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Opioid errors reported in Australian inpatient palliative care services: a retrospective review.

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ABSTRACT

Opioids are a high-risk medicine frequently used to manage palliative patients' cancer related pain and other symptoms. Despite the high volume of opioid use in inpatient palliative care services, and the potential for patient harm, few studies have focused on opioid errors in this population.

OBJECTIVES

To: i) identify the number of opioid errors reported by inpatient palliative care services; ii) identify reported opioid error characteristics; iii) determine the impact of opioid errors on palliative patient outcomes.

METHODS

A 24 month retrospective review of opioid errors reported in three inpatient palliative care services in one Australian state.

RESULTS

Of the 55 opioid errors identified, 84% reached the patient. Most errors involved morphine (35%) or hydromorphone (29%). Opioid administration errors accounted for 76% of reported opioid errors, largely due to omitted dose (33%), or wrong dose (24%) errors. Patients were more likely to receive a lower dose of opioid than ordered as a direct result of an opioid error (57%), with errors adversely impacting pain and/or symptom management in 42% of patients. Half (53%) of the affected patients required additional treatment and/or care as a direct consequence of the opioid error.

CONCLUSION

This retrospective review has provided valuable insights into the patterns and impact of opioid errors in inpatient palliative care services. Iatrogenic harm related to opioid under-dosing errors contributed to palliative patients' unrelieved pain. Better understanding the factors that contribute to opioid errors and the role of safety culture in the palliative care service context warrants further investigation.

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KEY WORDS

Palliative Care; Opioid; Medication Errors; Incident Reporting; Patient Safety; Hospice care.

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BACKGROUND

Medication delivery errors pose one of the greatest risks to patient safety.[1] Several drug-classes, classified as 'high-risk' medicines, are more likely to cause significant patient harm if they are prescribed or administered incorrectly.[2] Opioids are a high-risk medicine frequently prescribed and administered to palliative patients in order to manage complex pain and other symptoms. The risk of medication errors, and resultant patient harm(s), is increased in palliative patients who tend to be older, have multiple co-morbidities, and are taking numerous medications.[3]

Palliative care clinicians have identified that safe opioid use is a patient safety priority.[4] Despite the high volume of opioid use in palliative care services, few studies have reported on medication safety events causing patient harm in this population.[5]

AIM

To: i) identify the number of opioid errors reported by specialist palliative care inpatient services; ii) identify reported opioid error characteristics; and iii) determine the impact of opioid errors on palliative patient outcomes.

METHODS

Design: A retrospective review of opioid errors reported over two years (March 1, 2013 – February 28, 2015).

Setting: Three specialist palliative care inpatient services in metropolitan New South Wales (NSW), Australia: two 40-bed units (Services 1 and 2); and a 20-bed unit (Service 3).

Services 1 and 3 used paper medication charts to record opioid orders and administrations, Service 2 utilised an electronic medication management system. Services 2 and 3 employed full time clinical pharmacists.

Inclusion criteria: Errors involving: a Schedule 8 opioid ('opioid'); reported via the services' internal incident management system; and, an inpatient aged ≥18 years, admitted to the palliative care service during the review period.

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Incident reporting systems: At the time of this review, mandated incident reporting was undertaken using one of two electronic incident management/reporting systems in NSW ('State').

Opioid management: All palliative care services in NSW are required to adhere to the State mandated: incident management, medication handling, and high-risk medicine management policies.[6] The opioid delivery process is required to be witnessed by another person, with an independent double check prior to administration (Supplementary Textbox 1).

Data collection

A custom data collection tool was developed and piloted to capture reported opioid errors. An error was defined as 'a*ny unplanned event which causes, or has the potential to cause, harm to a patient'*, and includes errors that are intercepted before causing patient harm ('near miss').[7]

Ethics: The review was approved by the hospital and University Human Research Ethics Committees.

Data analysis

Detailed descriptive statistics and percentage analysis was used to quantify and characterise opioid errors. Quantitative data analysis was undertaken with the IBM SPSS Statistics V25 software package. The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy[8] and Index[9] were used to guide categorisation of opioid incidents according to incident type and patient outcome.

RESULTS

Opioid error characteristics

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 (Service 1: 1.0; Service 2: 0.6; Service 3: 1.7) (Supplementary Figure 1).

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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*) (Supplementary Table 1).

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) than as required ('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).

Reported opioid error types

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 (Supplementary Table 2). 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) (Table 1). 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 1).

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 (Supplementary Table 2).

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Table 1: Reported opioid error types and dosage characteristics

Opioid over-dose characteristics				
Error category	**Error type**	**Opioid ordered**	**Opioid administered**	**Over-dosage[10]**
Prescribing	Medication charting – duplicated dose	Morphine SC 20 mg PRN	Additional morphine SC 20 mg PRN over 24 hours	2-fold
	Medication charting	Hydromorphone PO 0.5 mg regular intended/2 mg re-charted in error	Hydromorphone PO 2 mg	4-fold
	Conversion error	Morphine PO to Hydromorphone SC		1.5-fold
		Fentanyl TD to Hydromorphone SC		2-fold
Administration	Wrong dose	Oxycodone PO 20 mg PRN	Additional oxycodone PO 20 mg PRN	2-fold
		Morphine PO 20 mg regular	Morphine PO 40 mg	2-fold
		Oxycodone PO 10 mg PRN	Oxycodone PO 20 mg[a]	2-fold
		Hydromorphone PO 5 mg regular	Hydromorphone PO 10 mg	2-fold
		Morphine SC 60 mg via syringe driver	Morphine SC 60 mg via two syringe drivers	2-fold
	Wrong drug	Morphine SC 5 mg regular	Hydromorphone SC 5 mg	6-fold
		Morphine SC 10 mg regular	Hydromorphone SC 10 mg	6-fold
		Fentanyl SC 350 mcg (via syringe driver)	Morphine SC 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
Opioid under-dose characteristics				
Problem type	**Error type**	**Opioid ordered**	**Opioid administered**	**Under-dosage (% of ordered dose)[10]**

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Administration	Wrong dose	Morphine SC 40 mg regular	Morphine SC 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 SC 5 mg regular	Morphine SC 5 mg	12%
		OxyContin PO 10 mg regular	MS Contin PO 5 mg	33%
		Hydromorphone SC 1.5 mg PRN	Fentanyl SC60 mcg	50%

Error type	**Number of doses omitted**	**Frequency**
Omitted dose	1	9
	2	3
	3	2

PO – per oral; SC – subcutaneous; TD – transdermal; [a] two instances of same wrong dose error in different patients

Patient impact

One-third (33%, n=18) of opioid errors resulted in patient harm (Supplementary Table 3), 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.

Over half of patients (57%, n=26), received a lower dose of opioid than ordered ('under-dose') as a direct consequence of an error, with 42% (n=11) of these patients requiring PRN opioids to manage their increased pain (n=9) or shortness of breath (n=2) immediately following the error.

Thirty nine percent (n=18) of patients experienced an opioid over-dose due to the opioid error, ranging from 1.5 to 11-fold higher doses of the intended opioid order being administered (Table 1). Opioid toxicity was documented in 39% (n=7) of these patients, however administration of an opioid reversal agent was not required.

DISCUSSION

The percentage of reported medication errors involving opioids in this review is almost three-fold higher than that previously reported in other health care

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settings.[10,11] Comparatively, opioid errors comprised up to 12% of all reported medication errors in acute care[10] and nursing homes[11] internationally. These differences may reflect the higher volume of opioids used in palliative care inpatient services compared to other health care settings.

The differences in opioid error reporting noted in this review may be linked to the use of electronic medication management systems versus paper based systems, as the lowest overall incidence of both reported opioid errors and omitted dose errors, came from the service utlising the electronic system. In contrast, omitted doses comprised up to two-thirds of reported adminstration errors in the two services using paper medication charts. Electronic medication management systems have been shown to reduce medication errors in other clinical settings,[12] 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,[13] and this factor warrants further exploration in the palliative care service context.

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 under-dosing, which is over double the rate reported in other hospital settings (57% vs 23%), where opioid overdose is a more likely error outcome.[14] Although wrong drug and wrong dose administration errors caused opioid under-dosing in this review, omitted opioid doses were the primary contributor to opioid under-dosing and subsequent adverse impact on patients' previously well managed pain.

Unrelieved pain is a major issue in specialist palliative care[15] and it appears opioid errors, particularly omitted dose errors, may be contributing to the burden of palliative patients' pain. Better understanding the factors that contribute to or mitigate opioid errors, including systems factors and the impact of error reporting culture, and

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developing strategies to prevent iatrogenic pain occurring as a result of opioid errors, is a priority for this clinical setting and population.

Strengths and limitations

A major strength of this review is that it: examined reported opioid errors across three similar inpatient palliative care services; identified opioid error incidence; and characterised reported opioid errors in accordance with accepted taxonomies.[8,9] A limitation of this review is that, as medication errors are consistently under-reported it is conceivable that that the actual number of medication errors patients experienced during their admission may have been higher than those reported.[16] 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.

CONCLUSIONS

Establishing a baseline profile of opioid error characteristics and incidence 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.

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CONTRIBUTORSHIP

All authors (NH, TS, DR, SL, JP) contributed to the design of the study. NH undertook the data collection and all authors participated in data analysis and interpretation. All authors have critically reviewed the manuscript and given approval to submit the final version.

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COMPETING INTERESTS

The authors have no competing interests to declare.

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Supplementary Textbox 1: Mandated medication handling requirements for Schedule 8 medicines in NSW, Australia[1]

- 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 checks 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.

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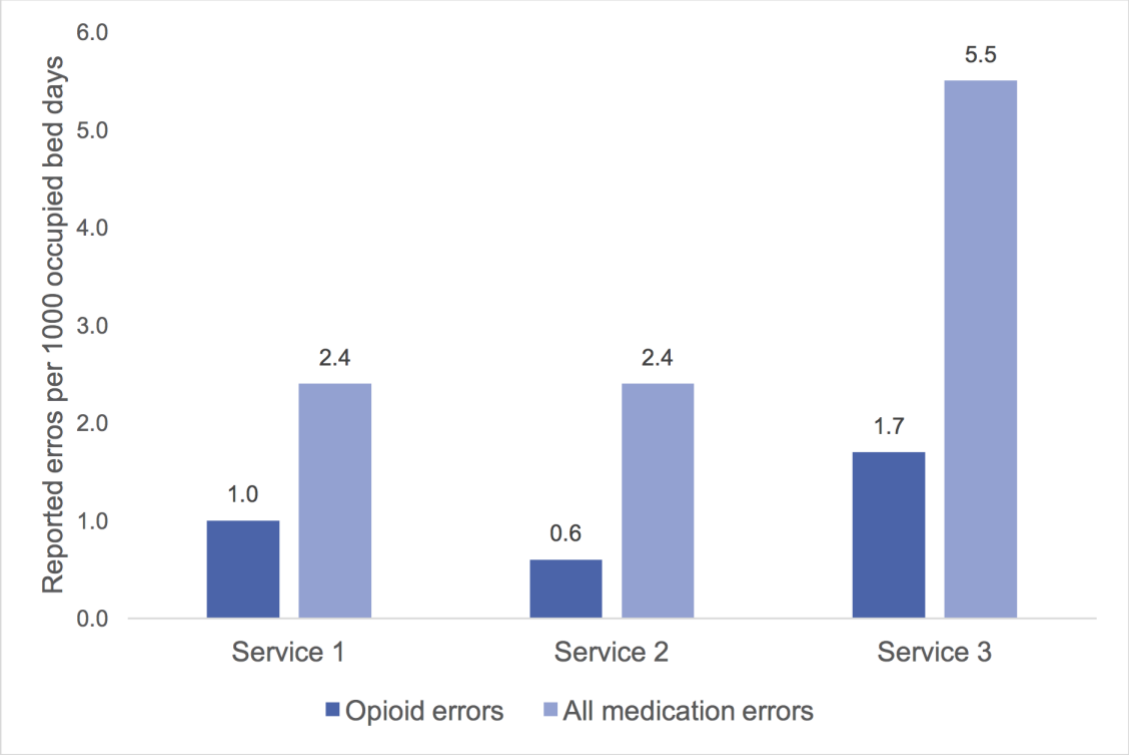

Supplementary Figure 1: Reported opioid errors versus all medication errors, per 1000 occupied bed days, in review period

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Supplementary Table 1: 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 (±9.2)	67.3 (±9.9)	68.0 (±10.5)	71.3 (±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 (±13.5)	30.9 (±24.6)	32.8 (±20.3)	27.2 (±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)

[a]Other 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).

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Supplementary Table 2: 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)
Prescribing	**Total**	**7**	**(31.8)**	**1**	**(7.1)**	0	0	**8**	**(14.5)**
	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)
Near miss	**Total**	**2**	**(9.1)**	0	0	**1**	**(5.3)**	**3**	**(5.4)**
	Wrong patient	2	(100)	0	0	1	(100)	3	(100)
Dispensing	**Total**	**0**	**0**	**1**	**(7.1)**	**1**	**(5.3)**	**2**	**(3.6)**
	Drug preparation error	0	0	0	0	1	(100)	1	(100)
	Expired medicine dispensed	0	0	1	(100)	0	0	1	(100)

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Supplementary Table 3 – Patient outcome of opioid errors

National Coordinating Council for Medication Error Reporting and Prevention error category[1]	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 of relevant physiological or psychological signs.*
[c] *Intervention: change in therapy or active medical treatment.*

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