.2)	185	(71.7)	9066	(70.7)	9565	(70.6)
SAC not allocated	16	(3.4)	2	(0.8)	158	(1.2)	176	(1.3)

Table 4.2 Percentage of reported opioid incidents in the NSW public health service by service type [January 1, 2011 – December 31, 2014]

Service type	Reported opioid errors		Service type	Reported opioid errors	
	n	%		n	%
Drug - Alcohol Services	2014	14.9%	Adolescent Health	29	0.2%
Pharmacy	1283	9.5%	Surgical - Gynaecology	29	0.2%
Medicine - General	1133	8.4%	Women's Health - General	29	0.2%
Aged Care - Geriatrics	788	5.8%	Paediatric Surgery	28	0.2%
Ambulatory Care	620	4.6%	Burns - Severe	22	0.2%
Surgical - General	477	3.5%	Outpatient Services	21	0.2%
Palliative Care	467	3.4%	Clinical	18	0.1%
Emergency Medicine	445	3.3%	Pharmacology/Toxicology	18	0.1%
Intensive Care	437	3.2%	Spinal Services	18	0.1%
Ambulance Emergency	436	3.2%	Transplant Services	15	0.1%
Surgical - Orthopaedics	400	3.0%	Rheumatology	13	0.1%
Rehabilitation	341	2.5%	Surgical - Cardiothoracic	13	0.1%
Pain Management	296	2.2%	Trauma Services	13	0.1%
Medical/Radiation Oncology	258	1.9%	Aged Care - Community	12	0.1%
Other	202	1.5%	Imaging	12	0.1%
Obstetrics - Maternity	175	1.3%	Stroke	12	0.1%
Mental Health - Inpatient	172	1.3%	Endocrinology	10	0.1%
Anaesthetics	166	1.2%	Surgical - Neurosurgery	9	0.1%
Recovery	130	1.0%	Mental Health - Community	8	0.1%
Cardiology	125	0.9%	Surgical - Ophthalmology	8	0.1%
Respiratory Medicine	124	0.9%	Forensic Inpatient Services	7	0.1%
Operating Theatre	119	0.9%	Surgical - Hand	7	0.1%
Paediatrics	117	0.9%	Ambulance Aeromedical	6	0.0%
Haematology	113	0.8%	Immunology & Allergy	6	0.0%
Renal Medicine	105	0.8%	Ambulance Patient Transport	5	0.0%
Surgical - Colorectal	86	0.6%	Infection Control	5	0.0%
Gastroenterology	84	0.6%	Surgical - Oral Maxillo-Facial	5	0.0%
Surgical - Vascular	78	0.6%	HMO/VMO	4	0.0%
Neurology	74	0.5%	AIDS - Infectious Diseases	3	0.0%
Neurosurgery	64	0.5%	Mental Health - Rehabilitation	3	0.0%
Mental Health - Forensic Inpatient	61	0.5%	Public Health	3	0.0%
Neonatology	61	0.5%	Aboriginal Health Services	2	0.0%
Cardiothoracic	57	0.4%	Dental - Oral Health	2	0.0%
Surgical - Urology	57	0.4%	NETS	2	0.0%
Aged Care - Psychogeriatrics	53	0.4%	Ambulance Administrative Services	1	0.0%
Paediatric Oncology	52	0.4%	Ambulance Education/Training	1	0.0%
Community Nursing	42	0.3%	Ambulance Rapid Response	1	0.0%
Surgical - Plastic & Reconstructive	37	0.3%	Ambulance SCAT	1	0.0%
General Practice	36	0.3%	Ambulatory Care - Paediatric	1	0.0%
Ambulance Equipment	34	0.3%	Child Protection	1	0.0%
Surgical - ENT - Otolaryngology	31	0.2%	Occupational Therapy	1	0.0%
			Patient Transport	1	0.0%
			Service Not Specified	1318	9.7%
			Total	13555	100%

Seven SAC 1 notifications involving hydromorphone (n=3), morphine (n=3) and fentanyl (n=1) were reported. In this trend search, two SAC 1 notifications involving hydromorphone (n=1) and fentanyl (n=1) occurred in cancer services. All SAC 2 notifications in cancer and palliative care services involved hydromorphone; whereas, oxycodone (n=15), morphine (n=12) and fentanyl (n=11) resulted in the majority of SAC 2 notifications in all other services combined. Cancer and palliative care services were significantly more likely to report errors with hydromorphone ($\chi^2_1=787, p<.001$) and morphine ($\chi^2_1=17, p<.001$), compared to all other services combined (Figure 4.1).

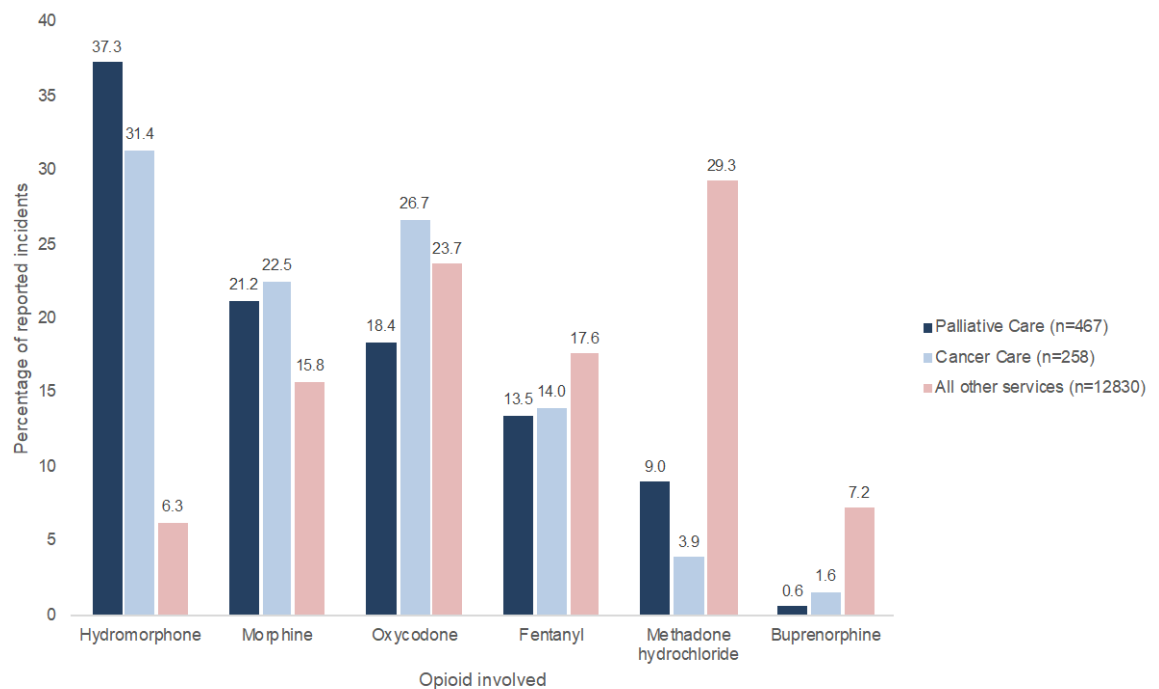


Figure 4.1 Incident reports by service type and opioid involved (2011-2014) (N=13555)

4.5.2 Dataset 2

Of the 500 extracted records, 379 incident reports from palliative care and cancer services met the inclusion criteria for data analysis ('opioid incidents') (Figure 4.2). Two-thirds (64%, n=241) of opioid Incidents were reported in palliative care services.

Error SAC ratings were similar for both service types with two-thirds of incidents rated SAC 4 (cancer services: 69%, n=95; versus palliative care: 66%, n=159), and one-third rated SAC 3 (cancer services: 30%, n=42 versus palliative care: 30%, n=73). Two SAC 2 errors were reported in palliative care, both involving hydromorphone. The majority of opioid incidents across both service types involved

hydromorphone (35%, n=131), morphine (23%, n=88) or oxycodone (20%, n=74) (Figure 4.3).

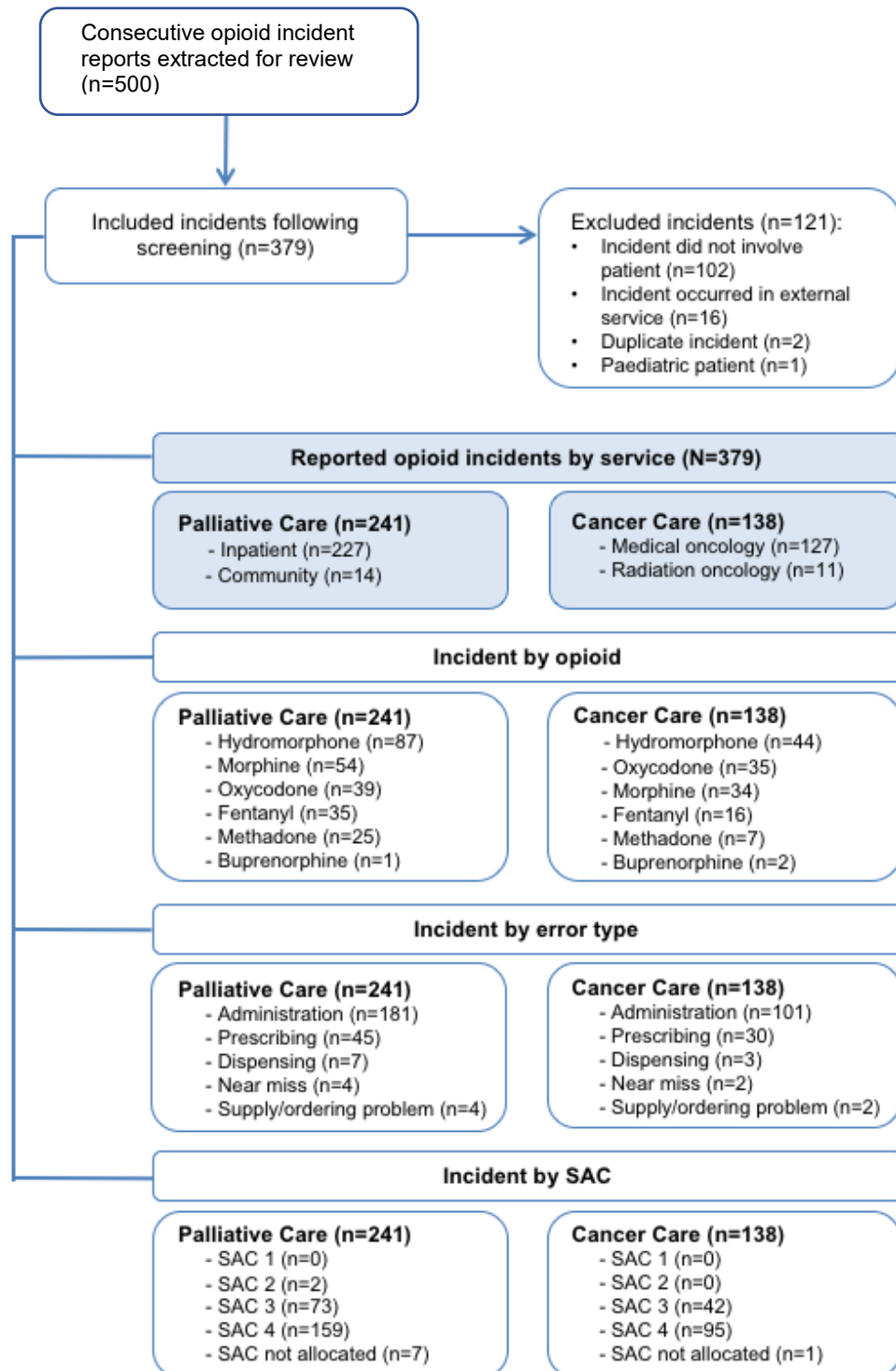


Figure 4.2 Overview of incident reports included for analysis (N=379)

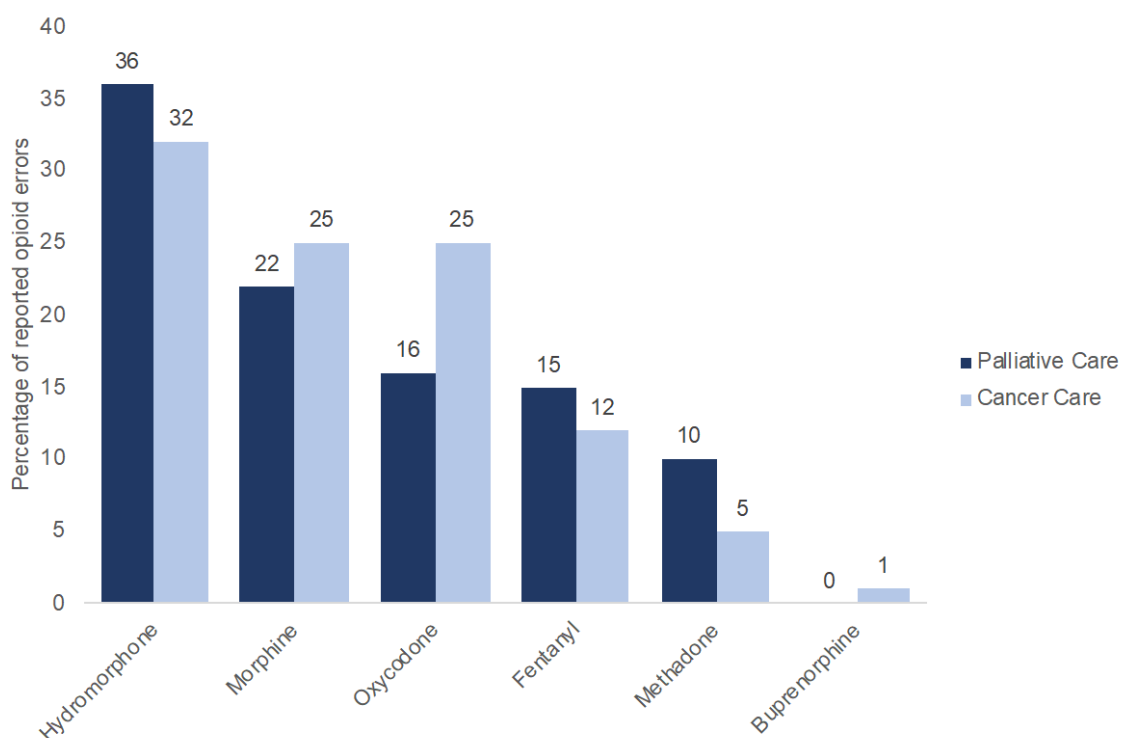


Figure 4.3 Opioid errors by service type and opioid involved (N=379)

Opioid incidents by problem type

In both palliative and cancer care services, opioid administration errors comprised approximately three-quarters (74%, n=282) of reported errors (Table 4.3).

Prescribing errors accounted for one-fifth (20%, n=75) of errors with much smaller numbers of dispensing (3%, n=10), near miss (2%, n=6) and drug supply issues (2%, n=6) reported.

Administration errors

Omitted dose (29%, n=81), wrong dose (15%, n=42) and wrong route (14%, n=38) errors were the leading reported administration error types overall (Table 4.3).

Palliative care services reported significantly more omitted dose errors ($\chi^2=15$, $p<.001$) compared to cancer services, whereas cancer services reported significantly more wrong route errors ($\chi^2=15$, $p=.001$). All omitted doses, bar one, were non-therapeutic omissions, not doses withheld based on clinical judgement. Three-quarters (74%, n=28) of wrong route errors occurred when opioids were administered subcutaneously instead of orally, almost half of which (47%, n=13) occurred with hydromorphone.

Table 4.3 Reported opioid incidents by service and problem type (N=379)

Problem type	Incident type	Palliative Care		Cancer Care		Total		p-value*
		N=241	(%)	N=138	(%)	N=379	(%)	
Administration	Total	181	(75.1)	101	(73.2)	282	(74.4)	0.55
	Omitted dose	66	(36.5)	16	(15.8)	82	(29.1)	<.001
	Wrong dose	22	(12.2)	20	(19.8)	42	(14.9)	0.12
	Device – wrong rate	20	(11.0)	5	(5.0)	25	(8.8)	0.07
	Transdermal patch error	14	(7.7)	11	(10.9)	25	(8.8)	0.43
	Device – other error	14	(7.7)	4	(4.0)	18	(6.4)	0.41
	Wrong route	13	(7.1)	25	(24.8)	38	(13.5)	0.001
	Wrong drug	13	(7.1)	12	(11.9)	25	(8.8)	0.22
	Wrong patient	6	(3.3)	2	(2.0)	8	(2.8)	**
	Incomplete administration	5	(2.8)	2	(2.0)	7	(2.5)	**
	Wrong technique	4	(2.2)	2	(2.0)	6	(2.1)	**
	Wrong time	4	(2.2)	2	(2.0)	6	(2.1)	**
Prescribing	Total	45	(18.7)	30	(21.7)	75	(19.8)	0.35
	Medication charting	20	(44.4)	18	(60.0)	38	(50.1)	0.15
	Wrong dose	10	(22.2)	4	(13.3)	14	(18.7)	**
	Wrong drug	8	(17.8)	3	(10.0)	11	(14.7)	**
	Wrong dosage form	2	(4.4)	2	(5.0)	4	(5.3)	**
	Opioid conversion error	2	(4.4)	0	0	2	(2.7)	**
	Wrong route	1	(2.2)	1	(2.5)	2	(2.7)	**
	Wrong patient	1	(2.2)	1	(2.5)	2	(2.7)	**
	Device – wrong rate	1	(2.2)	0	0	1	(1.3)	**
	Delayed order	0	0	1	(3.2)	1	(1.3)	**
Dispensing	Total	7	(2.9)	3	(2.2)	10	(2.6)	**
	Labelling error	2	(28.6)	1	(33.3)	3	(30.0)	**
	Wrong device	2	(28.6)	0	0	2	(20.0)	**
	Wrong amount	1	(14.3)	1	(33.3)	2	(20.0)	**
	Wrong patient	1	(14.3)	0	0	1	(10.0)	**
	Unauthorised dispensing	1	(14.3)	0	0	1	(10.0)	**
	Communication error	0	0	1	(33.3)	1	(10.0)	**
Near miss	Total	4	(1.7)	2	(1.4)	6	(1.6)	**
	Wrong drug	2	(50.0)	0	0	2	(33.3)	**
	Wrong dose	1	(25.0)	0	0	1	(16.7)	**
	Wrong route	1	(25.0)	0	0	1	(16.7)	**
	Wrong patient	0	0	1	(50.0)	1	(16.7)	**
	Drug preparation	0	0	1	(50.0)	1	(16.7)	**
Supply/ordering problem	Total	4	(1.7)	2	(1.4)	6	(1.6)	**
	Nil stock	4	(100)	2	(100)	6	(100)	**

*df=1; **Count not strong enough to provide statistical evidence

Prescribing errors

Prescribing errors accounted for 20% (n=75) of reported incidents. Medication charting errors comprised half (50%, n=38) of all reported prescribing errors, over one third (39%, n=15) of which were due to ambiguous written opioid orders. One-quarter (23%, n=9) of charting errors occurred when re-charting opioid orders, including discharge medications. Wrong dose (20%, n=15) and dosage form (immediate versus extended release) errors (5%, n=4) collectively accounted for one quarter of prescribing errors, almost half of which (47%, n=9) involved hydromorphone.

Other errors

Dispensing (3%, n=10) and opioid supply/ordering (2%, n=6) problems were less frequently reported; however, almost half (44%, n=7) of these incidents directly resulted in patient harm due to clinically significant opioid underdose.

Patient impact

Of the 379 errors reported, 93% (n=353) reached the patient (Table 4.4). Almost half (49%, n=184) of opioid errors that reached the patient required clinical intervention to preclude or manage harm. Patient impact/outcome was not recorded in the incident report in 43% (n=161) of incidents, limiting data analysis. In this data set, palliative care services recognised and notified significantly more incidents involving opioid underdosing ($\chi^2=11$, $p=.001$), whereas opioid overdose was significantly more recognised and notified in cancer services ($\chi^2=13$, $p<.001$). There were no significant differences in patient harm reported ($p=.684$), or reported need for clinical intervention ($p=.434$) following an opioid error for patients aged 65 years or over (57%, n=202) in either service type. Almost half of all omitted doses (48%, n=39) resulted in patients requiring additional monitoring and/or PRN opioids to manage increased pain. The majority (79%, n=30) of wrong route errors resulted in opioid overdose, and over half (55%, n=23) of wrong dose errors resulted in opioid overdose ranging from 1.5 to 10-fold higher doses being administered than ordered.

Table 4.4 Impact of reported opioid errors on patient outcomes by service type

	Palliative Care		Cancer Care		Total		p-value*
	N=241	(%)	N=138	(%)	N=379	(%)	
Error reached patient							
Yes	223	(92.5)	130	(94.2)	353	(93.1)	0.15
No	16	(6.6)	4	(2.9)	20	(5.3)	
Could not determine	2	(0.8)	4	(2.9)	6	(1.6)	
Patient outcome (NCC MERP error category (Hartwig, Denger, & Schneider, 1991))							
Category B - error occurred, did not reach patient	15	(6.2)	3	(2.2)	18	(4.7)	0.19
Category C - error reached patient, no patient harm ^a	11	(4.6)	5	(3.6)	16	(4.2)	0.65
Category D - error reached patient, required monitoring ^b and/or intervention ^c to preclude harm ^a	72	(29.9)	53	(38.4)	125	(33.0)	0.11
Category E - error resulting in temporary patient harm ^a which required intervention ^c	37	(15.4)	20	(14.5)	57	(15.0)	0.87
Category F - error resulting in temporary patient harm ^a which required initial or prolonged hospitalisation	2	(0.8)	0	0	2	(0.5)	**
Error reached patient - patient impact/outcome not documented	104	(43.2)	57	(41.3)	161	(42.5)	
Incident dose outcome (patient reached)							
Opioid underdose	134	(60.1)	53	(40.8)	187	(53.0)	0.001
Opioid overdose	66	(29.6)	64	(49.2)	130	(36.8)	<.001
Could not determine	23	(10.3)	13	(10.0)	36	(10.2)	

^a Harm: Impairment of physical, emotional, or psychological function or structure of the body and/or pain resulting from error (Hartwig et al., 1991)

^b Monitoring: observation or recording of relevant physiological or psychological signs (Hartwig et al., 1991)

^c Intervention: change in therapy or active medical treatment (Hartwig et al., 1991)

*df=1; **Count not strong enough to provide statistical evidence

Error contributory factors

Active failures, described as errors made by the clinician, were identified as contributing to opioid errors in over half (59%, n=222) of incident reports, primarily due to non-compliance with medication handling policy (36%, n=80) (Table 4.5). Notably, one-third (30%, n=111) of incident reports did not have a contributory factor documented, limiting accurate analysis. Poor clinical communication contributed to 17% of opioid errors, due to ambiguous or illegible opioid orders (n=41), and deficits in clinical hand-over (n=23). Additionally, staff workload and/or sub-optimal skill mix was noted to have contributed to 9% of opioid errors (n=34), while clinician inexperience contributed to 8% (n=31). At an organisational level, drug supply issues (n=6), absence of medical personnel (n=3), and issues with medication chart access (n=2) contributed to 3% of errors.

Table 4.5 Opioid error contributory factors identified in incident reports per the Yorkshire Contributory Factors Framework (Lawton et al., 2012)

Factor	Palliative Care		Cancer Care		Total	
	N=241	(100%)	N=138	(100%)	N=379	(100%)
Active failures	143	(59.3)	82	(59.4)	222	(59.4)
- violation (non-compliance with medication handling policy)	52	(36.4)	28	(34.1)	80	(36.0)
- slip, lapse or mistake	28	(19.6)	6	(7.3)	34	(15.3)
- unable to determine	63	(44.1)	48	(58.5)	111	(50.0)
Situational factors	25	(10.4)	9	(6.5)	34	(9.0)
Individual factors - inexperience	23	(92.0)	8	(88.9)	31	(91.2)
Patient factors	2	(8.0)	1	(11.1)	3	(9.8)
Task characteristics			<i>Nil identified</i>			
Team factors			<i>Nil identified</i>			
Local working conditions	26	(10.8)	13	(9.4)	39	(10.3)
Staff workload	17	(65.4)	11	(84.6)	28	(71.8)
Management of staff and staffing levels (skill mix)	5	(19.2)	1	(7.7)	6	(15.4)
Equipment and supplies – device malfunction (syringe driver)	4	(15.4)	1	(7.7)	5	(12.8)
Lines of responsibility			<i>Nil identified</i>			
Supervision and leadership			<i>Nil identified</i>			
Latent/organisational factors	5	(2.1)	6	(4.3)	11	(2.9)
Support from central functions	5	(100)	6	(100)	11	(100)
Physical environment			<i>Nil identified</i>			
Policies and procedures			<i>Nil identified</i>			
Scheduling and bed management			<i>Nil identified</i>			
Training and education			<i>Nil identified</i>			
Latent external factors	6	(2.5)	0	0	6	(1.6)
Design of equipment and supplies - transdermal patch adhesion	6	(100)	0	0	6	(100)
External policy context			<i>Nil identified</i>			
General factors						
Communication systems	36	(14.9)	28	(20.3)	64	(16.9)
- Written communication	25	(69.4)	16	(57.1)	41	(64.1)
- Clinical handover	11	(30.6)	12	(42.9)	23	(35.9)
Safety culture			<i>Nil identified</i>			

4.6 Discussion – Study 2

This retrospective review study has provided insights into the characteristics of reported medication errors with opioids in palliative and cancer care services at a state-wide level. As acknowledged previously, when analysing clinical incident notifications multiple sources of data/information are required to understand the context. Given the wide variation between services and facilities in NSW Health, accurate comparisons cannot be made based on incident notification numbers alone as many variables can influence incident reporting.

During the four year reporting period, palliative and cancer care services in NSW reported significantly more incidents with hydromorphone and morphine compared to all other services combined. These data may reflect that the patient population in palliative and cancer care services are more likely to be using opioids (in particular hydromorphone and morphine) for pain than other services. This also highlights the risk of patient harm in an already vulnerable patient population (Myers & Lynn, 2001). In contrast, incidents with oxycodone and morphine are the most frequently reported in other services in the NSW public health system (Clinical Excellence Commission, 2019).

Opioid administration and prescribing errors were the most frequently reported problem type, consistent with opioid error reporting trends in other health care settings (Carson, Jacob, & McQuillan, 2009; Desai et al., 2013; Dy, Shore, Hicks, & Morlock, 2007). However, opioid prescribing error reporting was slightly lower in palliative and cancer services than identified in other acute care units (15% vs. 21%) (Dy et al., 2007). The complexity of patients, interpretation of error, differing drug utilisation between settings, and variability in staff reporting, are other factors that may contribute to this finding.

There were notable differences in reported administration error types and subsequent dose errors between services. Of note, and somewhat unexpectedly, palliative care services reported significantly more omitted dose errors than cancer services, with a correspondingly significant rate of opioid under dose directly due to error. This is in contrast to opioid dose outcomes in another study where over half (53%) of all reported opioid errors in acute care settings resulted in opioid overdose (Dy et al., 2007).

Conversely, in this study, the reporting of opioid overdose due to error in cancer services was significantly greater than reported in palliative care services, likely attributable to the significantly higher number of wrong route errors, most of which involved hydromorphone given subcutaneously instead of orally. While wrong route errors, both with opioids (Dy et al., 2007) and other drugs (Barker, Flynn, Pepper, Bates, & Mikeal, 2002), are relatively infrequent in other adult healthcare settings, hydromorphone is over three-times more potent when delivered subcutaneously compared to orally (eviQ Cancer Treatments Online, 2018), considerably adding to the risk of patient harm from opioid overdose.

Patients over 65 are more likely to be exposed to, and experience harm from, medication errors (Myers & Lynn, 2001). Over half of patients who experienced an opioid error in this study were aged 65 years over; however, there were no significant differences in the degree of patient harm following an error for these patients, compared to those aged under 65 years. These findings warrant further investigation, as almost half the incident reports did not document patient outcome following the error, limiting data analysis.

Initial analysis of factors contributing to opioid errors suggest active failures underpinned errors in almost half of all incident reports. Importantly, contributory factors are identified by the clinician completing the incident report and have not been validated. Error contributory factors skewed towards human error in this study, which may be due to the notifiers' limited understanding of latent causes of error and the tendency to report the error or individual factor itself as the cause (Lawton et al., 2012; Mahajan, 2010). All reported error contributory factors were adequately represented by the Yorkshire Contributory Factors Framework (Lawton et al., 2012) in this study. A comprehensive analysis of opioid error contributory factors, combining data from incident reports and clinicians' perceptions, is warranted to identify individual, organisational and/or latent factors that may be contributing to opioid errors in cancer and palliative care services.

Based on the results of this retrospective review of opioid error data across NSW, further exploration of opioid error prevalence, error contributory factors, and patient impact at a local level, and in the context of specialist palliative care inpatient service delivery, are essential next steps to better understand these results.

4.6.1 Limitations

NSW Health clinicians and managers maintain a culture of reporting clinical incidents to ensure action is taken to improve the safety and quality of care provided to patients. However, comprehensive and timely reporting is reliant on the clinician notifying, leading to potential for variation in reporting patterns. Though counts or rates have been used in this study it is acknowledged that when analysing clinical incident notifications multiple sources of data/information is required to understand the context, the safety and quality issues, and opportunities for improvement. Given the wide variation between services and facilities in NSW Health, accurate comparisons cannot be made based on incident notification numbers alone. Many variables can influence incident reporting. Lower rates of reporting are not a reliable indicator of safer care. Further qualitative, rather than quantitative, interpretation of the data is also required (Clinical Excellence Commission, 2018).

The incident analysis is based only on information contained in the 'incident description' 'contributing factors' and 'review of incident' section in the Incident Information Management System (IIMS) notifications. If the information was not documented in these sections, or the selected search terms were not used or were spelt differently, the incidents will not have been captured during this review. It should be noted that all reviews of incident data are retrospective and can reflect both hindsight and outcome bias.

Data from this study relied solely on opioid errors reported via clinical incident management systems, which identify significantly fewer medication errors than measurement by audit and/or observation, suggesting opioid errors are likely to occur more frequently than is currently being reported (Australian Commission on Safety and Quality in Health Care and NSW Therapeutic Advisory Group Inc., 2013; Levinson, 2012; Munzner, Welch, & Richardson, 2012; Westbrook et al., 2015). Medication errors are known to be widely under-reported, with great variations in reporting practices across services (Institute of Medicine, 2007). Additionally, data analysis was predicated on the incident narrative as reported by the incident notifier, which may not capture all relevant information pertaining to the incident (Vincent, 2007). Incident notifications are the notifier's perception and not necessarily a true interpretation of facts or reality and as the incident narrative is completed

retrospectively it may reflect both hindsight and outcome bias. The incident narrative also does not contain any context (e.g. complexity of patients or services, drug utilisation by patient group or setting) and the variation in reporting patterns (as timely reporting is reliant on the notifier) limits the ability to use this data to make any accurate comparisons between services and settings. Finally, contributing factors are identified by the clinician completing the incident report making reporting subject to interpretation and bias.

The de-identified nature of the datasets precluded calculation of opioid error prevalence and limited in-depth statistical analysis, as service and patient characteristics were not available. Despite these limitations, this study has provided valuable insights into reported opioid error characteristics and patient impact of opioid error in cancer and palliative care services, which, to our knowledge, has not been previously reported.

It should be noted that at the time of this study the majority of NSW health services were using hand written medication charts. Since the study electronic medication management systems that are improving the reliability of medication management have been implemented and significant investment has been made by NSW Health and the Clinical Excellence Commission to address errors and to improve systems in relation to medication management.

4.7 Summary – Study 2

Identifying the prevalence, characteristics and patient impact of reported opioid errors is a crucial first step in better understanding and addressing opioid errors clinically, and establishing a baseline of opioid error data against which local opioid incident data can be compared. Results from this study will be used to inform retrospective reviews of reported opioid errors in local palliative care services.

4.8 Context for Study 3

Study 2 identified the characteristics and patient impact of opioid errors reported in palliative and cancer care services in NSW over approximately three years. The study indicated that in palliative care services: i) errors with hydromorphone and morphine were the most frequently reported, ii) opioid administration errors were the leading problem type reported, iii) omitted dose errors accounted for the majority of

reported administration errors, and iv) patients were more likely to experience an opioid under dose, than overdose, as a direct result of an opioid error, adversely impacting pain management. Study 3 sought to further explore the scope of opioid errors in local specialist palliative care inpatient services and compare the findings to those reported in NSW palliative care services in Study 2.

Study 3 was a retrospective review of reported opioid errors in three specialist palliative care inpatient services in metropolitan NSW. In addition to identifying opioid error characteristics and patient impact at a local level, Study 3 sought to establish the volume of opioid use and opioid error incidence within the participating services, as this could not be identified from the data sets in Study 2. Study 3 continues to scope the extent and patient impact of opioid errors, specifically in local specialist palliative care inpatient services.

4.9 Publication reference - Study 3

The results of Study 3 were published as a short report in *BMJ Supportive and Palliative Care*, a peer reviewed scholarly journal targeting clinicians and healthcare workers undertaking clinical work in palliative medicine, specialist or generalist palliative care, supportive care, psychosocial-oncology and end-of-life care. This chapter contains an edited version of the published short report (Appendix 1) and additional data from a 7-day snapshot audit, undertaken to quantify the frequency of opioid delivery in inpatient palliative care services.

Heneka, N., Shaw, T., Rowett, D., Lapkin, S. & Phillips, J. (2018).
Opioid errors in inpatient palliative care services: a retrospective
review. *BMJ Supportive and Palliative Care*, 8(2), 175-179.

BMJ Supportive and Palliative Care: Impact factor: 2.385; ISI JCR Ranking 2017: 35/94 (Health Care Sciences & Services).

The published short report was picked up by the Australian Science Media Centre and included on the Scimex (Scientific Media Exchange) website, an online news portal aimed at helping journalists cover science and research (Appendix 1). As a result, Fairfax Media featured an article on the short report, in both print and online news nationally (Appendix 1), and ABC News Breakfast, a national radio broadcast,

interviewed the PhD Candidate (NH) on January 8, 2018. The short report was also promoted by BMJ Supportive and Palliative Care, as the ‘best article to read this month’ (Appendix 1).

4.10 Objectives – Study 3

The objectives of Study 3 were to:

- i) quantify the number of opioids ordered and administered in specialist palliative care inpatient services;
- ii) identify the number of opioid errors reported by specialist palliative care inpatient services;
- iii) determine the impact of opioid errors on palliative patient outcomes; and
- iv) identify reported opioid error characteristics.

4.11 Methods – Study 3

Study methods have been described in Chapter 3. As outlined in Chapter 3, this study includes two parts: i) a retrospective seven-day snapshot audit of opioid orders and administrations (Study 3a), and ii) a retrospective audit of reported opioid errors from three specialist palliative care inpatient services in NSW over 24 months (Study 3b).

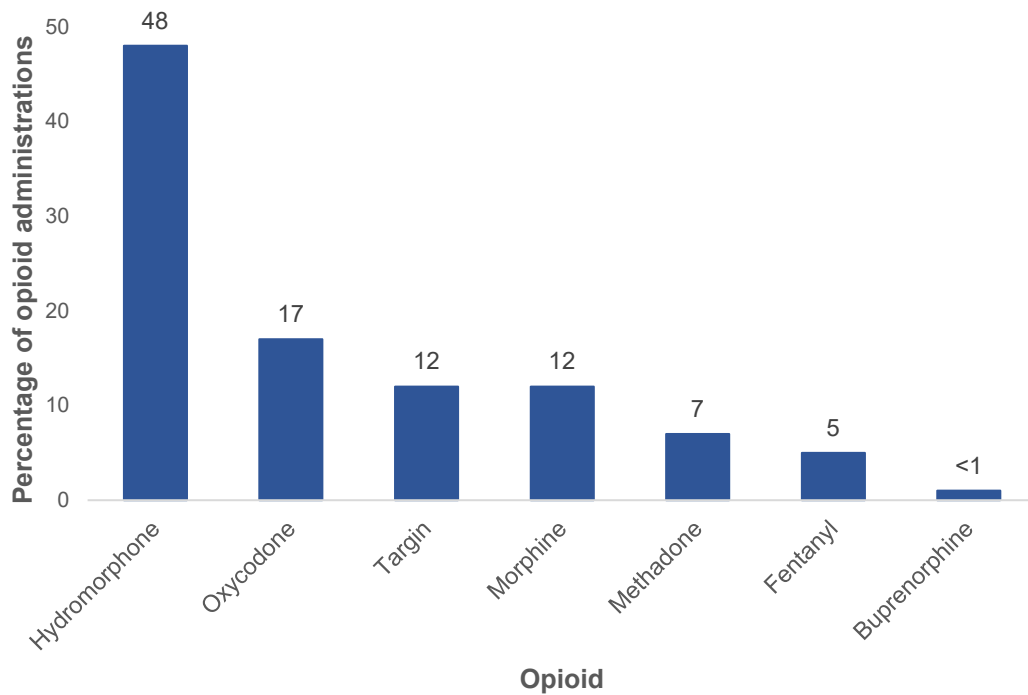
4.12 Results - Study 3a (snapshot audit)

The seven-day snapshot audit captured opioid orders and administrations for 120 palliative inpatients in three specialist palliative care inpatient services (Table 4.6). Patients spent an average of 5.4 days (± 2.4) in the palliative care unit in the audit period. Almost all (98%) palliative inpatients had at least one opioid order (regular, PRN or STAT). One-third of patients (29%) had two or more regular opioid orders, and almost half (44%) had two or more PRN orders. Hydromorphone accounted for almost half (48%) of all opioid administrations (Figure 4.4).

Table 4.6 Overview of service characteristics and opioid orders per patient in seven-day snapshot audit of three specialist palliative care inpatient services

	Service 1	Service 2	Service 3	Total
Service characteristics				
Number of available beds in audit period (n)	39	38	20	97
Number of patients in audit period (n)	48	45	27	120
Percentage occupancy in audit period (%)	83.9%	98.1%	87.9%	92.0%
Mean number of days patient on ward in audit period (\pm SD)	5.0 (\pm 3.4)	6.0 (\pm 2.1)	5.0 (\pm 2.7)	5.4 (\pm 2.4)
Opioid orders per patient in snapshot audit period				
Total number of patients with an opioid order (regular, PRN and/or STAT) n (%)	48 (100%)	44 (97.8%)	25 (92.6%)	117 (97.5%)
Regular opioid orders in audit period n (%)				
Number of patients with nil regular opioid order	12 (25.0%)	6 (13.6%)	11 (44.0%)	29 (24.8%)
Patients with one regular opioid order only	23 (47.9%)	21 (47.7%)	11 (44.0%)	55 (47.0%)
Patients with two regular opioid orders	8 (16.7%)	10 (22.7%)	3 (17.9%)	21 (17.9%)
Patients with three regular opioid orders	2 (4.2%)	5 (11.4%)	0 (6.0%)	7 (6.0%)
Patients with four regular opioid orders	1 (2.1%)	1 (2.3%)	0 (1.7%)	2 (1.7%)
Patients with five regular opioid orders	2 (4.2%)	1 (2.3%)	0 (2.6%)	3 (2.6%)
PRN and stat opioid orders in audit period n (%)				
Patients with nil PRN order	1 (2.1%)	0	0	1 (0.9%)
Patients with one PRN order	20 (41.7%)	29 (65.9%)	16 (64.0%)	65 (55.6%)
Patients with two PRN orders	16 (33.3%)	8 (18.2%)	8 (32.0%)	32 (27.4%)
Patients with three PRN orders	7 (14.6%)	5 (11.4%)	1 (4.0%)	13 (11.1%)
Patients with four PRN orders	4 (8.3%)	2 (4.5%)	0	6 (5.1%)
Patients with STAT opioid order	3 (6.3%)	0	4 (16.0%)	7 (6.0%)

Figure 4.4 Percentage of opioid administrations in seven-day snapshot audit, provided to 120 inpatients in the participating specialist palliative care inpatient services (n=3)



In total, there were 10,031 opioid doses ordered (regular, PRN and/or STAT) and 1,732 opioid doses administered across the three specialist palliative care inpatient services in seven days (Table 4.7). This equates to 86 opioid orders per patient over seven days, or 12 opioid orders per patient, per day. Opioids were administered 247 times per day, equating to one opioid administration approximately every six minutes in the specialist palliative care inpatient service.

Table 4.7 Overview of opioid orders and administrations in seven-day snapshot audit for three specialist palliative care inpatient services

	Service 1	Service 2	Service 3	Total
Opioid orders and administrations in snapshot audit period				
Regular opioids				
Total regular opioid doses ordered in audit period (n)	444	698	100	1242
Total regular opioid doses administered in audit period n (%) ^a	377 (84.9%)	690 (98.9%)	83 (83.0%)	1150 (92.6%)
PRN opioids				
Total PRN opioid doses ordered in audit period	2928	1783	4070	8781
Total PRN opioid doses administered in audit period n (%)	141 (4.8%)	225 (12.6%)	208 (5.1%)	574 (6.5%)
STAT opioids				
Total STAT opioid doses ordered in audit period (n)	4	0	4	8
Total STAT opioid doses administered in audit period n (%)	4 (100%)	0	4 (100%)	8
Total opioid doses ordered in audit period	3376	2481	4174	10,031
Total opioid doses administered	522	915	295	1732

^a All omitted doses were therapeutic omissions or dose omissions due to the patient being off the ward (e.g., for investigation/treatment).

4.13 Results – Study 3b (local retrospective review)

Study 3b was a retrospective review of consecutive clinical incidents with opioids reported by three NSW specialist palliative care inpatient services.

4.13.1 Opioid error prevalence

Opioid errors accounted for 32% (n=55) of all reported medication errors (N=174), equating to 0.9 (± 1.5) opioid errors per 1000 occupied bed days (Figure 4.5).

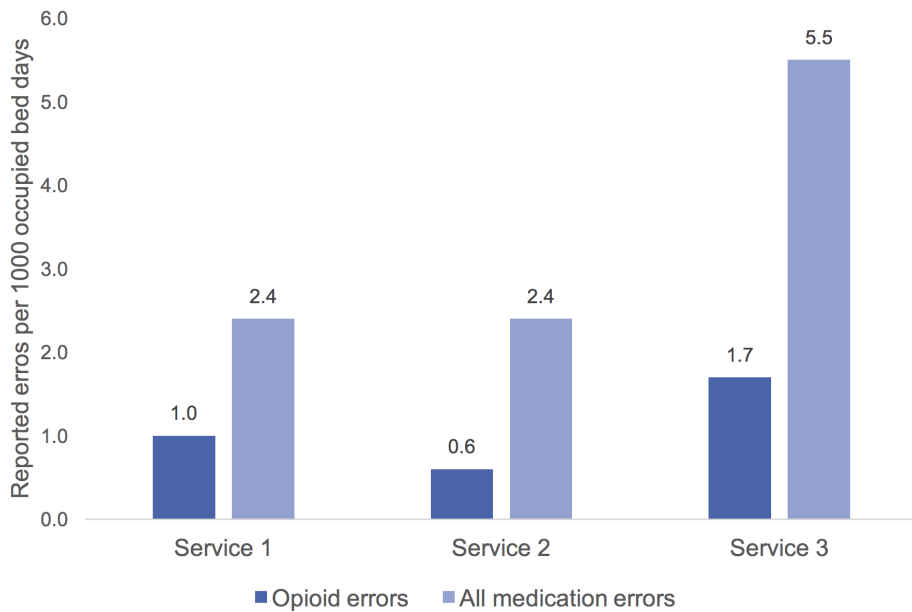


Figure 4.5 Comparison of reported opioid errors and all reported medication errors per 1000 occupied bed days in specialist palliative care inpatient services (n=3)

4.13.2 Patient impact

Eighty four percent (n=46) of reported opioid errors reached the patient. The mean age of the affected patients was 71.3 years (± 10.7). Most patients (84%, n=46) had cancer and almost two-thirds (62%, n=54) of patients died during this admission. The mean length of stay for these patients was 27.2 days (± 20.0) (Table 4.8).

Table 4.8 Patient demographics – patients involved in reported opioid errors (N=55)

Demographics		Service 1		Service 2		Service 3		Total	
		N=22	(100%)	N=14	(100%)	N=19	(100%)	N=55	(100%)
Gender	Male	14	(63.6)	5	(36.0)	9	(47.4)	28	(50.9)
	Female	8	(36.4)	9	(64.0)	10	(52.6)	27	(49.1)
Age (years)	Mean (SD)	76.3 (\pm 9.2)		67.3 (\pm 9.9)		68.0 (\pm 10.5)		71.3 (\pm 10.7)	
	Median (IQR)	77.5 (15)		68.5 (18)		65.0 (18)		72.0 (18)	
Cancer diagnosis	Yes	16	(72.7)	12	(85.7)	18	(94.7)	46	(83.6)
	No	6	(27.3)	2	(14.3)	1	(5.3)	9 ^a	(16.4)
Primary reason for admission	Symptom management	11	(50.0)	5	(35.7)	15	(78.9)	31	(56.4)
	End of life care	4	(18.2)	3	(21.4)	1	(5.3)	8	(14.5)
	Pain control	3	(13.6)	4	(28.6)	1	(5.3)	8	(14.5)
	Respite	2	(9.1)	1	(7.1)	2	(10.5)	5	(9.1)
	Palliative rehab	2	(9.1)	0	0	0	0	2	(3.6)
	Supportive care	0	0	1	(7.1)	0	0	1	(1.8)
Length of stay (days)	Mean (SD)	19.9 (\pm 13.5)		30.9 (\pm 24.6)		32.8 (\pm 20.3)		27.2 (\pm 20.0)	
	Median (IQR)	15.5 (14)		25.0 (32)		30.0 (22)		22.0 (24)	
Died during admission	Yes	12	(54.5)	8	(57.1)	14	(73.7)	34	(61.8)
	No	10	(45.5)	6	(42.9)	5	(26.3)	21	(38.2)

^aOther than cancer diagnosis: COPD (n=2- 1), heart failure (n=1), cardiac amyloidosis (n=1), end stage liver failure (n=1), end stage renal disease (n=1), lung function failure (n=1), motor neuron disease (n=1), sepsis (n=1).

One-third (33%, n=18) of opioid errors resulted in patient harm (Table 4.9), requiring clinical intervention as a direct consequence of the error. An additional one-fifth (20%, n=11) of patients required monitoring and/or a clinical intervention to preclude harm following an opioid error.

Table 4.9 Impact of reported opioid errors on patient outcomes

National Coordinating Council for Medication Error Reporting and Prevention error category (Hartwig et al., 1991)	N=55 (100%)
Category B - error occurred, did not reach patient	9 (16.4)
Category C - error reached patient, no patient harm ^a	11 (20.0)
Category D - error reached patient, required monitoring ^b and/or intervention ^c to preclude harm ^a	11 (20.0)
Category E - error resulting in temporary patient harm ^a which required intervention ^c	18 (32.7)
Error reached patient - patient impact/outcome not documented	6 (10.9)

^a Harm: Impairment of physical, emotional, or psychological function or structure of the body and/or pain resulting from error; ^b Monitoring: observation or recording (Hartwig et al., 1991) of relevant physiological or psychological signs; ^c Intervention: change in therapy or active medical treatment.

Over half of patients (57%, n=26), received an opioid underdose as a direct consequence of an opioid administration error (Table 4.10). Almost half of these patients (42%, n=11) subsequently required PRN opioids to manage their increased pain (n=9) or shortness of breath (n=2).

Table 4.10 Reported opioid error underdose characteristics

Administration error type	Opioid ordered	Opioid administered	Under-dosage (% of ordered dose)^a
Wrong dose	Morphine s/c 40 mg regular	Morphine s/c 4 mg	10%
	Hydromorphone PO 80 mg regular	Hydromorphone PO 8 mg	10%
	Morphine PO 120 mg regular	Morphine PO 60 mg	50%
	Oxycodone/Naloxone 10/5 regular	Oxycodone/Naloxone 5/2.5	50%
Wrong drug	Hydromorphone s/c 5 mg regular	Morphine s/c 5 mg	12%
	OxyContin PO 10 mg regular	MS Contin PO 5 mg	33%
	Hydromorphone s/c 1.5 mg PRN	Fentanyl s/c 60 mcg	50%
Omitted dose	Number of doses omitted		Frequency
	1		9
	2		3
3		2	0%

Thirty nine percent (n=18) of patients experienced an opioid overdose due to the opioid error, ranging from 1.5 to 11-fold higher doses of the intended opioid order being administered (Table 4.11). Opioid toxicity was documented in 39% (n=7) of these patients; however, administration of an opioid reversal agent was not required for any of these patients.

Table 4.11 Reported opioid error over dose characteristics

Opioid over-dose characteristics				
Problem type	Error type	Opioid ordered	Opioid administered	Over-dosage^a
Prescribing	Charting – duplicated dose	Morphine s/c 20 mg PRN	Additional morphine s/c 20 mg PRN	2-fold
	Charting	Hydromorphone PO 0.5 mg regular	Hydromorphone PO 2 mg	4-fold
	Conversion error	Morphine PO	Hydromorphone s/c	1.5-fold
		Fentanyl transdermal	Hydromorphone s/c	2-fold
Administration	Wrong dose	Oxycodone PO 20 mg PRN	Additional oxycodone PO 20 mg	2-fold
		Morphine PO 20 mg regular	Morphine PO 40 mg	2-fold
		Oxycodone PO 10 mg PRN	Oxycodone PO 20 mg ^b	2-fold
		Hydromorphone PO 5 mg regular	Hydromorphone PO 10 mg	2-fold
		Morphine s/c 60 mg via syringe driver	Morphine s/c 60 mg via two syringe drivers	2-fold
	Wrong drug	Morphine s/c 5 mg regular	Hydromorphone s/c 5 mg	6-fold
		Morphine s/c 10 mg regular	Hydromorphone s/c 10 mg	6-fold
		Fentanyl s/c 350 mcg (via syringe driver)	Morphine s/c 400 mg (via syringe driver)	11-fold
	Transdermal patch – not removed	Fentanyl 12 mcg	Fentanyl 12 mcg patch insitu 7 days	Unable to determine
		Fentanyl 25 mcg	Buprenorphine 5 mg patch insitu 6 days	Unable to determine
		Fentanyl 25 mcg	Buprenorphine 25 mg patch insitu 3 days	Unable to determine
		Fentanyl 37 mcg	Patch insitu 3 days following order to remove	Unable to determine
	Wrong patient	Endone PO 5 mg regular	Oxynorm PO 10 mg	Two-fold

s/c – subcutaneous; PO – per oral;

^a dose calculations using EviQ opioid conversion calculator (eviQ Cancer Treatments Online, 2018)

^b two instances of same wrong dose error in different patients

4.13.3 Opioid error characteristics

Two thirds of reported opioid errors involved morphine (35%, n=19) or hydromorphone (29%, n=16). Opioid errors were more likely to occur with regular (78%, n=43) PRN orders (27%, n=10), and occurred more frequently with oral (49%, n=27) than subcutaneous (36%, n=20) or transdermal opioid administration (15%, n=8). The peak time for opioid errors was between 08:00 and 08:59 hours (20%, n=10), reflecting main medication delivery times in all participating services.

Administration errors

Opioid administration errors accounted for three-quarters (76%, n=42) of reported opioid errors, and were the most frequently reported opioid error type at each service (Table 4.12). Omitted opioid doses (33%, n=14) were the leading administration error reported. All omitted doses were non-therapeutic omissions, rather than doses withheld based on clinical judgement. Wrong dose errors (24%, n=10) occurred primarily with oral opioids (82%, n=9). One-fifth (19%, n=8) of administration errors occurred due to missing transdermal patch errors (n=4) or non-removal of original transdermal patch (n=4) (Table 4.12).

Prescribing and other errors

Opioid prescribing errors comprised 15% (n=8) of reported opioid errors and were most frequently reported with regular hydromorphone (63%, n=5). Prescribing errors were primarily due to medication charting errors (50%, n=4), opioid conversion (25%, n=2), or wrong drug errors (25%, n=2). A very small number of 'near miss' (wrong patient) (5%, n=3) and dispensing errors (4%, n=2) were reported (Table 4.12).

Table 4.12 Overview of reported opioid incidents by problem type

Problem type	Incident type	Service 1		Service 2		Service 3		Total	
		N=22	(100%)	N=14	(100%)	N=19	(100%)	N=55	(100%)
Administration	Total	13	(59.1)	12	(86.7)	17	(89.5)	42	(76.4)
	Omitted dose	9	(69.2)	0	0	5	(29.4)	14	(33.3)
	Wrong dose	3	(23.1)	4	(33.3)	3	(17.6)	10	(23.8)
	Transdermal patch error – missing or not removed	0	0	3	(25.0)	5	(29.4)	8	(19.1)
	Wrong drug	1	(7.7)	3	(25.0)	2	(11.8)	6	(14.3)
	Wrong patient	0	0	1	(8.3)	2	(11.8)	3	(7.1)
	Device – wrong rate	0	0	1	(8.3)	0	0	1	(2.4)
	Total	7	(31.8)	1	(7.1)	0	0	8	(14.5)
Prescribing	Medication charting	3	(42.9)	1	(100)	0	0	4	(50.0)
	Opioid conversion error	2	(28.6)	0	0	0	0	2	(25.0)
	Wrong drug	2	(28.6)	0	0	0	0	2	(25.0)
	Total	2	(9.1)	0	0	1	(5.3)	3	(5.4)
Near miss	Wrong patient	2	(100)	0	0	1	(100)	3	(100)
	Total	0	0	1	(7.1)	1	(5.3)	2	(3.6)
Dispensing	Drug preparation error	0	0	0	0	1	(100)	1	(100)
	Expired medicine dispensed	0	0	1	(100)	0	0	1	(100)
	Total	0	0	1	(7.1)	1	(5.3)	2	(3.6)

4.14 Discussion - Study 3

This local retrospective review has identified the percentage of reported opioid errors in specialist palliative care inpatient services was almost three-times higher than reported in other inpatient settings (Carson et al., 2009; Desai et al., 2013; Mc Donnell, 2011), and double that reported by hospitals, individual practitioners, and community pharmacies collectively (Prairie Research Association, 2014). These differences are visually represented in Figure 4.6. Comparatively, opioid errors made up: 9% (n=507) of medication related safety reports in a Canadian paediatric hospital over four years (Mc Donnell, 2011); 10% (n=3105) of medication errors reported in 396 USA nursing homes over 12 months (Desai et al., 2013); 12% (n=54) of medication errors reported over five years in a 620 bed acute general hospital in Ireland (Carson et al., 2009); and 16% (n=6076) of all medication incidents based on national incident data (inpatient, outpatient, community) reported over six years in Canada (Prairie Research Association, 2014).

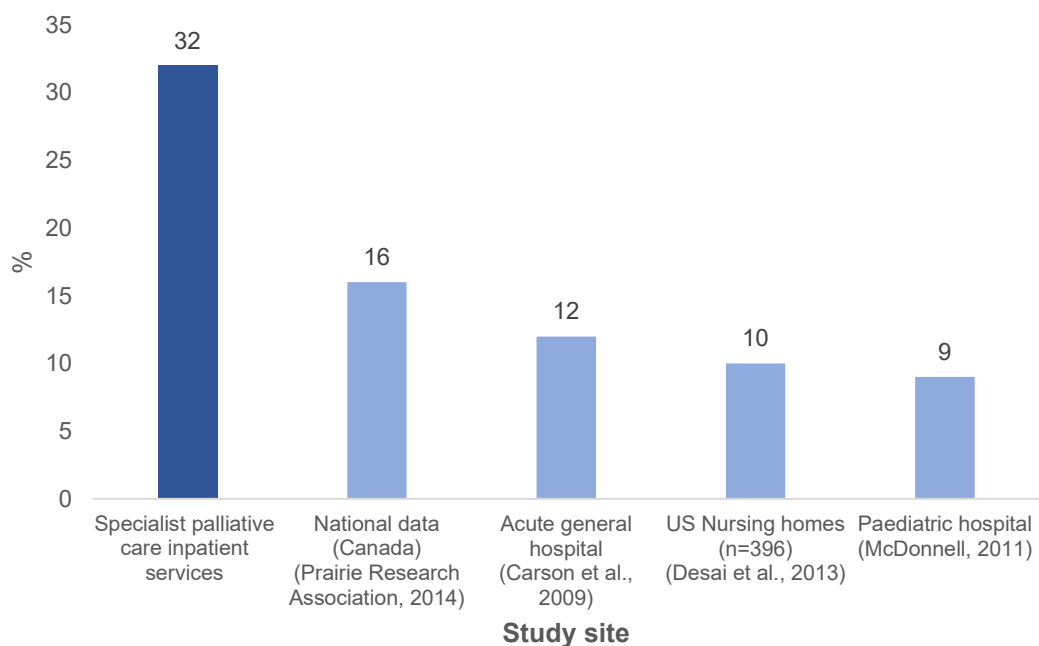


Figure 4.6 Comparison of rate of reported opioid errors as percentage of all reported medication errors types

The higher percentage of opioid error reporting may be due to the frequency of opioid delivery, and the volume of opioid orders, in specialist palliative care inpatient services. As identified in the seven-day snapshot audit, an opioid is

delivered approximately every six minutes in this specialist setting . However, it may also reflect differences in error reporting culture in the specialist palliative care inpatient services compared to other healthcare settings. While this could not be ascertained from the incident reports in this study, further exploration from the perspective of palliative care clinicians may provide further insights into the prevalence of reported opioid errors in specialist palliative care inpatient services.

Patient impact

Over half of palliative inpatients in this review required clinical intervention and/or monitoring to preclude or manage iatrogenic harm(s) as a direct consequence of an opioid error. The majority of opioid errors in this review resulted in opioid underdosing, which is over double the rate reported in other hospital settings (57% vs 23%), where opioid overdose is a more likely error outcome (Dy et al., 2007). Although wrong drug and wrong dose administration errors caused opioid underdosing in this review, omitted opioid doses were the primary contributor to opioid underdosing and subsequent adverse impact on patients' previously well managed pain.

Unrelieved pain is a major issue in specialist palliative care (Pidgeon et al., 2016) and it appears opioid errors, particularly omitted dose errors, may be contributing to the burden of palliative patients' pain. Better understanding of the factors that contribute to or mitigate opioid errors, including systems factors and the impact of error reporting culture, and developing strategies to prevent iatrogenic pain occurring as a result of opioid errors, is a priority for this clinical setting and population.

Opioid error characteristics – administration errors

Opioid administration errors accounted for the majority (76%) of all reported opioid errors in this study, reflecting trends in opioid error prevalence reported in other health care settings (Carson et al., 2009; Desai et al., 2013; Dy et al., 2007; Mc Donnell, 2011). However, administration error types in this study differed from other healthcare settings (Figure 4.7).

Wrong dose (13%-49%) and wrong drug (27%-35%) errors are the most commonly reported opioid administration errors in healthcare settings internationally (Desai et al., 2013; Dy et al., 2007; Mc Donnell, 2011; Prairie Research Association, 2014) as

illustrated in Figure 4.7. Whereas, these administration error types were reported far less frequently in the specialist palliative care inpatient services in this study. Further

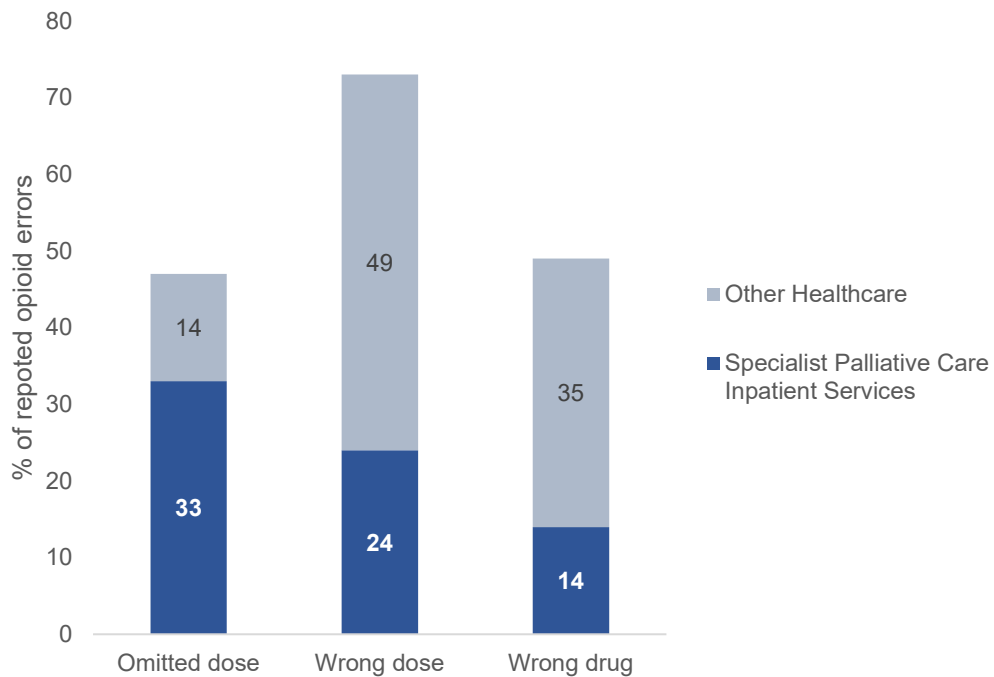


Figure 4.7 Comparison of opioid administration error types as percentage of all reported opioid administration errors in specialist palliative care inpatient services in the PERISCOPE project and other healthcare settings

exploration of these differences in error types is warranted in the specialist palliative care inpatient context.

In contrast, the specialist palliative care inpatient services in this study reported 2.5 times more omitted dose errors, compared to other healthcare settings (Prairie Research Association, 2014), with omitted dose accounting for one-third of reported opioid administration errors. All reported omitted dose errors in this study were non-therapeutic omissions (i.e., a reason for dose omission was not documented) (Latimer, Chaboyer, & Hall, 2011), not doses withheld based on clinical judgement, patient refusal, or drug unavailability (Australian Commission on Safety and Quality in Health Care, 2016). Comparatively omitted dose errors (all drug types) have been shown to account for up to 25% of all reported medication errors internationally (National Patient Safety Agency, 2010) and up to 11% in Australian studies (Latimer et al., 2011; Lawler, Welch, & Brien, 2004; O'shea, Spalding, & Carter, 2009).

Given the relationship between the high rate of omitted dose errors and the degree of iatrogenic patient harm in specialist palliative care inpatient services identified in this study, it is critical to better understand the underlying factors contributing to omitted dose errors in this care setting.

One factor may be related to the use of electronic versus paper medication management systems in specialist palliative care inpatient services. In this study, the lowest overall prevalence of both reported opioid errors and omitted dose errors came from the service utilising the electronic medication management system. In contrast, omitted doses comprised up to two-thirds of reported administration errors in the two services using paper medication charts. Electronic medication management systems have been shown to reduce medication errors in other clinical settings (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008), which may account for the differences observed in this review; however, further investigation is warranted to confirm this observation.

Another difference between the services was the proportionally greater number of prescribing errors reported by the service without an onsite clinical pharmacist. The presence of an onsite pharmacist may help identify and avert opioid prescribing errors before they are administered (Herndon et al., 2016), and this factor warrants further exploration in the palliative care service context. While the percentage of reported opioid prescribing errors in this study is similar to that reported in inpatient acute care (Carson et al., 2009; Dy, 2016) and nursing homes (Desai et al., 2013), the small number of prescribing errors reported in this study limits meaningful comparisons with other healthcare services. Further investigation from the perspective of palliative care clinicians is required to better understand these results.

Frequency of opioid delivery in specialist palliative care inpatient services

The seven-day snapshot audit identified a high volume of opioid orders per palliative inpatient and a high frequency of opioid administrations in specialist palliative care inpatient services. To our knowledge, this is the first report to quantify opioid delivery in specialist palliative care inpatient services. Hence, as comparable data could not be identified in the literature, these results will be explored in more depth with palliative care clinicians in a future study.

4.14.1 Strengths and limitations

A major strength of this review is that it examined reported opioid errors across three similar specialist palliative care inpatient services, identified opioid error prevalence, quantified opioid delivery, and characterised reported opioid errors in accordance with accepted taxonomies (Hartwig et al., 1991; National Coordinating Council for Medication Error Reporting and Prevention, 1998). A limitation of this review is that as medication errors are consistently under-reported it is conceivable that the actual number of medication errors patients experienced during their admission may have been higher than those reported (Westbrook et al., 2015). The variations in opioid error reporting practices noted between services may reflect differences in service systems and/or error reporting cultures across services; however, this could not be confirmed by this review alone.

The seven-day snapshot audit does not account for different bed-occupancy rates, variations in patient opioid needs and opioid delivery practices. Therefore, the seven-day snapshot audit data needs to be interpreted with some caution. Without a larger scale assessment of opioid errors as a proportion of opioid involved, further conclusions cannot be drawn. However, this seven-day snapshot audit does provide some insights into the volume and frequency of opioid delivery across specialist palliative care inpatient services.

The impact of broader systems factors that may be contributing to opioid errors, irrespective of the opioid involved, warrants further consideration.

4.15 Summary

Establishing a baseline profile of opioid error characteristics and prevalence in palliative care inpatient services is an important first step to quantifying the burden of this problem. Like most errors, opioid errors in this specialist setting occur as a result of a complex interplay of systems, health professional and patient factors. Better understanding these factors and their role in opioid errors is required. Given the variations in reporting practices between services in this review, further exploration of service characteristics and error reporting culture is also warranted.

The following chapter reports the final retrospective review (Study 4) undertaken in the PERISCOPE project, which sought to explicitly explore opioid error contributory

factors documented in clinical incident reports in two specialist palliative care inpatient services.

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Chapter 5: Exploring reported opioid error contributory factors in specialist palliative care inpatient services

5.1 Chapter preface

Chapter 4 reported the results of two retrospective reviews of clinical incidents with opioids reported in NSW and local palliative care services. These reviews identified that opioid administration errors account for three-quarters of reported opioid errors in specialist palliative care inpatient services, and that omitted dose errors are the most frequently reported error type in this setting. Half of palliative inpatients who experience an opioid error will require a clinical intervention to manage or preclude harm.

Having determined opioid errors prevalence, patient impact and characteristics, it was essential to next identify opioid error contributory factors in specialist palliative care inpatient services. As mentioned previously, only two specialist palliative care inpatient services participated in this final retrospective review as reported opioid error contributory factors were not accessible from the remaining palliative care services in the PERISCOPE project. This chapter reports the results of a retrospective review of reported opioid error contributory factors (Study 4) undertaken in two specialist palliative care inpatient services in NSW.

5.2 Publication reference

This study was published in 2018 in the *Journal of Palliative Medicine*, a peer reviewed journal which covers medical, psychosocial, policy, and legal issues in end of life care. This chapter contains an edited version of the published study.

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). 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.

Journal of Palliative Medicine: Impact factor: 2.49

5.3 Overview

Medication safety with opioids is increasingly being recognised as a palliative care patient safety priority (Dietz et al., 2013; Dy, 2016; Heneka, Shaw, Azzi, & Phillips, 2018). Opioid errors account for one-third of all reported medication errors in specialist palliative care inpatient services (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b). Yet, little is known about the factors contributing to opioid errors in this specialist setting. Understanding the factors contributing to opioid errors is an essential first step in reducing error occurrence and resultant patient harm (Lawton et al., 2012).

System versus individual clinician factors

Factors contributing to medication errors can be broadly categorised into two groups: errors caused by systems factors, and errors due to individual clinician factors (McBride-Henry & Foureur, 2006). Few medication errors have a single cause, with most errors occurring as a result of differing combinations of individual, team, environmental and/or organisational factors (Institute of Medicine, 2007; Lawton et al., 2012; Reason, 2008). Adopting a systems approach to medication errors recognises that the health care settings in which clinicians work are, themselves, subject to latent failures, which manifest as error promoting conditions in the workplace (Lawton et al., 2012). Hence, focussing solely on the actions of the clinician (active failures) when errors occur will not prevent error recurrence, if, in fact, failings within the system itself are the issue (Lawton et al., 2012; McBride-Henry & Foureur, 2006).

Integral to a systems approach to patient safety is the use of incident reporting systems. These systems are widely used in healthcare to identify, investigate and respond to medication errors (Australian Commission on Safety and Quality in Health Care, 2017; Institute of Medicine, 2007; Kohn, Corrigan, & Donaldson, 2000; Smetzer & Cohen, 2007). While preliminary analysis of opioid error contributory factors in palliative care services across NSW has been undertaken (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018a), in almost half of incident reports (44%, n=63) an error contributory factor was not documented, limiting data analysis. This study sought to explore opioid error contributory factors reported over three years in

specialist palliative care inpatient services to better understand the individual and systems factors that may be contributing to opioid errors in this specialist setting.

5.4 Objective

The objective of this study was to identify opioid error contributory factors documented in clinical incident reports, in specialist palliative care inpatient services.

5.5 Methods

Study methods have been described in Chapter 3.

As previously mentioned, only two of the specialist palliative care inpatient services in the PERISCOPE project participated in this study (Service 1 and Service 3). Service 2 could not be included in this study as a rebuild of the services' incident management system prevented extraction of documented error contributory factors for the retrospective review period.

5.6 Results

5.6.1 Incident characteristics

A total of 78 opioid incidents met the inclusion criteria, with an equal number of incidents identified in each service (n=39), representing 1.7 reported opioid incidents per 1000 occupied bed days. The majority of incidents involved palliative care inpatients with cancer (86%, n=63), who had been admitted for symptom management (59%, n=43) and died during their admission (70%, n=51). The mean length of stay was 23.3 (\pm 20.0) days (Table 5.1).

Three quarters of incidents were due to administration errors (76%, n=59), with a smaller number of prescribing errors (19%, n=15) and near miss incidents (5%, n=4) reported (Table 5.2). The most common administration errors were omitted opioid doses (34%, n=20), accounting for a third of all administration errors, followed by wrong dose errors (17%, n=10). Prescribing errors were predominately related to medication charting errors (33%, n=5). Almost half of all errors occurred at times, which coincide with peak medication administration and/or change of shift, namely between: 08:00 to 08:59 (13%, n=10); 20:00 to 20:59 (13%, n=10); 14:00 to 14:59 (10%, n=8); or 22:00 to 22:59 (10%, n=8).

Table 5.1 Patient demographics: reported clinical incidents with opioids

Demographics		Service 1		Service 3		Total		P-value
		N=37	(100%)	N=36	(100%)	N=73	(100%)	
Gender	Male	20	(54.1)	18	(50.0)	38	(52.1)	0.816
	Female	17	(45.9)	18	(50.0)	35	(46.7)	
Age (years)	Mean (SD)	75.2	(±10.9)	69.1	(±10.6)	72.2	(±11.1)	0.018
	Median (IQR)	76.0	(13)	71.0	(18)	74.0	(18)	
Cancer diagnosis	Yes	29	(78.4)	34	(94.4)	63	(86.3)	0.085
	No	8	(21.6)	2	(5.6)	10 ^b	(13.7)	
Primary reason for admission	Symptom management	20	(54.1)	23	(63.9)	43	(58.9)	0.329
	End-of-life care	8	(21.6)	4	(11.1)	12	(16.4)	
	Pain control	5	(13.5)	6	(16.7)	11	(15.1)	
	Respite	2	(5.4)	3	(8.3)	5	(6.8)	
	Palliative rehab	2	(5.4)	0	0	2	(2.7)	
Length of stay (days)	Mean (SD)	18.9	(±14.1)	27.9	(±24.0)	23.3	(±20.0)	0.206*
	Median (IQR)	14.0	(21)	20.5	(26)	17.0	(23)	
Died during admission	Yes	22	(59.5)	29	(80.6)	51	(69.9)	0.074
	No	15	(40.5)	7	(19.4)	22	(30.1)	

^a Three patients experienced more than one incident during admission; two near miss incident were not linked to a specific patient in the incident report. ^b Other than cancer diagnosis: heart disease/failure (n=3), COPD (n=2), end stage renal disease (n=1), ischemia (n=1), motor neuron disease (n=1), pulmonary fibrosis (n=1), sepsis (n=1).

*Adjusted with age as covariate.

Collectively, two-thirds of reported incidents involved hydromorphone (37%, n=29) or morphine (28%, n=22). The remaining errors involved fentanyl (15%, n=12), oxycodone (9%, n=7), methadone (6%, n=5), and oxycodone/naloxone (4%, n=3). Administration errors occurred most frequently with hydromorphone (34%, n=20), morphine (25%, n=15), and fentanyl (20%, n=12), whereas the majority of prescribing errors (n=9, 60%) involved hydromorphone.

Table 5.2 Opioid incidents by problem type (N=78)

Problem type	Incident type	Service 1		Service 3		Total	
		N=39	(100%)	N=39	(100%)	N=78	(100%)
Administration	Total	26	(66.7)	33	(84.6)	59	(75.6)
	Omitted dose	10	(38.5)	10	(30.3)	20	(33.9)
	Wrong dose	4	(15.4)	6	(18.2)	10	(16.9)
	Transdermal patch – missing or not removed	-	-	7	(21.2)	7	(11.9)
	Wrong patient	3	(11.5)	2	(6.1)	5	(8.5)
	Wrong drug	4	(15.4)	-	-	4	(6.8)
	Wrong route	1	(3.8)	3	(9.1)	4	(6.8)
	Syringe driver error	1	(3.8)	2	(6.1)	3	(5.1)
	Incomplete administration	2	(7.7)	1	(3.0)	3	(5.1)
	Challenge – non-compliance with policy	-	-	2	(6.1)	2	(3.4)
	Clinical management	1	(3.8)	-	-	1	(1.7)
Prescribing	Total	11	(28.2)	4	(10.3)	15	(19.2)
	Medication charting	4	(36.4)	1	(25.0)	5	(33.3)
	Opioid conversion error	3	(27.3)	-	-	3	(20.0)
	Wrong dose	2	(18.2)	1	(25.0)	3	(20.0)
	Wrong drug	2	(18.2)	-	-	2	(13.3)
	Illegible order	-	-	1	(25.0)	1	(6.7)
	Delayed order	1	(14.3)	1	(25.0)	1	(6.7)
Near miss – arrested or interrupted sequence	Total	2	(5.1)	2	(5.1)	4	(5.2)
	Wrong patient	2	(100)	1	(50.0)	3	(75.0)
	Wrong dose	-	-	1	(50.0)	1	(25.0)
Total		39	(100)	39	(100)	78	(100)

5.6.2 Error contributory factors

Analysis of the 78 incident case report summaries identified four primary factor domains per the Yorkshire Contributory Factors Framework (Lawton et al., 2012): i) active failures, ii) individual factors, iii) communication systems, and iv) staff workload (Table 5.3). For a number of incidents (n=8), multiple contributory factor domains applied.

Active failures

Active failures were identified in two-thirds (n=53) of reported opioid incidents, of which 42% (n=22) were violations, specifically, non-compliance with medication management policies.

Active failures - violations

Non-compliance was identified in three policy areas: safe medication administration, second person checks prior to administration, and medication charting. Violations of safe medication administration policy (n=14) included: failure to correctly document opioid administrations, either in the patient's medication chart or the Schedule 8 drug register (n=5); and failure to check medication charts between and during shifts (n=4). Failure to fully implement a second person check prior to opioid administration was noted in four incidents, and led to wrong dose or wrong route errors, all of which resulted in opioid overdose. Non-compliance with medication ordering/prescribing policies was relatively infrequent (n=2), comprising medication charting errors only (Table 5.3). Two incidents reported challenges to practices when non-compliance with medication administration policy was identified. In both cases the nurse being challenged proceeded with the incorrect administration procedure and the challenging nurse reported the violation.

Active failures – slips, lapses and mistakes

Slips, lapses and mistakes collectively comprised half (51%, n=27) of active failures. Slips (n=11) and lapses (n=5) occurred more frequently during opioid administration processes (n=15, 94%); whereas, mistakes (n=11) were predominantly identified in the prescribing process (n=8, 73%). Slips resulted primarily in wrong dose (n=3) and wrong drug (n=2) errors. All lapses resulted in omitted doses, mainly during night shift (n=3). In all cases the incident report noted nursing staff could not recall why the dose had been omitted, they had simply forgotten to do so. Mistakes during prescribing comprised opioid conversion errors (n=3), wrong dose (n=3) and wrong drug (n=2) errors (Table 5.2).

Individual factors

Individual factors were identified as contributing factors by the notifier in 12% (n=9) of incidents. In one third of individual factors (n=3), staff workload also underpinned the incident. Inattention and/or distraction were the primary individual factors identified (n=4) followed by inexperience (n=3) and fatigue (n=2). All incidents linked with individual factors occurred during the opioid administration process.

Communication systems

Communication related factors were evident in 17% (n=13) of incidents, all of which resulted in opioid errors that reached the patient. Deficiencies were primarily identified in communication during clinical handover (n=8) and in written communication (n=5). Poor clinical handover caused dose omissions for multiple patients, which adversely impacted patients' previously well-managed pain. Failure of medical staff to document and/or handover changes to route of opioid administration also contributed to omitted doses. The interpretation of written opioid orders was affected by ambiguous written orders (n=3), e.g., '*chart with morphine order altered from 3mg to 4mg, (clinician) signature could be mistaken as 8 mg*', and poorly handwritten orders (n=2), which resulted in dose misinterpretation by the administering nurses.

Staff workload

Factors related to the work environment at the time of the incident, such as increased workload due to staffing levels and/or high unit workload, were explicitly identified in 10% (n=8) of incidents, predominantly resulting in omitted doses. Multiple incident reports cited the '*...busy nature of the ward*' as a contributing factor to opioid incidents, at times underpinning non-compliance with policy, such as failing to implement a two-person medication check. Increased workload contributed to opioid errors regardless of staff experience (Table 5.3).

Table 5.3 Opioid incident contributing factors categorised by Yorkshire Contributory Factors Framework domains (Lawton et al., 2012)

Contributory factor and domain (proximal to latent) (Lawton et al., 2012)	N =78 (100%)	Key subthemes	Incident example (from incident narrative)
Active failures (proximal)	53 (67.9)		
Violation	22 (41.5)	Non-compliance with medication management policy	<p>Administration error – missing transdermal patch: ‘Patient fentanyl 50mcg patch was due for change/administration. Nursing staff were unable to locate previous patch on patient for removal. The palliative care plan was signed to say that the patch was sighted on the morning shift on [date] but not the (previous) afternoon or night shift. Care plan states that fentanyl patches should be sighted on all shifts, had this occurred on the afternoon and night shifts the patch may have been identified as loose or missing sooner.’ Site Incident ID_18</p> <p>Prescribing error – order not ceased resulting in wrong dose: ‘Whilst checking patient’s syringe driver it was discovered that the contents of the syringe differed from the order given. There were two medication orders for a syringe driver, one had not been cancelled from the previous day when the next one was written. Order for [date] was hydromorphone 5mg, new order was hydromorphone 6mg. The correct medication was reloaded on [date]. Contents of incorrect syringe driver discarded. The Medical Officer has been advised to be sure to cancel orders when another is written.’ Site Incident ID_49</p>
Slip	11 (20.8)		<p>Administration error - wrong drug: ‘Hydromorphone 2 mg subcutaneous given at regular drug round instead of morphine 2 mg subcutaneous. I discussed this error with the two nurses involved. Both are experienced in palliative care nursing and both understand the difference in strength between the two drugs. Neither could offer an explanation for the error.’ Site Incident ID_42</p> <p>Prescribing error – wrong dose: ‘Rechart of medications done, oxycodone 40mg bd re-charted (unintentionally) as oxycodone 40mg d, with 0800 the only time entered. No oxycodone given at 2000 on [date].’ Site Incident ID_21</p>
Mistake	11 (20.8)		<p>Prescribing error – wrong dose: ‘Patient had been taking 4/24 9mg oral morphine, yesterday this was changed to bd 60mg MS Contin. Medical staff had made an error in calculating dosage when changing MS Contin, however, as the dosage was within the normal range of MS Contin given frequently in the unit this was not picked up, and the higher dose was given on two occasions.’ Site Incident ID_41</p>
Lapse	5 (9.4)		<p>Administration error – omitted dose: ‘During regular drug round, noted three doses of regular 4/24 10 mg oral morphine had not been given overnight. Nurses on shift</p>

Contributory factor and domain (proximal to latent) (Lawton et al., 2012)	N =78 (100%)	Key subthemes	Incident example (from incident narrative)
			<i>unable to explain or recall why dose omitted, other than agreeing that morphine not given.</i> Site Incident ID_56
Could not be determined	4 (7.5)		
Situational factors	9 (11.5)		
Individual factors	9 (100)	Inattention/distraction Inexperience Fatigue	Administration error – wrong drug: <i>'Regular subcutaneous morphine 10 mg due, subcutaneous hydromorphone 10 mg given instead. The incident was discussed with the nurses concerned who are both experienced palliative care nurses. They stated they had given several subcutaneous hydromorphone injections prior to this patient and did not pay sufficient attention to this (patient's medication order).'</i> Site Incident ID_43
Local working conditions	8 (10.3)		
Staff workload	8 (100)	Staffing levels at time of incident High unit workload	Administration error – omitted dose: <i>'Patient stated this morning that nocte Oxycontin 70 mg had not been administered. Oxycontin PM dose not signed for in medication chart. Patient requiring 1 x breakthrough subsequent AM. Reviewed roster - 3 x staff had taken sick leave, with 1 x hospice casual and 1 x permanent RN on the PM shift (sick leave replaced with 1 x agency RN & 1x agency EEN).'</i> Site Incident ID_31 Administration error – wrong drug: <i>'Suspected wrong drug used in subcutaneous infusion pump – morphine instead of fentanyl. Two regular staff involved in incident, neither staff member had a history of medication errors. Ward extremely busy at time of incident with more than normal requirements of breakthrough analgesia required for multiple patients.'</i> Site Incident ID_19
Applies across all factor types (proximal to latent)	13 (16.6)		
Communication systems	13 (100)	Poor clinical handover Written communication	Administration error – omitted dose: <i>'Patient seen by Medical team at 1600 [date]. Subcutaneous infusion pump (SCIP) ordered and team handed instruction over to afternoon shift nursing staff. Team noted in progress notes that patient was a high falls risk and should be transferred to different bed. Nursing staff failed to hand over instructions regarding SCIP order to Pt's accepting nursing staff and as a result the SCIP was not commenced. At 0200, night staff found the SCIP order and commenced same.'</i> Site Incident ID_34

Contributory factor and domain (proximal to latent) (Lawton et al., 2012)	N =78 (100%)	Key subthemes	Incident example (from incident narrative)
			<p>Administration error – transdermal patch not removed: <i>‘Patient presented to unit with fentanyl patches insitu. Medical review indicated that the patient was becoming intolerant to fentanyl and was rotated to another oral opioid, however nil documentation in progress notes of request to remove fentanyl patch noted. Found to still have patches on body when there was a verbal order to remove. On review of medication chart, order to remove patch was written over initial order, the modified request is unclear.’</i> Site Incident ID_20</p> <p>Administration error – wrong dose due to poorly written order: <i>‘(Nurse A) and I gave patient subcutaneous hydromorphone at 1000. When I went to give another dose later, Nurse B checking it with me said that the order was 5 mgs to 6 mgs. Nurse A and I had given 3mgs for the dose before instead of 5 mgs as we read the order as 3 mg. It was a new (as-required/PRN) re-chart and Nurse B knew it was 5 mg from the previous order, and the patient was generally having a 6 mg dose.’</i> Site Incident ID_39</p>
Multiple	8 (10.2)		
<ul style="list-style-type: none"> • Active failure: violation • Situational factors: individual factors • Local working conditions: staff workload 	8 (100)	Non-compliance with medication management policy Fatigue High unit workload	<p>Administration error – wrong dose: <i>‘At 2300 patient was given 20mg breakthrough of oxycodone instead of 10mg. The wrong strength of medication was taken out of the cupboard and used. The shift was busy and the medication was not checked correctly against the order as outlined in the policy. Was also night shift and staff were fatigued.’</i> Site Incident ID_30</p>

5.6.3 Error mitigating factors

A number of incidents (n=8) highlighted the nurses' role in preventing opioid errors. In one example, nurses intercepted a potential 10-fold overdose of hydromorphone before it was administered (Table 5.4). Nurses also instigated additional checks of opioid orders that were considered 'unusual' (for example, very high doses or doses that were not routinely ordered) by cross-referencing with what had been recorded as dispensed and administered in the drug register previously, before administering the opioid. Adherence to medication management policy, such as second person checks prior to administration, was noted in a small number of incident narratives (n=4) to have prevented errors from reaching the patient, or mitigated patient impact following an error (Table 5.4).

Table 5.4 Examples of error mitigating factors identified in incident narrative

Nurses' role in preventing opioid error:

'Patient was admitted to ward from [external service], according to the medical discharge summary and medication chart from [external service], patient was on regular hydromorphone 0.75 mg per oral q4h, however, regular hydromorphone 7.5 mg per oral q4h was ordered by doctor. Nurse A and I double checked the dose given at [external service] and advised doctor who corrected the order on the medication chart.' (Site Incident ID_54)

Adherence to medication management policy:

'When checking patient to locate the fentanyl patch on the afternoon shift, patch was found to be missing. Medication chart indicated that patch had been applied to Right side of patient's chest. On the morning shift (of the same day), per the patient's care plan, fentanyl patch had been checked and recorded to say it was insitu. Nurses contacted the morning shift who confirmed patch was insitu on patients right chest when showered that morning. Medical staff notified and a stat order given to replace fentanyl patch. Fentanyl patches are sighted and recorded on the patients care plan each shift this is an example of how well this process works, the patient didn't suffer unnecessary pain as the missing patch was identified quickly.' (Site Incident ID_04)

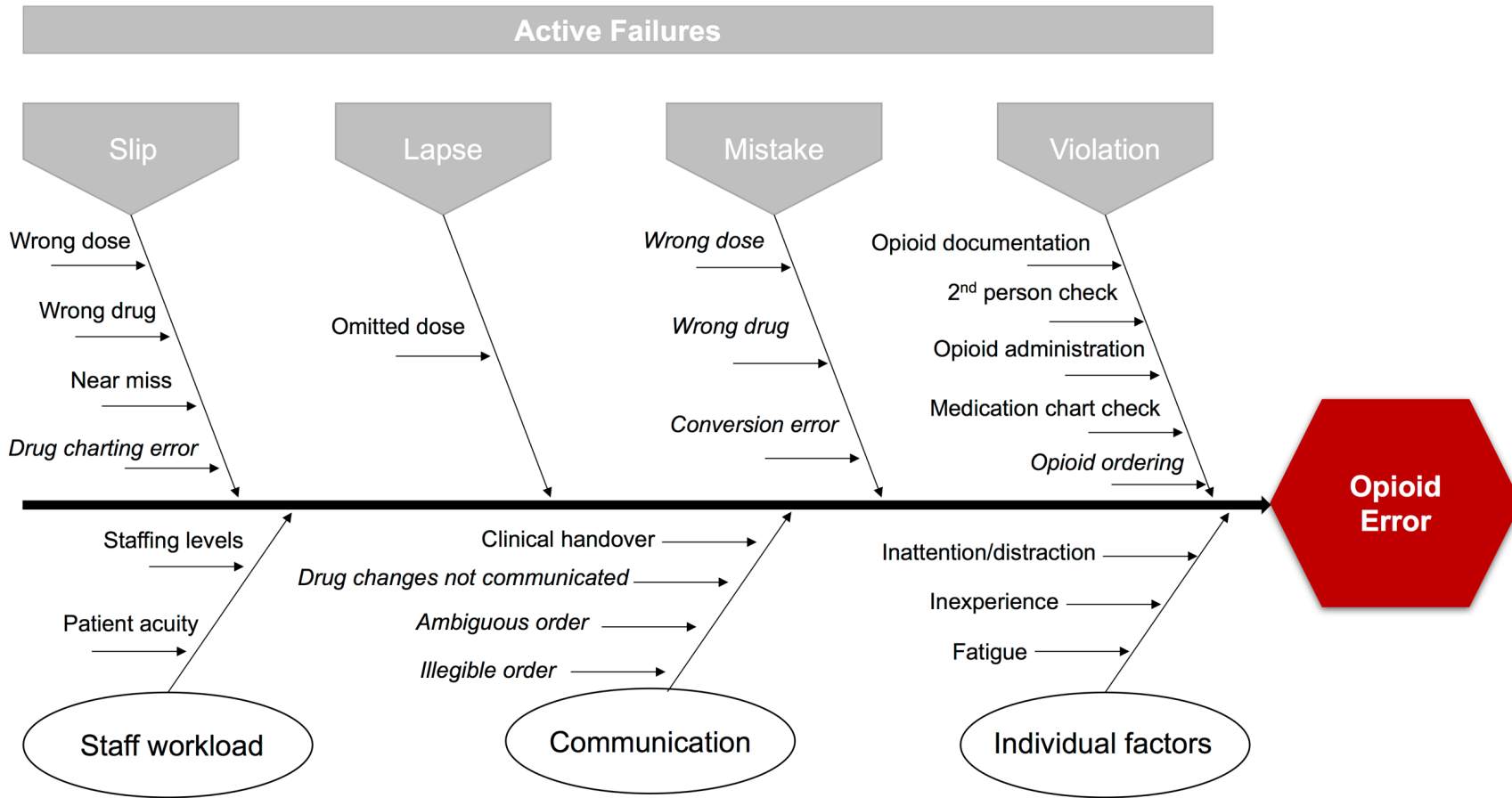
5.7 Discussion

This retrospective review has provided valuable insights into the characteristics of, and factors contributing to, reported opioid errors in specialist palliative care

inpatient services. Opioid errors were primarily reported during the administration process, versus the prescribing process, consistent with findings from other health care services (Carson, Jacob, & McQuillan, 2009; Desai et al., 2013; Dy, Shore, Hicks, & Morlock, 2007). While none of the errors resulted in serious adverse events or death, opioid errors impacted adversely on patients' symptom management, with almost half of the patients affected requiring clinical intervention as a direct consequence of an opioid error, largely due to omitted dose errors.

Local working conditions and clinical communication failures appear to play a role in facilitating opioid errors; however, the focus on contributing factors in this multi-incident analysis tended towards active failures (Figure 5.1). Active failures were most often due to violations, primarily during the administration process. Unlike slips and lapses, which are unintentional, violations are an intentional, behavioural choice (Reason, 1990). Given the number of opioid errors due to violations of medication management policy, understanding the factors that prompt non-compliance with policy, and strengthening adherence to these policies, is essential to reducing opioid errors and patient symptom burden in specialist palliative care services. Factors contributing to non-compliance with medication management policy are comprehensively explored in Chapters 6 and 8.

Slips and lapses (skill-based errors) were readily identified during the administration process; however, in-depth analysis was restricted, as information provided in the incident summary was often limited. Errors in prescribing were more likely to be knowledge-based (mistakes), than a result of a slip or lapse. However, whether the errors were due to rule-based, knowledge-based, or other mistakes (Reason, 1990), it could not be determined from the incident summary, as this information was not documented by the incident notifier. These deficiencies in the analysis highlight the need to further explore the systems factors and/or conditions that prompt slips, lapses and mistakes throughout the opioid delivery process. Given both services utilised paper-based medication charts, the implementation of digital health solutions, such as electronic medication management systems and clinical decision support tools, which have been shown to reduce these error types (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008), warrants consideration.



Italics denotes error in the prescribing process

Figure 5.1 Opioid error contributory factor categories (Lawton et al., 2012; Reason, 1990)

Despite the predominance of active failures, several latent or ‘systems’ factors contributed to opioid errors in this analysis. Similar to factors contributing to medication errors in other hospital settings (Brady, Malone, & Fleming, 2009; Parry, Barriball, & While, 2015; Santell, Hicks, McMeekin, & Cousins, 2003; Tully et al., 2009), a combination of sub-optimal communication systems and local working conditions, directly contributed to, and/or facilitated opioid errors in specialist palliative care services. Poor clinical communication has been associated with increased administration errors of all drug types (Parry et al., 2015), as has the quality of written prescriptions (Brady et al., 2009). Identifying opportunities to improve clinical handover, particularly when changes to opioid orders are made, and encouraging nurses to question and report ambiguous written opioid orders, are key considerations to address the clinical communication gaps identified in this study.

The relationship between clinical staff workload and rates of opioid error in specialist palliative care services warrants further investigation. Increased workload has been linked with higher rates of medication administration and prescribing errors in acute care settings (Dean, Schachter, Vincent, & Barber, 2002; Parry et al., 2015; Tully et al., 2009). In this analysis, high unit workload at the time of the incident was identified as an error contributing factor, reflecting the complexity of patient care and corresponding medication regimens in palliative care service provision (Australian Institute of Health and Welfare, 2014). However, it could not be conclusively determined if additional latent factors, such as management of staffing levels or patient scheduling, contributed to increased workload.

Latent organisational and/or external factors, such as physical environment, scheduling and bed management, and/or external policy context, did not appear to contribute to error producing conditions in this analysis. However, further investigation is required to confirm or refute this finding.

Beyond error contributing factors, the role of palliative care nurses in identifying and intercepting opioid errors was evident in the incidents reported. An important next step in addressing opioid errors in specialist palliative care services, is to better understand the factors that empower, or disempower, nurses to challenge opioid orders and practices they perceive to be incorrect. Also critical is an understanding of service safety culture, which cannot be ascertained from incident reports alone,

rather, requires input from clinicians and other stakeholders involved in patient and/or medication safety within specialist palliative care services.

5.7.1 Limitations

This analysis reports opioid errors from two specialist palliative care inpatient services in one Australian state and may not be generalisable. Medication incidents are consistently under-reported (Westbrook et al., 2015) and dependent on clinicians' recognition that an incident has occurred, and their willingness to report the incident (Australian Commission on Safety and Quality in Health Care and NSW Therapeutic Advisory Group Inc., 2013). Data analysis in this study was predicated on the incident narrative as reported by the incident notifier, which may not capture all relevant information pertaining to the incident (Vincent, 2007).

While this study has provided initial insights into factors contributing to opioid errors in specialist palliative care inpatient services, further research is necessary to confirm or refute the study findings.

5.8 Summary

In order to support safe opioid medication processes in specialist inpatient palliative care services, it is essential to better understand the factors and conditions that may give rise to error, beyond the errors made by clinicians at the front line of medication delivery. This study has provided a starting point from which further exploration of the conditions that may underpin active failures, and the latent factors impacting safe opioid delivery processes can be undertaken. An essential next step is identifying and understanding palliative care clinicians' and service managers' perceptions of factors contributing to opioid errors in their service, and the impact of service safety culture on opioid incident reporting.

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Chapter 6: Palliative care clinicians' perceptions of opioid error contributory factors in inpatient palliative care services

6.1 Chapter preamble

Chapter 5 explored reported opioid error contributory factors from clinical incident reports in two specialist palliative care inpatient services. This chapter reports the findings of a qualitative study undertaken with palliative care clinicians in the three NSW palliative care services that participated in Phase 1 of the PERISCOPE project.

6.2 Publication reference

This chapter was published in 2019 in *Palliative Medicine*, a peer reviewed scholarly journal targeting palliative care clinical practice, and contains an edited version of the published study exploring opioid error contributory factors from the perspective of palliative care clinicians (Appendix 1).

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). Clinicians' perceptions of opioid error contributing factors in inpatient palliative care services: A qualitative study. *Journal of Palliative Medicine*, 33(4) 430-444.

Palliative Medicine: Impact factor: 3.78; ISI JCR Ranking 2017: 15/94 (Health Care Sciences & Services), 24/154 (Medicine, General & Internal), 28/180 (Public, Environmental & Occupational Health).

6.3 Overview

Analysis of reported opioid errors in inpatient palliative care services suggests active failures are the major contributory factor to opioid errors in this service type (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018a; Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b). To fully understand the factors contributing to opioid errors in inpatient palliative care services and confirm or refute the findings from analysis of incident reports alone, it is essential to explore error contributory factors from the perspective of palliative care clinicians.

6.4 Objective

To explore palliative care clinicians' perceptions of the factors contributing to opioid errors in Australian specialist inpatient palliative care services.

6.5 Methods

Study methods have been described in Chapter 3.

Participants are reported using the following key (Study ID_Clinician Type_Classification_Age_Gender [M: Male; F: Female]), for example, ID01_Nurse_RN_35_F.

Clinician Classification key: CNC: Clinical Nurse Consultant; CNE: Clinical nurse educator; CNS: Clinical nurse specialist; CON: Consultant; EEN: Endorsed enrolled nurse; GM: Governance manager; INT: Intern; NUM: Nurse unit manager; REG: Registrar; RMO: Resident medical officer; RN: Registered nurse.

6.6 Findings

Qualitative data was collected from 58 clinicians who participated in one of eight focus groups, or a semi-structured interview (n=20), conducted between March 1 and November 30, 2017. The mean length of the focus groups was 41 (± 8) minutes and 34 (± 11) minutes for the semi-structured interviews. Participants comprised nurses (n=44), doctors (n=12), and pharmacists (n=2) (Table 6.1). The majority of participants were female (82%) and the mean age 42.3 (± 11.8) years. Almost two-thirds of participants (62%, n=36) had worked in the services' palliative care unit for three or more years, while half (50%, n=28) had worked in the palliative care specialty for six or more years. Six participants (medical n=2, nursing n=3, and pharmacy n=1) were unit medication safety working group members.

Table 6.1 Participant demographics (N=58)

Characteristic		N=58	(100%)
Gender	Female	50	(86.2)
	Male	8	(14.8)
Age (years)	Mean (SD)	42.3	(±11.8)
	Median (IQR)	41.0	(17)
Discipline	Nursing	44	(75.8)
	Medical	12	(20.8)
	Pharmacy	2	(3.4)
Classification	Endorsed enrolled nurse	3	(5.2)
	Registered nurse	29	(50.0)
	Clinical nurse educator	2	(3.4)
	Clinical nurse specialist	5	(8.6)
	Nurse unit manager	4	(6.9)
	Intern	1	(1.7)
	Senior resident medical officer	1	(1.7)
	Registrar – basic trainee	1	(1.7)
	Registrar – advanced trainee	1	(1.7)
	Consultant	8	(13.8)
	Pharmacist	2	(3.4)
	Governance manager	1	(1.7)
Years in discipline*	< 1 year	2	(3.4)
	1-2 years	6	(10.3)
	3-5 years	7	(12.1)
	6-10 years	9	(15.5)
	11-15 years	6	(10.3)
	16-20 years	10	(17.2)
	21 years or more	17	(29.3)
Years in palliative care*	< 1 year	10	(17.2)
	1-2 years	6	(10.3)
	3-5 years	12	(20.7)
	6-10 years	16	(27.6)
	11-15 years	6	(10.3)
	16-20 years	4	(6.9)
	21 years or more	3	(5.2)

Table 6.1 Participant demographics (N=58) (cont.)

Characteristic	N=58	(100%)	
Years in unit*	< 1 year	13	(22.4)
	1-2 years	9	(15.5)
	3-5 years	12	(20.7)
	6-10 years	14	(24.1)
	11-15 years	6	(10.3)
	16-20 years	2	(3.4)
	21 years or more	1	(1.7)
Highest qualification attained (n=47) (excludes medical)	Certificate in nursing	1	(2.1)
	Certificate IV	1	(2.1)
	Diploma	2	(4.2)
	Advanced diploma	2	(4.2)
	Bachelor degree	18	(37.5)
	Graduate certificate	11	(22.9)
	Master's degree	7	(14.6)
	PhD	1	(2.1)
Role in opioid delivery process	Administration	39	(67.2)
	Prescribing	11	(19.0)
	Quality and safety	3	(5.2)
	Dispensing	1	(1.7)
	Prescribing, quality and safety	1	(1.7)
	Dispensing, quality and safety, surveillance	1	(1.7)
	Administration, quality and safety	1	(1.7)
	Resident medical officer supervision	1	(1.7)
Frequency of opioid delivery (prescribing/ dispensing/ administration)*	Frequently (daily)	47	(81.0)
	Occasionally (several times per week)	4	(6.9)
	Rarely (several times per month)	5	(8.6)
	Never**	1	(1.7)
Employment status*	Full-time	35	(60.3)
	Part-time	21	(36.2)
	Causal	1	(1.7)
Primary shifts worked*	Day	25	(43.1)
	Afternoon	3	(5.2)
	Night	2	(3.4)
	Combination	27	(46.6)

* Missing data (n=1)

Six primary contributory factor domains aligning with the Yorkshire Contributory Factors Framework (Lawton et al., 2012), and 13 descriptive sub-themes, were identified during thematic content analysis:

1. Active failures

- Human error is inevitable
- Active failures and opioid underdosing

2. Situational factors

- Task characteristics - opioid preparation and delivery
- Individual factors - clinician inexperience
- Patient factors - palliative patient complexity

3. Local working conditions

- Skill mix
- Staff workload
- Palliative care workforce

4. Latent organisational factors – Physical environment

- Physical environment - drug preparation areas

5. Latent organisational factors – Support from central functions

- Support from central functions - care transitions
- Support from central functions - absence of pharmacy input
- Support from central functions - paper-based medication charts

6. Communication systems

- Clinical communication: written and verbal

Error contributory factors were identified by participants in every phase of opioid delivery. These contributory factors were perceived to create error producing conditions from the time of patient admission to the palliative care service (Figure 6.1).

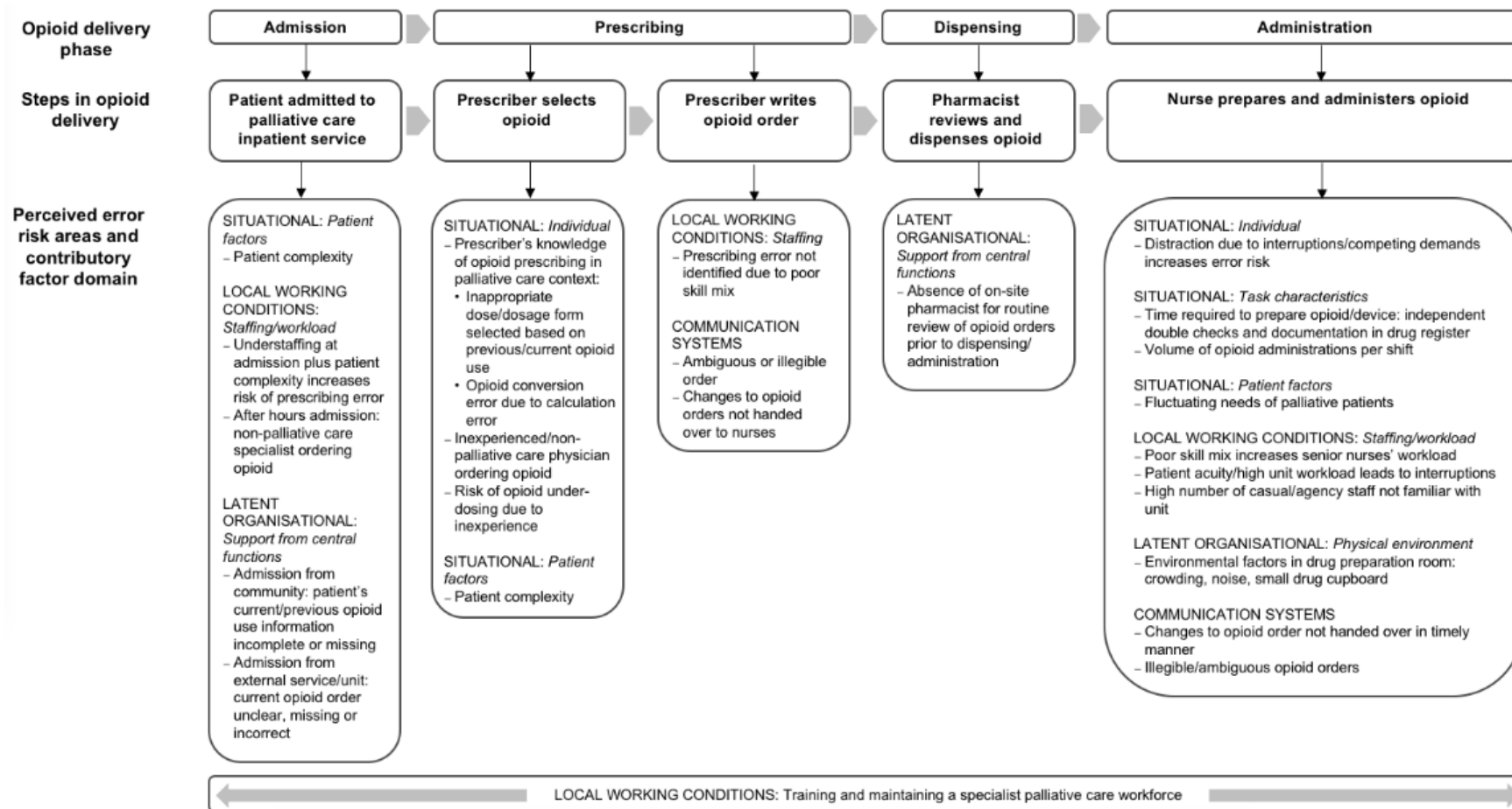


Figure 6.1 Perceived risk areas for opioid errors across the opioid delivery process in specialist palliative care inpatient services (adapted from Leape et al (1995), and corresponding contributory factor domain(s) (Lawton et al., 2012)

6.6.1 Active failures

Human error is inevitable

All participants had an in-depth awareness of the dangers associated with opioids, the potential for errors and harms, and a practical understanding of opioid management policies and practices:

Whenever I've tried to write up a protocol or a process about managing opioids...you recognise how many complex steps actually are involved...and decision making process, and...when you're doing it all the time, you just forget that actual high level of complexity (and) high risk clinical activity (ID22_Physician_CON_58_F).

However, participants readily acknowledged that active failures, such as slips, lapses and mistakes, were inevitable during opioid delivery:

We are aware that human error plays a part in medication administration, I don't think there's any way around that, completely; we can be as diligent as you want, but at times (errors will still happen) (ID47_Nurse_RN_22_F).

While serious opioid errors were perceived to be infrequent events, other opioid errors were perceived to occur more frequently:

I think serious opioid errors are uncommon. Minor issues of all descriptions are relatively common, and I think that that is partially related to the volume of opioid use here in the specialist inpatient unit (ID09_Physician_CON_56_F).

Considering the volume of opioid administrations in inpatient palliative care services; however, participants perceived that the incidence of opioid errors was comparatively low:

We roughly calculated an average of over 3000 opioid administrations in one month (in the unit), and there was one error... I'm not minimising the seriousness of a drug error,

any error is dangerous, and needs to be treated extremely seriously, but given the volume of (opioid) administrations in this unit (this is actually low) (ID23_Nurse_CNE_50_F).

Participants reflected on opioid error types they had observed in the palliative care unit, acknowledging that errors occurred across the medication delivery process:

The largest proportion probably come down to either a prescriber error at the time or an administration error (ID32_Physician_CON_48_M).

Participants suggested omitted opioid doses were potentially the most commonly occurring error:

...the missed dose is quite frequent...there is no doubt there's an element of human error that we haven't been able to eliminate entirely (ID32_Physician_CON_48_M).

Mistakes with opioid conversions, were also perceived to be common:

...opioid conversions are the huge danger area...and that happens many times when you're trying to stabilise pain, we're changing routes and we're changing drugs (ID22_Physician_CON_58_F).

Active failures and opioid underdosing

Participants acknowledged that arriving at the correct opioid dose was challenging, particularly with opioid conversions. While there was a perception that overdosing due to conversion error is problematic:

...you hear about the very dramatic (errors), I automatically think of hydromorphone/morphine and patients being overdosed (ID17_Nurse_RN_63_F);

Underdosing due to error was equally concerning:

They don't always choose too large (a dose), sometimes I think the dose is dangerously small...we had one case

recently where sub-cut morphine was changed to sub-cut hydromorphone, but in my estimation they gave about a 1/3 of the dose needed (ID55_Physician_REG_34_F).

It was suggested that under prescribing was not limited to mistakes with opioid conversions, but rather opioid underdosing due to error was perceived to be more widespread:

So we worry about the overdose, obviously, because that's a life threatening problem, but, patients underdosed is also a major problem (ID22_Physician_CON_58_F).

Despite the acknowledged frequency of active failures, participants involved in quality and safety oversight were highly cognisant of the differences between active failures and systems factors that contributed to opioid errors. It was evident all services actively sought to identify and address these systems factors:

I really do believe in improving systems rather than looking so much at people, because if systems are improved then people also improve automatically; so having very good governance systems, policies and procedures, leadership that provides that clinical supervision at the point of care, reporting errors as they happen and learning from those errors after a thorough investigation, without blaming people...that's the only way really that we can improve patient safety, and reduce the number of opioid errors (ID31_Nurse_GM_38_M).

6.6.2 Situational factors

Task characteristics – opioid preparation and delivery

Participants described a number of notable differences in opioid delivery in palliative care, compared to other care settings. They acknowledged the volume of opioid administrations is significantly higher in palliative care, compared to other inpatient settings, primarily due to the needs of the inpatient population:

I've probably given 15-20 (opioid administrations) today, that's one shift, one ward, no PRN, you can have shifts where you've given 30 (opioid administrations), you have one unstable patient who you've given six (opioid administrations) and you feel like you're constantly in front of the drug cupboard (ID49_Nurse_RN_30_F).

Participants also perceived the amount of time spent preparing and administering opioids each shift, compared to other units, was much greater. Preparing opioids for administration was seen to be time consuming, due to mandated double checking and documentation requirements. Additionally, the sheer volume of opioid administration in palliative care impacted on the time available to perform other duties:

We just said to each other the other day, 'How's your day?', she said, 'I didn't get out of the (drug) cupboard the whole shift' and I said, my shift was the same. And you'd hear it all the time ... because...you can literally be standing in that (drug) room and not leave. Yesterday, we did five (infusion pumps) in a row...and then the time doing the drug check, and all the breakthroughs...it's hours, hours, hours (ID38_Nurse_RN_41_F).

In addition to the time spent delivering opioids, participants also felt that substantially higher opioid doses are used in palliative care, compared to other care settings:

It's different, totally different, in another hospital you wouldn't use this dosage (of opioids) (ID01_Nurse_NUM_48_F).

For participants new to palliative care, a combination of the high frequency of opioid use and the high doses administered was a marked difference to their previous experience:

I've only been nursing for three months, and over in the medical ward they're really reluctant to give some opioids, and here, because it's a lot to do with pain management, I

don't think the nurses are as hesitant; the biggest thing I've noticed, was ... not just the frequency, but how much more (opioids) we use here, they're big, scary drugs, and here it's just like, 'no, give it' (ID44_Nurse_RN_25_F).

Similarly, for doctors, opioid prescribing in palliative care was perceived to differ from other specialties:

...previously I didn't really put people on morphine so much because there was no real indication to do so, and if people were already on morphine...they were generally under a pain team so I just let them manage the medication, and here, there's just a lot of experience (prescribing opioids) with most people on opioids (ID54_Physician_REG_27_F).

Hence, the time burden of opioid delivery methods and the complexity of specific routine tasks, such as opioid conversion, were perceived to directly contribute to opioid errors:

...when they're doing complicated dose conversions, not only are they converting from one variety of opioid to another, but they're converting the route or the formulation, so oral to subcutaneous, or long-acting to fourth hourly, or subcut morphine to hydromorphone, methadone rotations; the more the complexity of the dosing, the more chance there is for error, if there's multiple steps, is my experience (ID09_Physician_CON_56_F).

Compounding the risk of error during opioid preparation were frequent interruptions:

I think a point that's critical is when you're there at the drug cupboard and you're drawing something up and people are talking to you and everything is busy...you know you're trying to do your drug calculations, draw up the right dose, and it can be a really busy hub in that drug room...it's not even your nurses interrupting, it's the

doctors saying, I'm sorry, I can see you're doing your drugs but...but...or there's a patient being taken for a scan and the wardsman needs something...and it only takes that really quick thing for you to pick the wrong thing, for something to happen (ID02_Nurse_RN_35_F).

However, participants were generally pragmatic about interruptions and acknowledged that was part of the nature of the palliative care unit:

Things happen and they can't just wait half an hour for us to finish the drug round, we get interrupted all the time and we just have to deal with it, that's what I think anyway, the reality of it (ID17_Nurse_RN_63_F).

Individual factors – clinician inexperience

Clinician inexperience was perceived to be a key contributing factor to opioid errors. During opioid selection and prescribing there was a perception that opioid errors occur edmore frequently when junior doctors were responsible for prescribing, especially if more experienced clinicians are not available to guide them:

When we have to make after hours calls...(the doctors) often they're going by what we (nurses) see...if it's a more junior doctor, or a doctor from (another service), there could be so much room for an error there (ID20_Nurse_RN_28_F).

The risk of a wrong dose error was thought to be compounded when prescribers are: ‘unfamiliar with opioid dosing and with opioid conversions between types of opioids’ (ID32_Physician), as many non-palliative care doctors or junior doctors are:

I think we've got to realise that we have a lot of new and young registrars that haven't seen, you know, someone on fentanyl and hydromorphone and methadone, and then being converted to a syringe driver... (ID11_Nurse_RN_62_F).

During opioid administration, participants reflected that working with less experienced palliative care nurses, particularly casual or agency staff, was perceived to amplify the error risk:

I think...when we have casual (staff)...or people who aren't familiar (with opioids)...there just seem to be a number of errors if we use inexperienced staff
(ID48_Nurse_RN_44_F).

Nurses new to the specialty noted the considerable learning curve with opioids in the palliative care context, particularly with dosage forms: ‘*when I just started, I didn't know the long acting and the short acting thing*’ (ID7_Nurse), and similar sounding drug names:

The OxyNorm's, the oxycodone's, the Endone's...and MS Contin's...and they're all similar dosages, and I try to be very, very careful and triple check, quadruple check exactly what we're giving (ID12_Nurse_RN_62_M).

Less experienced nurses also reflected that they were not yet confident identifying prescribing errors and were concerned this could result in errors that reached the patient:

But for someone like me (new graduate), that's scary, because I have seen it getting picked up, and for someone that's less experienced, I find that very scary that, that there's a potential for an error there through my lack of knowledge (ID20_Nurse_RN_28_F).

Patient factors

Increasingly, palliative patients were presenting with complex conditions and medication regimens, and, when this was coupled with inexperienced clinicians, opioid errors were perceived to be more likely to occur:

...the patient that is being looked after in palliative care, is very complex with a lot of co-morbidities...and

polypharmacy...it leaves the more junior staff in a very difficult situation because they have to provide care, and when they do that, often times this is where errors tend to happen (ID42_Nurse_RN_55_F).

The fluctuating needs of palliative patients were also noted to add to error risk because of the resultant increased workload:

I think sometimes when the ward is very busy, so you've got 17 to 20 patients, and there's a lot of unstable patients, or deteriorating patients that need a lot of breakthroughs, the doctors are changing orders frequently, you have anxious families, that all adds up...and you could really do with extra staff numbers then (ID11_Nurse_RN_62_F).

6.6.3 Local working conditions

Skill mix

Clinician skill mix, (i.e., the balance in staffing levels based on qualifications, levels of competence, abilities, knowledge and experience (Cahill, 1995)), was one of the most frequently reported factors perceived to contribute to opioid errors:

If an inexperienced doctor charts a wrong dose, an inexperienced nurse is far less likely to pick that up, and sometimes the safeguard is having experienced nurses, so if there's a combination of inexperienced junior doctors and inexperienced nursing staff, I think that is where the potential for error is high (ID53R_Physician_RMO_27).

Poor nursing skill mix was perceived to increase the number of patients and volume of opioid administrations that senior nurses had to manage. This in turn was thought to increase the risk of error, primarily because of the extra time pressure and workload put on senior nurses:

For me, when you have a good skill mix, nothing is going to go wrong, even though it's chaotic, even though it's really busy, you've got the good staff on, you can handle it. If you

are the only senior (nurse), you have to make the decisions. You have to help the new staff, the new grad, you have to guide them, help them to even (administer). You have to check not only twice, you have to check five times to make sure they're all on the right track. That is time consuming, and takes away your energy as well, that's how errors can come easily (ID60_Nurse_RN_60_F).

Staff workload

During the admissions process, clinician workload was raised as a risk factor for prescribing error, due to the impact of understaffing on the time required to undertake a comprehensive patient assessment:

I think most of the prescribing errors happen at admission - they're (palliative care medical team) understaffed for admissions and the complexity of our patients has increased, the constant turnover means complex patients are being admitted daily and their (clinicians) proportional workload to manage those admissions I think is too high (ID21_Physician_CON_41_F).

Unit workload generally was identified as a major factor contributing to error:

...of course, it's workload that could be contributing to errors, time is a big contribution to errors (ID61_Nurse_RN_35_F).

In addition to the amount of time spent preparing and administering opioids and attending to patient care, participants noted the non-clinical tasks that comprised their workload each shift, and the impact that had on error risk:

What's expected of our nurses on a day to day basis, in addition to what they're doing for the patients, (is) they really do have to have that shifting focus and then complete concentration on a regular level, I think we need to help them more to be able to do that work safely, I think they're

inundated now with paperwork and tasks that sometimes takes the focus off the care of the patient, and the concentration required with some of the medications (opioids) (ID41_Pharmacist_42_F).

Management of staff and staffing levels

A lack of permanent fulltime palliative care nursing workforce was a perceived error risk, with service managers highlighting the challenge of training and maintaining an adequately specialised and experienced palliative care workforce:

It's hard to keep a (palliative care) workforce that is very agile, that is very specialised; so you might find there are two nurses who are specialised per shift and the workloads are such that those two nurses are caring a lot in terms of supporting the junior staff as well as supporting the patients... often times this is where errors tend to happen...it's probably really around skilling (in) this space; it's hard with the changing population and with the (palliative) patient that is very, very complex...the doctors, they come, they make errors, and then you see how they develop, after two, three months they are so good you don't hear (about) any errors and then they go, and then it starts again, it's sort of like a rollercoaster (ID31_Nurse_GM_38_M).

6.6.4 Latent organisational factors

Physical environment

The risk of error during opioid preparation was perceived to be compounded by environmental aspects of the drug room, such as the size of the drug room, which participants reported added to interruptions and/or distraction:

In our treatment room it gets super busy and super noisy, so when you're trying to draw up a complicated (subcutaneous infusion pump), or even you're just trying to move because

someone's got to get into the cupboard, you can (make an error) (ID45_Nurse_RN_29_F).

Support from central functions – care transitions

Multiple factors were perceived to increase the risk of opioid error when a patient was first admitted to the inpatient palliative care service, particularly when transitioning from the community into the inpatient setting:

I think (there's a risk) in the transition from community to inpatient, because there may be more than one prescriber of the opioid and what the actual patient has been taking may be different from what's being prescribed...and that there's not a uniform medication list between GP, the community team, and the inpatient team necessarily (ID48_Nurse_RN_44_F).

As ready access to information on patients' previous and current opioid intake was not always available, participants reflected on how these missing details adversely impacted on the team admission assessment of the patient:

There's an area of restraint of not being able to necessarily have all of the information that you need to make that assessment (ID32_Physician_CON_48_M).

Similarly, information for patients being admitted from another health service may be missing or incorrect:

There might be a transcription error on documents the patient brings with them or the patient might not know the dose that they've been on...I think errors can happen that way as well (ID56_Physician_INT_28_M).

In addition, participants observed opioid doses for patients coming from other, non-palliative care services were often incorrect:

It's quite often that somebody gets admitted and the (opioid) dose that they're on is definitely not the correct dose (ID58_Nurse_CNS_29_F).

Support from central functions – absence of pharmacy input

Pharmacist participants acknowledged that palliative patients were increasingly presenting with less common opioid combinations, which made error identification challenging, even for experienced clinicians:

I think we're seeing more people with unusual combinations (of opioids on admission)...we're seeing people who might have MS Contin or Dilaudid...it's quite common now for people to be on a fentanyl patch and Dilaudid and that's a real error prone combination I think because, depending on experience, some nurses will recognise whether a breakthrough is in the right ball park for the medication, but there's very few that would recognise whether the fentanyl and the Dilaudid strength are right... (ID41_Pharmacist_42_F).

Participants in services without access to a dedicated palliative care pharmacist perceived that the lack of routine pharmacist review, especially at admission, contributed to error:

They used to have a process whereby all admissions (orders) were checked and that is now an ad hoc process...so that, I think, is a big safety gap (ID21_Physician_CON_41_F).

Also, a lack of routine pharmacy review of orders on the ward prior to dispensing was perceived to contribute to error:

We don't have enough clinical pharmacists on the ward so they don't come to review the charts frequently, that is a concern...I would like to see them review charts at least twice a week, they can review the charting, route, the generic name...you know if the medication route is wrong but no-one checks, or the doctor charted for bd but only put down one time in the chart (ID01_Nurse_NUM_48_F).

Support from central functions – paper-based medication charts

Participants who had worked with both paper-based medication charts and electronic medication management systems, perceived paper-based charts directly contributed to omitted dose errors:

I worked in (other palliative care service) and the main issue there was we missed lots of drug. And that was because of the paper chart. Since I came here (electronic medication chart), I can't think of going back to a paper chart...because it (the electronic chart) alerts us all the time. We can't miss it. (ID60_Nurse_RN_60_F)

6.6.5 General factors: Communication systems, and safety culture

Effective clinical communication was considered an essential foundation of patient safety:

Communication between doctors and nurses, and the way that happens, is incredibly important, to set up the relationship that's going to be safe for the patients, it's critical (ID22_Physician_CON_58_F).

However, poor inter-professional communication, especially when patients' opioid orders were changed, contributed to delayed or omitted opioid doses:

So if anything for a patient changes, as a nurse, our job is to then let the doctor know that this has just changed, the patient's in more pain, or whatever. It'd be really nice if that was reciprocated, in terms of, they've charted a new drug for a patient, especially an opioid, can you let us know that that has been charted? Just a quick tap on the shoulder and say "Hey, we've just charted this" (ID13_Nurse_RN_45_F).

Poor written communication, particularly doctors' opioid orders, was another factor perceived to contribute to error. While 'prescribing in illegible writing'

(ID41_Nurse) was relatively commonly identified, nurses reported they were confident asking for clarification before administering the opioid:

We're generally pretty good in going and saying: 'Can you rewrite this again? We can't read it!'

(ID44_Nurse_RN_29_F).

More problematic were orders that had not been correctly re-charted or clearly ceased:

(Right now) there's one (chart)...that has everything on that page ceased, and not a nice, neat, it's, you know, scribble-scribble-scribble...at first glance at that chart, you go, 'that's all ceased'...and right in the middle of it, there's an oxycontin. That doesn't give us much of a chance, does it?

(ID45_Nurse_RN_29_F).

Of note, safety culture was not identified as an error contributory factor, with participants overwhelmingly reporting the existence of a strong, non-punitive opioid safety culture:

I think it's supportive, which is really good, because you can get quite anxious when you've (made an error) and you feel terrible. I think all the nurses support each other and certainly management supports us as all, obviously. Things have to be reported, that's just the way it's got to be. There has to be some accountability and some monitoring, officially. That's how it is (ID43_Nurse_RN_48_F).

6.7 Discussion

This study has identified a range of systems factors that contribute to opioid errors from the perspective of palliative care clinicians across multiple disciplines, which have not been previously reported. While factors contributing to medication errors in acute care are well understood (Brady, Malone, & Fleming, 2009; Lawton et al., 2012; McBride-Henry & Foureur, 2006), error contributory factors in the specialist

palliative care inpatient services are an emerging area of research (Heneka et al., 2018b).

6.7.1 Active failures

Active failures were acknowledged as contributing to opioid errors in inpatient palliative care, due predominantly to lapses resulting in omitted dose errors, and mistakes in opioid conversion and selection. Interestingly, participants reported that active failures were more likely to result in opioid underdose than overdose. The concept of opioid underdosing, as a result of omitted dose errors, and other opioid error types, has been recently highlighted as a potential area of concern in specialist palliative care inpatient services (Heneka et al., 2018a; Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018c). While it is estimated over half (52%) of patients in acute care will experience an opioid overdose as a result of opioid error (Dy, Shore, Hicks, & Morlock, 2007), a recent retrospective review study found that 57% of palliative inpatients received an opioid underdose as a direct result of opioid error (Heneka et al., 2018c), confirming the perceptions of clinicians in this study.

6.7.2 Situational factors

Most palliative care inpatients have at least one, if not multiple, opioid orders, including regular and PRN opioid orders (Australian Institute of Health and Welfare, 2018). The opioid delivery process is complex and time consuming, with mandated double checking and strict documentation requirements for each opioid administration (Ministry of Health NSW, 2013, 2015). There are multiple opportunities for errors at each step of the process; hence, it is unsurprising that the process of opioid delivery itself was identified as a major error contributory factor.

Opioid delivery in the inpatient palliative care setting differs from other health care settings in that large volumes of opioids are administered each day, often at considerably higher doses, and, increasingly, in combination with other opioids rarely seen in other settings. The high volume of opioid use may explain why opioid errors in palliative care services are reported at almost triple the rate of opioid errors in other health care settings (Carson, Jacob, & McQuillan, 2009; Desai et al., 2013; Heneka et al., 2018c).

Opioid delivery also routinely requires clinicians to undertake complex calculations when converting between opioids, including between long and short acting formulations and routes of administration, all of which are prone to error (Webster & Fine, 2012). Hence, clinician inexperience was identified as an error contributory factor in this study. In the acute care setting, factors such as workload, skill mix/supervision and clinician knowledge have been identified as critical factors contributing to prescribing errors by junior doctors (Coombes, Stowasser, Coombes, & Mitchell, 2008). Similarly, in this study the risk of opioid prescribing errors by junior doctors was considered heightened if more experienced clinicians were not available to review the opioid order.

Irrespective of care setting or drug type, medication administration places complex, and often competing, demands on the administering nurse (Jennings, Sandelowski, & Mark, 2011; Pirinen et al., 2015). Nurses are required to: adhere to multiple medication administration policies (Baker, 1997; Jennings et al., 2011), effectively manage the administration process and the medications themselves (Jennings et al., 2011; Pirinen et al., 2015), attend to patient care responsibilities (Barker, Flynn, Pepper, Bates, & Mikeal, 2002; Huynh et al., 2016; Jennings et al., 2011), navigate drug delivery devices, and the physical environment of the unit (e.g., size and location of the drug room) (Jennings et al., 2011). As such, medication administration is not a discreet process with a defined start and end point, rather, is inseparable from other tasks undertaken in the multifaceted nursing role (Jennings et al., 2011).

Clinicians in this study, especially nurses, confirmed this finding, acknowledging that the bulk of their shift is spent attending *primarily* to opioid administration. For palliative care nurses, managing interruptions and competing demands was seen as an inevitable but routine part of opioid preparation, determined by: the fluctuating needs of the patient population; the additional time burden of opioid preparation compared to other, less high-risk medicines; and increased workload due to issues with nursing staffing and/or skill mix ratios. Quantifying the time burden of opioid delivery in the palliative care inpatient context may help inform management of staffing levels, as time spent on medication administration is frequently underestimated (Jennings, Sandelowski, & Mark).

The phenomena of ‘interruptions’ during medication administration are thought to be inevitable, precisely because medication administration does not have a clearly delineated start and end-point (Jennings et al., 2011). As interruptions increase the risk of medication error (Westbrook, Woods, Rob, Dunsmuir, & Day, 2010), reducing them is a patient safety priority. However, as noted by the clinicians in this study, the feasibility of reducing interruptions in a palliative care unit is challenging, given the nature of the workflow, and will most likely require a strategy that considers the multiple systems factors at play, such as: the physical environment of the drug preparation area, workload, patient acuity, and skill mix (Jennings et al., 2011).

6.7.3 Local working conditions

The challenge of training and maintaining a specialist palliative care workforce was noted to affect both staff management and workload. Sub-optimal skill mix was perceived to directly increase workload, particularly for more experienced clinicians, and increase the risk of error. This was most evident for experienced palliative care nurses who, in addition to managing their own patient load, were often also ensuring new graduates, agency, or casual staff adhered to the mandated opioid checking processes. Multiple studies report associations between increased medication administration errors and: poor skill mix (McGillis Hall, Doran, & Pink, 2004), higher patient to nurse ratios (Aiken et al., 2011; Valentin et al., 2009), clinician workload (McBride-Henry & Foureur, 2006; Parry, Barriball, & While, 2015), and perceived adequacy of staffing (McKeon Christine, Fogarty Gerard, & Hegney Desley, 2008). Given these findings, clinician rostering should ensure that there is an optimal balance of experienced team members rostered on each shift to support and mentor less experienced palliative care clinicians (Flynn & McKeown, 2009).

The few studies that have explored the relationship between skill mix/workload and medication errors in the palliative care setting are limited to exploration of staff stressors and wellbeing (Ablett & Jones, 2007; Peters et al., 2012). These studies confirm that high workloads are commonplace in palliative care service delivery, and are a major contributor to clinician stress (Ablett & Jones, 2007; Peters et al., 2012). Better understanding of the impact of repetitive, high-risk opioid delivery and

resultant workload on palliative care clinicians' stress levels is important, particularly in terms of building a sustainable palliative care workforce.

6.7.4 Latent organisational factors

The absence of a standardised medication management system, between the inpatient and community service, and the patient's general practitioner and/or specialist(s), was seen as a barrier to undertaking an accurate medication history on admission, which increased the risk of prescribing error. Incomplete medication histories on admission account for up to two-thirds (67%) of prescribing errors in acute care (Tam et al., 2005); however, data in the palliative care service context could not be identified.

The absence of an on-site pharmacist was also perceived to increase the risk of prescribing errors, as, although nurses routinely check opioid orders for errors prior to administration, review by the on-site pharmacist was seen as an additional, high-risk medicine safety check. A review of clinical incident reports identified palliative care services without on-site clinical pharmacist reported a proportionally greater number of prescribing errors, compared to those with on-site pharmacy support (Heneka et al., 2018c). The palliative care pharmacist's role in reducing opioid errors includes anticipating patients' opioid needs during transitions of care, opioid order review and reconciliation, safe use of opioids in the management of pain, and clinician education (Herndon et al., 2016; Kuruvilla, Weeks, Eastman, & George, 2018). Clinical pharmacy support in palliative care has been shown to contribute favourably to patient outcomes (Lee & McPherson, 2006) and palliative care service delivery (Atayee, Best, & Daniels, 2008; Austwick, Brown, Goodyear, & Brooks, 2002). As such, consideration of a dedicated pharmacist role in specialist palliative care services is warranted to reduce opioid prescribing errors and support safe opioid delivery.

In the earlier study of opioid error characteristics in specialist palliative care inpatient services it was suggested the use of paper-based medication charts, versus electronic medication management systems, may be contributing to the substantial burden of omitted dose errors reported in this setting (Heneka et al., 2018c). Clinicians in this study confirmed this finding, highlighting the electronic medication management system alerts them to outstanding doses and prompts opioid administration. Indeed,

in the single specialist palliative care inpatient services using an electronic medication management system in the aforementioned study, there were nil reported omitted dose errors in a two year review period (Heneka et al., 2018c).

6.7.5 Communication systems

Communication system factors contributing to opioid error in this study were predominantly identified by nurses and related to clinical communication shortfalls on the part of the ordering physician. While poor written communication was generally promptly rectified, failure to hand over changes to patients' opioid orders in a timely manner was reported to directly lead to error. Written and oral clinical communication deficits have been well documented as factors contributing to medication errors in acute and aged care settings (Parry et al., 2015). A progressive shift to electronic medication management systems will go some way to alleviating written communication errors, as errors due to illegible or ambiguous orders are effectively eliminated compared to handwritten orders (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008). Again, there is scant research on the relationship between clinical communication and medication errors in the palliative care context; however, palliative care clinicians have identified poor interdisciplinary communication and unclear medication documentation as relatively common causes of error in palliative care services (Dietz et al., 2013; Dietz, Plog, Jox, & Schulz, 2014).

6.7.6 Error protective factors

The presence of a strong, non-punitive service safety culture was evident in this study, and appears to be a protective, rather than error contributory factor in the participating specialist palliative care inpatient settings. Gaining a deeper understanding of the elements that contribute to the creation of a strong opioid/medication safety culture in palliative care warrants further exploration.

6.8 Strengths and limitations

A key strength of this study was the number of participants from multiple disciplines who were actively involved in opioid delivery and/or medication safety oversight, allowing data saturation to be reached. A limitation of this study is that the analysis was confined to the perceptions of factors contributing to opioid errors in specialist

inpatient palliative care services, and, as such, may not be generalisable to other palliative care settings, or other services routinely using opioids.

6.9 Summary

There are multiple systems factors, beyond active failures, that contribute to opioid errors in specialist inpatient palliative care services, which must be considered in any quality and safety initiatives targeting safe opioid delivery in this service type.

Adequate staffing and skill mix are critical to ensure clinicians can manage high workloads and safely navigate opioid delivery. Acknowledging that palliative care nurses spend a substantial amount of time engaged in opioid preparation, and are simultaneously managing multiple competing demands when handling high-risk opioids, is an essential medication safety consideration and a workforce issue.

Further exploration of opioid safety culture is also warranted to better understand the cultural factors supporting and promoting safe opioid delivery in specialist palliative care services.

6.11 References

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Chapter 7: Palliative care clinicians' perceptions of opioid error mitigating factors in specialist palliative care inpatient services

7.1 Chapter preamble

Chapter 6 reported the findings of a qualitative study which explored palliative care clinicians' perceptions of factors contributing to opioid errors. This chapter reports the second half of the data and examines clinicians' perceptions of opioid error mitigating factors in specialist palliative care inpatient services.

This chapter has been accepted by *Collegian: The Australian Journal of Nursing Practice, Scholarship and Research*, for the 2019 special palliative care issue:

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7.2 Overview

Patient safety underpins high quality care across all healthcare settings (Kohn, Corrigan, & Donaldson, 2000). In the palliative care context, patient's fragility, comorbidities, significant symptom burden, and the need for input from multiple healthcare providers, places them at greater risk of exposure to and harm from medical error (Dy, 2016; Myers & Lynn, 2001). The consequences of medical error can impede end-of-life goals and provision of comfort measures, considerably adding to the distress and suffering of patients and their caregivers (Casarett, Spence, Clark, Shield, & Teno, 2012; Dy, 2016). As a result the importance of, and focus on, patient safety in palliative care has increased (Casarett et al., 2012; Dietz, Borasio, Schneider, & Jox, 2010).

The timely and effective treatment of pain is a palliative patient safety priority (Dy, 2016; Shekelle et al., 2013). Opioids are routinely used in palliative care services for the management of pain and other symptoms (Australian Adult Cancer Pain Management Guideline Working Party, 2014; Therapeutic Guidelines Limited, 2016). Increasingly, opioid safety in the palliative care inpatient setting is being

identified as a patient safety priority (Dietz et al., 2010; Dy, 2016; Heneka, Shaw, Azzi, & Phillips, 2018a). Compared to other healthcare settings, opioid delivery for the vast majority of palliative care patients includes: multiple opioid orders and formulations, including regular and PRN orders, often administered via different routes (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2019). There is a higher frequency of opioid delivery in inpatient palliative care services than in the acute care setting, with considerably higher opioid doses also used compared to all other healthcare settings (Australian Institute of Health and Welfare, 2018; Heneka et al., 2019).

Despite the high frequency and high doses of opioids used in specialist palliative care inpatient services, serious patient harm is exceedingly rare (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b; Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018d). Additionally, palliative care clinicians perceive the prevalence of opioid errors in specialist palliative care inpatient services is low, given the high frequency of opioid delivery in this setting. While factors contributing to opioid errors in inpatient palliative care services are becoming better understood (Heneka et al., 2018b; Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018c; Heneka et al., 2019), little is known about the factors that mitigate opioid errors in these services. Identifying opioid error mitigating factors is essential to better understand how to best support safe opioid delivery in specialist palliative care inpatient services.

7.3 Objectives

The objectives of this study were to explore palliative care clinicians' perceptions of factors that mitigate opioid errors in specialist palliative care inpatient services .

7.4 Methods

Study methods have been described in Chapter 3.

As in Chapter 6, participants are reported using the following key (Study ID_Clinician Type_Classification_Age_Gender [M: Male; F: Female]), for example, ID01_Nurse_RN_35_F.

Clinician Classification key: CNC: Clinical Nurse Consultant; CNE: Clinical nurse educator; CNS: Clinical nurse specialist; CON: Consultant; EEN: Endorsed enrolled

nurse; GM: Governance manager; INT: Intern; NUM: Nurse unit manager; REG: Registrar; RMO: Resident medical officer; RN: Registered nurse.

7.5 Findings

The participant demographics are reported in Chapter 6. Three primary themes and four subthemes related to opioid error mitigating factors were identified in this study:

1. A positive safety culture underpins safe opioid delivery

- Clear expectations regarding safe opioid delivery
- Empowering clinicians to practise safely
- Working as a team
- Promoting a non-punitive approach to error

2. Opioid error reporting is encouraged and expected

- Rectify or report?
- Reflecting and learning from error

3. Education is empowering

4. Sustaining an opioid safety culture requires ongoing targeted attention

7.5.1 A positive safety culture underpins safe opioid delivery

Participants overwhelmingly described the existence of a positive opioid safety culture in their services, which they perceived to be fundamental to preventing opioid errors and supporting safe opioid delivery. Opioid safety culture was linked to four central factors: i) clearly communicated and consistent expectations from management regarding safe opioid delivery; ii) a culture of empowering clinicians to practice safely; iii) interdisciplinary teamwork; and, iv) establishing and promoting a non-punitive error reporting culture.

Clear expectations regarding safe opioid delivery

For unit managers, acknowledging the high volume use of high-risk opioids, and privileging the importance of consistent, safe, opioid delivery, underpinned the services' approach to opioid safety:

We've said that because we do so many (opioids) instead of expecting that we would, as a result of that, have a high rate (of errors), we've said...we should be experts at it and

we should be the best at it. Which is another change in cultural focus. I think we've continued to raise the profile in suggesting that it's (opioid delivery) a really pivotal part of what we do. I think it's that culture of, 'this is important' (ID33_Nurse_NUM_39_F).

Participants reflected on the importance of 'a top down approach', with management taking a lead role to promote awareness of opioid delivery policies, and consistently communicating and enforcing their expectations regarding safe opioid delivery. Participants also noted that the consistent messages from management regarding how opioid delivery policy was implemented, was vital to upholding safe opioid practices within the unit:

For me [the safety culture] is from the top down, definitely management has a huge influence on the culture...everyone is aware of what is going on and wants to be sure that the right thing is being done...(it's) all consistent, that's what I've noticed, everybody does it the same; it's not just one person that does it this way, everyone is doing it the same, that's what I think is great (ID47_Nurse_RN_26_F).

The ever-present risk and potential consequences of an error during opioid preparation was readily identified by participants. Participants stressed that, fundamental to safe opioid delivery, was the importance of respecting both the opioids, and the opioid delivery process itself:

We missed a drug when we were making up (an infusion pump), and there was a thousand things that happened that day, but it just made me realise that...when we do these breakthroughs, and we're dealing with the (opioids) that this is really important - actually, we're not going to talk right now because I'm doing a pump; and sometimes I think...that we deal with such huge doses that sometimes you get a bit blasé with the doses that you're dealing with, and it was a really good reminder for me...make sure you're

focused on only giving the drugs...give these drugs the respect they deserve (ID37_Nurse_RN_44_F).

It was acknowledged that a positive safety culture required a multi-faceted approach encompassing situational awareness, vigilance and a non-punitive, organisation wide commitment to upholding safety culture:

It's that combination of alertness, awareness, everyone being aware of inexperience, and an open, blame-free culture (ID09_Physician_CON_56_F).

Empowering clinicians to practise safely

Participants reflected on the positive impact of a culture that empowered and reinforced the need to practise safely in accordance with each clinicians professional responsibilities, especially when dealing with opioids. These participants recognised that opioid errors harmed the patient and the clinician:

Preventing the errors is a safeguard for us as well as the patient...it's a safeguard for our professional registrations as well; if you're a registered nurse, it's just part of your professional responsibility to make sure that you maintain your standards (ID43_Nurse_RN_48_F).

Mandated policies for opioid handling/management were seen as very effective in reducing opioid errors when policies were strictly adhered to:

We're very strict...and again, it's just policy. We've had a lot of new staff start over the last year or two, and I think because they've come into that culture as existing, with all the strictness around doing things the right way (following policy)...that's the funny thing, we're just doing it the right way, it's not like we're re-inventing the wheel (ID35_Nurse_NUM_47_F).

Adherence to opioid delivery policies was perceived to be strengthened by a service culture that supported clinicians to challenge each other if policy non-compliance was identified:

I think we've empowered our staff to feel comfortable in doing things the right way, and challenging people if they don't want to do it the right way...at the end of the day, you're responsible for your registration...if something goes wrong and you're in a court of law, nobody's actually going to back you when (you didn't follow) policy (ID34_Nurse_CNE_50_F).

Participants consistently acknowledged the power of a positive service culture that created an expectation of opioid adherence to ensure safe opioid delivery. This positive culture enabled them to feel confident, safe and supported, to challenge any perceived or actual opioid policy breaches, and for many this was in stark contrast to their previous experiences:

I came from a culture where it was like...why would two people go to a bedside? But here, really promotes that...I'm very confident now in saying 'you actually need to come with me' ...because really, the culture now is that you just don't do that, and I've never been in a unit before where it's been like that (ID37_Nurse_RN_44_F).

Participants noted and reflected on the differences between palliative care and other services, in relation to opioid safety, noting that the expectations and enforcing of independent double checking standards were much higher in the palliative care service compared to units they had previously worked:

I've never worked anywhere that's been so thorough checking their (opioids) (ID48_Nurse_RN_44_F);

No, neither have I, and I've got 30 years nursing experience. It's keeping me safe and the patients safe, and that's what I like about it (ID42_Nurse_RN_55_F).

Working as a team

Effective inter-disciplinary team work was central to opioid safety and contributed positively to safety culture. The complexity of opioid prescribing and administration meant that participants relied on, and expected that, their interdisciplinary colleagues worked diligently to ensure all opioid orders/administrations were correct, or were open to being challenged. Participating physicians stressed that, from the medical perspective, inter-disciplinary team work in palliative care was essential to ‘*enable the nurses to do their job*’ (ID51_Physician_CON_37_M). They described actively encouraging nurses to question orders they felt were incorrect: ‘*...if it’s wrong, I’m happy to be questioned*’ (ID55_Physician_INT_34_F); and all physicians noted they routinely consulted with nurses to check opioid orders:

When I’m calculating something, if it’s particularly complex or warrants double checks I often ask one of the nurses, what do you think?’ (ID56_Physician_INT_28_M).

Similarly, nurse participants described how they were confident querying opioid orders they perceived to be incorrect, or initiating discussions about changes to patients’ opioid orders:

So I said to the doctor, are you sure this is what you want? I think the intention was (for administration) today, but they re-charted it for tomorrow morning...they’re human too...if we see something, we question it. I think we’re spoiled here, that we do have a good relationship with our doctors (ID48_Nurse_RN_44_F).

Participants from services with full-time palliative care pharmacists greatly valued and noted the high level of interdisciplinary collaboration their presence afforded, particularly in regards to opioid management:

We’re really fortunate that we have pharmacists on site, they’re very open to anybody spending time with them, clarifying anything, if the doctors are not here and the nurses are uncertain about why the breakthrough dose is such as it is (ID34_Nurse_CNE_50_F).

From the pharmacist's perspective, an important outcome of the tasks they routinely undertook, such as opioid order review, management of opioid supply, and targeted opioid education, was a reduction in workload, particularly for palliative care nurses:

A lot of what we do...also helps the nursing staff, it reduces the workload, to me that's very important to assist them (nurses) in that way, reducing their workload, (as) they have plenty to do (ID40_Pharmacist_60_F).

Promoting a non-punitive approach to error

Creating and promoting a non-punitive error reporting-culture was a key strategy each service had adopted to support opioid safety. Error-reporting was seen as an opportunity to improve individual and unit performance, and also critically assess and identify potential systems failures that may be contributing to error:

We work in a unit where we certainly want to identify errors, but we don't want to take a punitive approach to the error...it's not about dragging that person over the coals, it's very much about improving performance, improving patient safety and then looking at the system and saying 'is there something more than just talking to the individual about what we're going to do here?' (ID32_Physician_CON_48_M).

It was also acknowledged that a punitive reporting culture has a negative impact on, and was counter-productive to, a positive safety culture:

I think there have been some times when it was a bit more punitive than supportive if you know what I mean, and it always had a negative effect on the culture (ID16_Physician_CON_39_F).

Transforming a punitive culture into a positive reporting culture was noted by multiple participants to require significant and sustained effort. Participants, especially those in leadership or management roles, described the steps they had taken to transform the error reporting culture over time. This extended to reinforcing

the importance of opioid error reporting, and supporting clinicians to identify and report errors:

...creating a safe reporting culture...and having a safe conversation together, so me making them feel safer, less vulnerable professionally over a period of time didn't come easy, but over time, I think it's pretty much going okay now (ID57_Nurse_NUM_50_M).

Ultimately, participants perceived that having a positive safety culture within their services, promoted a culture of error reporting:

I don't think we have a culture where we're frightened to report anything. I don't think we have a culture where we're afraid to own up to any mistakes... I think we're all accepting of each other, and if a mistake is made, you have to do something about it, and I don't think there's a culture of shielding that (mistakes) from management (ID47_Nurse_RN_22_F).

7.5.2 Opioid error reporting is encouraged and expected

Participants perceived that opioid errors, on the whole, were quite accurately and routinely reported, compared to other medications:

...with opioids, it's more serious, we have to do a report...I'm pretty sure that all opioid errors would be reported (ID18_Nurse_RN_28_F).

This was perceived in part, to be related to palliative patients' needs, whereby their medication orders are routinely reviewed by multiple clinicians over the course of the day:

There's enough eyes looking at the medication chart over a period of 24 hours to think that we are, hopefully, reporting them all (ID16_CON_39_F).

Participants also suggested that the mandated 24 hourly checks of the drug book helped identify opioid administration errors, which were subsequently reported:

If it's not the person making the mistake reporting it, someone else will; the next shift might pick up a mistake, they might see something in the drug book doesn't correlate and they'll report it; or they'll tell our manager and the manager will report it (ID14_Nurse_RN_53_F).

While the overwhelming majority of participants perceived the unit had a positive and supportive error reporting culture, a very small number of participants described they were sometimes reluctant to report an opioid error as they did not perceive the reporting culture in their service to be non-punitive:

...the problem I think with reporting is it becomes a bit of a blame thing...once it's reported...it seems like someone also has to have the blame (ID08_Nurse_RN_36_F).

Despite this reluctance, error reporting culture was considered a key element of opioid safety, with participants suggesting that reporting more errors did not necessarily reflect poor practice, but rather a positive safety culture:

I've certainly seen that elsewhere...that it reflects badly on the unit, the more incidents you have. It doesn't look good, so you're not encouraged to (report) in other places, but they do encourage it here, to help highlight the issues so that we can rectify (ID25_Nurse_RN_29_F).

Rectify or report?

Mandated policies related to opioid management, such as independent second person checks prior to administration, were perceived to routinely intercept potential errors:

...our safety checks pick up a lot of those (opioid) errors before they actually happen (ID09_Physician_CON_56_M).

In contrast to opioid administration errors, participants suggested that not all opioid prescribing errors were reported. This was primarily because nurses in particular,

were more likely to try to rectify prescribing errors first, and, if the error was promptly rectified, were unlikely to report the error:

Generally if I find a prescribing problem you just go and get (the doctor) to fix it, you don't put a report in (ID18_Nurse_RN_28_F).

Participants suggested that prescribing errors were readily fixable, and timely administration of the correct opioid order, and effective pain management, was the priority for this patient population:

I think often you can rectify the problem quite simply...you go to the doctor to change it, so, rather than report it, it's quicker just to fix it; I think we don't report it because it's fixable...we report falls and pressure areas because we can't fix them on the spot but if it's a medication error we just go and get the chart fixed, and it's done (ID45_Nurse_RN_29_F).

Participants perceived that errors intercepted during the mandated two-person check, and before reaching the patient ('near misses'), are rarely reported, re-iterating the purpose of the independent double check for minimising opioid errors:

If you went to give it (opioid) and one of you decided 'oh that's the wrong patient', that would be rectified, that's why you've got two people, and I don't know that that would be...that may happen, and it wouldn't ever be reported (ID6_Nurse_RN_59_F).

The exceptions were: i) incidents which resulted in a narcotic discrepancy (e.g., wrong opioid drawn into syringe and/or opioid discarded), which were promptly reported; and ii) incidents where clinicians were: 'not happy to give (the medication)' (ID04_Nurse_RN_42_F) after identifying an error, for example, an opioid order is wrong, or a wrong drug has been taken to the bedside:

If your double checking identifies something before you've drawn it all up and are going to give it then you've prevented it from being a problem, but I guess if someone's actually willing to go and take it to the patient, and there's

the potential it would have been given without resistance, that would be reported (ID05_Nurse_RN_28_F).

Reflecting and learning from error

For the majority of participants, error reporting was seen as an opportunity for the clinician involved to reflect on practice, and the service to identify potential systems deficits:

If someone identifies that they missed something and they report it, then you're reflecting on your own practice...I think you're going to be much more vigilant, just from reporting it. Then the (service) follow through also happens. It's viewed in a constructive rather than a punitive fashion...but we do want vigilance around it (ID32_Physician_CON_48_M).

Participants stressed ‘we're not blasé about mistakes, everyone takes it really seriously’ (ID38_Nurse_RN_41_F); and several participants reflected on their own experiences with opioid errors at a personal and professional practice level. Participants who shared examples of opioid errors they had made universally described great distress and spoke of how the experience had strengthened their commitment to the required safety processes:

I think those of us, personally speaking, who have made a drug error with an opioid, then you know you never ever do it again. It was scary at the time. I thought, "Oh my God, I think I'm having a heart attack" but everyone was okay. It was fine. The patient was okay. The family was okay. At the time, I was like, "I think I'm going to die." But you never do it again. You triple check. You quadruple check (ID61_Nurse_RN_35_F).

Participants also shared how they had self-reported opioid errors and reflected on how their practice changed following an opioid error:

I've reported myself on an (opioid) error that I've made and...I was mortified by the error, it just changed my

practice...I've never felt that somebody from above has come down on me in a punitive way, and I have changed or bettered my own practice because I've been so upset that I've made an error that I'm fairly sure I would not do that again (ID6_Nurse_RN_59_F).

7.5.3 Education is empowering

Participants highlighted the importance of education targeting opioid use in the palliative care context as a strategy to reduce error. While each clinician was responsible for adhering to opioid practices, investing in the clinical nurse educator ('CNE') role was seen as pivotal to instilling and reinforcing safe opioid practices:

I think (the CNE) has played a really big role in...giving nurses a really good base for practicing safely. They realise and understand that they're responsible and they're at risk if they don't follow those basic rules...I think (they're) empowered to be able to understand that by practicing safely they are also protecting themselves (ID41_Pharmacist_42_F).

All services provided a comprehensive orientation program for new clinical staff with a substantial focus on opioids. New palliative care nurses routinely spent one-on-one time with the clinical nurse educator to familiarise themselves with the intricacies of opioid administration as part of orientation:

When I first started here, [the CNE] was with me for at least a couple of days...at first it was like, 'oh my gosh, I've got so much to learn, I'd better pay attention'; that's another sort of safeguard because she went through things as an educator, everything was explained at that time – 'this is how we do it', just so it becomes a part of your everyday practices right from the start, that was really good (ID47_Nurse_RN_22_F).

In addition to investing in opioid education at orientation, each service invested in ongoing education, as exemplified in this quote: '*...there is a lot of education in*

regards to opioids' (ID20_Nurse_RN_28_F). Participants described both formal (e.g., information sessions conducted by pharmacists; weekly tutorials for junior medical officers; one-on-one opioid conversion exercises with the clinical nurse educator), and informal education that occurred within the day to day operations of the service:

Informal education, obviously, happens all the time on the consultant teaching ward rounds. We usually have a combination of a registrar and a resident...if we know that it's a junior registrar combined with an inexperienced RMO, the consultants are on high alert, as are the senior members of the nursing staff, to be checking that things are okay, and to be alert for any possible issues to be reported back, so trying to be open, encouraging the junior doctors to know that there's no fear or blame, and that they should always ask, is part of the education process, too (ID09_Physician_CON_56_F).

Ongoing education was also seen as critical to instilling clinician confidence to safely handle opioids, challenge any perceived opioid errors, and to respond appropriately to identify opioid errors:

I think nurses are very happy to challenge orders...I think just learning about the opioid conversion, learning what that means and why it's important (makes them confident to challenge), so being empowered by education (ID34_Nurse_CNE_50_F).

7.5.4 Sustaining an opioid safety culture requires ongoing, targeted attention

While culture was seen as critical to supporting opioid safety, participants in managerial or dedicated patient safety roles spoke of deficits in safety culture in preceding years. Participants suggested that clinicians attitudes towards opioid safety from previous management had adversely impacted the opioid safety culture, and error prevalence, in the past:

There had been a culture of under reporting, and people believing that by reporting, you are getting your colleague

in trouble, or if it didn't harm the patient you don't have to report it...unfortunately it was a culture that was supported by the (manager) so the staff didn't see anything wrong by under reporting...that's the culture that actually permitted more significant incidents to actually happen
(ID31_Nurse_RN_38_M).

They also described how creating a positive opioid safety culture had required substantial changes to clinicians' attitudes and clinical practice, and ongoing, proactive measures to sustain it. Clinician complacency was a common barrier each service had to manage when looking to improve opioid safety culture initially:

We've done a lot of work over two years...I think initially there was a complacency (about opioids)...the sheer volume made (clinicians) overconfident...people had a sense of corner cutting... (ID57_Nurse_NUM_50_M).

Another critical part of strengthening the opioid safety culture was the open acknowledgement and management of opioid errors:

That was a big cultural shift...not only looking at processes and trends, but also raising the profile of (errors), so making it very important that if an error happens that we need to look at that...and talk about (errors) very regularly
(ID33_Nurse_NUM_39_F).

7.6 Discussion

This qualitative study identified that creating and sustaining a positive opioid safety culture is fundamental to mitigating opioid errors in specialist palliative care inpatient services. For the palliative care clinicians in this study, opioid safety culture was predicated on clear and consistent expectations from leadership, clinicians empowered to work together and practise safely, and a non-punitive approach to errors when they occur.

The clinicians in this study illustrated that a positive safety culture is created when there are shared values, attitudes, competencies and behaviours that reflect the

palliative care services' commitment to safe opioid delivery (Nieva & Sorra, 2003). These factors were perceived to be critical to instilling and supporting palliative care clinicians' adherence to safe opioid delivery practices, and central to reducing opioid errors in specialist palliative care inpatient services. This is an important finding as it is widely accepted that a positive safety culture is fundamental to reducing or preventing errors in any healthcare setting (Hodgen A, Ellis L, Churruca K, & Bierbaum M, 2017; Kohn et al., 2000).

Safety culture has long been believed to be a predictor of an organisation's safety performance (Wakefield, McLaws, Whitby, & Patton, 2010). In a positive safety culture it is recognised that errors are inevitable, and the organisation works proactively to identify factors that promote error causing conditions and seeks to rectify them (Nieva & Sorra, 2003; Reason, 2008). In this study, opioid safety was prioritised by unit and patient safety managers who acknowledged the risk involved in opioid delivery, and privileged safe opioid delivery as a fundamental component of quality palliative care service provision. This was reflected in the discussion with frontline clinicians, who reported a high level awareness of opioid safety expectations from management, and felt compelled and supported to adhere to the policies for safe opioid prescribing and administration. When opioid errors did occur, a non-punitive error reporting culture promoted reporting, and supported clinicians to reflect and learn from the error. In turn, the service endeavoured to identify error contributory factors from a systems perspective and implemented targeted strategies to address these.

Safety culture and error reporting

A notable finding in this study was palliative care clinicians overwhelmingly positive perceptions of the error reporting culture in their services. Error reporting is an essential component of patient safety which facilitates individual and organisational learning from error, and the development of error mitigating strategies (Institute of Medicine, 2000). Critical to effective error reporting is a non-punitive error reporting culture, where clinicians feel safe to report errors without fear of repercussion or disciplinary action (Institute of Medicine Committee on Quality of Health Care, 2001; World Health Organisation, 2005).

Palliative care clinicians in this study strongly perceived error reporting was encouraged and expected in their service, and stated they felt safe to do so. However, the non-punitive error reporting culture identified in this study differs from other studies in similar services. A Turkish study of palliative care nurses' perceptions of safety culture found almost half (48%) reported hospital management response to an error was punitive (Dincer, Torun, & Aksakal, 2018). These nurses perceived errors reflected an inability to carry out their professional role and thought they would be judged by their peers and punished by management (Dincer et al., 2018). Similarly, a US study found palliative care nurses felt high levels of error reporting reflected negatively on their job performance, and error reporting was associated with subjective feelings of incompetence and guilt (Boyer, McPherson, Deshpande, & Smith, 2009). These starkly contrasting perceptions of error reporting culture in palliative care services may reflect the personal and/or professional drivers which are barriers to error reporting, or they may be attributable to differences in palliative care services' investment in creating an overarching positive safety culture.

In this study it was evident that a positive safety culture did not simply 'happen' in participating palliative care services. Rather, it required targeted and deliberate action, and took several years to establish (Kohn et al., 2000). Managers in this study, tasked with elevating the opioid safety culture within their service, spoke openly of the challenges in changing and re-building a culture of safety, and the importance of a non-punitive approach to errors when they occur. Factors such as complacency, entrenched clinical practice, leadership that did not prioritise patient safety, and/or a punitive error reporting culture, were some of the key obstacles that needed to be addressed in the creation of a positive safety culture. However, once established, the organisations' safety culture influenced perceptions of: what clinicians came to consider as 'normal' safety behaviour (e.g., two nurses go to the bedside to administer an opioid), what motivated clinicians to engage in 'safe' behaviours (e.g., clinicians feeling empowered to follow opioid handling policy), and the translation of safe behaviours into routine clinical practice (e.g., palliative care nurses intercepting opioid prescribing errors) (Grissinger, 2014; Weaver et al., 2013).

Palliative care nurses error interception practices

Palliative care nurses in this study were pivotal in identifying and intercepting opioid errors, particularly prescribing errors, before they reached the patient. Nurses' capacity to intercept and rectify prescribing errors has been noted to commonly occur in other inpatient care settings (Cullen, Bates, & Leape; Rothschild et al., 2005). These actions may reflect nurses' commitment to prioritising patients' safety and comfort, and ensuring patient's pain management is not adversely impacted due to error (Hewitt & Chreim, 2015; McBride-Henry & Foureur, 2006).

One of the key facilitators of opioid error interception practices by palliative care nurses in this study was a supportive nursing practice environment. This was characterised by highly collaborative interdisciplinary relationships, supportive management, and organisational commitment to quality care (e.g., targeted opioid education and continuous quality improvement) (Aiken, Clarke, & Sloane, 2002; Flynn, Liang, Dickson, Xie, & Suh, 2012). Cohesive interdisciplinary teams are critical to patient safety in any healthcare setting (Committee on Quality Health Care in America, 2001; Firth-Cozens, 2001), and have been shown to increase the interception of medication errors in acute care (Flynn et al., 2012). In a high functioning interdisciplinary team, trust between clinicians is high (Firth-Cozens, 2001). This was apparent for the palliative care clinicians in this study who proactively sought advice from one another if there was uncertainty about an opioid order, and were empowered to challenge and rectify opioid errors when they were identified (Firth-Cozens, 2001). This level of collegial, interdisciplinary teamwork ultimately fosters the delivery of high quality, safe, patient care (Committee on Quality Health Care in America, 2001; Zwarenstein, Goldman, & Reeves, 2009), and was another key opioid error mitigating factor in specialist palliative care inpatient services.

Mitigating errors through education

The nature of opioid delivery in specialist palliative care inpatient services varies substantially from other healthcare settings (Heneka et al., 2019). Clinicians new to specialist palliative care inpatient services acknowledge the steep learning curve associated with opioid delivery in this setting, and experienced palliative care clinicians recognise the inherent risk of error with routine complex tasks such as

opioid conversions (Heneka et al., 2019). Hence, another facet of organisational support for opioid safety in this study was reflected in the in-depth opioid education provided at orientation to the service, and through ongoing formal and informal education opportunities for all disciplines.

Clinicians in this study reported their confidence and ability to identify opioid errors stemmed largely from a solid opioid education, tailored to the specialist palliative care inpatient context. Notably, all palliative care services in this study employed a dedicated clinical nurse educator who was also pivotal to shaping, driving and reinforcing safe opioid delivery practices across the palliative care service. Additionally, palliative care pharmacists provided opioid specific education and ready support for any opioid related queries. Academic detailing (i.e., tailored clinical education provided peer-to-peer), is increasingly being used as a quality improvement tool, and is considered one of the most effective strategies to improve patient safety, particularly in conjunction with small group interactive education (Scott, 2009). Hence, the roles of the clinical nurse educator and pharmacist in the palliative care service are critical to supporting safe opioid delivery, which in turn, is essential to reducing opioid errors in specialist palliative care inpatient services.

7.6.1 Strengths and limitations

A substantial number of palliative care clinicians from multiple disciplines participated in this study, enabling data saturation to be reached. This study has provided insights into opioid safety culture in inpatient palliative care services, which has not been previously reported. Safety culture varies widely between and within organisations (Pronovost & Sexton, 2005; Singer et al., 2003) hence, these findings may not be generalisable to other palliative care services/settings, or other healthcare services handling high volumes of opioids.

7.7 Summary

Opioid safety is highly prioritised in inpatient palliative care services. A positive opioid safety culture, which empowers all clinicians to practise safely, and promotes a non-punitive approach to error occurrence and reporting, is fundamental to supporting safe opioid delivery in the palliative care context. The roles of the clinical

nurse educator and pharmacist appear to be pivotal in instilling and supporting safe opioid delivery, and this warrants further investigation.

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Chapter 8: Conclusion and recommendations

8.1 Introduction

Chapter 1 described how the PERISCOPE project was driven by palliative care clinicians' perceptions that opioid errors in their services were contributing to iatrogenic patient harm, and reducing these errors was a quality improvement priority (Heneka, Shaw, Azzi, & Phillips, 2018a). As outlined in Chapter 2, empirical research into opioid errors in inpatient palliative care services is sparse, with only three studies having examined this phenomenon since 2010 (Heneka, Shaw, Rowett, & Phillips, 2015). Given the paucity of this research a thorough exploration of opioid error scope, patient impact, contributing and mitigating factors in specialist palliative care inpatient services was warranted. Chapters 4 to 7 presented the results of four studies undertaken to explore and understand this knowledge gap, and better understand the nature of opioid error occurrence in specialist palliative care inpatient services.

This final chapter integrates the mixed methods data from the PERISCOPE project's five studies to answer the research questions posed in Chapter 3. Meta-inference of the entire project's data answers the final research question, and allows for a series of recommendations to support safe opioid delivery in specialist palliative care inpatient services to be generated. Joint displays for each research question, as described in Chapter 3 are included as appendices.

8.2 Research Question 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

The NSW state-wide (Study 2) and local (Study 3) retrospective review data were member checked during the semi-structured interviews and focus groups (Study 5) as medication errors are known to be widely under-reported (Westbrook et al., 2015) Data were then integrated to answer research Question 1: *What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?* (refer Appendix 11 for joint display).

8.2.1 Opioid error prevalence

In the PERISCOPE project opioid errors accounted for one-third of all reported medication errors in the three specialist palliative care inpatient services, and occurred at a mean rate of 0.9 (± 1.5) opioid errors per 1000 occupied bed days (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018d). This reported opioid error prevalence rate is almost three-fold greater than what is reported in other inpatient specialities (Carson, Jacob, & McQuillan, 2009; Desai et al., 2013; Mc Donnell, 2011; Prairie Research Association, 2014). Palliative care clinicians perceived this error prevalence rate was largely due to the high frequency of opioid delivery in their service. This perception was confirmed during the PERISCOPE project which found the frequency of opioid delivery in specialist palliative care inpatient services is substantial, with each patient receiving approximately 12 opioid administrations per day. This equates to an opioid being delivered approximately every 6 minutes in the specialist palliative care inpatient service.

8.2.2 Patient impact of opioid errors

Despite the high frequency of opioid prescribing and administration, serious patient harm from opioid errors was exceedingly rare in the PERISCOPE project. The vast majority of opioid errors reported at the state-wide and local level caused minor harm (SAC 3) or no harm at all (SAC 4) (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018b; Heneka et al., 2018d). Clinicians in the PERISCOPE project confirmed this finding and suggested that serious opioid errors were a rare occurrence in specialist palliative care inpatient services. However, approximately half of all opioid errors that reached the palliative inpatient in the PERISCOPE project necessitated clinical intervention to preclude or manage actual or potential harm(s).

In the PERISCOPE project palliative inpatients across NSW were significantly more likely to experience an opioid under-dose due to opioid error than inpatients in NSW cancer services (Heneka et al., 2018b), despite cancer pain management being core business for both clinical specialties (Australian Adult Cancer Pain Management Guideline Working Party, 2014; Australian Institute of Health and Welfare, 2018b). Approximately 60% of palliative inpatients received an opioid under-dose due to error, with almost half experiencing an exacerbation of their previously well managed pain (Heneka et al., 2018b; Heneka et al., 2018d).

The rate of opioid under-dosing due to error identified in the PERISCOPE project is also much higher than that reported in the acute care setting, where opioid overdose following an opioid error is far more common (Dy, Shore, Hicks, & Morlock, 2007). In the acute care setting, less than a quarter of reported opioid errors result in an opioid under-dose (Dy et al., 2007).

For palliative inpatients the predominant harms from opioid errors are attributable to opioid under-dosing. Iatrogenic harm due to opioid errors increases palliative patients burden of pain and adversely impacts previously well-managed symptoms in this vulnerable patient population.

8.2.3 Opioid error characteristics

Opioids involved

The PERISCOPE project found that NSW palliative care services were significantly more likely to report hydromorphone and morphine errors compared to all other NSW Health services combined (Heneka et al., 2018b). In both NSW acute care services and acute care internationally, errors with oxycodone, morphine and fentanyl are the most commonly reported opioid errors (Clinical Excellence Commission NSW Health, 2018; Desai et al., 2013; Dy et al., 2007; Mc Donnell, 2011). These differing patterns of opioid errors reflect the frequency with which these opioids are used in this specialist setting. In the seven-day snapshot audit undertaken in the PERISCOPE project, hydromorphone administrations accounted for almost half (48%) of all opioid administrations in specialist palliative care inpatient services. The higher usage of hydromorphone in the specialist palliative care inpatient services is not surprising, given that these services provide care to palliative patients with the most complex symptom management needs, including complex and/or refractory pain (Palliative Care Australia, 2018; Therapeutic Guidelines Limited, 2016).

Problem and error type

Opioid administration errors accounted for three-quarters of all reported opioid errors in the PERISCOPE project, and prescribing errors for one-fifth of opioid errors (Heneka et al., 2018b; Heneka et al., 2018d). Opioid administration errors were perceived to be relatively accurately reported by clinicians in the PERISCOPE

project, particularly when compared to errors with non-high-risk medications, due to mandated 24-hourly checks for narcotic discrepancies in the opioid drug registers. (Heneka, Shaw, Rowett, Lapkin, & Phillips, 2019). Conversely, palliative care clinicians acknowledged that opioid prescribing errors, particularly opioid conversion errors, occurred more frequently than reflected in incident reports, contradicting the results from the state-wide and local retrospective reviews (Studies 2 and 3). Clinicians acknowledged prescribing errors were more likely to be rectified when they were first identified, and subsequently not reported, if the error was readily fixable (Heneka et al., 2019).

Problem types seen in other healthcare settings are very similar to those reported in the PERISCOPE project (Carson et al., 2009; Desai et al., 2013; Dy et al., 2007; McDonnell, 2011). However, opioid administration error types identified in the PERISCOPE project showed markedly differing patterns compared to other healthcare settings.

Omitted dose errors resulting in opioid under-dosing, were the most frequently reported opioid error type, accounting for one-quarter of all reported opioid errors, and one-third of reported opioid administration errors in the PERISCOPE project (Heneka et al., 2018b; Heneka et al., 2018d). Omitted dose errors were reported at over double the rate in the PERISCOPE project compared to international acute care settings, where only 14% of reported opioid administration errors are due to omitted dose errors (Prairie Research Association, 2014). The rate of omitted dose errors reported by NSW palliative care services in the PERISCOPE project was also significantly greater when compared to NSW cancer services (Heneka et al., 2018b). These data suggest omitted opioid dose errors in palliative care services may be more prevalent than in other healthcare settings, even when opioid use is comparable (e.g., in the cancer care setting). The major contributor to opioid under-dosing due to error in the PERISCOPE project was the high proportion of omitted dose errors reported in palliative care services, which palliative care clinicians acknowledged substantially contributed to this error outcome (Heneka et al., 2019).

Another major difference in reported opioid administration error types in the specialist palliative care inpatient services, compared to other inpatient settings, was the substantially lower number of wrong drug and wrong dose errors. In the

PERISCOPE project, these error types were reported at one-fifth (wrong drug) to one-third (wrong dose) the rate reported in acute care (Desai et al., 2013; Dy et al., 2007; Prairie Research Association, 2014). The factors that may account for this lower proportion of wrong drug and wrong dose errors in specialist palliative care inpatient services are explored in greater detail in Section 8.4.1.

There are some notable differences in opioid error prevalence, patient impact and characteristics in specialist palliative care inpatient services compared to other acute care and/or inpatient settings. These are likely attributable to the frequency of opioid delivery in specialist palliative care inpatient services, and the volume of specific opioids used to manage palliative patients complex pain and other symptoms.

8.3 Research Question 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?

Studies 2, 4 and 5 data were integrated to answer research Question 2: *What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?* (refer Appendix 12 for joint display). These studies examined the incident narrative of clinical incident reports, at a state-wide (Study 2) and local level (Study 3), to provide a preliminary understanding of reported opioid error contributing factors in the palliative care delivery context. Semi-structured interviews and focus groups (Study 5) explored opioid errors contributing factors from the perspective of palliative care clinicians and service managers.

8.3.1 Individual factors

The state-wide and local data in the PERISCOPE project found active failures (i.e., human error on the part of the clinician) (Lawton et al., 2012) contributed to approximately two-thirds of opioid errors in the palliative care setting (Heneka et al., 2018b; Heneka, Shaw, Rowett, Lapkin, & Phillips, 2018c). Palliative care clinicians in the PERISCOPE project openly acknowledged human error is an inevitable aspect of opioid errors, and medication errors generally, which cannot be entirely eliminated, despite every effort to mitigate it (Heneka et al., 2019).

By far the most prominent individual factor contributing to opioid error in the PERISCOPE project was perceived to be clinician inexperience. This finding reflects

the international literature which suggests that, regardless of the clinical setting or specialty, clinician inexperience is a known medication error risk factor (Brady, Malone, & Fleming, 2009; Coombes, Stowasser, Coombes, & Mitchell, 2008; Keers, Williams, Cooke, & Ashcroft, 2013). The higher frequency of opioids administered on a daily basis in specialist palliative care inpatient services compared to other care settings, combined with substantially higher opioid doses and diverse opioid combinations, was perceived to increase the risk of errors with opioids for inexperienced palliative care clinicians (Heneka et al., 2019). Additionally, the inherent complexity of palliative patient management and rapid fluctuation of palliative inpatients symptom management needs posed additional challenges for inexperienced palliative care clinicians (Heneka et al., 2019). In the PERISCOPE project, junior doctors, and nurses new to palliative care, all acknowledged the steep learning curve associated with opioid delivery in the specialist palliative care context, compared to other acute care settings, and the resultant heightened risk of opioid error for inexperienced clinicians (Heneka et al., 2019).

While palliative care clinicians in the PERISCOPE project acknowledged the role of human error and clinician inexperience as opioid error contributing factors, clinicians also stressed it was essential to consider the systems factors that may be contributing to human error and causing opioid errors to occur (Heneka et al., 2019).

8.3.2 Systems factors

The systems factors contributing to opioid errors identified in the retrospective reviews of clinical incident narratives involving opioids (Studies 2 and 4) were limited to staff workload and clinical communication factors (Heneka et al., 2018b; Heneka et al., 2018c). This is not a wholly unexpected finding as incident reporting is often skewed towards active failures and individual factors, and rarely considers the broader systems factors that may have contributed to the error (Lawton et al., 2012; Mahajan, 2010). While clinicians in the PERISCOPE project confirmed the results from the retrospective reviews, they identified multiple additional systems factors they perceived directly contributed to opioid errors in the specialist palliative care inpatient setting. The confirmatory and enhanced findings from the quantitative and qualitative data relating to opioid error contributing factors in the PERISCOPE project, are illustrated in Figure 8.1.

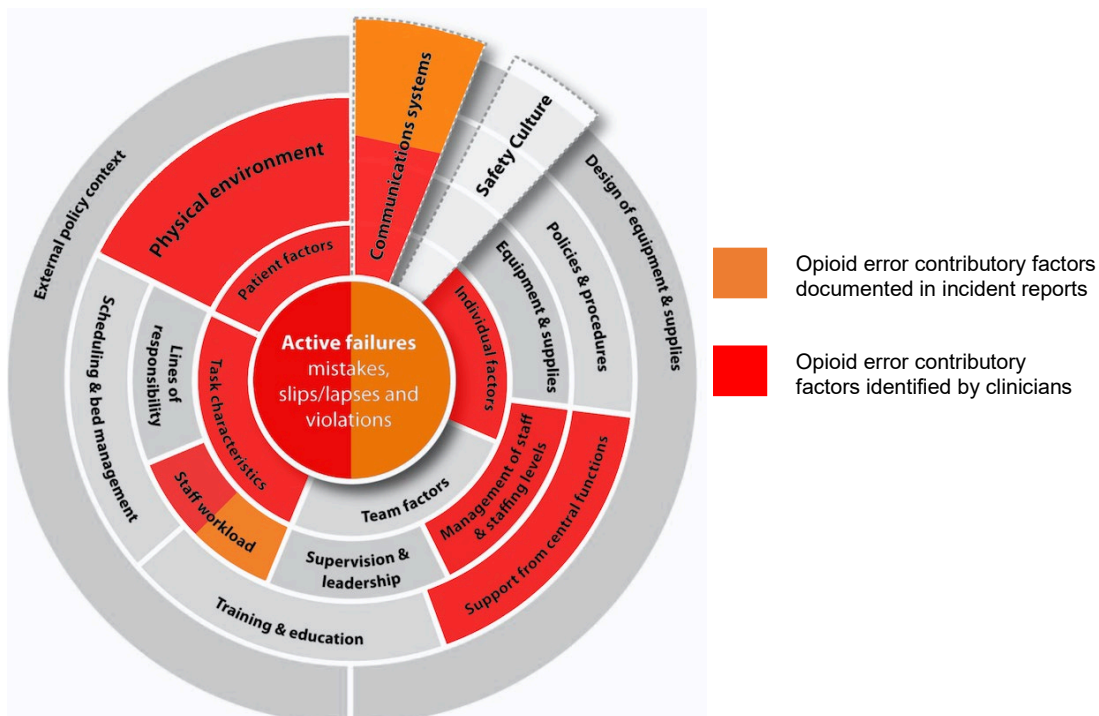


Figure 8.1 Opioid error contributory factors reported in clinical incident reports (orange) and identified by palliative care clinicians (red) in the PERISCOPE project, categorised per the Yorkshire Contributory Factors Framework (Lawton et al., 2012)

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

The systems factors contributing to opioid errors in the PERISCOPE project encompassed: i) suboptimal management of skill mix and registered nurse ratios; ii) the nature of opioid administration in specialist palliative care inpatient services; iii) absence of a pharmacist in the multi-disciplinary team; and iv) clinical communication factors. These factors are discussed in detail below.

Suboptimal management of skill mix and registered nurse ratios

The most pervasive opioid error contributing factor in the PERISCOPE project related to sub-optimal skill mix and registered nurse ratios. These factors, in turn, underpinned almost all the other error contributory factor domains identified by clinicians. Poor skill mix, from a nursing perspective, was seen to increase the number of patients and volume of opioid administrations that senior nurses had to manage, increasing their workload and the subsequent risk of error (Heneka et al.,

2019). In the current era of cost containment, medication errors have been noted to increase as the proportion of registered nurses on a unit decreases, and the number of less qualified nursing staff (i.e., Enrolled Nurses, Assistants in Nursing) and/or agency staff, increases (Breckenridge-Sproat, Johantgen, & Patrician, 2012; Frith, Anderson, Tseng, & Fong, 2012; Picone et al., 2008). From an interdisciplinary perspective, experienced palliative care nurses were pivotal in the identification of opioid prescribing errors, particularly when junior doctors, or non-palliative care specialists were initiating opioid orders. Subsequently, when inexperienced nurses and doctors were rostered together, the risk of opioid error was perceived to be much greater (Heneka et al., 2019).

The need for optimal interdisciplinary skill mix is heightened in specialist palliative care inpatient services as the palliative inpatient population has very complex symptom management needs (Australian Institute of Health and Welfare, 2018b; Palliative Care Australia, 2018). As such, palliative care clinicians require increasingly complex, specialised, knowledge and skills to provide comprehensive patient care, and continuity of care, with no single clinician likely able to meet all the complex needs of the palliative patient (Hall & Weaver, 2001; Nancarrow et al., 2013).

The PERISCOPE project identified that the error risks due to workforce skill mix was amplified when the specialist palliative registered nurse to inpatient ratio was insufficient (Heneka et al., 2019). There has been compelling evidence for over two decades that a lower proportion of registered nurses to patients is associated with significantly higher rates of medication errors (Frith et al., 2012; McGillis Hall, Doran, & Pink, 2004; Patrician et al., 2011), including in specialist units, such as intensive care, intermediate care, and medical-surgical units (Whitman, Kim, Davidson, Wolf, & Wang, 2002). Lower registered nurse ratios, have also been shown to decrease nurse surveillance of medication errors, resulting in poorer patient outcomes following an error (Flynn, Liang, Dickson, Xie, & Suh, 2012).

The continuously rotating nature of less experienced doctors, into and out of the specialist palliative care inpatient service (e.g., junior medical officers, out of hours non-specialist prescribers), also substantially increases the risk of opioid prescribing

errors if experienced clinicians are absent, and prescribing errors are not intercepted (Heneka et al., 2019).

Nature of opioid administration in specialist palliative care inpatient services

The process of opioid administration itself in the specialist palliative care inpatient context was identified as an error contributory factor in the PERISCOPE project. Palliative care clinicians highlighted the considerable differences in opioid administration in specialist palliative care inpatient services, compared to other inpatient settings (Heneka et al., 2019). Both the frequency of opioid administration and high opioid doses routinely delivered in specialist palliative care inpatient services, posed a substantial opioid error risk for palliative patients. The high frequency of opioid administration resulted in palliative care nurses spending a large part of each shift preparing and administering opioids (Heneka et al., 2019). The independent double checking process mandated for opioid delivery, while highly effective in reducing errors with these high-risk medicines, (Institute for Safe Medication Practices, 2013) is a time consuming process. Additionally, the fluctuating pain management needs of the palliative inpatient population means that opioid administration is not restricted to defined medication rounds, and palliative care nurses can spend several hours each shift administering PRN opioids to meet clinical need, and recording to meet regulatory requirements (Heneka et al., 2019).

Opioid preparation and administration is also a complex task that requires considerable concentration. However, interruptions during the opioid administration process were common in the PERISCOPE project, and palliative care nurses acknowledged these interruptions increased their risk of making an error (Heneka et al., 2019). Although all local participating services strove to create a 'quiet' space in the drug room to minimise interruptions and allow nurses to focus on opioid preparation, in reality, drug rooms were busy hubs which were often cramped and noisy.

Additionally, all local services had also trialed a 'do not interrupt' approach to medication rounds which has been widely adopted across the globe (Australian Commission on Safety and Quality in Health Care, 2013; Freeman, McKee, Lee-Lehner, & Pesenecker, 2013; Relihan, O'brien, O'hara, & Silke, 2010). However, this formalised process was not perceived to have meaningfully reduced the number of

interruptions during opioid preparation. These findings are reflected in the literature which confirms the challenges of significantly reducing interruptions during medication administration, and identifying the complex relationship between interruptions and medication error (Raban & Westbrook, 2014; Westbrook et al., 2017). Palliative care nurses in the PERISCOPE project acknowledged that, ultimately, interruptions were inevitable in their day-to-day clinical practice, and were one of many competing priorities that they actively endeavoured to manage (Heneka et al., 2019).

Absence of a pharmacist in the multi-disciplinary team

One of the most notable differences in the error prevalence rates between specialist palliative care inpatient services was attributed to the absence of a dedicated clinical pharmacist in the palliative care unit. The single specialist palliative care inpatient service in the PERISCOPE project that did not employ a palliative care pharmacist, reported all but one prescribing error in the local retrospective review (Heneka et al., 2018d). Clinicians in this service suggested that the lack of opioid order review by a clinical pharmacist directly contributed to opioid prescribing errors, in the palliative care unit (Heneka et al., 2019). This finding is reflected in the international literature, where the median prescribing error rate (all drug types) is almost three times higher in medications administered in the inpatient setting prior to pharmacist review compared to orders screened by pharmacists prior to administration (9.9% versus 2.7%) (Lewis et al., 2009).

In relation to palliative care service delivery, pharmacists have long been accepted as an integral part of the interdisciplinary palliative care team (Lee & McPherson, 2006; Lucas, Glare, & Sykes, 1997; Wilson, Wahler, Brown, Doloresco, & Monte, 2011). In Australia, palliative care pharmacists are actively involved in medication review (Gilbar & Stefaniuk, 2002) Palliative care pharmacists' recommendations regarding medications are well accepted by palliative care physicians and nurses, particularly for pain management (Wilson et al., 2011), and the proportion of palliative patients who achieve the desired therapeutic outcome following pharmacist input is high (Lee & McPherson, 2006). Hence, without a clinical pharmacist in the interdisciplinary palliative care team, the risk of opioid error, and resultant palliative patient harm, is considerably higher.

Clinical communication factors

Communication systems: The PERISCOPE project identified a lack of standardised electronic medical record systems that allows the patients' medical information to be seamlessly transferred between the inpatient unit, the community/outreach service, primary care and non-palliative care specialists. The lack of an integrated electronic medical record system heightened the risk of error when patients were first admitted to the inpatient unit, as opioids were often ordered without the prescriber being able to access all of the relevant information in a timely manner (Heneka et al., 2019).

Care transitions are a known medication error risk issue (National Health and Hospitals Reform Commission, 2009), with a recent Australian study suggesting that two medication errors occur for every three patients at the time of their inpatient admission (Roughead, Semple, & Rosenfeld, 2016). A recent USA nursing home study found that the risk of opioid prescribing errors for patients transitioning into nursing homes was significantly higher than for non-opioid medications (11.3% vs. 8.1%, $p=.001$) (Desai et al., 2013). Although the nursing home population differs in many respects from the inpatient palliative care population, there are some notable similarities. Palliative patients, like nursing home residents, are typically elderly, frail, have multiple co-morbidities, and experience persistent pain (Australian Institute of Health and Welfare, 2018a; Hunnicutt, Ulbricht, Tjia, & Lapane, 2017; Kasper J & O'Malley M, 2007). While a third (32%) of nursing home residents have an opioid prescription for pain management (Hunnicutt et al., 2017), nearly all (98%) of patients in the PERISCOPE project had at least one opioid order following admission to the palliative care unit. Hence, it is highly likely that the combination of patient characteristics, the aforementioned deficits in integrated electronic medical record systems, and the proportionally higher frequency of opioid orders, contributes to opioid prescribing errors in inpatient palliative care services.

Interpersonal communication: Poor written or verbal clinical communication was a contributory factor to opioid error in the PERISCOPE project (Heneka et al., 2018b; Heneka et al., 2018c, 2019). In healthcare settings generally, clinical communication deficits have been well documented as factors contributing to medication errors (Manojlovich & DeCicco, 2007; Parry, Barriball, & While, 2015; Redley, Botti, Wood, & Bucknall, 2017). In palliative care settings specifically, deficits in

interdisciplinary communication and unclear medication documentation are also reported as common causes of errors (Dietz et al., 2013; Dietz, Plog, Jox, & Schulz, 2014). As written communication deficits were generally quickly resolved in the PERISCOPE project (Heneka et al., 2019), the most problematic communication deficit was the lack of consistent contemporaneous handover of changes to opioid orders, from the ordering physician to the palliative care nurse. From the palliative care nurses' perspective, these deficits contributed to the already high rate of omitted opioid doses. Further exploration of clinical handover practices in inpatient palliative care services is needed to fully understand the barriers and facilitators to timely handover of medication order changes.

There are multiple systems level factors that contribute to opioid errors in specialist palliative care inpatient services. While some contributory factors are intrinsic to the process of opioid delivery itself, other factors reflect gaps in staffing and resource management.

8.4 Research Question 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

Study 5 (semi-structured interviews and focus groups) explored the specific strategies specialist palliative care inpatient services in the PERISCOPE project had implemented to mitigate opioid errors. Data from this study were integrated with the Study 3 (local retrospective review) and Study 4 (retrospective review of error contributing factors) to answer research Question 3: *What are the opioid error mitigating factors in specialist palliative care inpatient services?* (Refer Appendix 13 for joint display).

Many of the strategies to mitigate opioid errors in the PERISCOPE project were developed in direct response to specific errors, or patterns of errors, the service had identified following internal review of reported opioid errors. Underpinning these strategies was evidence of a positive opioid safety culture in all participating specialist palliative care inpatient services, which has been detailed in Chapter 7. In addition to an over-arching positive safety culture in specialist palliative care inpatient services, five opioid error mitigating factors were consistently evident in the PERISCOPE project: i) palliative care nurses' ability to identify and intercept opioid errors; ii) palliative care pharmacists in the interdisciplinary team iii) targeted

and ongoing opioid education; iv) strong interdisciplinary collaboration; and v) use of an electronic medication management system. These factors are reported in detail below.

8.4.1 Opioid error mitigating factors

Applying the Yorkshire Contributory Factors Framework (Lawton et al., 2012) (refer Chapter 3) to the PERISCOPE project data revealed that the majority of opioid error mitigating factors in specialist palliative care inpatient services aligned with systems factors related to supervision and leadership, management of staff/staffing levels, training and education, and support from central functions (refer Figure 8.2).

Most notably, the PERISCOPE project identified two opioid error mitigating factors which, if not present, were considered to be error contributory factors. Poor skill-mix (management of staff/staffing levels) and the absence of pharmacy input (support from central functions) directly contributed to opioid errors in the PERISCOPE project (Heneka et al., 2019), however, optimal skill-mix (nursing and interdisciplinary) and a full-time clinical pharmacist in the palliative care unit, appeared to directly reduce opioid errors in specialist palliative care inpatient services (Heneka et al., 2018c, 2018d, 2019).

Palliative care nurses' ability to identify and intercept opioid errors

Checking opioid orders was a routine part of palliative care nurses' opioid administration practices in the PERISCOPE project. As medication administrators, nurses are well positioned to safeguard against medication errors, and are thought to intercept up to 86% of prescribing or dispensing errors (Leape et al., 1995). In the PERISCOPE project palliative care nurses were pivotal in intercepting prescribing errors, as evidenced in incident reports (Heneka et al., 2018c) and from the perspective of palliative care clinicians (Heneka et al., 2019). This may account for the discrepancy between clinicians' perceptions that prescribing errors are relatively common, and the comparatively low prevalence (approximately 20%) of reported prescribing errors in specialist palliative care inpatient services (Heneka et al., 2018d, 2019).

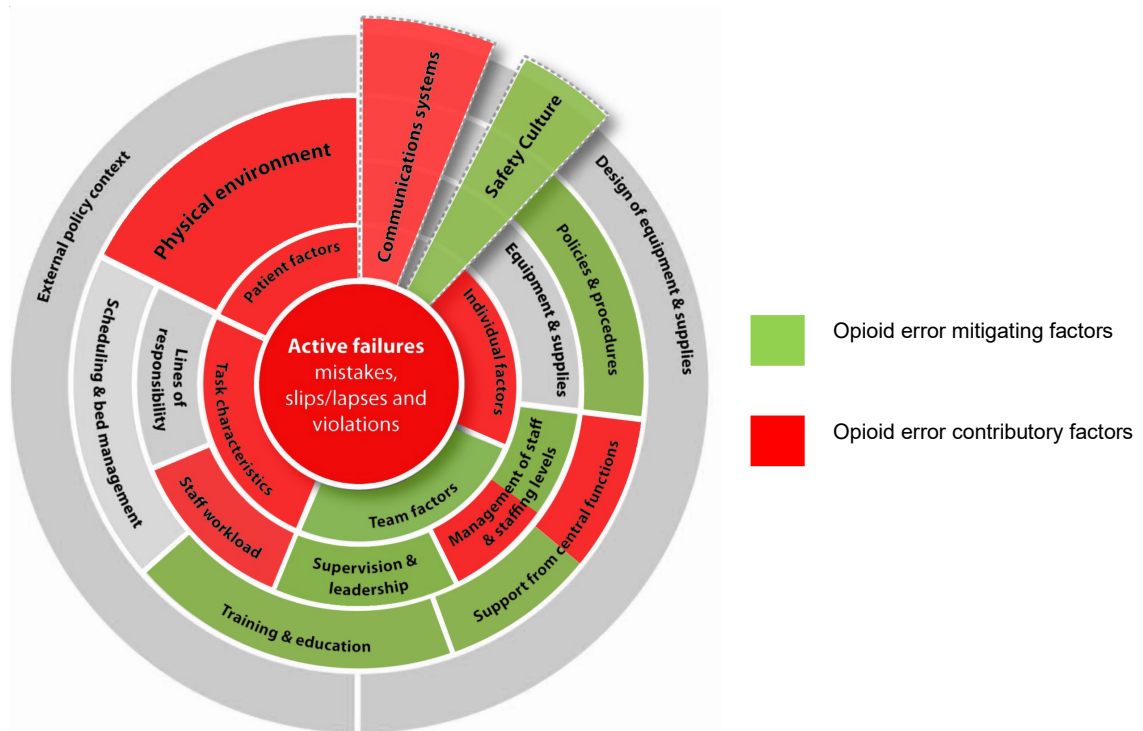


Figure 8.2 Comparison of opioid error mitigating (green) and contributory (red) factors identified in specialist inpatient palliative care services in the PERISCOPE project, categorised per the Yorkshire Contributory Factors Framework (Lawton et al., 2012)

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

The role of the nurse in intercepting errors before they reach the patient has been explored for over a decade (Balas, Scott, & Rogers, 2004; Flynn et al., 2012; Gaffney, Hatcher, & Milligan, 2016; Rothschild et al., 2006). A significant association between registered nurses' error interception practices and rates of medication error has been identified in medical-surgical units (Flynn et al., 2012). Critical care nurses have also been found to intercept two or more harmful medical errors per patient, per day, the majority (73%) of which are medication errors (Rothschild et al., 2006). While data in the palliative care context could not be identified, it is highly likely that nurses' interception practices in palliative care directly prevent prescribing, and other opioid errors, such as wrong drug and wrong dose errors, from reaching the patient.

Similar to studies in acute care (Cullen, Bates, & Leape; Hewitt & Chreim, 2015; McBride-Henry & Foureur, 2006), palliative care nurses in the PERISCOPE project

reported being confident asking for opioid orders to be changed if an error was identified, and acknowledged they prioritised timely administration of opioids to ensure effective pain management, over error reporting. Driving nurses' confidence to identify and challenge opioid errors in the PERISCOPE project was a safety culture where nurses felt empowered to speak up when an error was identified, felt confident and supported to adhere to opioid handling/management policies, and had ready access to opioid related training and education (Heneka et al., 2019).

Palliative care pharmacists in the interdisciplinary team

As previously mentioned, the two services in the PERISCOPE project whose interdisciplinary team included a palliative care pharmacist reported considerably fewer opioid prescribing errors than the service that did not, irrespective of the medication management system used (electronic versus paper-based) (Heneka et al., 2018d). In these two services pharmacists were highly valued members of the interdisciplinary team and palliative care physicians and nurses routinely sought advice from them. Additionally, pharmacists tailored opioid education to meet the needs of the unit, and pro-actively identified and conducted opioid safety related quality assurance activities.

The inclusion of a pharmacist in the interdisciplinary team in specialist palliative care inpatient services appears integral to mitigating opioid errors, driving the services' education and quality assurance activities to further support safe opioid delivery practices, and improving palliative patient outcomes (Gilbar, 2006; Herndon et al., 2016; Wilson et al., 2011).

Targeted and ongoing opioid education

Opioid related education was seen as pivotal to nurses' capacity to identify and intercept opioid errors in the PERISCOPE project. As reported in Chapter 7, each of the local palliative care services in the PERISCOPE project utilised a suite of opioid education options for all disciplines. Palliative care nurses reported feeling empowered to practice safely, largely driven by learning opportunities provided by the Clinical Nurse Educator, and the ongoing formal and informal education within the day-to-day operations of the unit.

Harnessing medication safety education to reduce medication errors and prevent error related harms has been a widely employed approach for over two decades (Australian Commission on Safety and Quality in Health Care, 2017; Institute for Safe Medication Practices, 2009; Leape, 1994). However, in isolation, education strategies are not a reliable approach to consistently mitigate medication errors. Rather, education is best employed in combination with strategies that are less reliant on human vigilance to be successful (e.g., forcing functions and constraints in electronic medication management systems, standardised protocols, and independent double check systems) (Institute for Safe Medication Practices, 2009).

Strong interdisciplinary collaboration

Palliative care clinicians in the PERISCOPE project acknowledged the existence of strong and collegial interdisciplinary relationships in their services. Collaboration with palliative care pharmacists was greatly valued by nursing and medical staff, and afforded additional checks of opioid orders and guidance with opioid management. Palliative care physicians reported routinely consulting with nurses to check opioid conversions, and were open to being questioned if they had made an error. Equally, palliative care nurses felt empowered to challenge opioid orders they perceived to be ambiguous, illegible or incorrect. Interdisciplinary collaboration extended to situational awareness of, and increased vigilance around, less experienced palliative care clinicians in the PERISCOPE project, particularly junior doctors, and non-palliative care specialists prescribing out of hours.

In a recent integrative review of 30 studies, interdisciplinary collaboration was shown to substantially contribute to the identification, interception and reduction of medication errors across a broad range of hospital settings (Manias, 2018). While none of the settings in this integrative review included palliative care services, qualitative data from the PERISCOPE project strongly suggests effective interdisciplinary collaboration is a key factor in mitigating opioid errors in specialist palliative care inpatient services.

Use of an electronic medication management system

An electronic medication management system was used in one palliative care service in the PERISCOPE project. A notable difference in opioid errors prevalence in this

service was the absence of reported omitted dose errors. Palliative care clinicians in this service perceived that electronic medication management systems directly reduced omitted dose errors by virtue of prompting clinicians to administer the missed dose, and preventing progression to the next due opioid administration. In contrast, omitted dose errors in the two palliative care services using paper based medication charts ranged from 29% to 69% of reported opioid administration errors (Heneka et al., 2018d).

Electronic medication management systems have been reported to significantly reduce the risk of medication errors in acute health care settings (13% to 99% relative risk reduction) (Ammenwerth, Schnell-Inderst, Machan, & Siebert, 2008; Redley & Botti, 2013). However, the impact of electronic medication management systems on omitted dose errors is varied. In one Australian study omitted dose errors occurred at less than half the rate in an acute care hospital using an electronic medication management system compared to a similar hospital service using paper-based medication charts (14% versus 33%) (Redley & Botti, 2013). Similar results were seen in a general surgery ward in the UK, with a 35% decrease in omitted dose errors following the introduction of an electronic medication management system (Franklin, O'Grady, Donyai, Jacklin, & Barber, 2007). However, a more recent Australian study found that, while the introduction of an electronic medication management system did not reduce the rate of omitted doses overall, it did lower the rate of non-therapeutic omissions from 26% to 4.4% of total omitted doses (Munzner, Welch, & Richardson, 2012). Given that omitted dose errors are the most frequently reported error type in specialist palliative care inpatient services, transitioning to electronic medication management systems for inpatient palliative care services currently using paper-based medication charts is an important consideration.

8.5 Research Question 4: What is required to support and strengthen safe opioid delivery practices in specialist palliative care inpatient services?

This final research question is answered through meta-inference of the collective PERISCOPE project data. The meta-inference process applied in the PERISCOPE project has been reported in detail in Chapter 3.

8.5.1 Understanding opioid delivery in specialist palliative care inpatient services

In order to support and strengthen safe opioid delivery practices in specialist palliative care inpatient services, it is essential to first understand that opioid delivery in this setting is complex and time consuming. In specialist palliative care inpatient services opioids are frequently administered, using high doses and opioid combinations that differ substantially from opioid usage in other inpatient settings. Integral to palliative inpatients' symptom management is palliative care clinicians' capacity to undertake opioid conversions, which, in itself, is a complex and error prone task. Preparing and administering a single opioid dose for a palliative inpatient is time consuming as safe opioid administration requires adherence to independent double checking and documentation, in accordance with high-risk medicine management policies (Ministry of Health NSW, 2013, 2015). Hence, the complexity and fluctuating symptom management needs of the palliative care inpatient means palliative care clinicians, particularly nurses, spend a large proportion of their shift primarily attending to administering regular and PRN opioids.

There are over 30 steps in the opioid delivery process in specialist palliative care inpatient services and each step is prone to human error (Heneka et al., 2018c; Leape, 2006). Having multiple processes in place to pro-actively identify and intercept opioid errors across the opioid delivery process, and before the error reaches the patient, is a critical starting point in supporting and strengthening safe opioid delivery in this setting. The PERISCOPE projects' meta-inferences of the data has revealed that arriving at this point is contingent on the following four elements:

- i) embedding a positive opioid safety culture;
- ii) enabling optimal skill mix and staffing;
- iii) providing comprehensive opioid related education; and
- iv) empowering clinicians to identify, intercept and report opioid errors.

Each element is described in the next section and the conceptual framework illustrating the relationships between the elements is depicted in Figure 8.3.

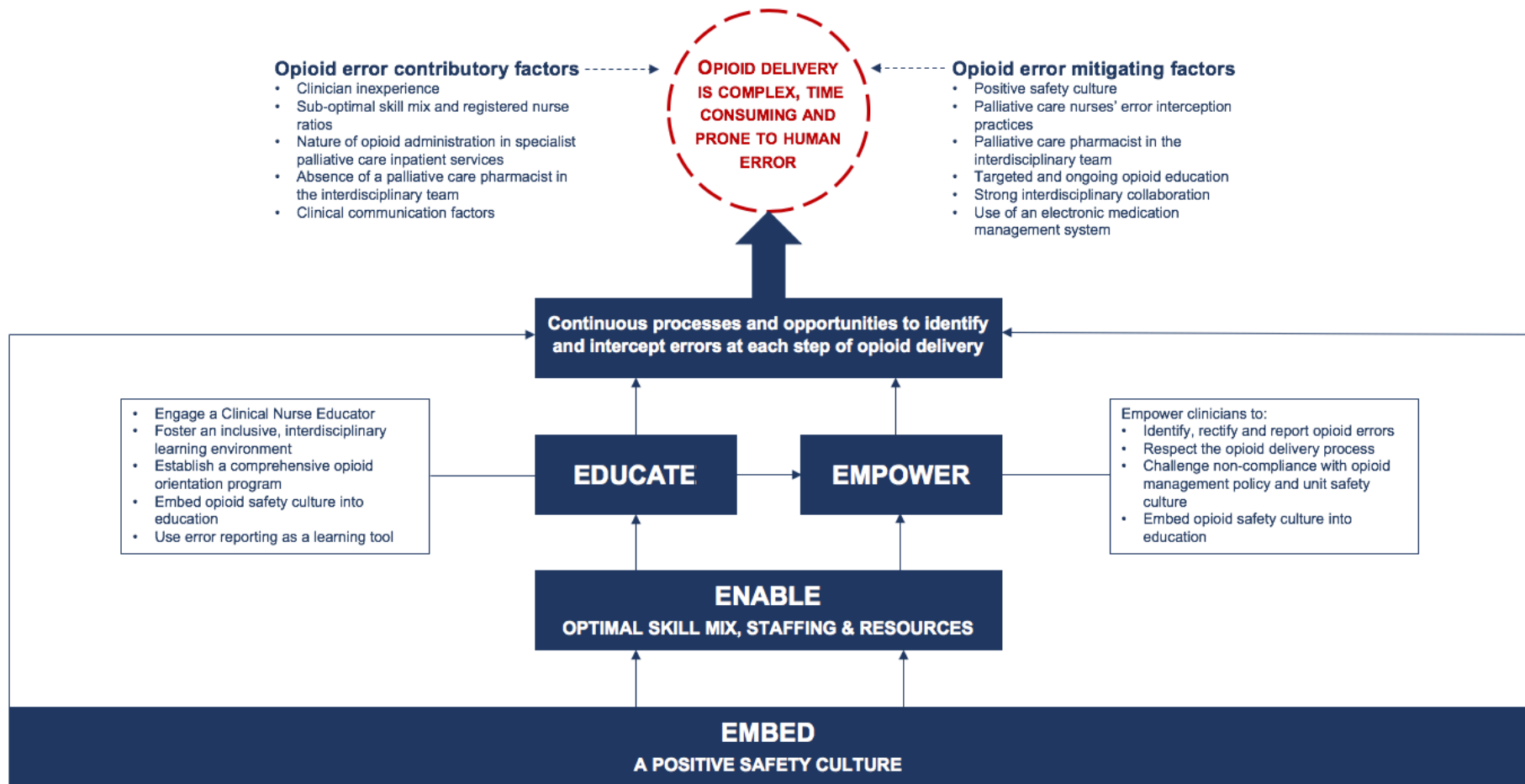


Figure 8.3 Conceptual framework of factors to support and strengthen safe opioid delivery in specialist palliative care inpatient services

8.5.2 EMBED a positive opioid safety culture

An organisation's safety culture has long been considered the most fundamental predictor of safety performance (Clarke, 1999; Scott, Mannion, Marshall, & Davies, 2003; Wakefield, McLaws, Whitby, & Patton, 2010). Highly evident in the PERISCOPE project was a strong commitment to creating, and sustaining, a positive safety culture, which included:

- **Leadership commitment to opioid safety:** acknowledgement of opioid delivery as a high-risk, time-intensive activity; opioid safety is a key organisational priority; strong leadership drives opioid safety culture (Flin, Burns, Mearns, Yule, & Robertson, 2006);
- **Awareness of opioid error potential:** acknowledgement at all staff levels that opioid errors can and will occur; awareness of individual and systems causes of opioid error (Sammer, Lykens, Singh, Mains, & Lackan, 2010);
- **Awareness and perceptions of opioid safety:** managerial expectations of opioid safety/opioid handling are consistent and clearly communicated; actions/behaviors that promote opioid safety (e.g., strict adherence to two-person check); perceptions of behavioral norms related to opioid safety (e.g., querying opioid orders perceived to be incorrect, challenging non-compliance with opioid delivery policy and/or unit safety culture) (Grissinger, 2014; Wakefield et al., 2010; Weaver et al., 2013);
- **A non-punitive response to error:** a 'no blame' response when opioid errors occur and/or are reported; a systems approach to error investigation and resolution (Sammer et al., 2010);
- **Opioid error recognition, reporting, feedback and communication:** clinicians empowered to identify and challenge opioid errors; encouraging error reporting; individual and organisational learning from opioid error; errors are followed up by management and used to inform quality improvement strategies (Hodgen, Ellis, Churruca, & Bierbaum, 2017);
- **Organisational support for opioid safety:** comprehensive opioid education at orientation to unit; ongoing formal and informal clinician education, including group learning and one-on-one learning opportunities; dedicated Clinical Nurse Educator role in unit; palliative care pharmacist as essential

member of interdisciplinary team; positive safety culture integrated into unit education activities (Flin et al., 2006; Sammer et al., 2010);

- **Team work within and across units:** high level interdisciplinary collaboration (nurses, doctors, pharmacists); interdisciplinary awareness of clinician inexperience; proactive provision of opioid related education and quality assurance activities by pharmacist (Flin et al., 2006); and
- **Job satisfaction:** adequate unit staffing and skill mix (Hodgen et al., 2017; Sammer et al., 2010).

Creating a systems wide approach that supports palliative care clinicians to safely navigate the complexities of opioid delivery in the specialist palliative care inpatient services delivery context, and promotes a non-punitive approach to error occurrence and reporting, is essential to minimising opioid errors. Embedding and sustaining a positive safety culture must be at the core of any initiatives to support and strengthen safe opioid delivery in specialist palliative care inpatient services. Hence this element lies at the foundation of the conceptual framework developed from the PERISCOPE project data. A positive safety culture shapes clinicians' opioid safety behaviours, values and attitudes, and drives the palliative care services' commitment to opioid safety management (Wakefield et al., 2010).

RECOMMENDATION 1: That palliative care inpatient services strive to establish and embed a positive opioid safety culture within their services that is: driven by leadership, promotes a non-punitive approach to error, provides strong organisational support for opioid safety, and fosters strong interdisciplinary collaboration.

8.5.3 ENABLE optimal skill mix, staffing and resources

Skill mix and staffing

From an organisational perspective, it is essential to acknowledge that opioid delivery in the palliative care inpatient setting is a high-risk clinical activity which consumes a large amount of time each shift, and differs substantially to delivery in other inpatient settings. The fluctuating needs of palliative care patients, and the task characteristics of opioid delivery place considerable time and workload burdens on palliative care clinicians. Appropriate ratios of registered nurses to palliative patients,

and optimal interdisciplinary skill mix, are fundamental to supporting safe opioid delivery in specialist palliative care inpatient services. As opioid delivery comprises a large proportion of the palliative care nurses' shift, budgetary consideration for the provision of supportive staff to alleviate palliative care nurses' non-clinical workload are also worth considering.

In the PERISCOPE project, the challenge of training and sustaining an agile palliative care workforce was noted as a direct contributor to sub-optimal staffing and skill mix, which, in turn, were the most pervasive opioid error contributing factors. The Australian palliative care workforce is ageing rapidly with approximately 70% of the total palliative care workforce over 40 years of age, and one-third over 50 years (Senate Community Affairs References Committee, 2012). It is likely that over the next decade, the number of palliative care clinicians retiring will lead to an inadequate workforce to meet the demands of an ageing, and growing, Australian population (Australian Institute of Health and Welfare, 2018b; Victorian Healthcare Association, 2011). Workforce planning needs have been acknowledged in the recently released 3rd national palliative care strategy and need to be driven at a national level (Australian Government Department of Health, 2018).

The absence of a palliative care pharmacist in the specialist palliative care inpatient services interdisciplinary is detrimental to opioid safety. Palliative care pharmacists' review of opioid orders is an important error safeguard for these high-risk medicines. Palliative care pharmacists also play an integral role in opioid education and quality assurance activities in the specialist palliative care inpatient service.

RECOMMENDATION 2: That palliative care inpatient services ensure optimal medical and nursing ratios and interdisciplinary skill mix, appropriate to palliative patients' acuity, each shift.

RECOMMENDATION 3: That a minimum ratio of palliative care pharmacist hours be mandated for all specialist palliative care inpatient services.

Resources

The complexity of opioid delivery in specialist palliative care inpatient services demands clinicians have ready access to resources that support clinical decision

making and help mitigate opioid errors. Omitted does errors were, by far, the most frequently reported opioid error type, and substantially contributed to opioid underdosing and iatrogenic patient harm. Electronic medication management systems appear to considerably reduce omitted does errors in specialist palliative care inpatient services, and their implementation should be a key consideration for palliative care services using paper-based medication charts.

RECOMMENDATION 4: Prioritise the transition to electronic medication management systems from paper-based charts to reduce omitted opioid dose errors.

8.5.4 EDUCATE

Education was the foundation for safe opioid delivery practices in the PERISCOPE project. Given the substantial differences in opioid delivery in palliative care, compared to other acute care services, a comprehensive orientation to opioid delivery in the palliative care context is essential for all clinicians first starting in palliative care. Education was seen one of the key drivers that empowered clinicians to recognise and challenge opioid errors. This was achieved through fostering an inclusive and safe learning environment that supported interdisciplinary learning, and ongoing formal and informal learning opportunities. Clinicians from all disciplines valued one-to-one education with the Clinical Nurse Educator, and the palliative care pharmacist. For palliative care nurses, the Clinical Nurse Educator was seen as pivotal to instilling and maintaining safe opioid delivery practices in the nursing team. In keeping with the characteristics of a strong opioid safety culture, error reporting was used as a powerful learning tool, giving clinicians the opportunity to reflect on and better their clinical practice, and facilitating system-wide change. Incorporating the services' approach to safety culture within the education program was integral to embedding and sustaining a positive opioid safety culture throughout the palliative care service.

RECOMMENDATION 5: That palliative care inpatient services ensure that a dedicated Clinical Nurse Educator is employed in the specialist palliative care inpatient service to: consistently instill safe opioid delivery practices for new and existing palliative care clinicians, and drive a coordinated opioid education program across the palliative care service.

RECOMMENDATION 6: That palliative care inpatient services provide opportunities for one-on-one, tailored learning as required, in addition to regular group-based learning activities.

8.5.5 EMPOWER

It was evident the large majority of clinicians in the PERISCOPE project felt empowered to identify, challenge and report opioid errors. Given the perceived number of opioid prescribing errors that occur in specialist palliative care inpatient services, empowering clinicians to recognise and intercept these errors is a key opioid error mitigating factor. However, empowerment requires the requisite knowledge and skills to identify when an error occurs, and a safety culture where clinicians feel supported to query errors and/or ask their colleagues for assistance when needed. In the PERISCOPE project this was achieved through a combination of targeted opioid education, a non-punitive error reporting culture, and strong interdisciplinary collaboration, underpinned by a positive opioid safety culture where the risks inherent with the opioid delivery process were acknowledged and respected.

RECOMMENDATION 7: That palliative care inpatient services empower clinicians to identify challenge and report opioid errors by providing comprehensive opioid education and fostering a positive, non-punitive opioid safety culture.

8.6 Significance of the PERISCOPE project

The PERISCOPE project is the first body of work to comprehensively explore opioid errors in the specialist palliative care inpatient service delivery context. The project aligns with multiple national standards, strategies and policies targeting medication safety, quality use of medicines, and palliative care delivery standards (Australia, 2018; Australian Commission on Safety and Quality in Health Care, 2017; Australian Commission on Safety and Quality in Health Care and NSW Therapeutic Advisory Group Inc., 2014) (refer Appendix 10).

8.7 Strengths and Limitations

The PERISCOPE project has a number of strengths. Data were drawn from both a state-wide clinical incident reporting system and within local services, enabling

direct comparisons and benchmarking of opioid errors in specialist palliative care inpatient services. A large number of clinicians from multiple disciplines enabled data saturation to be reached in the qualitative component of the PERISCOPE project, and facilitated comprehensive member checking within and across participating specialist palliative care inpatient services.

Limitations

While the limitations of each of the PERISCOPE project studies have been described in the relevant chapters, there are several limitations that need to be highlighted in this section. The PERISCOPE project focused on specialist adult palliative care inpatient services in metropolitan NSW only. However, palliative care in Australia is delivered in multiple generalist and specialist settings, including outpatient care and community-based/home care and paediatric palliative care. Hence the findings from this project may not be generalisable to other palliative care settings or geographical locations (e.g., regional, rural and remote services).

Although two dedicated cancer inpatient services had initially expressed interest in participating in the PERISCOPE project, a change in management and competing research priorities, saw both services decline participation when recruitment for the project commenced. A key challenge in recruiting additional cancer services to the PERISCOPE project lay in the nature of cancer service delivery outside of the inpatient context. There are few dedicated cancer inpatient services in NSW, with cancer patients generally dispersed throughout multiple wards in a hospital, depending on their reason for admission (e.g., surgical ward) and cancer type (e.g., respiratory ward). Hence, only palliative care services were included in the PERISCOPE project.

The PERISCOPE project recruited palliative care clinicians from multiple disciplines, and achieved strong participant engagement at each site, however, participation in this project was voluntary and the characteristics of participants, versus non-participants may have biased the study findings.

It is well known that medication errors are widely under-reported in hospitals (Levinson, 2012; Munzner et al., 2012; Westbrook et al., 2015) and emerging research suggests the same is true of palliative care units (Boyer, McPherson,

Deshpande, & Smith, 2009; MacLeod, Fletcher, & Ogles, 2011; Taylor, Fisher, & Butler, 2010). Although the PERISCOPE project sought palliative care clinicians' perceptions of opioid error reporting practices in their services to verify the clinical incident report data, it is highly likely these data do not accurately reflect the actual prevalence of opioid errors in specialist palliative care inpatient services.

Finally, research into patient safety and medication errors in palliative care is still an emerging area of research, with multiple gaps in published empirical data. Thus, one of the overarching challenges in the PERISCOPE project lay in the dearth of comparable literature in the palliative care context, which limited the conclusions that could be drawn.

8.8 Conclusion

Opioid errors in specialist palliative care inpatient services rarely have a single cause. Rather, opioid errors occur as a result of differing combinations of individual, team, environmental and organisational factors (Heneka et al., 2018b; Heneka et al., 2018c, 2018d). In order to support safe opioid delivery in specialist palliative care inpatient services, a systems approach to error management recognises that healthcare services themselves are subject to latent failures, which manifest as error promoting conditions in the workplace (Lawton et al., 2012). Hence, focusing solely on the actions of the palliative care clinician when opioid errors occur, will not prevent error recurrence, if, in fact, failings within the system itself are the issue (Lawton et al., 2012; McBride-Henry & Foureur, 2006). Importantly, a systems approach to opioid errors does not take away individual accountability for opioid safety, but expands accountability across the organisation to anyone who influences the medication use process (Cohen, 2007).

The PERISCOPE project identified opioid errors in specialist palliative care inpatient services differ in prevalence, characteristics and patient impact to other health care settings, and contribute to iatrogenic patient harm. Opioid error contributing factors in specialist palliative care inpatient services are multifactorial, encompassing a spectrum of factors from individual to latent systems factors. Accordingly, any strategies to reduce opioid errors must apply an integrated systems approach in order to be of impact.

Implications for practice

The PERISCOPE project has highlighted that opioid underdosing, not overdosing, was the most common patient outcome following an opioid error, and that omitted dose errors substantially contribute to this phenomenon in specialist palliative care inpatient services. It is important to recognise the dosing cascades that might follow from inadequate pain relief from such errors, the implications of worsening pain and distress for patients at the end of life, and their families/caregivers, and the additional nursing workload resulting from PRN analgesia administration.

A key finding of the PERISCOPE project was the evidence of a positive opioid safety culture in participating palliative care services which drove safe opioid delivery practices in specialist palliative care inpatient services. Assessing safety culture within the specialist palliative care inpatient service to identify areas of strength and areas for improvement, is an essential first step for any services considering strategies to support and improve this aspect of care. Pro-actively embedding and sustaining a culture of opioid safety is a critical practice component that empowers clinicians to safely deliver opioids in specialist palliative care inpatient services.

Implications for future research

Further exploration of safety culture in inpatient palliative care services is warranted to identify the similarities and differences in culture across a greater number of palliative care services, including services in differing geographical regions. In anticipation of the growth of palliative care delivery in the community/home setting, a systematic exploration of opioid errors by clinicians in these settings is also warranted. Given the unique features of paediatric palliative care it is worth extending this program of research into this setting to better understand how paediatric palliative care services manage opioid safety, and how opioid errors impact paediatric patients. With increasingly greater integration of palliative and cancer care services, understanding barriers and facilitators to opioid safety in the cancer care setting is equally important to ensuring these vulnerable patients are protected from iatrogenic harm due to opioid errors. Conducting rigorous studies in these multiple care settings will facilitate greater generalisability and applicability of study findings.

The absence of a standardised opioid error taxonomy may be a barrier to consistent reporting and effective benchmarking of opioid errors and patient impact within and across palliative care services. This will be explored in a future Delphi consensus process to develop and formalise the proposed taxonomy.

Finally, as the PERISCOPE project has established clinicians perceptions of opioid errors in specialist palliative care inpatient services, exploring the impact of opioid errors from the palliative patients' and family/caregiver perspective is a critical next step. Partnering and collaborating with consumers to develop this research will privilege their experiences and care needs following an opioid error, and better understand how to effectively facilitate their engagement in opioid safety throughout the patient and family/caregiver journey.

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doi:10.1177/1049909110391080

Appendix 1: Publications, permissions and associated media

Study 1

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

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Study 3

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). 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

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On Wed, 27 Feb 2019 at 10:57, Nicole Heneka <nicole.heneka1@my.nd.edu.au> wrote:

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I would like to request permission to include a copy of the following article in my Thesis, due for submission March 15, 2019. I am the first/corresponding author of this paper:

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The publication would be included in the appendices. Please let me know if you need any additional information.

Thank you very much.

Nicole

Kind Regards

Nicole Heneka

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Missed opioid doses a palliative pain

Publicly released: Mon 8 Jan 2018 at 0001 AEDT | 0201 NZDT

A review of reported medication errors involving opioids in palliative care has found that the majority of errors involve underdosing and may be contributing to the burden of palliative patients' pain. Australian researchers looked at opioid errors in three inpatient palliative care services in NSW and found that the rate of errors involving opioids was almost three times higher than in other healthcare settings. The most common types of errors were missed doses and wrong doses, with 57 per cent of patients receiving a lower dose of opioid than ordered.

Journal/conference: BMJ Supportive & Palliative Care

Organisation/s: The University of Notre Dame Australia, The University of Sydney, University of South Australia, University of Technology Sydney (UTS)

Funder: This work was supported by an Australian government, Collaborative Research Networks (CRN) programme scholarship (NH).

Media Release

From: University of South Australia

Palliative care study highlights need for more vigilance

An Australian review of palliative care services has revealed the impact of opioid medication errors on patients in the final weeks of their lives.

In a paper published in *BMJ Supportive & Palliative Care* today, researchers from NSW and the University of South Australia reveal that errors involving opioids are almost three times higher than previously reported in other healthcare settings.

Researchers looked at opioid errors in three inpatient palliative care services in metropolitan NSW over a two-year period, from 2013-2015. More than half of the errors (57 per cent) involved patients receiving a lower dose of pain relief than ordered, requiring clinical intervention in a third of cases. The majority of patients had cancer and were aged in their 70s.

Professor Debra Rowett, from UniSA's School of Pharmacy and Medical Sciences, says the study highlights the importance of understanding why opioid errors occur - particularly lower dosing - which may contribute to patients' pain.

"Palliative care clinicians have identified that safe use of opioids is a patient safety priority and this study is an important first step in quantifying and identifying opioid errors," Professor Rowett says.

"The high rate of errors in palliative care environments compared to other healthcare services most likely reflects the higher volume of opioids such as morphine being used for patients to manage their pain in the last stages of their lives."

Of 55 opioid errors identified, most involved morphine dosages (35 per cent) and two thirds related to administration errors. Researchers say better understanding the factors that contribute to or mitigate opioid errors is a priority in this clinical setting.

Medication errors pose one of the greatest risk to patient safety, researchers say, particularly those involving opioids, which are high-risk medicines. The risk is amplified in patients who are older, have multiple health issues and are taking numerous medications.

Notes to editors

Opioid errors in inpatient palliative care services: a retrospective review is published in the *British Medical Journal*. For a copy of the paper please email candy.gibson@unisa.edu.au

The review was undertaken by Nicole Heneka and Professor Jane Phillips from the University of Technology, NSW; Professor Tim Shaw, University of Sydney; Professor Debra Rowett, UniSA; and Dr Samuel Lapkin, St George Hospital, Sydney.

<https://www.theage.com.au/national/victoria/opioid-errors-add-to-suffering-of-ill-patients-study-finds-20180107-p4vyan.html>

HEALTH

Opioid errors add to patient suffering, study finds

Melissa Cunningham

A review of medication errors involving opioids in palliative care has found under-dosing may be contributing to the burden of the pain of terminally ill patients in the last weeks of their lives.

In a paper published in *British Medical Journal Supportive and Palliative Care* today, researchers from NSW and the University of South Australia found errors involving opioids are almost three times higher than previously reported in other healthcare settings.

The most common types of errors were missed doses and wrong doses, with the study finding 57 per cent of patients in palliative care received a lower dose of opioid than ordered.

The researchers looked at opioid errors in three inpatient palliative care services in metropolitan NSW.

The study found the errors adversely impacted on pain and symptom management in 42 per cent of patients, with more than half of them requiring additional treatment as a direct consequence of the opioid error.

The majority of patients examined had terminal cancer and were aged in their 70s.

Opioids are a high-risk medicine frequently used to manage palliative patients' cancer-related pain and other symptoms. But researchers found that, despite the high volume of use in inpatient palliative care services, few studies have focused on opioid errors in this population.

Professor Debra Rowett of the University of South Australia's school of pharmacy and medical

sciences said the study highlighted the importance of understanding why opioid errors occur - particularly lower dosing, which can contribute to the pain of terminally ill patients.

"Palliative care clinicians have identified that safe use of opioids is a patient safety priority and this study is an important first step in quantifying and identifying opioid errors," Professor Rowett said.

"The high rate of errors in palliative care environments compared to other healthcare services most likely reflects the higher volume of opioids such as morphine being used for patients to manage their pain in the last stages of their lives."

'Safe use of opioids is a patient safety priority.'

Of the 55 opioid errors identified, most involved morphine dosages (35 per cent) while two-thirds related to administration errors.

The researchers argued better understanding the factors that contribute to or mitigate opioid errors must be a priority in palliative care.

The researchers added medication errors posed one of the greatest risks to patient safety, particularly those involving opioids, which are high-risk medicines.

The risk is amplified in patients who are older, have multiple health issues and are taking numerous medications, the study said.

It also found medication errors are consistently under-reported.

MEDIA - BMJ: Best article to read this month

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If you can only read one article this month, make it...

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BMJ Supportive & Palliative Care

Dear Philippa,

It can be difficult to stay on top of the latest research and discussion in your field, so we've highlighted an interesting article recently published that we hope you enjoy!

[Opioid errors in inpatient palliative care services: a retrospective review](#)

Best wishes,

The *BMJ Supportive & Palliative Care* team

The logo for BMJ (British Medical Journal), consisting of the letters 'BMJ' in a bold, blue, sans-serif font. The 'M' is slightly larger and more prominent than the 'B' and 'J'.

Study 4

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). 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. Copyright 2018, Mary Ann Lieber Inc.

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Study 5

Heneka, N., Shaw, T., Rowett, D., Lapkin, S., & Phillips, J. L. (2018). Clinicians' perceptions of opioid error contributing factors in inpatient palliative care services: A qualitative study. *Journal of Palliative Medicine*. Advance online publication (published March 1, 2019).

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Appendix 2: Severity Assessment Code (SAC) tables

Severity Assessment Code (SAC)

STEP 1 Consequences Table: Use this table as a guide; the examples listed here are not exhaustive

	Serious	Major	Moderate	Minor	Minimum
Patient*	<ul style="list-style-type: none"> Patients with death unrelated to the natural course of the illness and differing from the immediate expected outcome of the patient management A national sentinel event (refer to the national sentinel events list)* 	<ul style="list-style-type: none"> Patient suffering a Major permanent loss of function (sensory, motor, physiologic or psychologic) unrelated to the natural course of the illness and differing from the expected outcome of patient management Suffering significant disfigurement as a result of the incident 	<ul style="list-style-type: none"> Patient with permanent reduction in bodily functioning (sensory, motor, physiologic, or psychologic) unrelated to the natural course of the illness and differing from the expected outcome of patient management Any of the following: <ul style="list-style-type: none"> Increased length of stay as a result of the incident Surgical intervention required as a result of the incident 	<ul style="list-style-type: none"> Patient requiring increased level of care including: <ul style="list-style-type: none"> Review and evaluation Additional investigations Referral to another clinician 	<ul style="list-style-type: none"> Patient with No injury or increased Level of care or length of stay
Staff	<ul style="list-style-type: none"> Death of staff member related to work incident or suicide Hospitalization of 3 or more staff 	<ul style="list-style-type: none"> Permanent injury to staff member Hospitalization of 2 staff Lost time or restricted duty or illness for 2 or more staff Pending or actual prosecution Threatened or actual physical or verbal assault of staff requiring external or police intervention 	<ul style="list-style-type: none"> Medical expenses, lost time or restricted duties or injury / illness for 1 or more staff 	<ul style="list-style-type: none"> First aid treatment only with no lost time or restricted duties 	<ul style="list-style-type: none"> No injury or review required
Visitor	<ul style="list-style-type: none"> Death of visitor or hospitalization of 3 or more visitors 	<ul style="list-style-type: none"> Hospitalization of up to 2 visitors related to the incident Pending or actual prosecution 	<ul style="list-style-type: none"> Medical expenses incurred or treatment of up to 2 visitors not requiring hospitalization 	<ul style="list-style-type: none"> Evaluation and treatment with no expenses 	<ul style="list-style-type: none"> No treatment required or refused treatment
Service	<ul style="list-style-type: none"> Complete loss of service or output 	<ul style="list-style-type: none"> Major loss of agency / service to users 	<ul style="list-style-type: none"> Disruption to users due to agency problems 	<ul style="list-style-type: none"> Reduced efficiency or disruption 	<ul style="list-style-type: none"> No loss of service
Financial	<ul style="list-style-type: none"> Loss of assets replacement value due to damage, fire, etc. >\$1M Loss of cash, investments, assets due to fraud, overpayment or theft >\$100K Work cover claims > \$100K 	<ul style="list-style-type: none"> Loss of assets replacement value due to damage, fire, etc. \$100K-\$1M Loss of cash, investments, assets due to fraud, overpayment or theft \$10K-\$100K Work cover claims \$50K-\$100K 	<ul style="list-style-type: none"> Loss of assets replacement value due to damage, fire, etc. \$50K to \$100K Loss of cash, investments, assets due to fraud, overpayment or theft to \$10K 	<ul style="list-style-type: none"> Loss of assets replacement value due to damage, fire, etc. up to \$50K 	<ul style="list-style-type: none"> No financial loss
Environmental	<ul style="list-style-type: none"> Toxic release off-site with detrimental effect. Fire requiring evacuation 	<ul style="list-style-type: none"> Off-site release with no detrimental effects Fire that grows larger than an incipient stage 	<ul style="list-style-type: none"> Off-site release contained with outside assistance Fire incipient stage or less 	<ul style="list-style-type: none"> Off-site release contained without outside assistance 	<ul style="list-style-type: none"> Nuisance releases

STEP 2 Likelihood Table

Probability	Definition
Frequent	Is expected to occur again either immediately or within a short period of time (likely to occur most weeks or months)
Likely	Will probably occur in most circumstances (several times a year)
Possible	Possibly will recur – might occur at some time (may happen every 1 to 2 years)
Unlikely	Possibly will recur – could occur at some time in 2 to 5 years
Rare	Unlikely to recur – may occur only in exceptional circumstances (may happen every 5 to 30 years)

STEP 3 SAC Matrix

		Consequence				
		Serious	Major	Moderate	Minor	Minimum
Probability	Frequent	1	1	2	3	3
	Likely	1	1	2	3	4
	Possible	1	2	2	3	4
	Unlikely	1	2	3	4	4
	Rare	2	3	3	4	4

STEP 4 Action Required Table*

Action Required*	
1	Extreme risk – Immediate action required – Notify Organization Director. Summary report for all SAC 1 incidents must be forwarded to Organization Director and Q&AD within 48 hours. Confidential Root cause analysis (RCA) investigation must be undertaken.
2	High risk – Notify Organization Director – Detailed investigation required. Ongoing monitoring of trended aggregated incident data may also identify and prioritize issues requiring a practice improvement project.
3	Medium risk – Concise analysis must be undertaken – Aggregate data analysis may also be done for practice improvement purposes.
4	Low risk – Concise analysis must be undertaken – Aggregate data analysis may also be done for practice improvement purposes.

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Appendix 3: Permission to reproduce Yorkshire Contributory Factors Framework

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Appendix 4: Study 3a - snapshot audit data extraction tool

Variables:

1. Study ID
2. Date of admission
3. Date of discharge
4. Number of days on ward in snapshot audit period
5. Opioid regular order 1-5 (opioid, route, dose, timing)
 - a. date ordered
 - b. time commenced
 - c. number of times administered in audit period (n)
 - d. ceased (if applicable)
6. PRN opioid order 1-5 (opioid, route, dose, timing)
 - a. date ordered
 - b. time commenced
 - c. number of times administered in audit period (n)
 - d. ceased (if applicable)
7. STAT opioid order 1-5 (opioid, route, dose, timing)
 - a. date/time ordered
 - b. time administered
 - c. number of times administered in audit period (n)

Appendix 5: Study 3b data collection tool (retrospective audit)

1. Patient data sheet			
Patient Demographics			
RiskMan/IIMS Incident #		Study Code	
Age in years		Gender	M / F
Reason for admission		Primary diagnosis	
Length of stay (days)		Died during admission	Y / N
Opioid Error Data			
Date of incident		Opioid	
Route		Dose	
Timing		Indication	
Site ID		Error type	
Error made by	[clinician role only]	Identified/reported by	[clinician/ staff role only]
Details of patient outcome following incident:			
Action by service following incident:			
Other notes:			
1. Incident as recorded in patient chart:			
2. Incident notes from RiskMan/IIMS:			
3. Contributing factors per RiskMan/IIMS:			

Appendix 6: Audit summary exemplar for qualitative study (Study 5)

Opioid Error Audit - Main Messages

- Over a three year audit period (2013-2015), opioid incidents were the major medication related clinical incident reported at [site] accounting for **two thirds** of all reported medication incidents.
- **Three quarters** of reported opioid incidents reached the patient at [site] with almost 40% of these patients requiring clinical intervention to manage symptoms directly related to the incident.
- Opioid **administration** and **prescribing** problems were the most frequently reported incident category at [site].
- **Omitted opioid doses** were the major reported administration incident type reported at [site].
- **Nurses** were instrumental in **identifying and rectifying potential prescribing incidents**, or alerting medical staff to other incidents that had already reached the patient.
- Patients were more likely to receive an **under-dose** of opioid as a result of opioid prescribing or administration incidents than an over-dose.
- Whereas administration incidents were more likely to result in an opioid under-dose, all reported **prescribing incidents** that reached the patient resulted in an opioid **over-dose** at [site].

Figure 1: [site] - Percentage of reported opioid incidents by problem type

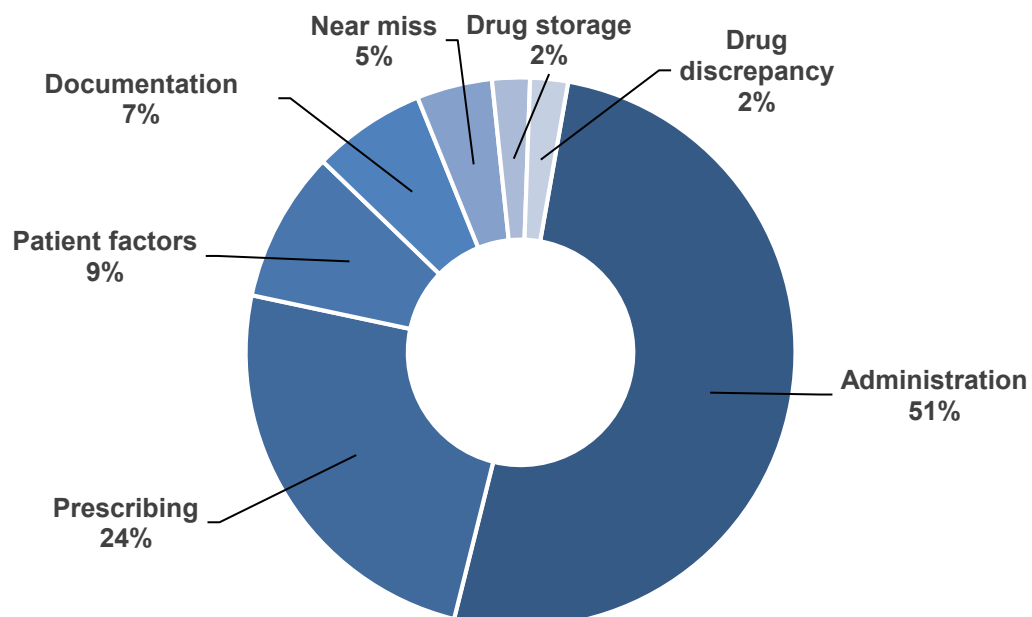


Table 1: Reported opioid incidents by problem and incident type

Problem type % (n)	Incident type	(N=45) (100%)
Administration 51.1% (n=23)	Omitted dose	10 (43.5)
	Wrong dose	4 (17.4)
	Wrong drug	4 (17.4)
	Wrong patient	3 (13.0)
	Wrong route	1 (4.3)
	Device – wrong rate	1 (4.3)
Prescribing 24.4% (n=11)	Medication charting	4 (36.4)
	Opioid conversion error	3 (27.3)
	Wrong dose	2 (18.2)
	Wrong drug	2 (18.2)
Patient factors 8.9% (n=4)	Patient self-administered opioid	2 (50.0)
	Drug discrepancy	2 (50.0)
Documentation 6.7% (n=3)	Withheld drug not documented	1 (33.3)
	Administered dose not signed in med chart	1 (33.3)
	Medication entry error in drug register	1 (33.3)
Near miss 4.4% (n=2)	Wrong patient	2 (100)
Controlled drug discrepancy 2.2% (n=1)	Medication entry error in drug register	1 (100)
Drug storage/wastage/security 2.2% (n=1)	Patient S8 drug storage	1 (100)

Appendix 7: Participant information sheet and consent form (master) Study 5

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Participant Information Sheet/Consent Form

Health/Social Science Research - Adult providing own consent

[Insert site name]

Title	Specialist palliative care clinicians' and health service managers' perceptions and experiences of opioid errors within their service: a mixed methods study.
Short Title	Perception of opioid errors in specialist palliative care.
Protocol Number	SVH reference: 16/230
Project Sponsor	University of Notre Dame Australia
Coordinating Principal Investigator/ Principal Investigator	Prof Jane Phillips
Associate Investigator(s)	Ms Nicole Heneka, Prof Tim Shaw, Dr Sam Lapkin
Location	[Location]

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, which is called: Specialist palliative care clinicians' and health service managers' perceptions and experiences of opioid errors within their service: a mixed methods study.

You have been invited because you are a clinician involved in the prescribing, dispensing or administration of opioids in a specialist palliative care service and/or you are a manager involved with the opioid medication process/patient quality and safety.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or colleague.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to be involved in the research described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Aim of the project

The aim of this project is to explore clinician (registered nurses, doctors, pharmacists) and health service managers (managers) perceptions of and attitudes towards opioid errors in specialist palliative care services. This includes: error type and incidence; reporting practices; patient and clinician impact; barriers and facilitators to safe opioid medication processes, e.g., ordering, dispensing, administration; and identification of priority areas for strategies to address local opioid errors.

Project background

Specialist palliative care services oversee a higher volume of opioid orders and administrations compared to other acute care services, with a corresponding increased potential for error. Addressing opioid errors in palliative care services has been identified as a quality improvement priority by senior clinicians, however, there is very little research on opioid error types and strategies to reduce opioid errors in specialist palliative care services. This project is an opportunity to gain an in-depth understanding of the contributing and mitigating factors to opioid errors so that tailored intervention and implementation strategies that address these errors in adult specialist palliative care services can be developed.

The results of this research will be used by the researcher, Nicole Heneka, to obtain a Doctor of Philosophy.

3 What does participation in this research involve?

This project is being conducted as a series of focus groups and semi-structured interviews conducted at [Insert site name]. Focus groups and semi-structured interviews will run for approximately 30-60 minutes. If you consent to participate, you will be asked to provide your preferred email address so the focus group and/or interview details can be sent to you. You will also be asked complete a short demographic survey (approximately 5 minutes to complete). No study activities (e.g, survey completion, provision of contact details), will occur before you have signed the consent form.

During the focus groups and semi-structured interviews, a facilitator will guide the discussion to explore the groups' perceptions of opioid error type and incidence; reporting practices; patient and clinician impact; barriers and facilitators to safe opioid medication processes, e.g., ordering, dispensing, administration; and identification of priority areas for strategies to address opioid errors in your service. Focus group discussions and semi-structured interviews will be audio recorded.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This project follows on from a quality audit of opioid errors in your service. The results of this audit will be presented at the start of the focus groups. There are three specialist palliative care services taking part in this research project, with approximately 30 participants in total.

Focus groups will be structured by roles in the opioid medication process, i.e., opioid ordering, opioid administration, opioid dispensing and/or quality and safety. For example, participants involved primarily in opioid administration (nurses) will be grouped together.

Semi-structured interviews can be conducted: face to face at [Insert site name]; by phone; or via Skype, at a time that suits you and the researcher(s).

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with professional staff or your relationship with [Institution].

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include: a better understanding of why opioid errors occur in this service and how they could be prevented; recommendations for future quality improvement projects to support and re-enforce safe opioid medication processes; an opportunity to reflect on your role in the medication process and identify strategies that support you in safe opioid medication processes; an opportunity to explore the impact of opioid errors on patients and identify practices which support patient safety.

7 What are the possible risks and disadvantages of taking part?

The risks associated with this study are perceived to be low. In the focus groups and semi-structured interviews we will be exploring opioid medication practices. You may feel that some of the questions we ask make you feel uncomfortable due to previous exposure to or awareness of medication errors. If you do not wish to answer a question, you do not need to answer. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

Whilst all care will be taken to maintain privacy and confidentiality in the focus groups, you may experience embarrassment if one of the group members were to repeat things said in a confidential group meeting.

8 What if I withdraw from this research project?

If you do consent to participate, you may withdraw at any time. If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing. If you do withdraw, you will be asked to complete and sign a 'Withdrawal of Consent' form; this will be provided to you by the research team.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

9 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include unforeseen events that affect the researchers capacity to complete the project.

10 What happens when the research project ends?

If you give us your permission by providing your consent, we plan to publish the results in a peer reviewed journal. In any publication, information will be provided in such a way that you and your place of work cannot be identified. The purpose of the published information is to inform the development of strategies to reduced opioid errors for health services in Australia and overseas. Results of the study will be provided to you, if you wish. Additionally, a report summarising the study findings will be prepared and/or presented in your service within 12 months of project completion.

Part 2 How is the research project being conducted?

11 What will happen to information about me?

By signing the consent form you consent to the research team collecting and using personal information about you for the research project. The personal information that the research team collect and use is limited to the questions found in the demographic survey. Any information obtained in connection with this research project that can identify you, e.g., as disclosed in the focus groups, will remain confidential. Any identifiable information that is collected from you in the demographic survey will also remain confidential.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Only the researchers named above will have access to your identifiable details. Information you provide will be non-identifiable prior to data analysis and held securely at the University of Technology Sydney under password protection.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your express permission. Any reports or publications resulting from this study will not identify your place of work.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please inform the research team member named at the end of this document if you would like to access your information.

12 Complaints and compensation

If you suffer any distress as a result of this research project, you should contact the research team as soon as possible. You will be assisted with arranging appropriate treatment and support.

13 Who is organising and funding the research?

This research project is being conducted by Prof Jane Phillips and Ms Nicole Heneka (University of Notre Dame Australia). No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of St Vincent's Hospital (Darlinghurst). The HREC reference for this study is: LNR/16/SVH/321: This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007). This statement has been

developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the following people:

Research contact person

Name Nicole Heneka
Position Co-ordinating investigator
Telephone 0400 674 378
Email nicole.heneka1@my.nd.edu.au

Name
Position Site Principal Investigator
Telephone
Email

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name [Name]
Position [Position]
Telephone [Phone number]
Email [Email address]

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name: St Vincent's Hospital HREC
HREC Executive Officer HREC Executive Officer
Telephone 02 8382 4960
Email SVHS.Research@svha.org.au
Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact

Name [Name]
Position [Position]
Telephone [Phone number]
Email [Email address]

University HREC Office contact

Name Dr. Natalie Giles
Position Research Ethics Officer
Telephone 08 9433 0964
Email Natalie.Giles@nd.edu.au

Demographic questions accompanying participant information and consent forms

This study has been approved by the St Vincent's Hospital Human Research Ethics Committee (LNR/16/SVH/321). Please ensure you have read and signed the consent form before completing this survey and providing your contact information. The following questions assist the research team in data analysis and interpretation of the focus groups/interviews. All responses to these questions will be non-identifiable. Only global data will be reported in the publishing of the results, individuals and the service they work at will not be identified. The last section asks you to select whether you would like to participate in a focus group, a semi-structured interview, or both; and to provide contact details so the research team can set up a time that suits you. Thank you for taking part in this study.

1. What is your age in years? _____

2. What is your gender? (Tick one answer only)
 - Male
 - Female

3. What is your discipline? (Tick one answer only)
 - Nursing
 - Medical
 - Pharmacy
 - Quality and Safety - Please specify your role: _____
 - Service Management- Please specify your role: _____
 - Other (please specify): _____

4. What is your classification (clinicians)? (Tick one answer only)

Nursing	Medical	Pharmacy
<input type="checkbox"/> Enrolled Nurse <input type="checkbox"/> Endorsed Enrolled Nurse <input type="checkbox"/> Registered Nurse <input type="checkbox"/> Clinical Nurse Educator <input type="checkbox"/> Clinical Nurse Consultant <input type="checkbox"/> Clinical Nurse Specialist <input type="checkbox"/> Nurse Practitioner <input type="checkbox"/> Nurse Unit Manager	<input type="checkbox"/> Intern <input type="checkbox"/> Resident Medical Officer <input type="checkbox"/> Senior Resident Medical Officer <input type="checkbox"/> Registrar – Basic Trainee <input type="checkbox"/> Registrar – Advanced Trainee <input type="checkbox"/> Consultant	<input type="checkbox"/> Pharmacy Assistant <input type="checkbox"/> Pharmacy Technician <input type="checkbox"/> Senior Pharmacist <input type="checkbox"/> Deputy Director of Pharmacy <input type="checkbox"/> Director of Pharmacy
<input type="checkbox"/> OTHER (Please specify): _____		

5. What is highest level of education you have attained (nurses and pharmacists only)? (Tick one answer only)
- Certificate IV
 - Diploma
 - Advanced Diploma
 - Bachelor Degree
 - Graduate Certificate
 - Post Graduate Diploma
 - Masters Degree
 - Other (please specify): _____
6. How many years have you been a nurse/doctor/pharmacist? (question tailored to discipline) (Tick one answer only)
- < 1 year
 - 1-2 years
 - 3-5 years
 - 6-10 years
 - 11-15 years
 - 16-20 years
 - 21 years or more
7. How many years of experience do you have specifically caring for patients in palliative care? (Tick one answer only)
- < 1 year
 - 1-2 years
 - 3-5 years
 - 6-10 years
 - 11-15 years
 - 16-20 years
 - 21 years or more
8. How many years have you worked in this unit? (Tick one answer only)
- < 1 year
 - 1-2 years
 - 3-5 years
 - 6-10 years
 - 11-15 years
 - 16-20 years
 - 21 years or more
9. What is your primary role in the opioid medication process?
- Prescribing
 - Dispensing
 - Administration
 - Quality and Safety
 - Other: Please specify:

10. How often do you prescribe/administer/dispense opioid medications (question tailored to discipline)?

- frequently (daily)
- occasionally (several times per week)
- rarely (several times per month)
- never

11. What is your employment status:

- Full-time
- Part-time
- Causal
- Agency
- Rotation
- Other - please specify:

12. Which shift(s) do you usually work?

- Day
- Afternoon
- Night
- Combination – please specify:
- Other - please specify:

[This section starts on new page which will be removed from the demographic data above].

- Preference for participation (can select both):
 - Semi-structured interview
 - Focus Group
- Format:
 - face to face
 - telephone
 - Skype

Please provide your email address so an interview can be scheduled and/or details of the focus groups can be sent to you:

Name:

Email:

Appendix 8: Exemplar data report provided to each participating service

Appendix 9: Ethics and site specific approvals

Table A9: Ethical and site specific approval overview

Study	Ethical approval reference	Site specific approval reference
Study 1	Not applicable – systematic review	Not applicable
Study 2	NSW Population and Health Services Research Ethics Committee: AU/RED Reference: LNR/16/CIPHS/8 Cancer Institute NSW reference number: LNR 2016/02/041 University of Notre Dame Australia: 017390S	Not applicable, included in ethical approval
Study 3 and Study 4	St Vincent's Hospital HREC: SVH File Number: 15/033; HREC Reference LNR/15/SVH/51 University of Notre Dame Australia: 015115S	St Vincent's Hospital HREC: LNRSSA/15/SVH/60 Hunter New England Local Health District HREC: LNRSSA/15/HNE/536 Calvary Health Care Kogarah Research and Ethics Committee: 2015.10.01
Study 5	St Vincent's Hospital HREC: SVH File Number: 16/230; HREC Reference LNR/16/SVH/321 University of Notre Dame Australia: 017042S	St Vincent's Hospital HREC: LNRSSA/17/SVH/243 Hunter New England Local Health District HREC: LNRSSA/17/HNE/188 Calvary Health Care Kogarah Research and Ethics Committee: Reciprocal approval for Catholic Ethical requirements met and acknowledged via correspondence; no separate approval number

Study 2



Working together to lessen
the impact of cancer

14 April 2016

Prof Jane Phillips
Director
Centre for Cardiovascular and Chronic Care
University of Technology Sydney
PO Box 123
Ultimo NSW 2007

Dear Prof Phillips,

NSW Population & Health Services Research Ethics Committee

AU RED Reference: LNR/16/CIPHS/8

Cancer Institute NSW reference number: LNR 2016/02/041

**Project Title: "Opioid errors in adult oncology and palliative care services Analysis
of statewide data (CEC NSW)."**

Thank you for your Low and Negligible Risk application submitted to the NSW Population & Health Services Research Ethics Committee. The Executive Committee has reviewed your documentation and has agreed that the aforementioned application meets the requirements of the *National Statement on Ethical Conduct in Human Research (2007)*. This approval is for a maximum of five years from the date of this letter, after which time a renewal application will be required if the protocol has not been completed.

The Committee reviewed and approved the following documents:

- Submission Checklist
- National Ethics Application Form LNR Version 2 (2011), submission code AU/6/F63329, dated 15 December 2015
- Protocol Version 1.1, dated 17 November 2015
- IIMS Data Request form, dated 23 December 2015
- Letter of Support from CEC, dated 8 September 2015
- NSW Health Privacy Form
- CV, Jane Phillips

Approval is now valid for the following sites:

- Centre for Cardiovascular and Chronic Care, University of Technology Sydney
- University of Notre Dame Australia, Sydney

The NSW Population & Health Services Research Ethics Committee has been accredited by the NSW Ministry of Health to provide single ethical and scientific review of research proposals conducted within the NSW public health system.

Cancer Institute NSW
ABN 48 538 442 594

Level 9, 8 Central Avenue, Australian Technology Park, Eveleigh NSW 2015
PO Box 41, Alexandria, NSW 1435
t +61 (0)2 8374 5600 f +61 (0)2 8374 3600 e information@cancerinstitute.org.au
www.cancerinstitute.org.au



The Committee is a joint initiative of the Cancer Institute NSW and NSW Ministry of Health. The Committee has been constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* and relevant legislation and guidelines.

Please note that ethical approval is valid for **5 years**, conditional on the following:

- Principal investigators will immediately report anything which might warrant a review of ethical approval of the research, including unforeseen events that might affect continued ethical acceptability.
- Proposed amendments to the research proposal or conduct of the research which may affect the ethical acceptability of the research are to be provided to the NSW Population & Health Services Research Ethics Committee for review.
- The NSW Population & Health Services Research Ethics Committee will be notified giving reasons, if the research is discontinued before the expected date of completion.
- The Principal Investigator will provide a progress report to the NSW Population & Health Services Research Ethics Committee annually and at the completion of the study.

Your first progress report will be due on 14/04/2017 and the duration of approval is until 14/04/2021, after which time a new submission to the Ethics Committee will be required.

You are reminded that this letter constitutes '*ethical approval*' only. This research project must not commence at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained. It is your responsibility to forward a copy of this letter together with any approved documents as enumerated above, to all site investigators for submission to the site's Research Governance Officer. Where relevant, copies will also need to be provided to the ChReL and the data custodian.

For further information about the NSW Population & Health Services Research Ethics Committee, please refer to our website www.cancerinstitute.org.au/research.

Should you have any queries about the ethical review of your research proposal, please contact me on 02 8374 3562 or email ethics@cancerinstitute.org.au.

The NSW Population & Health Services Research Ethics Committee wishes you well in your research endeavours.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'B Turner'.

Dr Brie Turner
Ethics and Research Governance Manager
Cancer Institute NSW

8 September 2015

TRIM Ref: D15/11077-5

Ms Nicole Heneka
PhD Candidate
University of Notre Dame Australia
School of Nursing
PO Box 944
BROADWAY NSW 2007



Dear Ms Heneka,

Re: Request for IIMS Data relating to opioid medication errors in adult oncology and palliative care services.

In regard to our letter dated 21 July 2015, the CEC has now received a response from the Cancer Institute NSW, confirming the study would be of value to the NSW Health system.

In light of this information, we are pleased to offer in-principle support for this request, subject to the CEC receiving a copy of the full ethics approval for the study.

In granting in-principle support, we also advise that the greatest benefit of IIMS analysis is the narrative, which helps highlight issues and system-related opportunities for improvement. Given the wide variation between services and facilities, accurate comparisons based on notification numbers alone cannot be made.

Caution is advised if using IIMS reporting counts or rates as the single source of benchmarking data for a project or program, as many variables influence incident reporting. Lower rates of reporting are not a reliable indicator of safer care. Qualitative, rather than quantitative, interpretation of the data is recommended.

CEC's Patient Safety Program Manager, Ms Cate Malone, will contact you to discuss the data you are seeking, to ensure the details of the IIMS data request search criteria are consistent with your study protocol and ethics application. Alternatively, please feel free to contact Cate directly via email cate.malone@health.nsw.gov.au.

Please note that all publications relating to the study and citing IIMS data require the following statement:

QUALITY IN SYSTEMS
EXCELLENCE IN CARE

Locked Bag 8 HAYMARKET NSW 1240
p. +61 2 9289 5500 f. +61 2 9289 5599
cec-info@health.nsw.gov.au | www.cec.health.nsw.gov.au

The incident review is based only on information contained in the 'incident description' and 'review of incident' section in IIMS notifications. If the information was not documented in these sections, or the selected search terms were not used or were spelt differently, the incidents will not have been captured during this review. It should be noted that all reviews of incident data are retrospective and can reflect both hindsight and outcome bias.

If you would like to discuss any elements of this letter, please feel free to contact to Murray Stone, Corporate Governance & Reporting Officer on 02 9269 5520 or via email murray.stone@health.nsw.gov.au. Please also forward a copy of the full ethics approval to the CEC via Murray, once obtained.

Yours sincerely



Dr Karen Luxford
Acting Chief Executive Officer

cc: Prof Jane Phillips (Principal Investigator)
Prof Tim Shaw
Adjunct A/Prof Debra Rowett
Dr Sam Lapkin

11 May 2017

Professor Jane Phillips & Ms Nicole Heneka
School of Nursing
The University of Notre Dame Australia
PO Box 944
Broadway NSW 2007

Dear Jane & Nicole,

Reference Number: 017039S

Project Title: "Opioid Medication Errors in Adult Oncology and Palliative Care Service in New South Wales: Retrospective Analysis of Incidents Reported to the NSW Clinical Excellence Commission."

Thank you for submitting the above project for Low Risk ethical review. Your application has been reviewed by a sub-committee of the university's Human Research Ethics Committee in accordance with the *National Statement on Ethical Conduct in Human Research* (2007, updated May 2015). I advise that approval has been granted conditional on the following issues being addressed:

- Researchers indicate that this project is for a PhD but name only one supervisor. Please include all researchers involved in this project in Section 1.5 of the application.
- Researchers to provide copies of other HREC approvals as stated in Section 1.8.
- Researchers to ensure that a copy of the data is stored in the School of Nursing, Sydney campus, as per university policy *Code of Conduct for Research*.

Please send your response addressing each of the issues as listed above, including supporting information where applicable, to me at Natalie.Giles@nd.edu.au by **13th June**. Failure to respond and/or communicate by this time could result in a suspension of the ethical review of the project.

Yours sincerely,



Dr Natalie Giles
Research Ethics Officer
Research Office

cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney

Study 3 and Study 4



St Vincent's Hospital

A facility of St Vincent's
& Mater Health Sydney

St Vincent's Hospital Sydney Ltd
ABN 77 054 038 872
390 Victoria Street
Darlinghurst NSW 2010
Australia

T + 61 2 8382 1111
F + 61 2 9332 4142
www.stvincents.com.au

16 February 2015

Ms Nicole Heneka
University of Notre Dame Australia
PO Box 944
Broadway NSW 2007

Dear Nicole

SVH File Number: 15/033

Project Title: Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit.

HREC Reference Number: LNR/15/SVH/51

Thank you for submitting the above project for ethical and scientific review.

Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010_055 'Ethical and Scientific Review of Human Research in NSW Public Health Organisations', this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive at a meeting on **9 February 2015** has granted ethical and scientific approval of the above multi-centre project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at the following sites:

- St Vincent's Hospital, Sydney
- Prince of Wales Hospital (NSW)
- Westmead Hospital (NSW)

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

- Study Protocol Version 1.1 dated 11/11/2014
- Data Collection Form Version 1.1 dated 10/02/2015

The Low and Negligible Risk Research Form (LNRFF) reviewed by the HREC was LNRFF AU/6/E13C120

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **9 February 2020**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an Annual Progress Report beginning in **February 2016**, to the HREC as well as a Final Study Report at the completion of the project in the specified format.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.
- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries about your project please contact the Research Office, Ph: (02) 8382-2075 or by E-mail: SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office web-site to be found externally at: www.stvincents.com.au/researchoffice or at <http://exwwwsvh.stvincents.com.au/researchoffice> (internally).

Please quote **SVH File Number 15/033** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,



Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Level 6, de Lacy Building

TRIM REF: D/2015/9428



St Vincent's Hospital

A facility of St Vincent's
& Mater Health Sydney

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ABN 77 054 038 872
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Darlinghurst NSW 2010
Australia

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www.stvincents.com.au

28 August 2015

Ms Nicole Heneka
University of Notre Dame Australia
PO BOX 944
Broadway NSW 2007

Dear Nicole,

SVH File Number: 15/033

Project Title: Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit.

Short Title: Opioid medication errors in adult palliative care and oncology: a quality audit

HREC Reference Number: LNR/15/SVH/51

Thank you for your request, dated 17 August 2015, to extend HREC approval to additional sites. This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the HREC Executive at a meeting on 21 August 2015 approved this request. After receipt of outstanding documentation on 26 August 2015, HREC approval has been extended to the following additional sites:

- Calvary Mater Newcastle, Edith St, Waratah NSW 2298 - Principal Investigator: Prof. Katherine Clark
- Calvary Health Care Sydney, 91-101 Rocky Point Road, Kogarah NSW 2217 – Principal Investigator: Ms Nicole Heneka
- St George Hospital, Gray Street Kogarah NSW 2217 – Principal Investigator: Ms Nicole Heneka

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that only an electronic copy of this letter will be provided; if you require the original signed letter, please contact the Research Office and we will be happy to provide it.

Should you have any queries about your project please contact the Research Office, Tel: (02) 8382-2075, or by E-mail SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website that can be found at : www.stvincents.com.au/researchoffice or at <http://exwwwsvh.stvincents.com.au/researchoffice> (internally).

Yours sincerely,

Dr Pamela Blaikie
Research Office Manager
Research Office
St Vincent's Hospital
Level 6, de Lacy Building

TRIM REF: D/2015/43876

3 August 2015

Professor Jane Phillips
School of Nursing
The University of Notre Dame Australia
P.O Box 944
Broadway NSW 2007

19 Mount Street (PO Box 1225)
Fremantle, Western Australia 6959
Telephone: +61 8 9433 0555
Facsimile: +61 8 9433 0544
Email: enquiries@nd.edu.au
Internet: www.nd.edu.au
ABN: 69 330 643 210
CRICOS PROVIDER CODE: 01032F

Dear Jane,

Reference Number: 015115S

Project title: "Exploring the incidence and types of opioid medication errors in the adult specialist palliative care and inpatient cancer setting: a quality audit."

Thank you for submitting the above project for review. It is noted that you have ethics approval for this project from St Vincent's Hospital HREC, approval number LNR/15/SVH/51. Your application has been assessed as qualifying for a Cross-Institutional approval and is therefore exempt from HREC review. I am pleased to advise that ethical clearance has been granted for this proposed study.

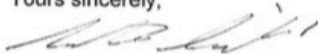
The UNDA students and researchers identified as working on this project are:

Name	School	Role
Ms Nicole Heneka	School of Nursing, Sydney	PhD Student

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

Should you have any queries about this project, please contact me at #2964 or Natalie.Giles@nd.edu.au.

Yours sincerely,



Dr Natalie Giles
Executive Officer, Human Research Ethics Committee
Research Office

cc: A/Prof Tracey Moroney, Dean, School of Nursing, Sydney

Study 5



St Vincent's Hospital

7 December 2016

Prof. Jane Phillips
University of Technology Sydney
PO BOX 123
Ultimo NSW 2007

A facility of St Vincent's
& Mater Health Sydney

St Vincent's Hospital Sydney Ltd
ABN 77 054 038 872
390 Victoria Street
Darlinghurst NSW 2010
Australia

T + 61 2 8382 1111
F + 61 2 9332 4142
www.stvincents.com.au

Dear Jane,

SVH File Number: 16/230

Project Title: Specialist palliative care clinicians' and health service managers' perceptions and experiences of opioid errors within their service: a mixed methods study.

Short Title: Perceptions of opioid errors in specialist palliative care services

HREC Reference Number: LNR/16/SVH/321

Thank you for your email, dated 1 December 2016, responding to issues raised regarding the above project, which was first considered by the HREC Executive on 21 November 2016.

Based on the information you have provided and in accordance with the NHMRC National Statement 2007 and NSW Health Policy Directive PD2010_055 'Ethical and Scientific Review of Human Research in NSW Public Health Organisations', this project has been assessed as low/negligible risk and is therefore exempt from full HREC review.

St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

This project meets the requirements of the National Statement on Ethical Conduct in Human Research. I am pleased to advise that the Committee at an Executive meeting on 6 December 2016 has granted ethical and scientific approval of the above multi centre project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Please note that it is not considered best practice to store research data on personal hardware. No identifiable participant data can leave a site. There always needs to be data security measures in place and a clear plan for permanent destruction of data needs to be adhered to at completion of the project.

The project is approved to be conducted at the following sites:

- St Vincent's Hospital, Sydney
- Calvary Mater Newcastle
- Calvary Health Care Kogarah

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documents have been approved:

- Study Protocol, Version 1.1 dated 16 September 2016
- Invitation to participate (clinician/health service manager), Version 1 dated 16 September 2016
- Appendix A_Survey, Version 1.1 dated 16 September 2016
- Appendix B_Participant Information Sheet and Consent Form including Demographic Survey, Version 1.1 dated 16 September 2016
- Appendix C_Question Routes, Version 1.1 dated 16 September 2016

The Low and Negligible Risk Research Form (LNRF) reviewed by the HREC was LNRF AU/6/6E89218.

Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **6 December 2021**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.
- The Co-ordinating Investigator will provide an Annual Progress Report beginning in **December 2017**, to the HREC as well as a Final Study Report at the completion of the project in the specified format.
- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by participants regarding the conduct of the project.
- Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the HREC Executive for review, in the specified format.
- The HREC Executive will be notified, giving reasons, if the project is discontinued before the expected date of completion.
- Investigators holding an academic appointment (including conjoint appointments) and students undertaking a project as part of a University course may also be required to notify the relevant University HREC of the project. Investigators and students are advised to contact the relevant HREC to seek advice regarding their requirements.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Ph: (02) 8382-4960 or by E-mail: SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, National Statement on Ethical Conduct in Human Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice and standard forms are available on the Research Office web-site to be found at: <https://svhs.org.au/home/research-education/research-office>

Please quote **SVH File Number: 16/230** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely,



Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

cc: Nicole Heneka
TRIM REF: D/2016/110332

13 March 2017

Professor Jane Phillips & Ms Nicole Heneka
School of Nursing
The University of Notre Dame Australia

Dear Jane and Nicole,

Reference Number: 017042S

Project title: "Specialist Palliative care clinicians' and health service managers' perceptions and experiences of Opioid errors within their service: A mixed methods study."

Thank you for submitting the above project for review. It is noted that you have ethics approval for this project from St Vincent's Hospital HREC, approval number LNR/16/SVH/321. Your application has been assessed as qualifying for a Cross-Institutional approval and is therefore exempt from HREC review. I am pleased to advise that ethical clearance has been granted for this proposed study.

Other researchers identified as working on this project are:

Name	School/Centre	Role
Dr Samuel Lapkin	St George Hospital	Co-Supervisor
Prof Tim Shaw	Sydney University	Co-Supervisor

All research projects are approved subject to standard conditions of approval. Please read the attached document for details of these conditions.

Should you have any queries about this project, please contact me at #2964 or Natalie.Giles@nd.edu.au.

Yours sincerely,



Dr Natalie Giles
Research Ethics Officer
Research Office

cc: A/Prof Joanna Patching, SRC Chair, School of Nursing Sydney

Broome Campus 88 Guy Street (PO Box 2287) Broome WA 6725
Sydney Campus 140 Broadway (PO Box 944) NSW 2007

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Photos

Appendix 10: PERISCOPE project alignment with national standards

The PERISCOPE project was developed to align with the following standards at the commencement of the project (2014):

(i) Australian Commission on Safety and Quality in Health Care:

- Safety and Quality Improvement Guide Standard 4: Medication Safety - (Australian Commission on Safety and Quality in Health Care) particularly:
 - Standard 4.4.1 - Medication incidents are regularly monitored, reported and investigated
 - Standard 4.5.2 - Quality improvement activities are undertaken to reduce the risk of patient harm and increase the quality and effectiveness of medicines use
 - Standard 4.11.1 - The risks for storing, prescribing, dispensing and administration of high-risk medicines are regularly reviewed
 - Standard 4.11.2 - Action is taken to reduce the risks of storing, prescribing, dispensing and administering high-risk medicines
- Guidelines for use of the National Inpatient Medication Chart
- Recommendations for terminology, abbreviations and symbols used in medicines documentation

(ii) Clinical Excellence Commission

- Medication Safety Self Assessment for Australian Hospitals ®

(iii) Ministry of Health (NSW) Policy Directives and Safety Information:

- Patient Safety and Clinical Quality Program PD2005_608
- Medication Handling in NSW Public Health Facilities PD2013_043 (ref)
- Incident Management Policy PD2014_004
- High-Risk Medicines Management Policy PD2015_029
- Safety Information 003/11 - Safe Storage of Accountable Medicines

(iv) Australian Adult Cancer Pain Management Guidelines

(v) Therapeutic Guidelines

- Palliative care

(vi) The National Strategy for Quality Use of Medicines (Australian Commission on Safety and Quality in Health Care and NSW Therapeutic Advisory Group Inc., 2014):

- Using medicines safely and effectively
- Providing facilities, systems, training opportunities and structures that support health practitioners and avoid medication errors

(vii) Palliative Care Australia's National Standards Assessment Program (NSAP) (Palliative Care Australia, 2005):

- Standard 11 - The service is committed to quality improvement and research in clinical and management practices

Appendix 11: Joint display for Research Question 1

Joint display A11.1 representing quantitative data integration, convergence and inference for Research Question 1: What is the prevalence, patient impact, and characteristics of opioid errors in specialist palliative care inpatient services?

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Quantitative data – State-wide data (Study 2)	Quantitative data – Local data (Study 3)	Data convergence	Mixed methods inference
Prevalence				
<i>Prevalence</i>	Could not be identified in quantitative data	Opioid errors accounted for 32% of all reported medication errors Prevalence: 0.9 (± 1.5) opioid errors per 1000 occupied bed days Rate of reported opioid errors almost three-fold higher than in other healthcare settings	Could not determine – follow-up with qualitative data	The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, may be related to the high volume of opioid delivery in inpatient palliative care.
<i>Volume of opioid administration over 24 hours</i>	Could not be identified in quantitative data	Snapshot audit findings: - mean 82.5 (SD \pm 44.8) opioid administrations per 24 hours/per unit - equivalent one opioid administration every 5.8 minutes	Could not determine – follow-up with qualitative data	
Patient Impact				
<i>SAC</i>	Data set 1: Four year trend search of reported opioid incidents (N=467) - SAC 1: n=0	Reported opioid errors over two years (N=55) - SAC 1: n=0	Confirmed – follow-up with qualitative data	Serious patient harm due to opioid error is exceedingly rare in specialist palliative care inpatient services.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Quantitative data – State-wide data (Study 2)	Quantitative data – Local data (Study 3)	Data convergence	Mixed methods inference
	<ul style="list-style-type: none"> - SAC 2: n=4 (0.9%) - SAC 3: n=133 (28.5%) - SAC 4: n=314 (67.2%) - SAC not allocated: n=16 (3.4%) <p>Data set 2: Analysis of case reports (N=241)</p> <ul style="list-style-type: none"> - SAC 1: n=0 - SAC 2: n=2 (<0.1%) - SAC 3: n=73 (30.3%) - SAC 4: n=159 (66.0%) - SAC not allocated: n=16 (6.6%) 	<ul style="list-style-type: none"> - SAC 2: n=0 - SAC 3: n=21 (38.2%) - SAC 4: n=34 (61.8%) 		
<i>NCC MERP Index</i>	<p>Data set 2: Case reports (N=241)</p> <ul style="list-style-type: none"> - Category B – error occurred, did not reach patient n=15 (6.2%) - Category C – error reached patient, no patient harm: n=11 (4.6%) - Category D - patient required monitoring and/or intervention to preclude harm: n=72 (29.9%) - Category E - error resulting in temporary patient harm which required intervention: n=37 (15.4%) - Category F - error resulting in temporary patient harm which required initial or prolonged hospitalisation: n=2 (0.8%) 	<p>Reported opioid errors (N=55)</p> <ul style="list-style-type: none"> - Category B – error occurred, did not reach patient n=6 (16.4%) - Category C – error reached patient, no patient harm: n=11 (20.0%) - Category D - patient required monitoring and/or intervention to preclude harm: n=11 (20.0%) - Category E - error resulting in temporary patient harm which required intervention: n=18 (32.7%) - Category F - error resulting in temporary patient harm which required initial or prolonged hospitalisation: n=0 	Confirmed	Approximately half of opioid errors that reach the palliative inpatient will require clinical intervention to preclude or manage harm.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Quantitative data – State-wide data (Study 2)	Quantitative data – Local data (Study 3)	Data convergence	Mixed methods inference
	- Error reached patient - patient impact/outcome not documented: n=104 (43.2%)	- Error reached patient - patient impact/outcome not documented: n=6 (10.9%)		
<i>Dose outcome following error</i>	<p>Data set 2: Case reports – error that reached patient (N=223, 92.5%)</p> <ul style="list-style-type: none"> - Opioid underdose: n=134 (60.1%) - Opioid overdose: n=66 (29.6%) - Could not determine: n=23 (10.3%) <p>Palliative patients were significantly more likely to receive an opioid underdose due to error ($\chi^2=11$, p=.001), than an opioid overdose compared to patients in cancer services</p>	<p>Reported opioid errors that reached patient (N=46, 83.6%)</p> <ul style="list-style-type: none"> - Opioid underdose: n=26 (56.5%) - Opioid overdose: n=18 (39.1%) - Could not determine: n=2 (4.3%) 	Confirmed	<p>Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose.</p> <p>Opioid underdose due to error in specialist palliative care inpatient services is almost three times higher than in acute inpatient care (23%).</p>
Error characteristics				
<i>Problem type</i>	<p>Data set 2: Case reports (N=241)</p> <ul style="list-style-type: none"> - Administration: 181 (75.1%) - Prescribing: n= 45 (18.7%) - Dispensing: n=7 (2.9%) - Near miss: n=4 (1.7%) 	<p>Reported opioid errors (N=55)</p> <ul style="list-style-type: none"> - Administration: n=42 (76.4%) - Prescribing: n= 8 (14.5%) - Dispensing: n=2 (3.6%) - Near miss: n=3 (5.5%) 	Confirmed	<p>Approximately three-quarters of reported opioid errors in specialist palliative care inpatient services are administration errors.</p> <p>Prescribing errors account for approximately one-fifth of reported opioid errors.</p> <p>Dispensing errors and near miss incidents are rarely reported.</p> <p>The proportion of reported administration and prescribing errors in specialist palliative care inpatient</p>

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Quantitative data – State-wide data (Study 2)	Quantitative data – Local data (Study 3)	Data convergence	Mixed methods inference
<i>Administration error types</i>	<p>Data set 2: Case reports – administration errors (N=181)</p> <ul style="list-style-type: none"> - Omitted dose: n=66 (36.5%) - Wrong dose: n=22 (12.2%) - Transdermal patch error: n=14 (7.7%) - Wrong drug: n=13 (7.1%) <p>Data set 1: Four year trend search of reported opioid incidents</p> <ul style="list-style-type: none"> - Omitted dose errors with opioids significantly higher in palliative care services compared to cancer services ($\chi^2_1=15$, $p<.001$) 	<p>Reported opioid administration errors (N=42)</p> <ul style="list-style-type: none"> - Omitted dose: n=14 (33.3%) - Wrong dose: n=10 (23.8%) - Transdermal patch error: n=8 (19.1%) - Wrong drug: n=6 (14.3%) 	<p>Confirmed – follow-up with qualitative data</p>	<p>services is similar to reported opioid errors in other healthcare settings.</p> <p>Omitted dose errors are the most frequently reported error type in specialist palliative care inpatient services, accounting for approximately one-quarter of all reported opioid errors.</p> <p>Omitted dose errors are also the leading administration error type in specialist palliative care inpatient services, accounting for one-third of reported administration errors.</p> <p>Specialist palliative care inpatient services report more omitted dose errors, but fewer wrong dose and wrong drug errors with opioids, compared to other healthcare settings.</p> <p>Omitted dose errors with opioids occur more frequently in specialist palliative care inpatient services than other healthcare settings, including settings where opioid use is similar (i.e., cancer services).</p> <p>Reported omitted dose errors in palliative care services are more than double the rate than identified internationally (14%).</p>

RESEARCH QUESTION 1: What is the prevalence, patient impact , and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Quantitative data – State-wide data (Study 2)	Quantitative data – Local data (Study 3)	Data convergence	Mixed methods inference
				Omitted dose errors are the primary contributors to opioid under-dosing due to error in palliative care patients.
<i>Prescribing error types</i>	Data set 2: Case reports – prescribing errors (N=181) <ul style="list-style-type: none"> - Medication charting: n=20 (44.4%) - Conversion error: n=2 (4.4%) - Wrong drug: n=8 (17.8%) - Wrong dose: n=10 (22.2%) 	Reported opioid prescribing errors (N=8) <ul style="list-style-type: none"> - Medication charting: n=4 (50.0%) - Conversion error: n=2 (25.0%) - Wrong drug: n=2 (25.0%) 	Unclear due to small numbers at local sites – follow-up with qualitative data	Medication charting errors account for half of reported opioid prescribing errors in specialist palliative care inpatient services.
<i>Opioid involved</i>	Data set 1: Four year trend search <ul style="list-style-type: none"> - Palliative care services State-wide significantly more likely to report hydromorphone ($\chi^2_1=787$, $p<.001$) and morphine ($\chi^2_1=17$, $p<.001$) errors compared to all other NSW Health services combined 	Reported opioid errors (N=55) Two thirds of reported opioid errors involved morphine (n=19, 34.5%) or hydromorphone (n=16, 29.0%)	Confirmed	Morphine and hydromorphone errors are the most commonly reported in specialist palliative care inpatient services.

Joint display A11.2 representing data integration, convergence and inference for Research Question 1: What is the prevalence, patient impact, and characteristics of opioid errors in specialist palliative care inpatient services?

RESEARCH QUESTION 1: What is the prevalence, patient impact , and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
Prevalence				
<i>Prevalence</i>	The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, may be related to the high frequency of opioid delivery in specialist palliative care inpatient services.	The frequency of opioid delivery in specialist palliative care inpatient services impacts opioid error prevalence <i>“I think that that (the number of opioid errors) is partially related to the volume of opioid use here in the specialist inpatient unit” (ID1_Physician)</i>	Confirm	The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, is likely related to the high frequency of opioid delivery in inpatient palliative care.
<i>Frequency of opioid administration in specialist palliative care inpatient services</i>	In specialist palliative care inpatient services, an opioid is administered approximately every 6 minutes.	The frequency of opioid delivery in specialist palliative care inpatient services is high <i>“We roughly calculated an average of over 3000 opioid administrations in one month (in the unit), and there was one error... I’m not minimising the seriousness of a drug error, any error is dangerous, and needs to be treated extremely seriously, but given the volume of (opioid) administrations in this unit (this is actually low) (ID19_Nurse)</i>	Confirm	The frequency of opioid delivery in specialist palliative care inpatient services is high. Given the frequency of opioid delivery in specialist palliative care inpatient services, palliative care clinicians perceive the prevalence of opioid errors to be low.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
<i>Error reporting culture</i>	Could not be determined from quantitative data	Opioid error reporting – encouraged and expected <i>‘I’ve certainly seen that elsewhere...that it reflects badly on the unit, the more incidents you have. It doesn’t look good, so you’re not encouraged to (report) in other places, but they do encourage it here, to help highlight the issues so that we can rectify’ (ID29_Nurse).</i>	Enhance	A non-punitive approach to error reporting was evident in the local specialist palliative care inpatient services in the PERISCOPE project. The higher prevalence of reported opioid errors in specialist palliative care inpatient services, compared to other inpatient settings, may also be due to a positive error reporting culture.
Patient impact of opioid errors				
<i>Patient harm</i>	Serious patient harm due to opioid error is exceedingly rare in specialist palliative care inpatient services.	Opioids pose a high risk for error, but serious errors are rare <i>‘I think serious opioid errors are uncommon, minor issues of all descriptions are relatively common’ (ID 1_Physician).</i>	Confirm	Serious patient harm due to opioid error is exceedingly rare in specialist palliative care inpatient services.
<i>Dose outcome following error</i>	Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose.	Opioid underdosing due to error <i>‘So we worry about the overdose, obviously, because that’s a life threatening problem, but patients under-dosed is also a major problem’ (ID4_Physician).</i> <i>‘They don’t always choose too large (a dose), sometimes I think the dose is dangerously small...we had one case recently where sub-cut morphine was</i>	Confirm	Opioid errors in specialist palliative care inpatient services are more likely to result in opioid underdose than overdose.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
		<i>changed to sub-cut hydromorphone, but in my estimation they gave about a 1/3 of the dose needed' (ID11_Physician).</i>		
Opioid error characteristics and error reporting practices				
<i>All opioid errors</i>	Reported opioid errors in specialist palliative care inpatient services reflect opioid error prevalence in other healthcare settings.	Mandated controlled drug management policy prompts error recognition and reporting <i>'...with opioids, it's more serious, we have to do a report...I'm pretty sure that all opioid errors would be reported' (ID18_Nurse).</i>	Enhance	Opioid errors are perceived to be more accurately reported in specialist palliative care inpatient services than medication errors with non-high risk medicines. The mandated management policy for controlled drugs (opioids) appears effective in facilitating reporting of opioid errors.
<i>Opioid administration errors - general</i>	Three-quarters of reported opioid errors in specialist palliative care inpatient services are administration errors.	Mandated controlled drug management policy prompts error recognition and reporting <i>'If it's not the person making the mistake reporting it, someone else will; the next shift might pick up a mistake, they might see something in the drug book doesn't correlate and they'll report it...' (ID14_Nurse).</i>	Enhance	The mandated management policy for controlled drugs (opioids) appears effective in facilitating recognition of opioid administration errors and prompts error reporting. Opioid administration errors in specialist palliative care inpatient services are perceived to be accurately reported.
<i>Opioid administration errors - omitted dose errors</i>	Omitted dose errors are the most frequently reported opioid error type in specialist palliative care inpatient services, accounting for	Missed doses and miscalculations <i>'...the missed dose is quite frequent...there is no doubt there's an element of human error that we</i>	Confirm Enhance	Omitted dose errors are the most prevalent opioid administration error in specialist palliative care inpatient services.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
	approximately one-quarter of all reported opioid errors, and one-third of opioid administration errors.	<i>haven't been able to eliminate entirely' (ID5_Physician).</i>		
<i>Opioid prescribing errors</i>	One-fifth of reported opioid errors in specialist palliative care inpatient services are prescribing errors	Rectify or report? <i>'I think often you can rectify the problem quite simply...you go to the doctor to change it, so, rather than report it, it's quicker just to fix it; I think we don't report it because it's fixable...we report falls and pressure areas because we can't fix them on the spot but if it's a medication (prescribing) error we just go and get the chart fixed, and it's done' (ID34_Nurse).</i>	Contradict	Opioid prescribing errors that are readily fixable are rarely reported. The prevalence of opioid prescribing errors is likely substantially higher than reported.
<i>Opioid prescribing errors - charting errors</i>	Opioid charting errors account for half of reported opioid prescribing errors in specialist palliative care inpatient services.	Error contributory factors: Clinical communication <i>(Right now) there's one (chart)...that has everything on that page ceased, and not a nice, neat, it's, you know, scribble-scribble-scribble...at first glance at that chart, you go, 'that's all ceased'...and right in the middle of it, there's an oxycontin. That doesn't give us much of a chance, does it?' (ID45_Nurse).</i> <i>'So I said to the doctor, are you sure this is what you want? I think the</i>	Enhance	Medication charting errors, including illegible or ambiguous written orders, are common in specialist palliative care inpatient services, however, they are usually promptly rectified.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
		<i>intention was (for administration) today, but they re-charted it for tomorrow morning...they're human too...if we see something, we question it' (ID48_Nurse).</i>		
<i>Opioid prescribing errors - opioid conversion errors</i>	Less than 3% of reported opioid prescribing errors were attributed to conversion errors in NSW palliative care services.	<p>Missed doses and miscalculations</p> <p><i>'...opioid conversions are the huge danger area...and that happens many times when you're trying to stabilise pain, we're changing routes and we're changing drugs' (ID22_Physician).</i></p> <p>Rectify or report?</p> <p><i>Generally if I find a prescribing problem you just go and get (the doctor) to fix it, you don't put a report in (ID18_Nurse).</i></p>	Contradict	<p>Opioid conversion errors are perceived to be the most commonly occurring opioid prescribing error type in specialist palliative care inpatient services.</p> <p>However, as with opioid prescribing errors generally, opioid conversion errors are often intercepted by palliative care nurses, rectified and not reported.</p>
<i>Opioid dispensing errors</i>	Dispensing errors were rarely reported (3%-4%).	Not identified in qualitative data	Could not determine	It is unclear why the rate of opioid dispensing errors is so low in specialist palliative care inpatient services than in other settings, and this warrants further exploration in the palliative care context.
<i>Near miss incidents</i>	Near miss incidents were rarely reported (2%-5%).	<p>Rectify or report?</p> <p><i>If your double checking identifies something before you've drawn it all up and are going to give it then you've prevented it from being a problem, but</i></p>	Enhance	Near miss incidents are generally only reported if the potential for patient harm was high, or if the incident resulted in a narcotic discrepancy.

RESEARCH QUESTION 1: What is the prevalence, patient impact, and characteristics of opioid errors reported in specialist palliative care inpatient services?

Domain	Mixed methods inference from Study 2 (State-wide review) and Study 3 (local review)	Qualitative data (Study 5)	Data convergence	Mixed methods inference
		<i>I guess if someone's actually willing to go and take it to the patient, and there's the potential it would have been given without resistance, that would be reported (ID5_Nurse).</i>		

Appendix 12: Joint display for Research Question 2

Joint display A12 representing data integration, convergence and inference for Research Question 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample quote</i> (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
INDIVIDUAL FACTORS				
Active failures (human error) [ACTIVE FAILURES]	Study 2 - State-wide data: - 59% (n=222) of reported opioid errors attributed to active failures Study 4 - Local review of error contributing factors: - 68% (n=53) of reported opioid errors attributed to active failures	Human error is inevitable <i>'We are aware that human error plays a part in medication administration, I don't think there's any way around that, completely; we can be as diligent as you want, but at times (errors will still happen)' (ID36_Nurse).</i> <i>'I really do believe in improving systems rather than looking so much at people, because if systems are improved then people also improve automatically' (ID31_Nurse).</i>	Enhance	Human error is an inevitable aspect of opioid errors, that cannot be completely eliminated. However, it is essential to also consider the systems factors that may facilitate human error.
Inexperience [SITUATIONAL FACTORS]	Study 2 - State-wide data: - 8% (n=31) of reported opioid errors attributed to clinician inexperience Study 4 - Local review of error contributing factors: - 3% (n=3) of reported opioid errors attributed to clinician inexperience	Situational factors: clinician inexperience <i>'I think we've got to realise that we have a lot of new and young registrars that haven't seen, you know, someone on fentanyl and hydromorphone and methadone, and then being converted to a syringe driver...' (ID10_Nurse)</i> <i>When we have to make after hours calls...(the doctors) often they're going</i>	Confirm Enhance	The nature of opioid delivery in specialist palliative care inpatient services (high frequency, high doses, unusual opioid combinations) poses considerable challenges for inexperienced clinicians such as: clinicians who are new to the palliative care unit; junior doctors; and non-specialist palliative care prescribers.

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample quote</i> (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
		<p><i>by what we (nurses) see...if it's a more junior doctor, or a doctor from (another service), there could be so much room for an error there (ID18_Nurse).</i></p> <p><i>I think...when we have casual (staff)...or people who aren't familiar (with opioids)...there just seem to be a number of errors if we use inexperienced staff (ID37_Nurse).</i></p>		
SYSTEMS FACTORS				
Skill-mix and workload [LOCAL WORKING CONDITIONS]	<p>Study 2 - State-wide data:</p> <ul style="list-style-type: none"> - 2% (n=5) of reported opioid errors attributed to sub-optimal skill mix - 7% (n=17) of reported opioid errors attributed to workload <p>Study 4 - Local review of error contributing factors:</p> <ul style="list-style-type: none"> - nil reported opioid errors attributed to sub-optimal skill mix <p>10% (n=8) of reported opioid errors attributed to workload</p>	<p>Nursing skill-mix and ratios</p> <p><i>'if you are the only senior (nurse), you have to make the decisions. You have to help the new staff, the new grad, you have to guide them, help them to even (administer). You have to check not only twice, you have to check five times to make sure they're all on the right track. That is time consuming, and takes away your energy as well, that's how errors can come easily' (ID57_Nurse).</i></p> <p>Interdisciplinary skill-mix</p> <p><i>'If an inexperienced doctor charts a wrong dose, an inexperienced nurse is far less likely to pick that up, and sometimes the safeguard is having experienced nurses, so if there's a combination of inexperienced junior</i></p>	Enhance	Sub optimal skill mix and nurse ratios directly increases palliative care nurses' workload and heightens the risk of opioid error.

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample</i> quote (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
		<p><i>doctors and inexperienced nursing staff, I think that is where the potential for error is high' (ID9_Physician).</i></p> <p>Workload and errors</p> <p><i>'I think most of the prescribing errors happen at admission - they're (palliative care medical team) understaffed for admissions and the complexity of our patients has increased, the constant turnover means complex patients are being admitted daily and their (clinicians) proportional workload to manage those admissions I think is too high' (ID21_Physician).</i></p> <p><i>'...of course, it's workload that could be contributing to errors, time is a big contribution to errors' (ID61_Nurse).</i></p>		
Task characteristics of opioid delivery [SITUATIONAL FACTORS]		Opioid delivery in palliative care is different		
<i>Time spent on opioid delivery</i>	Not identified in quantitative data	<p><i>'We just said to each other the other day, 'how's your day?', she said, 'I didn't get out of the (drug) cupboard the whole shift' and I said, my shift was the same. And you'd hear it all the time...because...you can literally be standing in that (drug) room and not leave. Yesterday, we did five (infusion pumps) in a row...and then the time doing the drug check, and all the</i></p>	Enhance	Opioid delivery consumes a large part of each shift for specialist palliative care nurses.

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample</i> <i>quote</i> (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
		<i>breakthroughs...it's hours, hours, hours' (ID30_Nurse).</i>		
<i>Opioid doses</i>	Not identified in quantitative data	<i>'It's different, totally different, in another hospital you wouldn't use this dosage (of opioids)' (ID1_Nurse).</i>	Enhance	Opioid doses in specialist palliative care inpatient services are considerably higher than in other care settings.
<i>Complexity of opioid delivery</i>	Not identified in quantitative data	<i>'...when they're doing complicated dose conversions, not only are they converting from one variety of opioid to another, but they're converting the route or the formulation, so oral to subcutaneous, or long-acting to fourth hourly, or subcut morphine to hydromorphone, methadone rotations; the more the complexity of the dosing, the more chance there is for error, if there's multiple steps, is my experience' (ID1_Physician). 'What's expected of our nurses (is) ...the concentration required with some of the medications (opioids)' (ID41_Pharmacist).</i>	Enhance	Opioid delivery in specialist palliative care inpatient services routinely involves complex tasks, with error potential at each step.
<i>Interruptions</i>	Study 2 - State-wide data: - Nil reported Study 4 - Local review of error contributing factors: - 5% (n=4) of reported opioid errors attributed to interruptions and/or distractions	<i>'I think a point that's critical is when you're there at the drug cupboard and you're drawing something up and people are talking to you and everything is busy...you know you're trying to do your drug calculations, draw up the right dose...and it only takes that really quick thing for you to</i>	Confirm Enhance	Preparing opioids for administration is a complex and time consuming task that requires concentration. Interruptions during the opioid preparation process are common, however, are seen as routine occurrences in the context of opioid

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample</i> <i>quote</i> (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
Patient factors [SITUATIONAL FACTORS]	Study 2 - State-wide data: - >1% (n=2) of reported opioid errors attributed to patient factors Study 4 - Local review of error contributing factors: - Nil reported	Patient factors and opioid errors <i>'...the patient that is being looked after in palliative care, is very complex with a lot of co-morbidities...and polypharmacy... it leaves the more junior staff in a very difficult situation because they have to provide care, and when they do that, often times this is where errors tend to happen'</i> (ID31_Nurse). <i>'... there's a lot of unstable patients, or deteriorating patients that need a lot of breakthroughs, the doctors are changing orders frequently, you have anxious families, that all adds up...and you could really do with extra staff numbers then'</i> (ID11_Nurse)	Enhance	delivery, that palliative care clinicians endeavour to actively manage. Although palliative inpatient care is increasingly complex, patient factors rarely contribute directly to opioid errors in specialist palliative care inpatient services. Rather, clinician inexperience and increased workload due to the fluctuating needs of palliative patients heightens the risk of error.
Physical environment [LATENT ORGANISATIONAL FACTORS]	Not identified in quantitative data	Local working conditions <i>'In our treatment room it gets super busy and super noisy, so when you're trying to draw up a complicated (subcutaneous infusion pump), or</i>	Enhance	The physical environment of the drug preparation area contributes to opioid error.

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample</i> <i>quote</i> (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
Absence of pharmacist input [LATENT ORGANISATIONAL FACTORS]	Study 3 - Local retrospective review: - palliative care services without a clinical pharmacist reported the highest number of opioid prescribing errors	<i>even you're just trying to move because someone's got to get into the cupboard, you can (make an error)' (ID45_Nurse).</i> Gaps in support from central functions <i>'We don't have enough clinical pharmacists on the ward so they don't come to review the charts frequently, that is a concern...you know if the medication route is wrong but no-one checks, or the doctor charted for bd but only put down one time in the chart' (ID01_Nurse)</i>	Confirm	Absence of a clinical pharmacist in the specialist palliative care inpatient service increases opioid prescribing errors.
Clinical communication factors [OVERARCHING FACTOR]				
<i>Communication systems</i>	Not identified in quantitative data	Errors on admission <i>'I think (there's a risk) in the transition from community to inpatient, because there may be more than one prescriber of the opioid and what the actual patient has been taking may be different from what's being prescribed...and that there's not a uniform medication list between GP, the community team, and the inpatient team necessarily' (ID48_Physician).</i>	Enhance	A lack of centralised patient information increases the risk of error during palliative patient care transitions.

Domain [ALIGNMENT WITH YORKSHIRE CONTRIBUTORY FACTORS FRAMEWORK]	Quantitative data (Studies 2 - 4)	Qualitative data theme and <i>sample</i> quote (Study 5)	Data convergence	Mixed methods inference
RESEARCH QUESTION 2: What are the individual and systems factors that contribute to opioid errors in specialist palliative care inpatient services?				
<i>Interpersonal communication</i>	<p>Study 2 - State-wide data:</p> <ul style="list-style-type: none"> - 15% (n=36) of reported opioid errors attributed to clinical communication deficits (written communication 70%, clinical handover 30%) <p>Study 4 - Local review of error contributing factors:</p> <ul style="list-style-type: none"> - 17% (n=13) of reported opioid errors attributed to clinical communication deficits (written communication 39%, clinical handover 61%) 	<p>Contemporaneous handover</p> <p><i>'So if anything for a patient changes, as a nurse, our job is to then let the doctor know that this has just changed, the patient's in more pain, or whatever. It'd be really nice if that was reciprocated, in terms of, they've charted a new drug for a patient, especially an opioid, can you let us know that that has been charted? Just a quick tap on the shoulder and say "Hey, we've just charted this"' (ID12_Nurse).</i></p> <p>Rectify or report?</p> <p><i>We're generally pretty good in going and saying: Can you rewrite this again? We can't read it! (ID44_Nurse).</i></p>	<p>Confirm</p> <p>Enhance</p>	<p>Clinical communication deficits, particularly with clinical handover, result in opioid errors in specialist palliative care inpatient services.</p> <p>In local services, ambiguous or illegible written orders are promptly challenged and clarified.</p>

Appendix 13: Joint display for Research Question 3

Joint display A13 representing data integration, convergence and inference for Research Question 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

Domain	Quantitative data (Studies 3 and 4)	Qualitative data theme and <i>sample quote</i> (Study 5)	Data convergence	Mixed methods inference
Safety culture				A positive, non-punitive, safety culture, underpins opioid safety in specialist palliative care inpatient services.
<i>Supervision and leadership</i>	Not identified in quantitative data	<p>Clear expectations regarding safe opioid delivery</p> <p><i>We've said that because we do so many (opioids) instead of expecting that we would, as a result of that, have a high rate (of errors), we've said...we should be experts at it and we should be the best at it...we've continued to raise the profile in suggesting that it's a really pivotal part of what we do. I think it's that culture of, 'this is important' (ID33_Nurse Unit Manager).</i></p> <p><i>'For me [the safety culture] is from the top down, definitely management has a huge influence on the culture...'</i> (ID36_Nurse).</p>	Enhance	A commitment to opioid safety from leadership is evident in specialist palliative care inpatient services.
<i>Policies and procedures</i>	<p>Study 4 - Local review of error contributing factors:</p> <ul style="list-style-type: none"> - 5% (n=4) of opioid error reports specifically identified adherence to 	<p>Empowering clinicians to practise safely</p> <p><i>We're very strict...and again, it's just policy. We've had a lot of new staff</i></p>	<p>Confirm</p> <p>Enhance</p>	Current opioid management/handling policies are effective in reducing opioid errors, and mitigating patient

RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

Domain	Quantitative data (Studies 3 and 4)	Qualitative data theme and sample quote (Study 5)	Data convergence	Mixed methods inference
	opioid management/handling policy had prevented the error from reaching the patient, or mitigated patient harm following an error	<i>start over the last year or two, and I think because they've come into that culture as existing, with all the strictness around doing things the right way (following policy)...that's the funny thing, we're just doing it the right way, it's not like we're re-inventing the wheel.</i>		harm from error, when they are consistently implemented.
<i>Error reporting culture</i>	Not identified in quantitative data	Promoting a non-punitive approach to error <i>I don't think we have a culture where we're frightened to report anything. I don't think we have a culture where we're afraid to own up to any mistakes... I think we're all accepting of each other, and if a mistake is made, you have to do something about it, and I don't think there's a culture of shielding that (mistake) from management (ID47_Nurse).</i>	Enhance	A non-punitive error reporting culture is evident in specialist palliative care inpatient services, and promotes a systems approach to error management.
Palliative care nurses' error interception practices	Study 4 - Local review of error contributing factors: - 10% (n=8) of identified opioid errors were intercepted by palliative care nurses and subsequently reported	Working as a team <i>So I said to the doctor, are you sure this is what you want? I think the intention was (for administration) today, but they re-charted it for tomorrow morning...they're human too...if we see something, we question it' (ID48_Nurse).</i>	Confirm Enhance	Palliative care nurses routinely identify and intercept opioid errors, particularly prescribing errors.
Palliative care pharmacists in the interdisciplinary team	Study 3 - Local retrospective review: - All bar one opioid prescribing error (88%, n=7) was reported in the	Working as a team <i>We're really fortunate that we have pharmacists on site, they're very open to anybody spending time with them,</i>	Confirm Enhance	A palliative care pharmacist in the interdisciplinary team appears to considerably reduce opioid

RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

Domain	Quantitative data (Studies 3 and 4)	Qualitative data theme and <i>sample quote</i> (Study 5)	Data convergence	Mixed methods inference
	service without a palliative care pharmacist.	<i>clarifying anything, if the doctors are not here and the nurses are uncertain about why the breakthrough dose is such as it is (ID34_Clinical Nurse Educator).</i>		prescribing errors, and is a valued team member.
Interdisciplinary collaboration	Not identified in quantitative data	Working as a team <i>'When I'm calculating something, if it's particularly complex or warrants double checks I often ask one of the nurses, what do you think?' (ID56_Physician).</i> <i>It's that combination of alertness, awareness, everyone being aware of inexperience, and an open, blame-free culture (ID09_Physician).</i>	Enhance	Effective interdisciplinary collaboration in specialist palliative care inpatient services is an additional error safeguard. Interdisciplinary collaboration is essential to mitigate the risk of opioid error by less experienced clinicians.
Education and training	Not identified in quantitative data	Education is empowering <i>I think nurses are very happy to challenge orders...I think just learning about the opioid conversion, learning what that means and why it's important (makes them confident to challenge), so being empowered by education (ID55_Clinical Nurse Educator).</i>	Enhance	Targeted and ongoing opportunities for opioid education empowers clinicians to identify and intercept opioid errors.
Electronic medication management system	Study 3 - Local retrospective review: - Nil reported omitted dose errors in service using electronic medication management system - Omitted dose errors ranged from 29% to 69% of reported opioid administration errors in specialist	Quality process and risk management <i>'I worked in (other palliative care service) and the main issue there was we missed lots of drug. And that was because of the paper chart. Since I came here (electronic medication chart), I can't think of going back to a</i>	Confirm	Electronic medication management systems appear to substantially reduce omitted opioid dose errors in specialist palliative care inpatient services. Given that omitted dose errors are the most frequently reported opioid error type in specialist palliative care

RESEARCH QUESTION 3: What are the opioid error mitigating factors in specialist palliative care inpatient services?

Domain	Quantitative data (Studies 3 and 4)	Qualitative data theme and <i>sample quote</i> (Study 5)	Data convergence	Mixed methods inference
	palliative care inpatient services using paper based medication charts	<i>paper chart...because it (the electronic chart) alerts us all the time. We can't miss it' (ID57_Nurse)</i>		inpatient services, and substantially contribute to iatrogenic patient harm, transitioning to electronic medication management systems for services currently using paper-based medication charts is warrants consideration.