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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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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.

1.8 References

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