Health Quality & Safety Commission New Zealand
Kupu Taurangi Hauora o Aotearoa

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Safe use of opioids measurement
Frequently asked questions

Contents

1. Why is the Commission interested in measuring opioid-related harm?

Opioid medicines (morphine, oxycodone, fentanyl, methadone, tramadol, codeine) are high-risk medications, which are excellent at controlling pain but have a number of unintended side-effects (eg, nausea, vomiting, constipation, urinary retention), and can also cause serious harm when given in high doses (eg, opioid induced ventilatory impairment [OIVI] and arrest).

Opioid-related Adverse Drug Events (ADEs) also impose significant costs on the health care system, due to the management of adverse drug events (ADEs) and prolong hospital stays for patient who suffer harm. The recent medication-related harm study in NZ,[25] where opioids contributed to 30 percent of ADEs, reports that patients stayed in hospital on average four days longer than patients who did not suffer an ADE. A meta-analysis[26] found an overall increase in costs between 7.4 percent and 47 percent. Opioid-induced constipation increased costs by up to 29 percent, bowel obstruction by 50 percent, confusion by nearly 20 percent and urinary retention by 14.5 percent.

Opioids are a leading contributor of health care associated harm ranging from patients experiencing mild distress to substantial patient harm and increased costs to hospital services in New Zealand. In response to these concerns, the Health Quality & Safety Commission (the Commission) sponsored an eighteen-month formative collaborative aimed to build District Health Board (DHB)-sector and private hospital engagement and capacity to identify interventions to reduce opioid harm.

Three bundle elements have been produced (OIC, OIVI and uncontrolled pain) and a composite care bundle (see the How-to Guide). This collaborative has finished but there is still enthusiasm within the sector to continue to work on reducing the burden of opioid-related harm. The Commission is therefore keen to facilitate further work with DHB and private hospitals.

The purpose of the opioid QSM and opioid implementation package is to outline the next steps and what the options are to make a significant difference in opioid-induced ADEs. The use of standardised definitions and data collection across sites will enable the use of these data at an aggregated national level.

The safe use of opioids work forms part of the high risk medicines work-stream of the medication safety programme, and strongly aligns with the Commission's strategic priority 3: Reducing harm and mortality; and Priority 4: Reducing unwarranted variations in patterns of care.

2. What does the Commission hope to achieve with its opioid work?

By providing tools and guidance on the implementation and monitoring of interventions, we aim to standardise practice in the monitoring of opioids in New Zealand hospitals. This will lead to improvements in practice with a reduction in harm to patients from the use of opioids; in particular, reductions in the rates of opioid-related constipation and ventilatory impairment.

Our aim is to reduce the harm from the therapeutic use of opioids in New Zealand hospitals.

Aim: To reduce opioid-related harm (specifically OIC and OIVI) in adult surgical inpatients (eg, general surgery, orthopaedics, urology, transplant) by 25 percent in participating hospitals within 12 months.

3. Is the Commission introducing opioid quality and safety markers (QSMs)?

Yes. We are working with DHBs to develop opioid QSMs in 2017–18. The QSMs will be implemented in 2018-19. We are aiming for providers to start collecting opioid QSM data (process and balance measures) from 1 October 2018, and submit these data to the Commission quarterly (with the October to December 2018 quarter due to the Commission by 8 February 2019). When the Commission and the DHBs are confident with the process, we will report the QSM information publicly.

4. What are QSMs?

QSMs (quality and safety markers) are sets of related indicators concentrating on specific areas of harm.

The markers have three parts:
1. process (certain care practices known to be effective)
2. outcomes (what happens with patients and the health system)
3. balance (a measure that is tracked to ensure an improvement in one area does not impact negatively on another area).

For more information about QSMs, go to the Commission website.

QSMs help providers focus on and prioritise an area of high harm. They can drive changes in behaviour or practice, and a shift to using evidence-based processes that are known to reduce harm and improve patient outcomes. They are also used to evaluate the success of quality improvement programmes and see whether desired changes in practice and reductions in harm and cost have occurred.

QSMs are usually a combination of process measures and outcome measures.

Process measures show whether desired changes in practice have occurred. The processes chosen are evidence based and usually ones that should occur nearly all the time (such as individualised care plans to reduce harm from falls). Because of this, thresholds are typically set high, for example, at 90 percent. Our reporting of the process measures shows DHBs' actual level of performance compared with the threshold for 'expected' performance.

Outcome measures focus on the occurrence of avoidable harm (such as a fractured neck of femur following a fall). They are shown at DHB and national levels, to demonstrate the size of the problem being addressed and changes over time.

In addition to the new opioid QSMs, the Commission has QSMs relating to:
- falls
- healthcare associated infections: hand hygiene and surgical site infection (cardiac and orthopaedic (hip and knee arthroplasty) surgeries)
- safe surgery
- pressure injuries
- medication safety: electronic medicine reconciliation.

5. What are the opioid QSMs?

The opioid QSMs comprise two process measures, a balance measure and one outcome measure (Table 1):

Table 1: Opioid quality and safety markers (QSMs)

Opioid quality and safety markers (QSMs)	
Process 1:	Percentage of patients with documented sedation scores
Process 2:	Percentage of patients with documented bowel function monitored
Balance:	Percentage of patients with uncontrolled pain
Outcome:	Percentage of patients with opioid-related adverse drug events

The data collection for the process and balance measures relies on the documentation of sedation scores, bowel function assessment and pain intensity in the health record. Good documentation supports care planning, communication and quality patient care.[31] In the absence of documentation it is assumed that the appropriate monitoring and action did not take place.

A limitation of these markers is that they do not assess the frequency of assessment or the effectiveness of any action and management.

The opioid QSM outcome measure will be captured through the National Minimum Dataset (NMDS) utilising data captured by each DHBs' routine clinical coding activity. OIVI and constipation will be specifically monitored. No additional auditing is required for the outcome measure.

6. Will there be public reporting of the opioid QSM results?

Yes. Ultimately QSM data will be reported publicly, just as they are for other Commission QSMs, such as falls, safe surgery and hand hygiene. However, we may choose not to report data publicly for the first few 'cycles' (eg, two quarters or more, as necessary) until the Commission and the DHBs are confident with the process.

7. The inclusion criteria include inpatients on a surgical ward. What about surgical outliers – are they included?

The inclusion/exclusion criteria are given in Table 2.

Table 2: Inclusion and exclusion criteria

Inclusion criteria
1. Patients aged 18 years and older (≥ 18 years) 2. Inpatients on a surgical ward (eg, general surgery, orthopaedic, urology transplant) including patients admitted under surgical services who do not receive a surgical intervention (eg, admitted for observation or pain control) 3. Patients must be on an opioid (administered regular or PRN)
Exclusion criteria
1. All inpatients admitted to a non-surgical ward

Surgical outliers are not to be included in the QSM audits. The opioid harm-reduction interventions are likely to be implemented by ward rather than by service, so the PDSA and QSM data collection should be by ward.

Whilst good practice dictates that surgical outliers who receive opioids must still receive appropriate care and monitoring, for the purposes of the QSM a pragmatic approach has been taken, limiting the QSM audit to inpatients on a surgical ward.

- Outliers may be on a ward(s) where the opioid harm-reduction interventions have not been implemented.
- Whatever the methodology, there needs to be consistency in its application as we track improvements in process and outcomes.
- By auditing 'by ward' we can simplify the definitions and the audit processes.

8. The SQM audit data collection is limited to those patients on an opioid. Why is this, when the audit methodology would be simpler if all patients were eligible?

When this definition was developed two points of view were considered.

a. Include all patients, that way you do not need to 'filter' for patients on opioids for data collection. Experience from the Collaborative suggest that the majority of patients on surgical wards were on an opioid: 82 percent surgical, 100 percent orthopaedic (MidCentral DHB data). This means that overall approximately 90 percent of patients on these wards will be on an opioid; or 1/10 of a random weekly audit sample will not be on an opioid.

b. Keep it pure with only those receiving opioids included – this will give a clearer picture of the impact of the interventions (as the opioid interventions are about reducing harm to patients on opioids – the focus should therefore be restricted to patients actually on opioids). When introducing interventions and undertaking local PDSA cycles, these activities will need to be undertaken in the context of patients on an opioid, so we will need to identify those patients on an opioid anyhow.

On balance, and with advice from the Commission's improvement advisor team, it was agreed that we should limit the opioid QSM audit to those patients on opioids, and this should be the same across all hospitals. This will enable us to see the direct impact of the opioid harm-reduction interventions.

9. What do we mean by 'on an opioid'?

The inclusion criteria include 'Patients need to be on an opioid (administered regular or PRN)'.

This includes eligible patients who were **administered** an opioid in the last 24 hours when the audit is undertaken:

a. Any opioid, strong and weak, including but not limited to: codeine, dihydrocodeine, fentanyl, methadone, morphine, oxycodone, pethidine and tramadol. For methadone, this includes methadone used for analgesia, but excludes methadone used for the opioid substitution therapy (OST). Other exclusions are other opioids/opioid-combinations use in OST (eg, Suboxone [buprenorphine + naloxone]); and low-dose opioid combination products (eg, paracetamol + codeine, ibuprofen + codeine).
b. At any frequency: regular, PRN, continuous or intermittent.
c. By any route: (eg, oral, intravenous, subcutaneous, neuraxial).

It only takes one dose for some patients to experience harm from an opioid. Although the likelihood of harm is less with smaller and less frequent dosing, a universal precautions approach has been adopted. Good practice says that all patients receiving opioids should be monitored for harm. This approach also simplifies the data collection process with not having to review the number of doses of opioid received by each patient.

10. Why are demographic data (age, gender and ethnicity) collected?

The Commission's Statement of Intent 2017–21[36] sets out four strategic priorities for 2017–21 (Figure 1), which underpin the Commission's planned activities for that period:

Figure 1: The Commission's four strategic priorities for 2017–21

One of these, strategic priority 2, is 'Improving health equity':

> 'Different population groups receive unequal benefits from the health and disability system. We only have to look at life expectancy statistics to know this: while New Zealanders overall are living longer, there is a difference of more than five years in life expectancy between Māori and New Zealand European populations. Children are another population group that, being dependent on others for care, may not access the health services they need.
>
> New Zealanders report economic barriers in accessing health care, which are increasing and becoming more common among Māori and people with low socioeconomic status.[37] We will contribute to a stronger understanding of health equity through our measurement and evaluation reporting and tools, and will make improving equity part of our improvement initiatives, where possible.
>
> This priority will help us to deliver the broader objective of achieving value and high performance from health spending.'[36]

Collecting age, gender and ethnicity information along with opioid process and balance measure data will help us determine if inequities exist between population groups, and whether or not our activities reduce those inequities over time.

It is recognised that not all DHBs will be able to report demographic data immediately, but ask the DHB do report these important data as soon as is practicable. The Commission will engage with DHB representatives regarding this.

The Commission will analyse each DHB's demographics using a similar methodology to that used for the Atlas of Healthcare Variation.

We require three demographic parameters to be reported: age, gender and ethnicity (Table 3). The reporting workbook is set up to capture these data.

a. **Age**: Report by age band from the drop-down list.

b. **Gender**: Report as *Male*, *Female* or *Other/not specified* from the drop-down list. Currently the Ministry of Health's data dictionary only requires DHBs to capture *Male* or *Female* gender. Unfortunately, there is no provision to report non-binary gender identities. When the data dictionary definition of gender is revised, the Commission will update its demographic reporting requirements.

c. **Ethnicity:** Report as *Asian, Māori, NZ European, Other* and *Pacific*, from the drop down list. Where possible, the Commission follows the Ministry of Health's *Ethnicity Data Protocols*.[38] If a person self-identifies with more than one ethnicity, prioritised ethnicity is used (Table 4): where Māori > Pacific > Asian > Other > NZ European. A person self-identifying as Tongan, Māori, NZ European would be recorded as Māori.

Table 3: Definitions of the demographic data required to be collected

Age	Gender	Ethnicity	
<25 years	Male	European	(level 1 code: 1)
25–34 years	Female	Māori	(level 1 code: 2)
35–44 years	Other/not specified	Pacific peoples	(level 1 code: 3)
45–54 years		Asian	(level 1 code: 4)
55–64 years		Other	(level 1 codes: 5, 6, 9)
65–74 years			
75–84 years			
85+ years			

Table 4: Prioritised ethnicity order[38]

Priority order	Ethnic group code (level 1)	Ethnic group code description
1	2	Māori
2	3	Pacific Peoples
3	4	Asian
4	5	Middle Eastern/Latin American/African (MELAA)
5	6	Other Ethnicity
6	1	European
9	9	Residual Categories

11. Why is a sedation score used to monitor opioid use when we already have the respiratory rate and AVPU score on the Adult Vital Signs Chart for the deteriorating patient?

Opioid induced ventilatory impairment (OIVI) is difficult to predict. A meta-analysis by Overdyke et al[33] demonstrated that only 30–40 percent of OIVI case had underlying comorbidities (eg, sleep-disordered breathing, obesity, renal impairment, pulmonary disease, neurological disorders) that placed them at increased risk for OIVI.

Respiratory rate is a late and unreliable sign of OIVI.[35] Sedation almost always precedes respiratory depression in patients on opioids. A number of studies investigating hypoxia in the postoperative period in patients receiving opioid analgesia have found that using respiratory rate as an indicator of respiratory depression may be of little value and that hypoxaemic episodes often occur with a normal respiratory rate.[1,2] A decrease in respiratory rate may not occur even in the presence of hypercapnia,[2,35] as inadequate ventilation can result from the other opioid effects on respiration (eg, upper airways obstruction, a reduction in tidal volume, irregularities in respiratory rhythm).[2,35] Central respiratory depression as measured by respiratory rate is only one element of OIVI.[2]

Lee et al,[34] through a series of insurance claims, showed that 62 percent of patients who developed OIVI experienced somnolence before the OIVI event.

Sedation scores are a more reliable method of detecting early opioid respiratory depression than is respiratory rate,[1,2,4-8,10] although monitoring respiratory rate is still important.[1] Sedation scores measure a patient's level of wakefulness and their ability to respond appropriately to verbal commands.[29]

Opioids therefore require regular assessment of pain, respiratory rate and sedation.

OIVI occurs on a continuum that is both unknowable and unpredictable before it manifests. Therefore, sedation scores must be serially measured as accurately as possible.

For the monitoring of opioids, the Australia New Zealand College of Anaesthetists (ANZCA) advises that a separate sedation scale is used, and that AVPU (alert, responds to voice, responds to pain or is unresponsive) is not required.[2,4,30]

The AVPU scale measures a patient's responsiveness, indicating their level of consciousness. However, the AVPU scale is not sensitive enough to detect the early stages of OIVI.[4] AVPU does not describe the amount of 'stirring' of the patient needed in order to assess the level of consciousness, whether by voice or by pain. Nor does it indicate the actual response of the patient. Therefore, it is recommended sedation scores are used to detect the early stages of OIVI.

Sedation scores should be monitored and recorded on a regular basis, with an increasing sedation score taken to mean a deterioration in the patient's condition related to opioid administration (until proven otherwise).[4]

12. Which sedation score should we use? Why was this recommendation chosen?

Whatever sedation score is used it must:[2]

1. represent a sensible and sensitive progression in sedation/CNS depression (and not other CNS changes like cognitive function or confusion)
2. have been developed to measure opioid-induced sedation effects (not conscious sedation)
3. have been developed for the target population (eg, adult surgical patients)
4. have validity and reliability
5. should be standardised across a hospital/hospital group/patient group.

A sedation score is preferred.

Any validated, standardised sedation score can be used that is appropriate to the patient in which it is used.

However, a hospital/DHB may choose to use an alternative scoring system.

Two sedation scores are recommended:

1. The modified Macintyre sedation score (Table 5).[2,4,30,35] This scale is an adaption of the sedation scale proposed by Macintyre, Loadsman and Scott.[2] The Macintyre sedation score is generally the one taught and used in Australia and in New Zealand. ANZCA suggested not including the 'S' or '1S' score included in the original scale.

2. The Pasero Opioid-induced Sedation Score (POSS) (Table 6).

Modified Macintyre sedation scale

The modified Macintyre sedation score is a four-point scale (see Table 5). The optimal aim is for a sedation score of 0 or 1. Each patient assessment must be documented.

The original sedation scale quoted by Macintyre, Loadsman and Scott[2] utilises sedation on a 4-point scale (0-3) with a sub-score (1s) for patients who are asleep but rousable. The 1s sub-score is used where the patient stirs in response to a mild stimulus but without waking them completely. With this scale the patient is roused but not brought to full wakefulness to assess their level of sedation.

The use of the 1s sub-score has been criticised[4] as a sedation score of 2 could be missed if the patient is not fully roused, and thus an opportunity for appropriate early intervention could be lost.

Similarly, use of 'patient is sleeping' is not recommended as its use often means that no attempt is made to wake the patient and thus severe or worsening OIVI may be missed.[1,2] Sleeping patients should be at least roused.[1] Attempting to rouse a sleeping patient can identify an over-sedated patient at risk of respiratory depression.

Table 5: The Modified Macintyre Sedation Scale
(Modified Macintyre; initially adapted from Ready[2,29,30,35])

Score	Description	Action / intervention
0	**Awake, alert**	The patient is awake, alert and responds appropriately to verbal command. Acceptable; no action necessary; may increase opioid dose if needed.
1	**Mild sedation** **Easy to rouse**	The patient rouses easily from sleep/rest, is able to stay awake and is alert and cooperative. Acceptable; no action necessary; may increase opioid dose if needed.
2	**Moderate sedation** **Easy to rouse, unable to remain awake (or difficulty staying awake)** **This is early respiratory depression**	Unable to remain awake: • The patient is frequently asleep or drowsy when observed. • The patient is drowsy on waking, able to follow commands but unable to remain awake (eg, falls asleep during conversation). A sedation score of 2 indicates that sedation is increasing and may worsen to a score of 3 if nothing is changed. The opioid dose must be reviewed. If the patient is on an opioid infusion, this must be stopped; decrease subsequent oral opioid doses. Consider administering naloxone. Notify a medical officer. Observations of the patient must increase in frequency until the sedation level improves.[29]
3	**Difficult to rouse** **This is severe respiratory depression**	The patient is difficult to rouse or is unrousable. The patient has difficulty with following commands or is unable to follow commands. A sedation score of 3 indicates a patient has already received too much opioid for continued safe care in a ward environment. If the patient is on an opioid infusion, this must be stopped. Administer naloxone. Notify a medical officer urgently. Call the medical emergency team (MET)/rapid response/code Blue.

When a patient is receiving opioids

- Aim for a sedation score of 0 or 1
- Always assess sedation scores at night
- If a sedation score is ≥ 2, stop further opioids and escalate to a medical officer; consider calling the rapid response team

The POSS sedation scale

The POSS sedation scale (Table 6) is commonly used is other jurisdictions,[8] and is recommended by the Institute for Safe Medication Practices (ISMP),[11] the American Society for Pain Management Nursing,[7] and the Joint Commission.[6]

A full sedation assessment requires the observation of how quickly the patient rouses when stimulated by the presence of the nurse, by a touch, or by conversation.[10] The patient's ability to stay awake once roused is a critical indicator of the level of sedation. To determine this, the patient should be asked to wake up and answer a simple question. A patient who is easy to rouse will be able to awaken readily and respond with a complete answer to the question without falling asleep (POSS sedation level 1 or 2). Falling asleep mid-sentence indicates a sedation level of 3 on the POSS.

Table 6: The Pasero Opioid-induced Sedation Scale (POSS)
(Adapted from references 8, 9 and 10)

Score	Description	Action / intervention
S	**Sleep, easy to rouse**	Acceptable; no action necessary; may increase opioid dose if needed.
1	**Awake and alert**	Acceptable; no action necessary; may increase opioid dose if needed.
2	**Slightly drowsy, easily roused**	Acceptable; no action necessary; may increase opioid dose if needed.
3	**Frequently drowsy, rousable, drifts off to sleep during conversation**	Unacceptable; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory; Decrease opioid dose 25 percent to 50 percent or notify prescriber or anaesthetist for orders; consider administering a non-sedating, opioid-sparing non-opioid, such as paracetamol or a NSAID, if not contraindicated.
4	**Somnolent, minimal or no response to verbal and physical stimulation**	Unacceptable; stop opioid; consider administering naloxone; consider calling the rapid response team; notify prescriber or anaesthetist; monitor respiratory status and sedation level closely until sedation level is stable at less than 3 and respiratory status is satisfactory.

In the POSS each level of sedation is aligned with suggested actions or interventions to facilitate decision making.

The POSS is recommended as a superior sedation scale for the measurement of opioid-induced sedation.[12] The validity and reliability of the POSS scale have been tested.[8] Nisbet and Mooney-Cotter[8] tested three scales: The Inova Health System Sedation Scale (ISS), the Richmond Agitation Sedation Scale (RASS), and the POSS. Both the RASS and the POSS demonstrated adequate degrees of reliability and validity. However, the POSS scored higher in combined measures of ease of use, nursing confidence, and the usefulness of information provided to make clinical decisions. The POSS also scored the highest agreement with the correct score (as assigned by an expert panel) and the correct nursing actions chosen by the nurse.

Other sedation scales

Several other sedation score systems are available. Some are less suitable than others for assessing sedation in patients receiving opioid. For example:

a. Many scales have been developed for the monitoring of conscious sedation, in ventilated patients, in critical care settings, or for research (eg, the RASS, the Ramsay Scale).[12]

These scales were not developed for the monitoring of unintentional and undesirable sedation from opioids used as analgesics. These scales include parameters other than sedation (eg, agitation and anxiety) which are not indicators of opioid-induced sedation. Nor have these scales been validated for the assessment of opioid-induced sedation. Such scales are not appropriate for the assessment of opioid administered for analgesia[7,8,10,13] in non-critical care, surgical settings.

b. The Inova Health System Sedation Scale (ISS) does not have enough discrimination between the scale items to adequately establish advancing sedation.[8]

Our goal is no opioid-induced harm, including no OIVI. It is not always possible to predict which patients will experience OIVI. Patients deemed to be 'low risk' may equally develop OIVI. Sedation monitoring should therefore be used in all patients, taking a universal precautions approach, regardless of the opioid, the dose, route or method of administration.[14] Increased sedation and respiratory rate monitoring are necessary when other sedating medicines are co-administered with opioids (eg, benzodiazepines, antihistamines).[14]

13. Should patients be woken to undertake a sedation score assessment?

It is recommended that patients should be woken to determine their level of sedation.[2,10] Assessment of a patient's sedation level is necessary to ensure sleep is normal and not actually excessive sedation. Not waking a patient leaves the patient open to the risk of increasing sedation being missed.

Some sedation scores use an 'asleep' sub-score (eg, the Pasero Opioid-induced Sedation Scale [POSS];[8] the original Macintyre sedation score [initially adapted from Ready[2,29,30]]). The 'asleep' sub-score is used where the patient stirs in response to a mild stimulus but without waking them completely. With this scale the patient is roused but not brought to full wakefulness to assess their level of sedation.

The Australia New Zealand College of Anaesthetists (ANZCA) when recommending the modified Macintyre sedation score suggest that the 1s sub-score should be omitted. It is argued that if the 1s sub-score is used, it is too easy to miss a sedation score of 2.[2,4] That is, the early detection of OIVI could be missed, and thus an opportunity for appropriate early intervention could be lost.

However, for stable patients who have been receiving stable opioid doses and demonstrate acceptable sedations scores (eg, Pasero Opioid-induced Sedation Scale; POSS 1 or 2[10]) it is acceptable to allow patients to sleep. If there is any question that the patient is sleeping or sedated the patient must be roused.

Rousal will stimulate respiration, therefore an assessment of respiration (depth, regularity, rate and noisiness) must be undertaken before the patient is roused. Patients with controlled pain and normal sleep will quickly fall back to sleep after their sedation assessment. Patients who do not fall back asleep require further assessment of their pain and analgesia.

14. The QSM suite includes a balance measure of uncontrolled pain. How is uncontrolled pain to be measured?

Uncontrolled pain is defined as two or more (≥ 2) consecutive at rest pain scores, at least 60 minutes apart, of ≥ 7/10 in 24 hours confirmed on completion of a pain assessment.

Routine pain assessment should include the assessment and documentation of pain at rest and on movement. However, for the reportable definition of uncontrolled pain only 'at rest' is to be used.

Some degree of pain on movement would be expected post-operatively as patients begin to mobilise, receive physiotherapy etc. Restricting the QSM definition to 'at rest' will provide greater consistency in reporting.

The assessment of pain at rest needs to be undertaken before any planned activity is undertaken (eg, physiotherapy, up to the toilet, dressing changes).

For the reporting of uncontrolled pain, the pain assessments should be at least 60 minutes apart. Providing a settling-in period acknowledges the dynamic phase of dose titration, allowing time for intravenous, oral or subcutaneous opioid administration to take effect. When initially titrating analgesia you will typically get two or more consecutive pain scores ≥ 7/10. For example, IV opioid protocols usually require pain assessments every three minutes for anyone with a pain score of 4 or more. It would not be uncommon to require two or more doses of opioid to reduce the pain score below 7, and this would lead to false positives if a settling in period is not provided for, skewing the QSM balance measure results.

However, if severe pain still persists after a reasonable settling-in period, this is less than desirable care, and equates to uncontrolled pain.

Patients with background chronic pain should be included in the opioid QSM audits. Some patients are admitted for surgery with a background of chronic pain (pain score consistently ≥ 7/10) which may or may not be related to the condition for which their surgery is for. These patients are typically admitted with an established chronic pain/pain complex. It is estimated that most surgical wards would have at least one such patient at all times. To exclude this sub-group would exclude too many patients, and complicate the sampling process. This is acknowledged as a limitation of the uncontrolled pain balance measure.

However, it is important that opioids are not used inappropriately to control pain. Additional opioid should not be the immediate default treatment. Patients with uncontrolled pain must receive a pain assessment, with non-opioid and non-pharmacological interventions being considered in the treatment plan.

Pain that is not responding to the prescribed analgesia/treatment should be discussed with the local pain team/nurse practitioner pain management/pain specialist/pharmacist.

The patient's own self-reported pain intensity is the most reliable indicator of pain they are experiencing. Pain is individualised and subjective. Therefore, a robust assessment of acute pain is imperative for the development of an effective pain management plan (Table 7). The assessment should include an assessment of pain intensity at rest and on movement. A pain assessment should be undertaken regularly and frequently.

Pain Assessment

The components of a comprehensive pain assessment are discussed in Table 7.

Table 7: Components of a comprehensive pain assessment[17,18,19,24]

Assessment	Rationale
Assess pain characteristics: • quality (eg, burning, sharp, shooting, spasms, pressure, cramping, deep aching) • severity (eg, using a pain intensity scale – see text below) • location (anatomical description, well or poorly localised, generalised pain)	Assessment of pain experience is the first step in planning pain management strategies. The most reliable source of information about the pain is the patient.

Assessment	Rationale
• onset (gradual or sudden) • duration (how long; intermittent or continuous) • precipitating or relieving factors (provocative or palliative symptoms; what makes the pain better or worse).	Descriptive pain intensity scales such as a visual analogue can be utilised to distinguish the degree of pain (see text below). The assessment of pain intensity should be undertaken at rest and on movement.[24] At rest is important for making the patient comfortable, and on movement (during mobilisation, deep breathing and coughing) is important for early mobilisation, the reduction of postoperative complications (eg, cardiopulmonary and thromboembolic events), and may improve long-term outcome after surgery.
Assess for signs and symptoms relating to pain.	Some people deny the existence of pain. Attention to associated signs may help the nurse in evaluating pain. An increase in blood pressure, heart rate, and temperature, shallow respiration, restlessness, facial grimacing, guarding behaviour, diaphoresis, pallor and pupil dilation may be present in a patient with acute pain.
Assess to what degree cultural, environmental, intrapersonal, and intrapsychic factors may contribute to pain or pain relief.	Such variables play a big role in modifying the patient's expression of pain. Some cultures simply express feelings, whereas others hold such expression. Nevertheless, health care providers should not prejudge any patient response but rather evaluate the unique response of each individual.
Assess the patent's anticipation for pain relief.	Some patients may be satisfied when pain is no longer massive; others will demand complete elimination of pain. This influences the perceptions of the effectiveness of the treatment of the treatment modality and patients' eagerness to engage in further treatments.
Assess the patient's willingness or ability to explore a range of techniques aimed at controlling pain.	Patients may overlook the effectiveness of non-pharmacological methods of pain relief, and may be willing to try them, either with or instead of traditional analgesic medications. Often a combination of therapies (eg, mild analgesics with distraction or heat) may be more effective. Some patients will feel uncomfortable exploring alternative methods of pain relief. However, patients need to be informed that there are other approaches to manage pain.
Assess the suitability of the patient as a patient controlled analgesia (PCA) candidate.	PCA allows the patient to manage the administration of opioid analgesic within prescribed limits. The criteria for implementing PCA include (refer to your local guidelines for your local criteria): • no allergy to opioid analgesics • no history of substance abuse • no history of renal, hepatic, or respiratory disease • no history of major psychiatric disorder • clear sensorium • cooperative and motivated about use • manual dexterity.

Assessment	Rationale
If the patient is on PCA, assess the following:	
Weigh the amount of pain medication the patient is using to his or her reports of pain.	If requests for medication are quite frequent, the patient's dosage may need to be increased to promote pain relief. If requests are very low, the patient may require further guidance to correctly use PCA.
Potential PCA complications such as excessive sedation; respiratory distress; urinary retention; nausea and vomiting; constipation; and IV site pain, or swelling.	Early assessment of complication is required to prevent serious adverse reactions to opioid analgesics.
If the patient is receiving epidural analgesia, assess the following:	
Tingling in the extremities, numbness, a metallic taste in the mouth.	These symptoms may be indicators of an allergic response to the anaesthesia agent or of incorrect catheter placement.
Potential epidural analgesia complications such as extreme sedation (relate this to the patient's sedation score), respiratory distress, urinary retention, or catheter migration.	Respiratory depression and intravascular infusion of anaesthesia (resulting from catheter migration) can be potentially life threatening.
Evaluate the patient's response to pain and management strategies.	It is essential to assist patients express as factually as possible (ie, without the effect of mood, emotion, or anxiety) the effect of pain relief measures. Inconsistencies between behaviour or appearance and what the patient says about pain relief (or lack of it) may be more a reflection of other methods the patient is using to cope with the pain rather than pain relief itself.
Evaluate what the pain suggests to the patient.	The meaning of pain will directly determine the patient's response. Some patients, especially the dying, may consider that the 'act of suffering' meets a spiritual need.

Pain intensity scales

Routine assessment of self-reported pain intensity is a better measure than pain assessed by a nurse or doctor.[20] However, pain intensity scales measure the intensity of pain only. They are not a substitute for a comprehensive pain assessment. They are valid and reliable measures of pain intensity, are quick and easy to use, and provide rapid feedback about the effectiveness of an intervention.[19,20]

> Any validated, standardised pain intensity score can be used that is appropriate to the patient in which it is used.

Commonly used pain intensity scores include[19,20,21,24] (Figure 2; note that there are other scales available and variants of the scales described here):

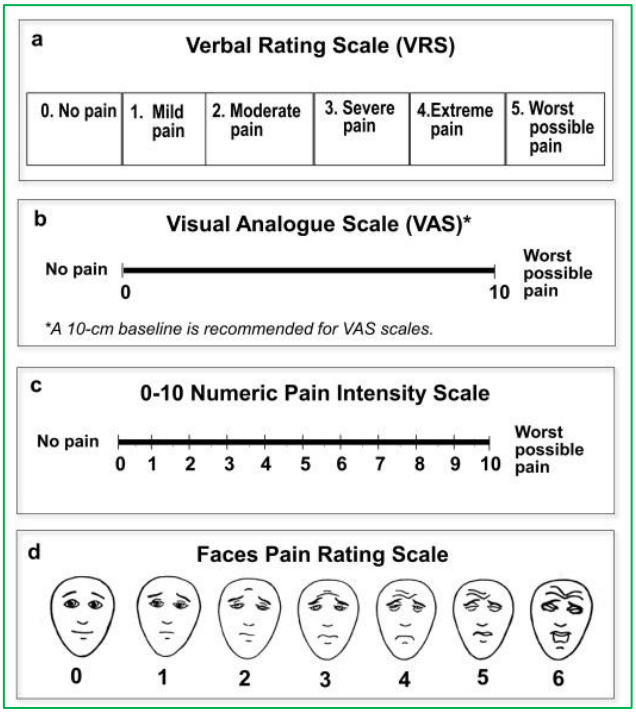
- verbal rating scale (VRS)
- visual analogue scale (VAS)
- numeric pain intensity scale (NPI)
- face pain rating scale.

1. **Verbal rating scale (VRS)**[19,21,24]
   The verbal rating scale (also known as the verbal descriptor scale) uses the verbal descriptors ‘no pain’, ‘mild pain’, ‘moderate pain’, ‘severe pain’, ‘extreme pain’, and ‘worst pain possible’. This scale can be administered verbally or visually, and the patient is instructed to pick the words that best describe his or her current pain intensity.

2. **Numeric pain intensity scale (NPI)**[19,22]
   The numeric pain intensity scale (also known as the numeric rating scale, NRS) is an 11-point scale from 0 (no pain) to 10 (worst possible pain). Patients are asked to rate the intensity of their pain on this scale.[22] The NPI can be administered graphically or verbally. This scale is suitable for patients aged nine and older who are able to use numbers to rate their pain intensity.[19]

3. **Face pain rating scale**[19,22,23,24]
   This pictorial scale (happy and unhappy faces) uses seven faces (0–6) ranging from a neutral face (no pain) to a grimace (worst pain). The patient is asked to select the picture that represents the pain that they are feeling. This tool is suitable for patients aged three and older.

Figure 2. Commonly used one-dimensional pain intensity scales[21]



The visual analogue scale (VAS) and the numeric pain intensity scale (NPI) correlate well, giving almost identical scores in the same patient at various times after surgery, and are equally sensitive in assessing acute pain intensity after surgery.[24] They work best for an assessment of a patient’s current (present) subjective feeling of pain intensity.

Multimodal analgesia

Multimodal analgesia could be considered as part of the pain treatment plan (Table 8).[14,18,19,20,22] The rationale for the multimodal approach is that lower doses of analgesics result in fewer or less severe adverse effects.[14]

Table 8: Multimodal approaches to analgesia[17-20,22]

Intervention	Example
Non-pharmacological considerations	• Providing information • Attention techniques • Distraction • Cognitive behavioural interventions • Meditation/mindfulness • Relaxation • Decreasing environmental stimuli (eg, temperature, sound, lighting) • Aromatherapy • Music therapy • Repositioning • Immobilisation • Heat and cold • Manual and massage therapies • Acupuncture • Transcutaneous electrical nerve stimulation (TENS)
Non-opioid considerations	• Paracetamol • Non-steroidal anti-inflammatory drugs (NSAIDs: eg, ibuprofen, naproxen, diclofenac, celecoxib, ketorolac, etoricoxib • Muscle relaxants (eg, diazepam) • Anxiolytics (eg, a benzodiazepine) • Local anaesthetic nerve block • Anticonvulsants (eg, gabapentin) • Ketamine • Clonidine • Nitrous oxide
Opioid	• Consider alternative routes of delivery

15. Sample size. The QSM asks for a sample of 10 patients per week. This will be a challenge in some hospitals where there are (for example) small patient numbers on opioids, or where surgical ERAS (enhanced recovery after surgery) programmes are used to encourage discharge early on day 3.

The 10 patients per week is a 'whole of hospital' measure. It is not for individual wards. You can sample more patients if you want to; the 10 patients per week is a minimum.

However, if 10 patients are not available for audit, then just report on the maximum number that you are able to report. It will take your hospital a little longer to demonstrate any change in outcomes from your interventions. Whatever your sample size, the Commission requires the numerator and the denominators for your data sets. The Commission's QSM reporting form asks for these data.

16. What is the audit sampling period?

The SQM audits are by convenience sampling over the previous 24-hour period. For example, take the latest set of observations and go 24 hours back; so if auditing at 1400 on Day 2, and the last set of observations was at 1300 on Day 2, go back to 1300 on Day 1, and audit from there.

Audit experience demonstrated that with short lengths of stay (LOS), using a 48-hour timeframe limited the number of patients available for audit.

17. How is constipation defined for the opioid QSMs?

For the opioid QSM, the outcome measures will be captured through the National Minimum Dataset (NMDS) utilising data captured by each DHBs' routine clinical coding activity. OIVI and constipation will be specifically monitored. No additional auditing is required for the outcome measure.

However, when implementing interventions to reduce the harm from opioid-induced constipation, and measuring their impact using PDSA (plan-do-study-act) cycles a specific definition of constipation is used.

Constipation in the context of patients on an opioid, is defined as a patient's bowels have not opened for three or more days (72 hours).

When dose the 'clock start from'?

a. Day 1 is the day on which the opioid is first administered.
b. If the bowels have not opened for (say) a couple of days before the opioid was administered, then this is not counted for the purposes of the intervention and the PDSA cycle – as we want to capture opioid-related constipation. However, the patient's constipation still needs to be treated. We are interested in the reduction in opioid-associated harm. To include patients with prior constipation would overestimate the direct harm from opioids alone.

18. Why does the implementation guide refer to opioid-induced ventilatory impairment (OIVI) when we used to simply refer to 'respiratory depression?

The effect of opioids on ventilation is greater than respiratory depression alone.[1,2,32] This complex effect on ventilation is more appropriately captured in the term opioid-induced ventilatory impairment (OIVI).

OIVI encompasses three factors that result from excessive opioid use:

1. respiratory depression (decreased respiratory drive; decreased central CO_2 responsiveness resulting in hypoventilation)
2. depressed consciousness (sedation; decreased arousal and protection)
3. upper airway obstruction (loss of supraglottic airway muscle tone; obstruction).

These three factors combine to decrease ventilation and hence reduce pulmonary gas exchange resulting in hypoxia and hypercapnia.[2] Hypercapnia has a direct depressant effect on the CNS, further exacerbating the effect of the opioid. This creates a dangerous clinical situation where physiologic reserve is compromised and patients can deteriorate very rapidly.

All patients are at risk of OIVI, which can be reduced if monitored appropriately and regularly, including sedation scores. If excessive sedation occurs, the dose of opioid must be reduced regardless of the reported pain level, with more frequent monitoring until an acceptable level of sedation is restored.[3,10]

Patients with sleep-disordered breathing (see Q21) are more susceptible to the ventilatory effects of opioids.[2]

19. At what frequency should patients receiving opioid analgesics be monitored?

There is no good evidence on which to base the ideal frequency of observations. Suggested good practice monitoring schedules for patients receiving opioid analgesia are provided in Table 9.

Evidence-based guidelines[13] recommend that serial sedation and respiratory assessments are undertaken to evaluate the response of all patients receiving opioids by any route of administration. These assessments should be undertaken when the patient is awake and when asleep (ie, patients need to be woken to undertake the sedation assessment).

Table 9: Suggested monitoring schedules for patients on analgesic opioids
(Adapted from references 10, 13 and 14)

Monitoring category	Monitoring schedule	Comment
Basal	Every 1 to 2 hours for the first 24 hours of opioid use, then every 4 hours if the patient is stable.	1. If excessive sedation occurs, the dose of opioid must be reduced regardless of the reported pain level, and sedation scores monitored more frequently until an acceptable level of sedation is restored. 2. Advancing sedation suggests the need for an increased frequency of assessment of sedation and respiration.
1. Epidural or intrathecal opioid	Every hour for the first 12 hours of opioid use, then if stable, every 2 hours for the next 12 hours, then every 4 hours.	
2. Opioid naïve patients on IV-PCA with a basal rate		
3. Co-administration with other sedating medicines (eg, benzodiazepines, antihistamines)		
4. After an increased dose of opioid; after aggressive titration of opioid		
5. Recent or rapid changes in renal or hepatic function		

20. For the quality and safety marker (QSM), what is the minimum documentation frequency required to meet the audit process measure criteria?

The minimum documentation requirements for the quality and safety marker (QSM) audit criteria are provided in Table 10. These are the minimum requirements. If clinically appropriate, the frequency of monitoring should be increased.

Table 10: The Quality and Safety Marker (QSM) minimum documentation requirements

Parameter	QSM definition	Minimum documentation frequency
Sedation score	**Process measure 1** Percentage of patients with documented sedation scores	At least once every 8 hours for the 24 hour audit period
Bowel activity	**Process measure 2** Percentage of patients with documented bowel function monitored	At least twice a day, morning (am) and afternoon (pm), for the 24 hour audit period

When establishing these minimum documentation frequencies, the preferred frequency for documenting sedation scores was 'with every set of observations'. This was based on audits undertaken at Lakes DHB. However, setting up algorithms or rules in electronic vital signs systems (eg, eVitals, PatientTrack) used to capture and report QSM data can be complex and challenging. We acknowledge these constraints and have set the minimum documentation frequency to permit consistent manual and electronic data capture, and thus future proof the opioid QSM methodology.

For the documentation of bowel activity, a time period between recordings has not been set; just that two recording must be documented – one in the morning and one in the afternoon.

Audit demonstrated no difference between 24-hours, 48-hours and twice a day documentation. With once daily documentation, experience from the Collaborative demonstrated that it may be considered 'someone else's job' to ask about and document bowel activity, with documentation being left for the next shift, with the result that no one captures the bowel activity. Patients are often confused, as they lose track of time; by asking multiple times a day patients are more likely to remember when they last toileted.

21. The STOP-Bang obstructive sleep apnoea (OSA) tool is recommended as a screening tool for patients at risk of OIVI. Why do we need to screen for sleep apnoea?

The incidence of opioid-induced sedation is influenced by many factors. The most frequently reported risk factors for OIVI are listed in Table 11. However, patients without such risk factors can also develop OIVI. OIVI can usually be avoided by careful titration of the opioid dose against the effect with careful observation and monitoring.

Lynn and Curry[16] demonstrated a large difference in the pattern of deterioration when the patient is awake and when they are asleep. In those with sleep apnoea there is a repetitive reduction in airflow and oxygen saturation during sleep followed by arousals. When on an opioid (or other sedating medicine), the arousal rescues the patient but eventually the capacity or reserve of the patient to recover with arousals becomes impaired and the patient may experience respiratory failure, with sudden death, during sleep.

Sleep-disordered breathing (SDB) is a broader term than obstructive sleep apnoea (OSA) which encompasses the spectrum of sleep and obesity-related hypoventilation syndromes, including OSA, central sleep apnoea (CSA) and upper airways resistance (snoring).[2,3]

Patients with SDB/OSA are at increased risk of upper airway collapse during normal sleep. This may be exacerbated by sedatives like opioids.[2] Patients therefore need to be screened for SDB/OSA with consideration given to reducing the initial dosing of opioid and increased monitoring of sedation and respiratory function.

The STOP-bang questionnaire screens for common risk factors of OSA. The acronym STOP-bang stands for[27,28]

Snoring
Tiredness or sleepy during daytime
Observed to stop breathing during sleep
high blood **P**ressure
Body mass index greater than 35 kg/m^2
Age greater than 50 years
Neck size greater than 43 cm (17 inches) for men, or 41 cm (16 inches) for women
male **G**ender

Table 11: Patients risk factors for over-sedation from opioids[1,6,8,13,14,15]

Patient risk factor for over sedation with opioids
Sleep-disordered breathing (SDB) / obstructive sleep apnoea (OSA)
Snoring Snoring is a sign of airways obstruction and should be acted on promptly. Snoring patients should be roused, instructed to take some deep breaths and repositioned. Even subtle snoring, or noisy respiration, can progress to a full obstruction and so must be addressed. Snoring is often reported as being 'normal' for patients, as the patient snores at home. The uncompromised patient has self-arousal mechanisms – being awaken by their own snoring and poor respiration. However, in the context of opioid administration and other sedating medications, patients maybe too sedated to self-rouse. Under these circumstances, snoring is an ominous sign and requires the nurse to intervene.
Obesity/body mass index (BMI) > 35 kg/m^2

Age
• Premature infants less than 12 months of age
• Infants less than 6 months of age
• Older age[6]
  ○ 61-70 years 2.8 times the risk of younger adults
  ○ 71-80 years 5.4 times the risk
  ○ > 80 years 8.7 times the risk

Renal impairment, including post-operative acute renal failure
Pulmonary disease
Cardiovascular disease: congestive heart failure, cardiac arrhythmias, coronary artery disease, hypertension
Altered CNS function
Concurrent use of other sedating medicines • Anaesthetic agents/longer duration of surgery with a general anaesthetic • Benzodiazepines • Antihistamines
Thoracic or other surgical incision that may impair breathing
Female gender
Opioid naïve
Smoker

22. How do we make the safe use of opioids programme relevant to all ethnic groups? How do we apply an equity lens to this work?

Patient education is a large component to implementing appropriate bowel hygiene including the use of laxatives, the use of the Bristol Stool Chart, fluid intake and exercise. It is important when educational materials are developed that equity and cultural appropriateness are considered. The How-to Guide provides some examples of educational materials developed during the Collaborative.

23. What patient monitoring form should we use, if we are using manual data capture processes?

Hospitals can choose any system or process for documenting their opioid monitoring data as part of their patients' health records.

The opioid implementation package includes an example observation form that can be used to capture the parameters necessary for monitoring opioid therapy.

The opioid implementation package includes an example observation form (Appendix 3) that can be used to capture the parameters necessary for monitoring opioid therapy. It is intended that this opioid monitoring form complements the adult vital signs chart (for example 'respiratory rate' is included in the adult vital signs chart but is not repeated in the suggested opioid observation chart).

Alternatively, opioid monitoring parameters could be included in the additional parameters fields at the bottom of the adult vital signs chart. Up to two additional parameters can be monitored using the chart.[39] These can be selected by each organisation to reflect local practice needs. It is recommended that any additional parameters are selected based on the need for monitoring at a frequency similar to that for the core vital signs so trends over time can easily be identified. This may mean selecting different parameters for charts used in different clinical areas. For example:

- an acute surgical hospital where vital signs are measured multiple times a day might select pain scores on rest and movement and neurovascular observations as additional parameters
- an acute mental health unit where vital signs are measured daily might find it more relevant to select bowel function and blood sugar level as additional parameters.

The Adult Vital Signs Chart is designed for all non-pregnant adult in-patients and the opioid programme is focussed on surgical in-patients. As such, it is preferred the opioid observation chart is used on surgical patients receiving opioids rather than modify the whole hospital chart for just surgical patients.

Some hospitals are using electronic vital signs systems to capture their data (eg, eVitals, PatientTrack).

24. What data collection form (audit form/audit tool) should we use if we are using manual processes?

The Commission has a preferred reporting tool for submitting your hospital's opioid QSM data (process and balance measures). Using this standard format ensures consistency in reporting, and simplifies data aggregation by the Commission.

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