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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)

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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-opiod-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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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.