

# CLINICAL FOCUS REPORT

BASED ON ANALYSIS OF CLINICAL INCIDENT REPORTS IN NSW HEALTH FACILITIES

# Patient Controlled Analgesia

Patient looking = learning = acting

This report was prepared by the Clinical Excellence Commission (CEC) Patient Safety Team.

The information contained has been de-identified and analysed in accordance with the Incident Information Management System (IIMS) datasets and, where relevant, the agreed root cause analysis (RCA) report classification sets used by the RCA Review Committees which it supports.

It should be noted that all reviews of incident data, including root cause analysis, are retrospective and can reflect both hindsight and outcome bias. Such reviews are conducted to better understand the impact which patient, system and human factors may have on the provision of clinical care and to facilitate ongoing improvement across the health system.

This report is intended to provide a snapshot of issues to be further explored. It has been prepared by the Patient Safety Team, including Margaret Scrimgeour, Dr John Sammut, Dr Tony Burrell and Bronwyn Shumack, in consultation with the CEC Medication Safety Team, the ACI-led PCA Monitoring Form group and the Clinical Contracts Team at Health Support Services.

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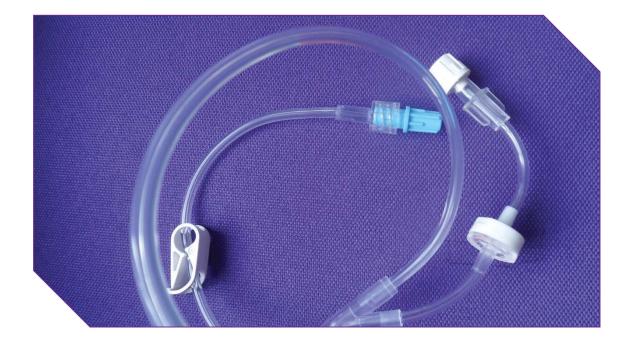
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## Background

Patient controlled analgesia (PCA)<sup>1</sup> has been available for a number of years and is becoming an increasingly popular method of controlling pain. It is safe and effective, provided there is careful patient selection, adequate patient education, appropriate prescribing and patient monitoring (1).

A serious incident reported in the NSW Incident Information Management System (IIMS)<sup>2</sup> and a recent Coroner's report prompted further analysis of incidents reported from across the State, to identify risks to patient safety associated with the use of PCA devices (PCAs).

PCAs have several modes of administration, the two most common being:

- demand dosing a fixed dose which is self-administered, as required
- continuous infusion plus demand dosing i.e., a constant rate background infusion which can be supplemented by demand dosing (2).

## The analysis process (method)

Clinical incident reports were extracted from IIMS, using the search terms "PCA", "naloxone" and "narcan". The entire database was searched, so that all incidents, from 2005 to the data extraction date (2 May 2012), were available for the review. All SAC1, SAC2 and 1,000 SAC3-4 incidents were extracted<sup>3</sup>.

The incidents were then analysed using a directed content methodology, based on the CEC clinical incident classification sets. Issues which emerged from the review were explored in as much detail as the content of the incident reports allowed. RCA<sup>4</sup> reports submitted to the Ministry of Health in relation to these incidents were also reviewed. The issues identified were validated in consultation with clinical staff.

<sup>1</sup> Macintyre 2001 (1) defines patient controlled analgesia as a process for providing pain relief using an electronic device, which allows the patient to self-administer intravenous analgesic drugs as required.

<sup>2</sup> IIMS is an electronic incident reporting and management system available to all NSW Health staff. It is used to notify all actual and potential clinical incidents and to record reviews and actions taken in response.

<sup>3</sup> The Severity Assessment Code (SAC) is used to rank the outcome for the patient when an incident occurs. SAC1 indicates a serious outcome, such as a procedure involving the wrong patient or an unexpected death. SAC4 indicates there was minimal or no harm and includes near-miss incidents.

<sup>4</sup> In the NSW Health context, RCA is a method used to investigate and analyse a clinical SAC1 incident, to identify the root causes and factors that contributed to the incident and to recommend actions to prevent a similar occurrence.

# Findings

The search of IIMS identified 4,671 incidents. The Severity Assessment Code (SAC) applied to these ranged from SAC1 – SAC4.

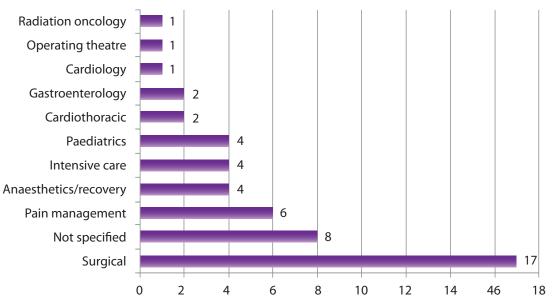
Three thousand, nine hundred and two incidents were excluded because the issue reported was unrelated to PCA, or there was insufficient information to allow meaningful analysis, leaving 759 incidents for analysis. The SAC rating of these is shown in Table 1.

#### Table 1: Incidents related to use of PCA by SAC Rating

SAC Rating	Count
SAC1	3
SAC2	50
SAC3	243
SAC4	463
Total	759

Incidents were most commonly reported by surgical services, reflecting the location for use of these devices overall. The services indicated in the SAC2 incidents are shown in Figure 1. In circumstances where more than one service involved, only the primary service is represented.

#### Figure 1: SAC2 Incidents by Specific Service



The issues identified have been grouped under the themes of:

- 1. Administration
- 2. Documentation
- 3. Communication
- 4. Equipment
- 5. Knowledge and skills
- 6. Observations and/or monitoring
- 7. PCA by proxy<sup>5</sup> (3)
- 8. Prescription
- 9. Risk management

5 PCA by proxy (D'Arcy 2008) (3) is when a person other than the patient activates the dosing mechanism of an analgesic infusion pump and delivers analgesic medication to the patient.

## What the analysis identified

Each of the three SAC1 incidents identified underwent an RCA. They are summarised below.

#### CASE 1

A 50-year old patient underwent colorectal surgery and was administered large doses of opioids intra- and post-operatively. He was then given fentanyl via PCA for pain management and suffered a cardiac arrest ten hours after surgery. Intravenous naloxone was administered and the patient returned to spontaneous respirations, however, he suffered an acute hypoxic brain injury and died three days later. The cause of the arrest was not identified. The Coroner's findings were inconclusive.

#### CASE 2

A young man, who had a history of self-harm, was admitted for removal of a foreign body. Following surgery, he was started on patient controlled analgesia while in recovery. He was located in a single room, monitored by two non-clinical staff for security reasons. One-to-one nursing supervision was therefore not considered necessary. About 48 hours after the surgery, the patient required his cannula to be resited after it became dislodged. The medical officer found nothing untoward about him. A few minutes later the patient was found unresponsive.

The case was referred to the Coroner, who made one recommendation: "...the current policy be amended so as to provide that once a patient is on Patient Controlled Analgesia (PCA), PCA observations are required to continue until a decision is taken to discontinue the PCA".

#### CASE 3

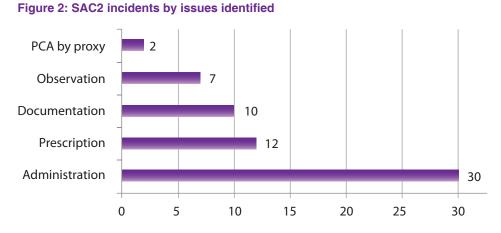
A male patient was admitted for a planned laparoscopic donor nephrectomy procedure. He had a history of obstructive sleep apnoea and used a continuous airway pressure (CPAP) machine at night. Following surgery, the patient was started on morphine via PCA. Despite his history, he did not use CPAP in the post-operative period. The patient was found unresponsive and required extensive ICU care and rehabilitation. He was found to have aspirated and sustained a significant hypoxic brain injury.

The RCA team investigating the incident identified a significant knowledge gap related to the risks associated with obstructive sleep apnoea. They also found that the use of morphine for patients with renal impairment can be problematic, as "morphine is metabolised to morphine-6 glucuronide (M6G). M6G has significant opioid effects and is dependent on renal function for elimination from the body. Acute kidney injury or chronic kidney disease will cause an accumulation of M6G and its effects, especially respiratory depression and sedation. The effects may be delayed, not becoming apparent for several hours".

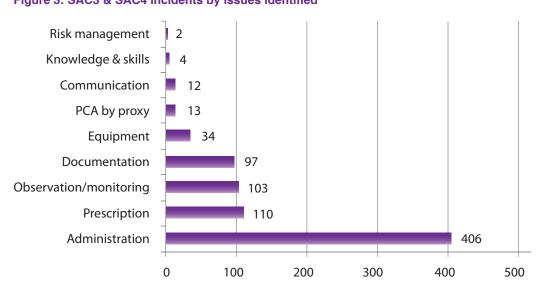
The RCA established that use of morphine in renal patients, except in small infrequent doses, was contra-indicated.

# Issues identified during the review of SAC2 – 4 incidents

The provision of medications via a PCA involves several components, from the time the decision is made to use it for delivery of pain relief. Doses must be prescribed, prepared, administered and their effects monitored. Each of these processes must be documented in the patient's medical record and related systems. Some incidents had more than one issue identified. The issues identified are shown in Figures 2 and 3 below.



#### Figure 3: SAC3 & SAC4 incidents by issues identified



The review identified that issues were reported across the whole process. The most common stage, however, was during administration (60 per cent of SAC2 and 57 per cent of SAC2-4). Paul et al (4) concluded that, while PCA errors are relatively uncommon, most occurred during administration. These issues were explored further to try to identify commonalities and underlying issues.

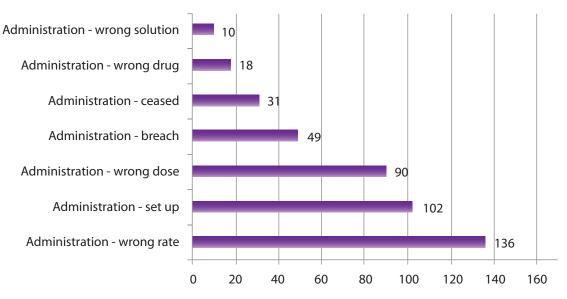
## Issues associated with administration

All administration errors identified in the SAC2-4 incidents were further classified as follows:

- Administration wrong rate
- Administration wrong set-up
- Administration wrong dose
- Administration wrong drug
- Administration wrong solution
- Administration ceased (or not ceased when ordered)
- Administration breach (of policy or protocol)

Figure 4 shows administration errors by sub-categories for SAC2, SAC3 and SAC4 incidents.

#### Figure 4: Administration errors by sub-category





Examples of these issues are shown below. It is acknowledged that many overlap. These have been placed where they best fit.

#### Administration-wrong rate

Programming the wrong rate was the most common error identified and the one most likely to put patients at risk. Twenty-one incidents described such issues at the time the PCA was started, or when the prescription was changed to a different drug. This included applying the wrong protocol i.e., using the fentanyl protocol when morphine was ordered, or the morphine protocol when fentanyl was ordered. This resulted in the wrong rate being set.

#### CASE 4

A patient arrived on the ward at midnight, with morphine being delivered by PCA. The PCA order was for a 1mg bolus. The machine, however, was programmed to allow a 2mg bolus. Eight hours later, he was found to have pinpoint pupils, blurred vision and was pale and diaphoretic. He was found to have had 96mls of morphine over the eight hours. When reviewed by the pain team, it became apparent that whoever had initiated the PCA not only programmed the wrong dose/ rate, but did not put up any background fluid. The patient reported that he had been instructed to press the button every five minutes, regardless of pain. He was over-sedated and required naloxone to reverse the effect.

#### CASE 5

The PCA was set-up as a continuous infusion, instead of the patient-controlled mode which was ordered. The patient was drowsy, but complaining of inadequate pain relief. No observations were recorded, as the patient was not accessing the machine. The PCA set-up was not checked at change of shift.

In 2003, Vincente et al (5), when citing a case where a patient died, highlighted recommendations in response to the death, which included "user interfaces for PCA pumps should be redesigned to make them easier to program, based on human factor engineering techniques".

Much work has been done on equipment design. The 2005 article by Beattle-Dulak (6), for example, explains how smart pumps used for PCAs may be pre-programmed to particular protocols being used in a facility. The pump will prevent medication errors, by alarming when the settings do not match the facility's drug protocol. It is not clear from the reviewed incidents if this function is well utilised, or whether, as Grissinger (7) suggests, the safety feature is being bypassed because of a perception of low risk, the extra work needed to use the safety feature, or a culture within the facility which supports at-risk behaviours.

### Administration-wrong set-up

This relates to the physical configuration of the PCA – as set-up by the staff members administering the medication(s). The issues identified included incomplete and/or wrong set-up of the devices, wrong syringes being used, syringes not being adequately secured, pumps not being locked, use of the wrong giving set, IV line set-up issues (such as PCA lines being "piggy-backed"), wrong infusion via PCA, wrong type of pumps, no anti-reflux valve attached. A number reflect an incomplete set-up process e.g., line not attached, although the pump is started, or the IV line not unclamped.

#### CASE 6

A patient was complaining of pain which was scoring 5/10 on the pain scale. Staff identified that the disposable PCA device had been set-up incorrectly, following surgery. The patient demand button was connected to the refill port. This meant that each time the patient pressed the patient demand button, doses were being pushed back into the syringe reservoir, instead of being delivered to patient. There was also no orange additive label attached to the original set (as required under IV medication labelling policy).

### CASE 7

Staff identified that the PCA was set-up incorrectly. The IV fluid line was set-up as the primary line, with the PCA attached by a side line, which was unclamped and fully open.

#### CASE 8

The patient was started on PCA, without the safety features described in the PCA policy being utilised. Firstly, the infusion used was not the pre-mixed syringe available in many areas of the hospital. It was mixed by nursing staff in the clinical unit. Secondly, the PCA extension set, with anti-siphon and a one-way valve, available in many areas of the hospital, was not used.

### CASE 9

A patient was receiving fentanyl via a PCA pump, however, the wrong infusion set was used (set for heparin or insulin infusion, instead of the PCA extension set, with anti-siphon valve and one-way valve in the "y" site). Further, despite being ordered, there was no maintenance fluid.

### Administration-wrong dose

These incidents included basic medication dose calculation and IV mixture/concentration errors. These most often occurred when pre-filled syringes were not used, or when the prescription was outside the standard dose. Forty per cent of the incidents also suggested that a programming error had occurred when the dose was entered on to the PCA. Examples included wrong bolus dose, PCA not changed to accommodate an increased or reduced dose.

#### CASE 10

A patient was transferred from HDU to the ward three days after a diaphragmatic hernia repair. His PCA was changed from morphine to fentanyl in the HDU. The PCA syringe was changed to fentanyl, but the pump was not re-programmed to the fentanyl protocol. This resulted in the patient receiving the wrong dose.

#### CASE 11

A patient was ordered hydromorphone 50mg/50ml. The PCA alarmed as "bag almost empty". When reloading the PCA, it was noted that "almost empty" bag was 100ml bag, not 50ml bag as ordered.

#### CASE 12

A patient had a PCA with fentanyl running. The PCA had been set-up using the tramadol protocol. This meant the patient was receiving four times the prescribed dose of fentanyl. A rapid response call was made for a low respiratory rate.

#### CASE 13

It was noted that the patient was on a ketamine continuous infusion and fentanyl PCA. On review of the orders, it was noted that original ketamine infusion was charted 200mg/100mls @ 2-5mls/hr. The order was then adjusted to a concentration of 200mg/50mls, so that it could be run as a continuous infusion through a PCA. The 2-5mls/hr rate for the original concentration was then not halved to take into consideration the new concentration. The patient was therefore receiving a double dose.

#### CASE 14

A patient transferred to ward from ICU. The patient was found to have PCA programmed five times the prescribed bolus, i.e., the order was for bolus 20mcg per 1 ml. The patient was receiving a 5 ml bolus.

#### CASE 15

A patient was receiving morphine via PCA at the start of a shift, as well as other fluids via an infusion pump. The PCA bag was due to be changed and was checked by two registered nurses. The wrong bag was inadvertently changed, which meant the patient had both a morphine infusion running at 50 mls/hr and the morphine PCA. When this was recognised 40 minutes later, the morphine was immediately ceased and PCA buzzer disconnected. The patient received 37mg morphine in 40 minutes.

## Administration-wrong drug

These incidents relate to situations where the patient was given the wrong drug/infusion, or where the infusion was changed and the wrong drug/infusion started. This includes situations where patients were ordered ketamine by continuous infusion and hydromorphone via PCA. The patient actually received ketamine by continuous infusion and ketamine via PCA. Another similar incident showed that a patient had two morphine infusions running, instead of morphine and ketamine.

#### Administration-wrong solution

These incidents related to situations where the wrong fluid was infused, or where the fluids may not be compatible, or were being infused through the same cannula, resulting in significant risk.

#### CASE 16

A morphine PCA infusion was made up with water for injections, instead of normal saline.

#### CASE 17

A patient had a PCA and an IV infusion, with insulin and antibiotics running through the same line. She was therefore receiving an insulin bolus each time she accessed the PCA.

### Administration-breach of protocol

A number of incidents identified issues with breaches of policy and/or protocol, including not changing the infusion set-up within the prescribed timeframe, not following patient identification processes and/or intravenous infusion policies.

### Administration-ceased/not ceased when ordered

A number of incidents identified that PCAs were discontinued without a valid order to do so, or were not ceased when there was a valid order.

# Issues associated with prescribing of medications for PCA

Issues associated with prescribing of medications to be administered by PCA were the second-largest group identified in this review. Incorrect, illegible, incomplete, or duplicate prescriptions were reported in over 100 of these incidents. The review also identified situations where the PCA orders were not charted on the correct chart, increasing confusion about what had been prescribed for the patient.

### CASE 18

A patient who was on a fentanyl PCA, had also been ordered and administered 20mg temazepam and an increased dose of tramadol. The acute pain service was not consulted about the temazepam and tramadol order. The patient became over-sedated and required ICU intervention. He was given naloxone 600mcg with no effect and then flumazenil 40mgs.

The above case reflects charting issues, but also the cognitive processes associated with assessing a patient before deciding to prescribe medication.

#### CASE 19

A child who weighed over 90 kg, had a PCA ordered following surgery. He was prescribed morphine based on his actual, rather than ideal weight, which, when combined with his obesity and likely obstructive sleep apnoea, resulted in significant respiratory depression. The rapid response team was called, when he was found with an obstructed airway and very low oxygen saturations.

## Observation and Monitoring

Most of the incidents in this category reflected inadequate monitoring of patients on PCAs. In a small number of cases the patient was monitored, but deterioration in his/her clinical condition was either not recognised, or the actions taken in response were delayed, inadequate, or not undertaken as would be expected.

#### CASE 20

A teenage boy suffered recurrent episodes of opioid narcosis while on a PCA, without any of the attending staff contacting the anaesthetic registrar, as prescribed in the hospital and LHD protocol. The sequence of events follows. While in the recovery unit, following surgery, he was reviewed by the procedural anaesthetist regarding pain management and respiratory rate. He was deemed fit for discharge to the ward and transferred. On arrival, he was demonstrating signs of opioid narcosis which was documented by both the receiving ward nurse and the escorting nurse responsible for the transfer. Appropriate immediate removal of the PCA occurred and the after-hours JMO was called to review the patient. After the review, the JMO called the after-hours medical registrar to discuss the problem. Two doses of intravenous naloxone were given and the patient made a brief recovery. A short time later, he was again noted to have a reducing respiratory rate and level of consciousness. The JMO was again called and further naloxone given after discussion with the medical registrar. The patient again recovered, for a longer period, before again relapsing into narcosis. The ward nursing staff called a rapid response. Further IV naloxone and subsequent IM naloxone were prescribed by the medical registrar.

The anaesthetic registrar was not notified of any of the above events, despite the LHD protocol for respiratory depression in a patient with a PCA being clearly written on every PCA prescription form. No advice was sought from the anaesthetic service about respiratory depression in a postanaesthetic patient just discharged from recovery. If anaesthetic service had been contacted (as per protocol) at the time of the initial respiratory depression, an appropriate management plan would have been instituted to prevent the two further relapses into narcosis.

Gevirtz (8) suggests that, once the management of PCAs moved from the domain of anaesthetic departments to a service controlled by surgeons and other specialists, there has been a higher number of complications.

#### CASE 21

A bariatric surgical patient required fentanyl 400 mcg, morphine 11 mg, tramadol 200mgs and paracetamol 1 gram, prior to returning to the ward with a PCA in situ. Six hours after transfer, he was found to be very drowsy, with slurred speech. He was connected to SaO2 monitor but no alarm limits were set, there was no documentation of the patient's level of arousal, or opioid use via the PCA. The device had not been checked since the patient returned to the ward.

#### CASE 22

A child was transferred from recovery to the intensive care unit. On arrival, the patient was escorted by a nurse and porter. No medical staff were present and there was no medical handover. The child had no monitoring in situ and the oxygen tank on the bed was empty. A 6mg bolus of morphine had been given in recovery and 9mg via PCA was programmed for 1mg boluses with a five-minute lockout. On arrival, the patient was very drowsy, with an audible snore, reduced respiratory effort and respiratory rate of less than 10 breaths per minute. When woken, the patient would breathe on command and soon fall back to sleep.

The morphine PCA was stopped. The patient was placed on a non-invasive face mask CPAP, as well as a morphine infusion at 10-20 mcg/kg/hr and midazolam at 0.5mcg/kg/hr. The patient had a respiratory arrest, requiring bag mask ventilation and naloxone.

#### CASE 23

While attending a patient's PCA observations, he was noted to have a respiratory rate of four breaths per minute. He had a continuous infusion through the PCA. The rapid response team was called and naloxone given.

## Documentation

Missing, or incomplete documentation is a common finding in any clinical incident review. Many incidents suggest that the patient had been reviewed, or that a prescription or infusion/syringe had been changed, but the decision and/or actions were not documented.

Labelling of syringes and/or infusion has also been included in this group. Although the number is not large, in each instance the infusion/syringe had to be changed, as it had been unlabelled at the time of set-up.

## Equipment

Incidents in this category were largely related to the unavailability of pumps and/or faulty pumps and equipment.

## PCA by proxy

Nine of the 13 PCA by proxy<sup>6</sup> incidents suggest that a member of the patient's family administered the drug. In four cases, the patient became seriously narcotised.

#### CASE 24

The overnight doctor reviewed a patient who was in severe pain. The doctor ordered a stat dose of morphine 5mg by subcutaneous injection and then pressed the patient's PCA button until he was no longer in pain. The patient was found unrousable and required naloxone.

<sup>6</sup> PCA by proxy (D'Arcy 2008) (3) is when a person other than the patient activates the dosing mechanism of an analgesic infusion pump and delivers analgesic medication to the patient.

#### CASE 25

On routine checking, a patient on a PCA was found to have oxygen saturations of 66 per cent and was extremely drowsy. The PCA dosage showed that the patient had 20mg of morphine in one hour. When questioned, a family member stated that she was pressing the button every five minutes to make sure the patient had no pain.

Vincente et al (9) suggest that there is a need to ensure that PCA buttons carry warning labels stating "for patient use only" and that visitors be informed that they must not push the button, even if the patient asks.

Nelson et al (10) noted that 38 per cent of respondents to a survey (95 of 252) worked in paediatric institutions where PCA by proxy was authorised in some situations. The authorised person was usually a nurse, but sometimes a family member.

## Communication

The issues identified included not informing the acute pain team that the patient was on a PCA and poor communication to the nursing/medical team about changes made, following a review by the acute pain team. This included written communication in the medical record about changes in the PCA.

## Knowledge and Skills

A very small number of incidents, mainly related to management of patients on PCAs by agency, casual, or very junior staff, suggested a lack of knowledge or skills among the staff involved.

## Risk management - patient selection

A few incidents suggest that poor patient selection was an issue. PCAs were sometimes ordered for patients with cognitive impairment, including dementia. Two reported that PCAs were ordered for patients who continually left the ward unsupervised, with the PCA in situ.

## Conclusion

The review identified that patients on PCAs may be at significant risk and that many required additional, unplanned care while receiving PCA. A number showed some evidence of being narcotised, with some requiring a clinical review, a rapid response call and higher-level care.

This suggests that there is a need for a greater level of governance around patient controlled analgesia and its related processes.

## Issues identified - for consideration

- 1. Poor patient selection increases the risk of PCA by proxy, or inadequate pain management.
- 2. There is inadequate oversight and training related to use of PCAs within facilities. The review found that this led to many errors in administration and reduced the effectiveness of pain management effectiveness.
- 3. There are variations in policy about what can be infused when a PCA is in situ, using the same IV line, e.g., blood.
- 4. Patients appear to be most at risk when being transferred from one area to another, or when there are changes to prescriptions.
- 5. When complications arise, the acute pain team/anaesthetist may not always be consulted.
- 6. Dose and rate confirmation processes may not be sufficiently robust. This is compounded by the use of abbreviations used in prescribing, e.g., mgs/mcg.
- 7. There would appear to be limited access to, or utilisation of, standing orders for the management of narcotised patients awaiting review.
- 8. Equipment is not standardised throughout facilities, e.g., standard PCA packs and pre-loaded versus non-pre-loaded.
- 9. The pre-programmed pump function (for common protocols) may not always be used.
- 10. Efforts to reduce or prevent duplication of charts/prescriptions may not be effective.
- 11.Patient and family information/warnings about PCAs may be variable and lack clarity.

## Recommendations

- LHDs establish local governance structures to ensure the safe and effective use of PCAs in each facility. These should be responsible for ensuring appropriate staff skill mix, training, supervision and support and the regular audit of patient selection, clinical care and monitoring related to PCA pain management. Such a governance structure should oversee the results of the regular audits of all incidents reported about PCA use (e.g. by Quality and Safety Committees).
- 2. Medical officers managing postoperative and other types of pain should consider multimodal analgesia. Opiate sparing may be achieved by combining analgesics with different mechanisms of action e.g. epidural opioids, regional block, non-steroidal anti-inflammatory drugs, regular paracetamol or ketamine.
- 3. Medical Officers responsible for prescribing of PCA pain management must be adequately trained in all aspects of PCA care, including appropriate patient selection, usual dosages and the management of complications related to PCA use. Lines of responsibility, that is: who to contact must be clearly communicated for each occasion of PCA prescription.
- 4. All registered nurses assigned to care for post-surgical or other patients using PCAs, participate in PCA specific education which includes content regarding set-up and use of PCAs, monitoring of patients, identification of at risk patients and actions to be taken if complications occur. Competency based training should be considered.
- 5. A register of staff skilled/trained in the use of PCA should be maintained and utilised, to ensure that they are present throughout the day/night.
- 6. The CEC endorses the finalisation and use of an adult PCA monitoring form and guideline (being developed by the ACI pain management network). The CEC also supports the proposed development of a paediatric PCA framework. Both these bodies of work will ensure that all patients using PCAs receive regular monitoring and appropriate care, should over- or undersedation be detected.
- 7. LHD patient flow/bed managers in conjunction with Nursing Unit Managers ensure that patients using PCAs are cared for by staff who have the specific skill set, training and oversight required to ensure safe and effective administration of pain relief via PCA.
- 8. Health Support Services, Clinical Contracts (HSS) work with suppliers to ensure that all PCA pumps available on the State contracts list are programmed with a limited number of standardised default protocols, to reduce programming errors and facilitate safe dosing. The initiating prescriber and who to contact if issues occur, should be clearly documented. Variation from these protocols must be clearly documented in the patient's medical record, including reason for variation, period for which the variation applies and contact details of the prescriber (in line with PD 2007\_077).
- 9. A standardised approach to PCA drug concentrations is achieved by use of pre-loaded syringes, poly bags and cassettes, which are most appropriate for each specific patient group (i.e. adults/paediatrics). There must be a documented clinical reason to vary this concentration. HSS contracts to facilitate this by providing LHDs with bulk order options for pre-loaded syringes, to reduce the cost of sourcing these locally.
- 10.LHDs must have in place standing orders and protocols for use of reversal agents in cases of over-sedation. If such an event occurs it should trigger a case review which is overseen by the above stated governance structures. With feedback provided to relevant clinical groups.

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