

High-Risk Medicine Standard: Opioid analgesics

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Opioid analgesics primarily act on opioid receptors in the central nervous system and gastrointestinal system, producing effects including analgesia, respiratory depression, sedation and constipation. Opioid analgesics are frequently used to treat moderate to severe pain. Examples of opioid analgesics include alfentanil, buprenorphine, codeine, fentanyl, hydromorphone, methadone, morphine, oxycodone, pethidine, remifentanyl, tapentadol and tramadol.

Errors involving opioids analgesics can include:

- administration of an incorrect formulation. For example, administration of a short-acting formulation when a long-acting formulation was intended (and vice versa)
- failure to adjust an opioid analgesic dose according to patient factors. For example, pain assessment, biochemistry, renal function, age, co-morbidities, opioid tolerance and drug interactions with other medicines
- prescribing and administration errors related to dose calculation errors. This includes transitioning between different opioid analgesics, formulations or routes of administration
- inappropriate use of opioid analgesic patches, including the use of fentanyl or buprenorphine patches for patients with acute pain or who are opioid naive. Other errors involving opioid analgesic patches include prescribing and applying patches at the incorrect time interval, cutting or only partially applying patches, inappropriate disposal of patches and failing to remove a patch before applying a new patch.

In addition, the prescribing of opioid analgesics for patients discharged from hospital needs to be undertaken with caution due to the risk of dependency, adverse effects, interactions with other medicines (e.g., central nervous system depressants, in particular benzodiazepines, gabapentinoids, and alcohol), cognitive and driving impairment, and falls. There is a correlation between an increase in opioid analgesic prescribing for acute conditions on discharge from hospital and opioid analgesic related harm including dependence, injury, overdose, antisocial behaviour and death in the community.

This standard outlines the minimum actions required to mitigate risks associated with opioid analgesics use. This standard does not contain clinical guidance on opioid analgesics use. This standard is to be read in conjunction with:

- Clinical Excellence Commission [High-Risk Medicine Standard: HYDROmorphone](#)
- Australian Commission on Safety and Quality in Health Care [Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard \(2022\)](#).

The Hydromorphone Standard outlines the minimum actions required to mitigate risks associated with hydromorphone use. In facilities where hydromorphone is used, the [High-Risk Medicine Standard: HYDROmorphone](#) must be implemented in addition to this standard.

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Minimum requirements for clinical protocols

The Drug and Therapeutics Committee must approve any clinical protocols relating to opioid analgesics and ensure inclusion of the following, at a minimum:

- requirement to consider, and provide advice on, prescribing alternatives to opioid analgesics, including non-pharmacological treatment when applicable
- additional requirements for patients on an opioid treatment program
- a statement that patients are to be screened for previous opioid analgesic adverse effects (including overdose) prior to prescribing
- instructions when naloxone is to be prescribed including for take home use
- recommendations for the appropriate use of codeine products in children and breastfeeding mothers. Refer to the Therapeutic Goods Administration [Safety review: Codeine use in children and ultra-rapid metabolisers](#) for more information
- recommendations for when it is appropriate to prescribe slow-release opioid analgesics
- a restriction on prescribers to have appropriate qualifications and expertise in order to be permitted to initiate and discharge patients on fentanyl transdermal patches and/or fentanyl oromucosal formulations
- a statement that the various oromucosal fentanyl formulations are rapid-acting and not interchangeable. Refer to the Australian Medicines Handbook [Fentanyl](#) for more information
- recommended opioid conversion tools to be used for converting opioid analgesic doses
- requirement that the oral morphine equivalent daily dose (oMEDD) is calculated for patients with chronic non-cancer pain. Recommended actions are to be provided when the calculated oMEDD meets the following circumstances:
 - Adult patients (aged up to 65 years) with an oMEDD in the following ranges: 60 - 199 mg; and, 200 mg or greater
 - Patients aged over 65 years with an oMEDD of 30 mg or greater
 - Adult patients who weigh less than 50 kg with a chronic medical illness with an oMEDD greater than 1.2 mg per kg per day
 - Children with an oMEDD greater than 1.2 mg per kg per day
 - Refer to the Agency for Clinical Innovation Pain Management Network webpage [Quick steps through Opioid Management](#) for more information
- management of opioid use disorder including appropriate referral

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- reduced starting doses for patients with risk factors such as advanced age, asthma, obstructive sleep apnoea or those receiving other medications that can potentiate the effects of opioid analgesics such as CNS depressants e.g., benzodiazepines, sedative hypnotics, barbiturates and gabapentinoids
- a schedule for frequency and type of clinical observations for all inpatients receiving an opioid analgesic is to be determined, including the frequency of clinical observations required for patients newly prescribed an opioid analgesic or for when an opioid analgesic dose has been increased.

Additional protocol requirements for opioid intravenous bolus injections, intravenous infusions and subcutaneous infusions

- Specify clinical areas where opioid intravenous bolus injections, intravenous infusions, subcutaneous infusions, or patient-controlled analgesic (including paediatric nurse controlled analgesic) may be used.
- Any specific training, qualifications, skills or competencies required to prescribe or administer opioid intravenous bolus injections and infusions (including patient-controlled analgesic and paediatric nurse-controlled analgesic).
- Prescribing and administration documentation requirements. Refer to the Agency for Clinical Innovation Pain Management Network [webpage](#) for relevant resources. Documentation requirements may differ across LHDs/SHNs.
- A rate limiting device such as an infusion pump is to be used for all opioid analgesic containing infusions.
 - Wherever possible this should be a 'smart' pump using a pre- programmed infusion protocol.
 - Dose error reduction software, where implemented, is to be turned on and not bypassed.

Governance requirements

Adherence to the requirements specified in this standard is to be monitored by governance committees (for example, Drug and Therapeutics Committee) and service managers (including, but not limited to, Directors of Pharmacy and Nurse Unit Managers). An implementation checklist is available and can be used by facilities and individual units to determine compliance with these requirements.=

Prescribing

- Where possible, use alternative analgesics to prevent opioid misuse.
- Different types of opioid analgesics should only be prescribed concurrently in specific circumstances.

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- Modified-release opioid analgesics are not to routinely be prescribed for management of acute pain. Refer to Australia and New Zealand College of Anaesthetists [PS41\(G\) Position statement on acute pain management 2023](#) for further information.
- Avoid using dose ranges when prescribing opioid analgesics. If variable dosing is used:
 - the prescriber is to provide specific clinical criteria to guide selection of the dose for administering clinicians
 - the prescriber is to specify the maximum individual dose, maximum daily dose, hourly frequency for administration and the maximum number of doses or maximum duration of treatment.
- The maximum dose per 24 hours is to be specified on when required (PRN) medication orders.
- Confirm the dose of the patient's regular opioid analgesics prior to admission to a facility with a reliable source such as the patient's community pharmacist, general practitioner or other medical specialist prior to prescribing where possible.
- Evidence-based assessment tool/s are to be used to assess patient's functional activity and to identify patients who may be at risk of opioid-related harm before prescribing opioid analgesics.
 - The results of the functional assessment are to be considered together with the patient's pain scores to guide appropriate choice of analgesic.
 - Refer to the Australian Commission on Safety and Quality in Health Care [Opioid Analgesic Stewardship in Acute Pain Clinical Care Standard](#) for more information.
- Regular review of inpatient opioid analgesic requirements is to be undertaken with particular attention to the duration of treatment.
- Develop an opioid analgesic weaning plan for patients, when clinically appropriate.
- Where applicable, prescribers are to include the trade name in the order when prescribing opioid analgesics to differentiate between medicines and formulations (for example, where brands are not therapeutically equivalent).
- When prescribing opioid analgesics with multiple formulations, prescribers are to indicate the required formulation on the medication order. For example, modified release or slow release.
- Opioid conversion tools are to be used when converting between opioid analgesics or routes of administration. For example, the [Opioid Calculator](#) developed by the Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists (FPM ANZCA) or [eviQ Opioid Conversion Calculator](#).

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- Where relevant, [SafeScript NSW](#) (real time prescription monitoring system) is to be utilised to access real-time information about patient's prescription history for high-risk medications (including opioid analgesics) to enable safer clinical decision-making.
- Prescribe appropriate treatments to prevent and manage opioid analgesic-induced adverse effects. For example, laxatives to prevent or treat constipation, and appropriate treatments for nausea, vomiting and pruritus.
- Identify if patients require the Take Home Naloxone intervention using the eligibility criteria in accordance with the NSW Health Policy Directive *Take Home Naloxone* ([PD2020_027](#)).

Storage and supply

- Store only one strength of an opioid analgesics in a patient care area, where possible. If more than one strength of an opioid analgesic is required, strategies are to be in place to reduce selection error.
- Store products with look-alike names and/ or packaging separately (see [Hydromorphone Standard](#) for specific requirements relating to hydromorphone).
- Patient care areas are to be checked at least weekly to identify and remove unnecessary stocked opioid analgesic products. This includes expired products or individually dispensed products whereby a patient has been discharged.
- Opioid analgesics provided on discharge are not to exceed a quantity greater than three day supply (if discharged from emergency) or seven day supply (after inpatient stay). A follow-up with the patient's general practitioner is recommended.
- Naloxone is to be available in patient care areas wherever opioid analgesics are used.
- Where appropriate, commercially prepared pre-mixed solutions of opioid analgesics are to be used.

Administration

- An independent second person check is to be employed when administering opioid analgesics. The second person check processes are outlined in the NSW Health Policy Directive *Medication Handling* ([PD2022_032](#)) including circumstances where a second person check is not mandated (for example, when a medicine is administered by an authorised prescriber).
- Slow-release opioid analgesic formulations must never be crushed, cut or dissolved.
- Monitor and manage opioid analgesic adverse effects such as nausea, constipation, and signs of overdose including respiratory depression.

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- When administering from a fixed interval variable dosing order, a repeat dose within the dose interval is allowed however, the maximum dose stated is not to be exceeded.
- In relation to opioid analgesic transdermal patches:
 - patches are not to be cut or only partially applied to achieve a smaller dose, except for matrix patches under unique circumstances. For example, where small doses are required for paediatric patients. This is to occur under the direction of a pain or palliative care specialist
 - patches are not to be exposed to extremes of temperature. Do not use heat packs or thermal blankets on patients with an opioid analgesic transdermal patch in situ. Exposure to heat could result in a temperature dependent increase in opioid analgesic release from the patch
 - for disposal, used patches are to be folded in half so that the medication is trapped within the adhesive surface, then discarded in a sharps disposal unit
 - the position of patch placement on the body is to be recorded on the medication order or in the patient's health care record (as applicable)
 - the time of the patch removal is to be recorded on the medication order or in the patient's health care record. It is to be signed and dated by the clinician and an independent second person check is to be employed in accordance with NSW Health Policy Directive *Medication Handling* ([PD2022_032](#)).

Medication review

- Where possible, a medication review is to be completed:
 - prior to administration of the first inpatient dose (if commenced as a new medication) with specific attention on the appropriateness of the opioid analgesic. This includes the indication, the dose prescribed in view of the patient's comorbidities and other medicines prescribed, particularly other opioid analgesics or sedative agents
 - within 24 hours of admission (if continuation of therapy).

Patient information/education

- Where possible, patients and/or carers who are discharged home on opioid analgesics are to receive confirmation of their current opioid analgesic regimen at the time of discharge. If patients have been initiated on new opioid analgesic therapy, the patient and/or their carer are to be provided with relevant education and written information (for example, a Consumer Medicines Information leaflet) regarding opioid analgesics. This includes:

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- information on adverse effects and how they are to be managed
 - explanation of risks associated with opioid analgesics including potential for drug interactions, overdose, dependence, falls, and cognitive and driving impairment
 - expected duration of pain and analgesic requirements, including maximum daily doses and a detailed opioid analgesic weaning plan (where required)
 - instructions for other pain management strategies (including non- pharmacological strategies)
 - advice for patients receiving transdermal opioid analgesics. For example, do not use heat packs or a thermal blanket.
- Written discharge instructions (including but not limited to; last dose administered during admission, the duration of therapy and proposed weaning plan) are to be provided to the patient's general practitioner and other relevant healthcare professionals.
 - Where possible, for inpatients prescribed an opioid analgesic, the patient's family and/or carers are to be advised to alert staff if they have concerns regarding a change in the patients' condition including an unexpected decrease in their level of consciousness, or other adverse effects associated with opioid analgesics. Refer to the CEC patient factsheet [Managing side effects of opioid analgesia in hospital](#) and [REACH resources](#) for more information.
 - Patients discharged on opioid analgesics and/or carers are to be provided with advice on safe storage and disposal of opioid analgesics. This includes advice to return any unused opioid analgesics to a community pharmacy for disposal. Patients who are using an opioid analgesic patch are to be provided with verbal and written information on safe handling and disposal of used patches.
 - Patients who are administered and/ or supplied with opioid analgesics on or prior to discharge, and carers accompanying them, are to be provided with appropriate advice on sedation and fitness to drive or operate machinery (when applicable). Refer to the NSW Health webpage [Driving safety and medicines](#) for more information.
 - Patients and/or carers who are supplied with naloxone on discharge are to be provided with education on responding to an opioid analgesic overdose and instructions on using the medicine. Refer to Australian Government webpage [How to administer naloxone](#) for more information.
 - Professional Health Care Interpreters are to be utilised for patients and/or carers who are not fluent in English or who have hearing or visual impairments.

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Staff education

- Local protocols are to address any specific training, qualifications, skills or competencies required to prescribe or administer opioid analgesics.
- Clinicians (where relevant to their scope of practice) are to receive education on the safe use of opioid analgesics. A Health Education and Training Institute eLearning module 'Safe use of Opioids' (Course code: 267525641) is available for this purpose.

Useful links

This standard does not cover specific requirements for treatment of opioid dependence or managing opioid analgesics via the neuraxial route. Refer to:

- NSW Health Policy Directive *Opioid Dependent Persons Admitted to Hospitals in NSW – Management* ([PD2006 049](#))
- NSW Health Guideline [NSW Clinical Guidelines: Treatment of Opioid Dependence 2018](#)
- NSW Health Guideline [Clinical guidelines for use of depot buprenorphine \(Buvidal® and Sublocade®\) in the treatment of opioid dependence](#)
- Local clinical protocols.

Other useful links include:

- Agency for Clinical Innovation Pain Management Network [webpage](#) (for chronic pain resources)
- Agency for Clinical Innovation Pain Management Network webpage [Quick steps through Opioid Management](#)
- Clinical Excellence Commission webpage [Last Days of Life](#)
- Australia and New Zealand College of Anaesthetists [PS41\(G\) Position statement on acute pain management 2023](#)

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