

Palliative Care Australia

Response to the National Opioid Analgesic Stewardship Program: Discussion Paper for Public Consultation

June 2021

Introduction

Palliative Care Australia (PCA) is the national peak body for palliative care. PCA represents those who work towards high quality palliative care for all Australians who need it. Working closely with consumers, our Member Organisations and the palliative care workforce, we aim to improve access to, and promote palliative care. We believe quality palliative care occurs when strong networks exist between specialist palliative care providers, primary care providers and support care providers and the community.

PCA Response to the National Opioid Analgesic Stewardship Program: Discussion Paper for Public Consultation

PCA commends the Australian Commission on Safety and Quality in Health Care (ACSQHC) for its leadership in progressing the development of the **National Opioid Analgesic Stewardship Program**. The use and management of opioids in the Australian health care system and around the world is a critical area of policy and health systems regulation. PCA recognises that governments and regulators need to take appropriate action to prevent and mitigate against the misuse of opioids and the increasing rates of opioid addiction and dependence in the general population.

PCA however, is also concerned that palliative care patients can be at risk of unintended harm and put at greater chance of increased pain and suffering when regulations at the legislative and health system level place restrictions without appropriate exemptions or separate arrangements for palliative care patients.

In May 2019, PCA published a Position Statement on <u>Sustainable Access to Prescription Opioids for use in Palliative Care.</u> This Position Paper outlines PCA's views about access to opioids for people living with a life-limiting illness and receiving palliative care including in acute settings. The recommendations (abbreviated) from the Position Statement are:

- 1. All prescribers are enabled to access appropriate opioids (oral and parenteral) consistently for pain and breathlessness management for people living with life-limiting illnesses, without the burden of unnecessary regulatory barriers.
- 2. Compulsory palliative care and opioid management education for all medical, nursing, allied health and pharmacists to be built into undergraduate curriculum.
- 3. Ensure an adequate supply and stock (imprest) of minimum levels of opioids commonly used in palliative care.

- 4. Nationally consistent and streamlined prescribing approval policies for opioids that promotes pain and addiction specialists working closely with palliative care.
- 5. The introduction of national real time monitoring for all opioid prescriptions with software that is enabled to identify palliative care prescriptions at point of care across acute, subacute, aged care and primary care sectors.
- 6. Palliative care teams to work with acute services to develop opioid stewardship policies informing clinical plans to ensure appropriate prescribing, de-prescribing, and dispensing of opioids with rapid communication to the primary care team and community pharmacy to reduce risk of forced tapering of appropriate opioid management.
- 7. The Australian Government to review (on a regular basis) the Palliative Care Schedule of the Pharmaceutical Benefit Scheme (PBS).
- 8. Review of the Medicare Benefits Schedule (MBS) specific to palliative care by way of item numbers and explanatory notes to facilitate consultation in primary and specialist practice.

The Position Statement which was endorsed by 12 other peak health bodies includes a series of recommendations for governments and regulators, some of which PCA is pleased to note have already been acted upon. The 12 endorsing bodies to the PCA Position Statement are:

- Australian College of Nurses (ACN),
- Australian College of Nurse Practitioners (ACNP),
- Australian College of Rural and Remote Medicine (ACCRM),
- Australian Healthcare and Hospital Association (AHHA),
- Australian and New Zealand Society of Palliative Medicine (ANZSPM),
- Australian Pain Society (APS),
- Painaustralia,
- Paediatric Palliative Care Australia and New Zealand (PAPCANZ),
- Palliative Care Nurses Association (PCNA),
- The Pharmacy Guild of Australia,
- Royal Australasian College of Physicians (RACP), and
- Society of Hospital Pharmacists of Australia (SHPA).

As reflected in the PCA Position Statement, efforts to reduce inappropriate prescribing that can lead to harm from misuse and abuse of opioids in the general population are warranted and stewardship measures in acute settings need to respond appropriately. If not addressed, a detrimental consequence can be that palliative care patients are being placed at risk of unintended harm through reduced or ceased opioid prescribing. Existing literature suggests that risks of opioid abuse are low in palliative care populations.¹ In palliative care, opioid use is usually limited to the final months of life and is therefore unlikely to lead to the same problems. Tolerance and dose escalation are of little consequence when the intent is time-limited symptom control.²

Stewardship measures in acute settings need to separate the unique and specific requirements of palliative care patients. Experience has clearly demonstrated that when health professionals believe they will be overly scrutinised or face punitive measures, they limit their prescribing of opioids including for patients nearing the end of life. Recently, the top 20% of opioid prescribers in Australia including almost 5000 GPs were sent letters warning them that their clinical practice was being scrutinised thereby challenging their professional opinion on patient clinical assessment. An

¹ Pinkerton, R., Mitchell, G., and Hardy, J. (2020), Stringent Control of Opioids: Sound Public Health Measures but a Step Too Far for Palliative Care? *Current Oncology Reports* 22(4), 1-9.

² Mitchell, G., Willmott, L., White, B., Piper, D., Currow, D., and Yates, P. (2019), A Perfect Storm: Fear of Litigation for End of Life care. *Medical Journal of Australia* 210 (10) 441.

unintended but predictable consequence appears to have arisen: reports of some practitioners choosing to abandon end of life care altogether rather than risk professional ruin should they persist in the use of opioid therapy.³

While supporting the options for better use of opioids in the acute setting and more prudent monitoring in non-cancer chronic pain, it is critical that acknowledgment is made in the National Opioid Analgesic Stewardship Program that considerations for opioid use in palliative care is a unique clinical context and that any changes in arrangements do not indirectly adversely impact the appropriate prescribing and use of opioids in palliative care.

In addition to the key issues raised in the Sustainable Access to Prescription Opioids for use in Palliative Care Position Statement, PCA makes the following comments using the ACSQHC discussion questions:

- ١. What are the barriers to improving appropriate prescribing of opioid analgesics?
 - a. What works currently and should be done more?
 - b. What doesn't work currently and should be done less?
- II. What are the system-wide challenges that need to be addressed?
- III. What are the gaps in current practices and processes that inhibit achieving positive patient outcomes / best practice?
- IV. What does best practice look like in 2025?
 - Ι. What are the barriers to improving appropriate prescribing of opioid analgesics?
 - a. What works currently and should be done more?
 - b. What doesn't work currently and should be done less?

A key barrier to improving appropriate prescribing of opioid analgesics is a lack of understanding about patients who are at risk of opioid misuse as compared to palliative care patients who need appropriate and often higher doses of opioids for longer periods to manage their pain and symptoms. Treatment of chronic pain with long term opioids and use of opioids at the end of life are two different issues⁴ and the National Opioid Analgesic Stewardship Program needs to reflect this difference.

The appropriate prescribing of opioids should not be limited to a framework solely for restriction of use, but rather support for appropriate dosing (which will often mean increased dosing) for palliative care patients. Otherwise, the greater risk may be that staff's fears will lead to underuse of opioids and patients dying in pain.5

The barriers that can affect palliative care patients are that regulatory regimes within acute settings do not acknowledge the complexity of opioid prescribing in the palliative care context and that both doses, frequency of administration and opioid combinations differ substantially compared to other acute care settings. This includes:

The complexities of prescribing,

³ Ibid.

⁴ Ibid.

⁵ Gerber, K., Willmott, L., White, B., Yates, P. Mitchell, G., Currow, D. and Piper, D. (2021), Barriers to Adequate Symptom Relief at the End of Life: A Qualitative Study Captures Nurses' Perspectives, Collegian, 19:25.

- variations in opioid prescribing policies,
- conversion of opioids across the entire health system,
- systematic reviews of prescribing that genuinely measure best practice, and
- measurement of errors that then informs practice change.

A research study capturing nurses' perspectives into barriers to adequate pain and symptom relief at the end of life identifies five main drivers of inadequate symptom management at the end of life. These relate to:

- 1) Fears regarding symptom relief (which included hastening death, causing addiction, loss of consciousness for the patient and legal/profession repercussions).
- 2) Lack of knowledge, experience and training nurses identified knowledge gaps regarding medication and palliative care, symptom assessments, recognition of dying, and relevant law
- 3) Personal, cultural and religious beliefs this influenced staff's willingness to offer pain relief, and patients' and families' willingness to accept it.
- 4) Lack of communication between medical teams, patients and families.
- 5) Institutional barriers played an important role as time constraints, lack of staff support and difficulties accessing medications, physicians and palliative care services hindered end of life symptom management.⁶

The unique requirements of opioid delivery in the inpatient palliative care setting differs from other health care settings and this may present a barrier to appropriate prescribing. Put simply, in inpatient palliative care settings, 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.⁷

Further, the phenomena of 'interruptions' during medication administration are thought to be inevitable, precisely because medication administration does not have a clearly delineated start and endpoint. As interruptions increase the risk of medication error, reducing them is a patient safety priority. However, 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 skills mix.⁸

There is a lack of a systematic and (encouraged) pathway for continuous professional development in quality use of opioids accessible from junior levels (graduate nurses and junior medical officers/pharmacists right up to senior people even in specialist practice) tailored to their scope of practice/competencies/to improve issues seen in health systems.

A critical barrier in any acute setting will be the potential risk of miscommunication where patients or their families face language and communication challenges. The risk of misunderstandings and miscommunication where translation is not possible or accurate can lead to problems with attributing pain and symptoms to their causes and to determining palliative care status. Consistent high quality consumer information which takes into account non-English speaking and other diverse needs groups is a current barrier. Further, another barrier is that consumer information in packs is

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⁶ Ibid.

⁷ Heneka, N., Bhattarai, P., Shaw, T., Rowett, D., Lapkin, S. and Phillips, J. (2019a) Clinicians' Perceptions of Opioid Error-Contributing Factors in Inpatient Services: A Qualitative Study. *Palliative Medicine*, 1-15. ⁸ Ibid.

not tailored to needs of palliative care patients – consumer information would be a helpful approach to build consumer understanding/confidence about use of medications for palliative care patients.

In the community setting, prescribing of opioids in the community requires a system which recognises GPs as important players and supports them to do this well and provides them with confidence that the system (and audits) are there to support them especially those who choose aged care or palliative care as a focus of their practice. A current barrier is that GPs often don't write up opioid medication orders, which can limit the ability of nurses to safely administer medications for patients in a timely manner. Nurses often play a key role in monitoring the written orders, picking up on errors, and spend further time attempting to gain opioid orders that comply with administration policy for the sake of patient care. This often delays optimum symptom management.

a. What works currently and should be done more?

The use of opioids in palliative care needs to be protected from the attempt to reduce opioid use in the management of non-cancer pain and post-surgery. The availability of appropriate opioid options for use in palliative care situations, which can be in institutional care or at home, need to be maintained and further developed. This could include extending the following exemption to other medications used for palliative care patients:

• Restricting the indication of fentanyl patches for the management of pain associated with cancer, palliative care and exceptional circumstances (page 12 of the Consultation Draft).

PCA supports the stewardship measure identified on page 14 of the Consultation Draft for:

• Limited prescribed quantity of opioid analgesics, except when directed by Pain Medicine or Palliative Care specialists.

Studies have suggested that where they are in place, the following approaches work well and should be encouraged more broadly:

- designated pharmacist to routinely check prescriptions before dispensing/administration;
- designated Clinical Nurse Educators (CNE) to support individual and group education;
- adequate interdisciplinary skill mix (e.g., senior nurse with junior doctor);
- strong interdisciplinary communication and collaboration;
- a positive safety culture which encourages error reporting; and
- electronic prescribing systems⁹

Feedback from the palliative care sector has also noted practices that work well:

- Services and facilities that utilise models that incorporate the use of pharmacists who have roles in reviewing practice, education, monitoring errors and patient/ carer education.
- Community pharmacists who have strong understanding of opioid prescribing and work to improve GP practices of prescribing.
- Regular education of training of staff (particularly doctors in acute settings and GPs) with a focus on quality use of medicines and integrated with other opioid education contrasting

⁹ Ibid and Heneka, N., Bhattarai, P., Shaw, T., Rowett, D., Lapkin, S. and Phillips, J. (2019b). Mitigating Opioid Errors in Inpatient Palliative Care: A Qualitative Study. *Collegian*. DOI: https://doi.org/10.1016/j.colegn.2019.09.005

when it is and isn't appropriate to prescribe within a clinician's broad practice may be more helpful than 'siloed training'. Training would also be beneficial for community pharmacists, junior medical officers, those working in private practice/hospitals, and community nurses.

A resource that is helpful to many in the sector currently is the Australian cancer pain guidelines: https://wiki.cancer.org.au/australia/Guidelines:Cancer_pain_management). These guidelines provide a visible evidence base summary to inform practice and set the standard for appropriate prescribing and should be resourced to remain current, and be integrated into point of care systems, e.g GP software.

b. What doesn't work currently and should be done less?

There are a number of practices in acute settings that should be done less or not at all. These include:

- Absence of a clinical pharmacist;
- punitive approach to error reporting;
- paper-based prescribing systems;
- lack of education around opioid prescribing in the palliative care context.¹⁰

Further, a culture that promotes a fear of overprescribing for palliative care patients and the fear of punitive action if they are seen to be overprescribing is not working.

Studies have identified that the absence of a palliative care pharmacist in the specialist palliative care inpatient services interdisciplinary team 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. The absence of an onsite pharmacist is perceived to increase the risk of prescribing errors, as, although nurses routinely check opioid orders for errors prior to administration, review by the onsite pharmacist is seen an additional, high-risk medicine, safety check.¹¹

GP paper based prescribing is often difficult to read and/or incomplete in meeting prescribing requirements so this practice should be minimised and preferably stopped.

II. What are the system-wide challenges that need to be addressed?

As has been noted by Willmott *et al, every* day, thousands of health professionals provide medical treatment to Australians as they approach the end of their lives. An important component of that medical treatment is provision of medication to alleviate pain and other symptoms. So that patients can experience the best possible medical care at the end of life, it is critical that medical treatment can be provided by health professionals who are not constrained by ill-informed concerns about potential or even likely legal or disciplinary consequences of providing pain and symptom relief that may incidentally hasten a patients' death. The available anecdotal evidence in Australia suggests

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¹⁰ Ibid.

¹¹ Heneka *et al* (2019a)

that under-medication of patients may be happening because of concern about potential regulatory repercussions of providing that treatment.¹²

Therefore, more education is needed to alleviate such fears and help staff feel confident in their practice and supported by the law. This may point to the need for health practitioners to have better understanding about the true nature of the regulatory risk so health professionals can practise treating palliative care patients with confidence.

Multiple studies report associations between increased medication administration errors and:

- Poor skill mix;
- Higher patient to nurse ratios;
- Clinician workload;
- And perceived adequacy of staffing ¹³

Given these findings, clinician rostering should ensure there is optimal balance of experienced team members rostered on each shift to support and mentor less experienced clinicians. A critical system issue is adequate staffing to minimise errors and to build in safety checks.

Further system issues, some which have been raised earlier include:

- Creating and sustaining a positive opioid safety culture that encourages interdisciplinary team work, error identification and reporting.
- sustaining the experienced palliative care workforce.
- supporting junior doctors/non-palliative care specialists (e.g., out of hours support and advice on medications and other symptom relief for palliative care patients).
- ready access to opioid prescription history during care transitions, e.g., patient admitted from community to specialist palliative care unit.
- Electronic prescribing and orders
- Education and training of all clinicians including prescribing, conversions, patient safety aspects
- Standardised conversion guidelines
- Routine education of patients and carer regarding opioid use, monitoring, safe storage, disposal (community clients).
- Tailoring to meet the needs of those with less health literacy, no English, those with prior addiction problems.¹⁴

Further, palliative care teams need to be resourced to provide education and support about opioid use for palliative care patients who may be presenting in the Emergency Department or in other parts of the acute system.

Research has also demonstrated that 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 for understanding an accurate medication history on admission, which increased the risk of prescribing error.¹⁵ A lack of understanding of medication history and

¹² Willmott, L., White, B., Piper, D., Yates, P., Mitchell, G. and Currow, D. (2018) Providing Palliative Care at the End of Life: Should Health Professionals Fear Regulation? 26 *Journal of Law Medicine*, 214.

¹³ Heneka *et al* (2019a)

¹⁴ From input by Dr Nicole Heneka and Palliative Care Nurses Australia (PCNA) to PCA (May 2021).

¹⁵ Heneka *et al* (2019a)

palliative care status will mean that palliative care patients may not have their pain and symptoms treated appropriately.

Written and oral clinical communication deficits have been well documented as medication error-contributing factors in acute care and aged care settings. 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.¹⁶

III. What are the gaps in current practices and processes that inhibit achieving positive patient outcomes / best practice?

PCA considers that within acute settings there can be inconsistent opioid conversion policies and a lack of knowledge of opioid conversions/calculations. Clinicians have reported that when pharmaceutical companies change aspects of packaging or the nature of formulations and doses and this is not clearly communicated including in highlighted labelling, errors do occur. A suggestion put forward to PCA is that pharmaceutical companies should be obligated to clearly record and identify on their packaging of opioids any changes to the formulation of the opioid and clearly reflect whether the dosage is immediate release or slow release.

In many settings, the role of the onsite pharmacist with palliative care expertise has not been as integral as they should be to achieve positive patient outcomes and best practice. Where pharmacists are not utlised to support opioid prescribing, there may be more errors in prescribing to the detriment of patient outcomes and best practice.

Other gaps include:

- Limited supervision of junior medical staff and other medical staff in monitoring prescription, medication orders.
- Referring to Specialist Palliative Care services when pain issues continue to be unresolved and / or escalating.

Studies have also highlighted the role of the clinical nurse educator (CNE) to mitigate against opioid errors in specialist palliative care inpatient services.¹⁷

IV. What does best practice look like in 2025?

In relation to what would be considered best practice by 2025, PCA offers the following:

Best Practice Guidance:

There is a need for a best practice guidance for the use of opioids in palliative care to be prepared. This will reflect that:

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¹⁶ Ibid

¹⁷ Heneka *et al* (2019b)

- Given the responses and efficacy of different opioids on people, acute settings and palliative care units require access to a suitable variety of opioid formulations so that the use of opioids can be tailored to the specific individual for optimal impact and reduced side effects.
- Health professionals should use both treatments and doses that are clinically indicated to alleviate the person's suffering. Opioids should not be avoided, and the minimum dose that achieves pain relief or reduction of chronic breathlessness should be prescribed. In some cases, the dose may appear very large, but as long as titration to that dose occur steadily, the risk of adverse events such as respiratory depression being induced by the treatment is negligible. Clinical practice that seeks to alleviate suffering will be respected by the law and not punished.¹⁸
- All prescribing is electronic (inpatient, outpatient and community) and includes conversion
 guidelines. National realtime prescription monitoring whilst designed mainly to reduce
 misuse could also be used as a tool to support medication reconciliation of the dose/type of
 opioid especially as people move between clinical settings. This may also stop hesitancy
 about new scripts if a clinician has real time data about when supply has run out or is
 expected to run out.
- Linked to the Therapeutic Goods Administration (TGA) listings and a regular review of the Palliative Care Schedule of the Pharmaceutical Benefit Scheme (PBS), best practice guidance in the acute setting will capture the evidence-based practice guidelines about palliative care medications and recommendation clinical indications.

Utilising Palliative Care Expertise:

Palliative care physicians and members of Palliative Care teams are key experts in the appropriate use of opioids including dosing, management of side effects and tailoring opioids to the particular pain and symptom management requirements of patients. PCA recommends that the **National Opioid Analgesic Stewardship Program** include reference to utilising palliative care teams as sources of expertise and guidance within acute settings on usage of opioids and also for referral processes should patients be identified as potentially nearing the end of their life in an acute setting including emergency departments.

Specialist Palliative Care advice / consultation (in person or via Telehealth) is used for patients with unresolved symptoms requiring escalating opioid doses to ensure best patient outcomes.

Access to pharmacists with palliative care expertise:

Best practice means acute hospitals have access to pharmacists with palliative care and who can assist provide education to clinicians within the acute setting about appropriate opioid prescribing and use.

Pharmacists have regular and ongoing role in review and monitoring of opioid prescribing and use, safety and quality programs. This includes hospital pharmacy, community pharmacy and also private hospital pharmacy. The Residential Medication Management Review (RMMR) processes in

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¹⁸ Mitchell *et al* (2019).

residential aged care could also be improved as sometimes opioids are just listed as 'risk' without a good knowledge of the residents underlying diagnosis and palliative intent.

Foster a Safety Culture:

Acute settings should have an opioid safety culture including four central factors:

1. Clearly communicated and consistent expectations from management regarding safe opioid delivery.

A positive safety culture requires a multi-faceted approach encompassing situational awareness, vigilance and a non-punitive, organisation wide commitment to upholding safety culture.

2. A culture of empowering clinicians to practise safely.

This positive culture enables clinicians to feel confident, safe and supported, to challenge any perceived or actual opioid policy breaches.

3. Interdisciplinary teamwork

Effective inter-disciplinary team work is central to opioid safety and contributes positively to safety culture. The complexity of opioid prescribing and administration means that participants rely on, and expect, that their interdisciplinary colleagues work diligently to ensure all opioid orders/administrations are correct or are open to being challenged. There should be an optimal balance of experienced team members rostered on each shift.

4. Establishing and promoting a non-punitive error reporting culture

Error reporting culture is considered a key element of opioid safety with the view that errors do not necessarily reflect poor practice, but rather a positive safety culture.¹⁹

All states / territories publish data on opioid errors. This would be broadened to include:

- gaps in supply,
- late and missed doses and clinical consequences which may include serious pain outcomes due to poor control leading to increased length of stay, readmission or clinical interventions which would otherwise not have been required.

Added to this list, best practice would require pharmaceutical companies to clearly record and identify on their packaging of opioids any changes to the formulation of the opioid and clearly reflect whether the dosage is immediate release or slow release.

Invest in Targeted Education for Clinicians in Acute Sector:

Education is needed for all clinicians in acute care settings so that they are confident in prescribing, seeking appropriate advice and support when necessary and understanding

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¹⁹ Ibid.

the differences in dosing and requirements for palliative care patients. This can be supported by the role of Clinical Nurse Educators (CNEs).

Standardised education and training programs (hospitals and community) working within an evidence based approach of quality use of medicines, that allows people to work confidently within their scope of practice

Adequate staffing and resources

Best practice will mean that acute settings have:

- Adequate staffing and resources
- Optimal nurse to patient ratios (both the above two will also minimise medication administration interruption)
- Designated clinical nurse educator (s) and pharmacist
- Electronic medication management systems; point of care opioid resources²⁰

Electronic prescribing systems

Best practice will mean that electronic prescribing systems replace paper-based systems and are easily accessed by all treating clinicians. There should be ready access to opioid prescription history during care transitions and a standardised medication management system, between the inpatient and community service and the patient's general practitioner and/or specialist(s).

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²⁰ Ibid