

Procedures in pain medicine clinical care standard

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Introduction

GOAL

The goal of the Procedures in Pain Medicine Clinical Care Standard is to articulate what is considered to be the appropriate and safe use of procedures in the practice of pain medicine.

SCOPE

This standard relates to the care of adult patients (aged 18 years and older) undergoing procedures for the diagnosis or treatment of cancer-related or chronic non-cancer pain. It covers the period from when a patient is referred for consideration of a procedure through to discharge including planning for follow-up care. The Procedures in Pain Medicine Clinical Care Standard is relevant to the care provided by Faculty of Pain Medicine (FPM) fellows and trainees in public and private hospital settings, day procedure services or consulting rooms.

CONTEXT

Chronic non-cancer pain is a common and costly multidimensional experience, affecting one in five adults in Australia^{1,2} and New Zealand³. Pain is also a common and distressing symptom for people with cancer⁴. Chronic pain cost New Zealand an estimated \$NZ13-14.9 billion in 2016⁵, and cost Australia an estimated \$A73.2 billion in 2018⁶, with annual costs projected to rise substantially over coming decades. The majority of these costs were attributed to productivity losses and reduced quality of life, rather than to healthcare costs.

A socio-psycho-biomedical conceptual framework acknowledges the complexity of pain experiences, and underpins assessment and management of chronic cancer-related and non-cancer pain by specialist pain medicine physicians⁷. Many patients benefit from multimodal and multidisciplinary management^{8,9}. For a minority, there may be a role for supplementing these therapies with invasive pain medicine procedures to assist in diagnosis, or palliate symptoms to improve function and quality of life.

Pain medicine procedures are interventions that breach the skin, usually with a needle or minimally invasive surgery, to deliver medicines or various forms of energy to affect deep tissues. It is acknowledged that more invasive surgery is occasionally performed to manage refractory pain, but such surgery is beyond the scope of this clinical care standard.

Pain medicine procedures are divided into diagnostic and therapeutic procedures based on intent:

- Diagnostic procedures use injections of local anaesthetic to temporarily block sensory signals from nerves or tissues that might contribute to the patient's pain experience. The goal is to help localise the origin of such signals to inform future care.
- Therapeutic procedures aim to reduce sensory contributors to the patient's pain experience for sustained periods to facilitate meaningful improvements in pain, function and quality of life. Examples include coeliac plexus neurolysis for intra-abdominal cancer pain, radiofrequency neurotomy for spinal pain, and spinal cord stimulation for neuropathic pain.

Pain medicine procedures are complex tasks that require good judgement in selecting patients, mitigating risks, guiding imaging to visualise target tissues, manipulating equipment to perform the procedure, assessing patient outcomes and planning concurrent and subsequent care.

These standards have been articulated in order to optimise clinical benefits and minimise the risk of complications from procedures. Concern about variation in the practice and quality of procedures was one of the drivers behind the FPM position statement on Procedures in Pain Medicine¹⁰. The promulgation of this clinical care standard is the first outcome of the process set out in that FPM position statement.

This clinical care standard seeks to reduce unwarranted variation that contributes to poorer outcomes and resource utilisation, while allowing the appropriate variability in practice required to match variations in individual patient needs.

Implementation of this clinical care standard should be undertaken within the context and requirements of national standards and other relevant guidelines for health service organisations and clinicians providing pain medicine services (Appendix 1).

Methodology

This clinical care standard was developed by the FPM of the Australian and New Zealand College of Anaesthetists (ANZCA), following development of its position statement on Procedures in Pain Medicine¹⁰. FPM has drawn on scientific evidence, and the expertise of its fellowship and outside training and governance bodies, to develop an optimum standard of clinical care to guide its fellows and trainees.

The methodology and format closely follow that of the Australian Commission on Safety and Quality in Health Care (the Commission) Clinical Care Standards program¹¹. The commission's program supports clinical experts and consumers to develop clinical care standards on health conditions and interventions that would benefit from a national coordinated approach. This is in recognition that:

- Appropriateness of clinical care is a major focus in improving the quality of health care provision.
- A gap between what we know and what we do exists.
- Unwarranted variation is variation in care that is not explained by the clinical circumstances or personal choices of the patient and occurs when there is:
 - Overuse of treatments or procedures that do not help people get better.
 - Underuse of care that we know can help.
 - Misuse (or errors) of doing something incorrectly and harming people.

Clinical care standards aim to support the delivery of appropriate evidence-based clinical care, and promote shared decision making between patients, carers and clinicians. Clinical care standards differ from clinical practice guidelines in that they address priority areas for improvement, rather than describing all the components of care for managing the condition¹¹.

The document development group comprised FPM fellows with relevant clinical, research and governance expertise. After contemplating the feasibility of consumer involvement from the outset, consumer consultation at key time points was elected instead.

By consensus, 10 aspects of the care delivery system for pain medicine procedures were identified that likely account for current unwarranted variation. Informed by current evidence from guidelines and standards, 10 corresponding **quality statements** were developed to describe the clinical care patients should be offered by FPM fellows and trainees. Each quality statement is operationalised by separate explanations for patients, FPM fellows and trainees, and health services.

Stakeholder and public consultation processes were conducted before finalisation of the document for use by FPM ANZCA, its fellows and trainees. This document shall be updated in keeping with any relevant future changes to the FPM Curriculum, training program, by-laws, and the ANZCA Continuing Professional Development Standard¹².

Procedures in Pain Medicine Clinical Care Standard – Overview



1. TRIAGE AND CLINICAL ASSESSMENT

Patients are offered timely and comprehensive assessment according to their clinical need. Decision-making as to the appropriateness of a pain medicine procedure is based on a socio-psycho-biomedical assessment.



2. PATIENT PREPARATION

Patients are provided with adequate information and time to consider the benefits, risks, aftercare and costs of the pain medicine procedure, and any alternatives, before providing written informed consent to proceed. Their health is optimised to mitigate risks associated with the procedure and any sedation or anaesthesia required.



3. SAFE AND SUFFICIENT FACILITIES

Patients undergo procedures in an environment that combines all elements necessary for safe and efficient conduct, recovery, and management of adverse events. Clinicians and healthcare services ensure that their facilities comply with national standards and are accredited for the procedures performed therein.



4. SEDATION AND ANAESTHESIA

Before the procedure, the role of sedation or anaesthesia is considered in the context of the individual patient and the planned procedure. Sedation, if used, must be conducted to ANZCA standards¹³ (or equivalent) and administered so that the reliability of diagnostic procedures is optimised.



5. IMAGING EQUIPMENT AND PRACTICE

Patients undergo image-guided procedures in an environment that combines all elements necessary for safe and efficient imaging. The facility provides necessary and safe imaging equipment and licensed imaging staff. Clinicians are trained in the appropriate and safe use of the equipment and interpretation of the images.



6. PROCEDURALIST

Clinicians who perform pain medicine procedures are knowledgeable, trained, and endorsed in the procedure being performed (or appropriately supervised). They are engaged in continuing professional development (CPD) that meets the current ANZCA CPD standard¹².



7. PROCEDURAL PERFORMANCE

Clinicians identify and adhere to current best-practice guidelines for performing the specific procedure, adapting the technique to safely accommodate anatomical variation in the patient.



8. DOCUMENTATION AND COMMUNICATION

Relevant, accurate, complete and timely information about a patient's care is documented in the healthcare record, including key images acquired during the procedure. Patients receive discharge instructions. Relevant information is communicated with the clinicians involved in care.



9. OUTCOME ASSESSMENT

Patients who undergo diagnostic blocks have real-time recording of pain intensity and function throughout recovery from local anaesthesia. Patients who undergo therapeutic procedures complete patient-reported multidimensional outcome measures at intervals relevant to the procedure. Beneficial and adverse outcomes are communicated with patients and referrers.



10. POST-PROCEDURAL CARE

Following completion of a procedure, patient progress is monitored closely and any complications are quickly recognised, managed and followed up. If the procedure has been performed by a clinician who is not involved in the patient's ongoing care, a high-quality handover to the treating doctor or team is given.



Quality statement 1:

Triage and clinical assessment

Patients are offered timely and comprehensive assessment according to their clinical need. Decision-making as to the appropriateness of a pain medicine procedure is based on a socio-psycho-biomedical assessment.

Purpose of this quality statement

To ensure that the decision to offer a pain medicine procedure is made in the context of a socio-psycho-biomedical assessment.

What this quality statement means



For patients

Your general practitioner or referring doctor is considering whether or not a pain medicine procedure might be of potential benefit to the management of your condition.

Your Specialist Pain Medicine Physician will undertake a full assessment of your health to determine all of the treatment options that might help you reduce your pain and achieve your goals. This assessment is important to be sure they can offer you the best advice and help you to make informed decisions about your care which may or may not include a procedure.

If a procedure is being considered, then they will assess your general health to determine any risks the procedure might pose and how best to reduce those risks. It is important to inform your doctor if you may be pregnant as some medicines, imaging and procedures carry risks during pregnancy.

If your specialist does not routinely perform the recommended procedure, they will refer you to a colleague who may perform the procedure. In this case, where the referring doctor has special expertise, the proceduralist may not need to repeat the referrer's assessment. Nevertheless, the proceduralist will need to confirm key details with you before they can safely plan your procedure.



For clinicians

A comprehensive referral enables the receiving clinician to determine clinical need and to allocate timely appointments for assessment and care. Ensure that there are triage processes for allocating appointments according to clinical need. Where the referral does not allow determination of relative clinical need and routine wait-time is long, it is the receiving clinician's responsibility to contact the referrer and request more information or ensure there are systems in place to do so.

A socio-psycho-biomedical assessment is the foundation of decision-making as to the appropriateness of a pain medicine procedure^{7,14}. If a comprehensive assessment has already been undertaken by an appropriately qualified referrer, review detailed findings and check any interval changes with your patient (including pregnancy status), before shared decision-making with regard to the role of any pain medicine procedure in the patient's care.

The proceduralist is responsible not only for the decision-making and components of care delivered personally, but also for the following components even if they are delegated to other clinicians:

- Conduct of a socio-psycho-biomedical assessment.
- Selection of appropriate patients, considering benefits, risks, alternatives.
- Patient information and consent.
- Risk mitigation.

Accordingly, maintain systems to ensure your delegate's competency to perform any such task(s).



For health services

Services with wait-lists¹⁵ should have referral management systems that:

- Involve clinicians in triaging referrals based on clinical urgency.
- Facilitate requests to referring doctors for additional information if deemed essential for triage and care.
- Assign appointments based on clinical need.

Services should provide consultation/examination rooms that meet national standards and enable clinical assessment. For interdisciplinary team assessments, provide sufficient space to comfortably accommodate the team, patient and family.

In addition, when sedation or anaesthesia is planned, have systems that enable pre-sedation/ anaesthesia assessment and risk mitigation protocols.

For teaching hospitals, ensure suitable staffing levels and policies for supervision of trainees, so that delegated tasks can be supervised sufficiently to ensure public safety¹⁶.



Quality statement 2: Patient preparation

Patients are provided with adequate information and time to consider the benefits, risks, aftercare and costs of the pain medicine procedure, and any alternatives, before providing written informed consent to proceed. Their health is optimised to mitigate risks associated with the procedure and any sedation or anaesthesia required.

Purpose of this quality statement

To ensure that patients are adequately prepared before decision-making or undergoing a pain medicine procedure.

What this quality statement means



For patients

If your doctor recommends that you have a pain medicine procedure, you will need to decide whether to go ahead with it. Some procedures are used to clarify your diagnosis and guide future care. Other procedures are used as treatments aimed at reducing the sensations that contribute to your experience of pain.

To help you make your decision, you will be informed about all the parts of the process including how to prepare, what to expect during and after the procedure, and any costs. Your doctor will also discuss the likely benefits and risks in your particular case, and how best to reduce those risks. You should also be given information about other options or alternatives to the procedure.

If you will need medicines to make you sedated or unconscious (anaesthesia) during the procedure, you may be asked to see another doctor before the procedure to assess your health, and help you to understand the benefits and risks of sedation or anaesthesia.

If you decide to have the procedure, you will be asked to give consent. Giving consent means that you understand what is involved in having the procedure, what the risks and benefits are, and that you agree to have the procedure.



For clinicians

Having considered whether a pain medicine procedure is indicated for the patient according to evidence-based guidelines, and having assessed the likely benefits and risks, provide the patient (or their responsible decision-maker where relevant) with clear and comprehensive information to facilitate shared decision-making and informed consent¹⁷.

Use language that they can understand. Arrange an interpreter if required. Information includes:

- Why the procedure has been offered, emphasising whether the procedure has diagnostic or therapeutic intent or both.
- How it will be undertaken.
- The probability of beneficial and adverse outcomes with reference to the published scientific literature, and to the patient's individual health status.
- Any financial costs.

- Alternatives to having the procedure, including any risks of not having the procedure.

Provide adequate time for the patient to consider the information provided and to ask questions before consenting. Respect the patient's decision and document it and their informed consent in the medical record, with a description of the information discussed and provided to the patient. If proceeding, implement standardised perioperative protocols for clinical risk mitigation (for example diabetes, anticoagulation management, fasting) according to national guidelines¹⁸.



For health services

Ensure that policies and processes support compliance with informed consent for procedural and anaesthesia care, and support risk mitigation including processes for assessment and planning ahead of day stay procedures.

In addition, when sedation or anaesthesia is planned, have systems that enable pre-sedation/ anaesthesia assessment, risk mitigation protocols and appropriate staffing according to ANZCA guidelines¹³ (or equivalent) (See also Quality statement 4).



Quality statement 3: **Safe and sufficient facilities**

Patients undergo procedures in an environment that combines all elements necessary for safe and efficient conduct, recovery, and management of adverse events. Clinicians and healthcare services ensure that their facilities comply with national standards and are accredited for the procedures performed therein.

Purpose of this quality statement

To ensure patients undergo pain medicine procedures in an environment that optimises patient safety and care.

What this quality statement means



For patients

When a procedure is undertaken, you can expect that it will be done in a place that has met the standards for healthcare buildings. You will be able to safely access and move around the building. The building will have adequate lighting, infection control, radiation safety, and communication and security systems to keep you safe.



For clinicians

Ensure that the physical environment, equipment and medications, staffing and information technology (IT) systems are adequate for the safe conduct of the planned procedure. Although some of these systems may be outside the clinician's control, clinicians should recognise any deficiencies, and should not proceed with a procedure in an environment that does not support its safe conduct.



For health services

The health service responsible for the facility will ensure that the facility meets building codes and regulatory standards^{19,20}. Health services should support the clinician to provide the physical environment, equipment and medications, staffing and IT systems that are adequate for the planned pain medicine procedures.

The health service shall ensure that all medications used in pain medicine procedures are stored and labelled according to relevant regulations and manufacturers' guidelines.

In addition, the health service should have policies and procedures regarding environmental safety, equipment maintenance, radiation safety, infection control, and ensure staff accreditation in the use of specialised equipment.

Health facilities should have protocols and procedures in place to deal with emergencies, patient recovery, transfer and discharge.



Quality statement 4: **Sedation and anaesthesia**

Before the procedure, the role of sedation or anaesthesia is considered in the context of the individual patient and the planned procedure. Sedation, if used, must be conducted to ANZCA standards¹³ (or equivalent) and administered so that the reliability of diagnostic procedures is optimised.

Purpose of this quality statement

To ensure that, if sedation or anaesthesia is required, patient safety is maintained throughout administration and patient recovery, and that any risks are anticipated and mitigated.

What this quality statement means



For patients

Before your procedure, your doctor will discuss how procedural pain can be anticipated and managed. Many procedures can be comfortably and more safely performed without sedation. Your doctor will discuss whether you might benefit from medicines to make you sedated or unconscious (anaesthesia) during some or all of the procedure.

If you need sedation or anaesthesia, a suitably-qualified doctor or nurse will check whether there are any particular risks for you. They may make short-term changes to your medicines. This is to make sure that you are given sedation or anaesthesia safely. They will talk with you about the risks and benefits, and what you can expect to be aware of during the procedure and as you recover. Discuss any preferences with your doctor.

Your sedation or anaesthesia will be given according to current professional guidelines. If you require anaesthesia, this will be given or supervised by a specialist anaesthetist. Even if the doctor performing your procedure is a qualified anaesthetist, a second anaesthetist will be present to focus entirely on you while you undergo anaesthesia. Sedation may sometimes be given by an anaesthetist but this is not always required. In any case, a clinician will be present to check your health and comfort during sedation.



For clinicians

Consider the roles of non-pharmacological expectation and anxiety management, together with non-sedating analgesics, in order to avoid or minimise sedation. Consider the risks of sedation or anaesthesia in the context of the specific procedure^{21,22} and patient.

Anaesthesia may be necessary for parts of invasive procedures wherein absolute motion control is required for safe conduct. Deep sedation or anaesthesia may also be required for patients whose past experiences predict they will not tolerate the planned procedure under conscious sedation.

Even when not essential, conscious sedation may enhance patient experience of procedures, but must be administered so that the reliability of diagnostic procedures is optimised. Cognitive clouding or amnesia may render diagnostic blocks futile.

When sedation or anaesthesia is planned, ensure the patient is assessed and counselled by an appropriately trained clinician to weigh the benefits and risks of the

procedure and anaesthesia together^{13,18}. Allow sufficient time to mitigate any identified, modifiable risks before the procedure (see also Quality statement 2). Reassess immediately prior to the procedure to exclude significant clinical deterioration.

Ensure the patient has given valid informed consent for the sedation or anaesthesia, in addition to the procedure itself²³. Ensure that conscious sedation, deep sedation or anaesthesia is planned and administered in appropriately accredited facilities, by suitably credentialed staff acting within their scope of practice, and that the patient is monitored throughout the procedure and recovery period in accordance with ANZCA guidelines¹³ (or equivalent) (See also Appendix 1, Related FPM/ANZCA Professional Documents).



For health services

Policies should ensure that pre-procedure sedation assessments are carried out by appropriately trained clinicians, in order to identify patients who are not suitable for sedation in the absence of an anaesthetist, and to plan for anaesthetist-administered sedation accordingly.

Deep sedation and anaesthesia should be provided in accordance with current ANZCA professional documents (or equivalent) (see Appendix 1, Related FPM/ANZCA Professional Documents). Ensure that systems are in place, and services adequately resourced, to implement those guidelines.

Conscious sedation should be provided in accordance with current ANZCA recommendations such as the Guidelines on Sedation and/or Analgesia for Diagnostic and Interventional Medical, Dental or Surgical Procedures¹³ and Guidelines for the Perioperative Care of Patients Selected for Day Stay Procedures¹⁸ (or equivalent). Ensure that systems are in place, and services adequately resourced, to implement those guidelines.

Ensure that clinicians who administer sedation or anaesthesia for pain medicine procedures, and those who supervise recovery, are credentialed by the health service organisation and operating within their defined scope of clinical practice and that they maintain their skills by participating in ongoing professional development and review of performance. Mandatory skills include recognising the deteriorating patient and appropriate emergency responses.



Quality statement 5:

Imaging equipment and practice

Patients undergo image-guided procedures in an environment that combines all elements necessary for safe and efficient imaging. The facility provides necessary and safe imaging equipment and licensed imaging staff. Clinicians are trained in the appropriate and safe use of the equipment and interpretation of the images.

Purpose of this quality statement

To ensure the safe and appropriate use of medical imaging to guide pain medicine procedures.

What this quality statement means



For patients

For many procedures, your doctor will need to use ultrasound or x-ray equipment to show images of your body part to help them perform the procedure safely and accurately. Therefore, exposure to radiation may be needed to perform the procedure.

If this is needed, your doctor will assess whether there are any specific risks or contraindications to make sure that the equipment can be used safely and appropriately in your case.

Your procedure will be done according to current professional recommendations, with equipment that meets local standards and guidelines, and considering your specific condition. Images of your procedure will be recorded and held on file for reference.



For clinicians

Clinicians should employ the imaging modality based on best practice clinical guidelines for any given procedure. It is essential that they maintain their competency in real-time image interpretation in the procedural context.

The clinician is responsible for assessment of patient suitability for the planned imaging modality and the relative risks and benefits of the specific modality. Patient consent will include risk relating to radiation as relevant, including any risk to a foetus during pregnancy.

The clinician must establish that their facility is able to provide the requisite imaging equipment. Ensure imaging equipment is accessible, functional, capable, calibrated, and compliant with regulatory requirements, and has an appropriate program of quality control testing. Ensure also that any required imaging staff are available for the planned procedure^{24,25}.

When radiographic imaging is necessary during the procedure, the clinician must ensure safety of the patient, support staff and themselves including personal protective equipment appropriate for the anticipated radiation exposure. In particular, a clinician who controls fluoroscopy exposure (that is uses a foot-pedal for intermittent exposures or continuous screening), should hold appropriate and current radiation safety certification (see Appendix 1, Radiation certification by jurisdictions).

Clinicians must follow radiation safety policies, procedures, and imaging protocols that apply the ALARA ("as low as reasonably achievable") dosing principle to each radiological procedure that they perform. Radiation exposure must be monitored according to guidelines.

Key images acquired during the conduct of the procedure must be stored in the patient's imaging record (see Quality statement 8).



For health services

The service facility provides imaging equipment that is functional, capable, calibrated, compliant with regulatory requirements, and has an appropriate program of quality control testing and compliance with the requirements of all radiation safety legislation²⁶⁻²⁸.

Where x-ray is required, the healthcare service shall apply the ALARA ("as low as reasonably achievable") dosing principle to all radiological procedures performed, and must document radiation safety policies and procedures which aim to minimise radiation exposure, in accordance with the ALARA principle²⁹.

Ensure the safe use of contrast media and have a protocol for the management of adverse reactions to contrast media.

Ensure that where there are specific competencies required for a particular imaging examination, the personnel involved with that imaging examination are suitably qualified, experienced and credentialed²⁹, or appropriately supervised.



Quality statement 6: **Proceduralist**

Clinicians who perform pain medicine procedures are knowledgeable, trained, and endorsed in the procedure being performed (or appropriately supervised). They are engaged in continuing professional development (CPD) that meets the current ANZCA CPD standard¹².

Purpose of this quality statement

To ensure that clinicians who undertake pain medicine procedures gain and maintain the requisite knowledge and skills to perform the specific procedure safely and effectively.

What this quality statement means



For patients

When you have a pain medicine procedure you can expect to be cared for by qualified doctors, nurses and technicians who have met necessary professional and health service organisation requirements and standards.

Your proceduralist will be able to discuss with you the purpose, goals, and expectations of the specific procedure for your pain condition, and will be able to explain to you what tasks may be expected of you before, during, and after the procedure.

You can expect your proceduralist to have the necessary up-to-date knowledge, training and skills to undertake your specific procedure. The procedure may be performed by a trainee appropriately supervised by a specialist pain medicine physician, with your informed consent.

Your proceduralist will be able to recognise and coordinate management of any complications of your procedure in the unlikely event that they occur.



For clinicians

Clinicians who perform procedures should have knowledge of the role of procedures in the broader context of the management of chronic non-cancer and cancer-related pain.

Ensure that your knowledge, training, skills and experience enable you to provide safe, high quality care to a patient undergoing the specific procedure, in accordance with expected professional standards. In addition to foundation knowledge afforded by FPM training⁷, proceduralists require knowledge specific to each procedure they intend to perform (see also^{30,31}):

- The putative mode of action and rationale.
- Image-guided anatomy and radiation safety.
- Best practice procedural guidelines for the given procedure.
- Regulations and manufacturers' instructions for the safe use of equipment.

In addition, specialist pain medicine physicians who intend performing pain medicine procedures should undertake relevant procedural skills training and maintain specialist

registration with the national medical registration body. FPM Fellows practising procedures are encouraged to seek endorsement via the FPM Procedures Endorsement Program to demonstrate their commitment to upholding the required standards.

Comply with your health service organisation's policies and procedures regarding your scope of clinical practice and mandatory skills training. Undertake continuing professional development activities that meet the current ANZCA CPD standard, and are relevant to the practice of pain medicine procedures and emergency responses.

Supervise trainees at a level appropriate to their skill and experience.



For health services

Identify credentials that are required for clinicians to perform each specific procedure, recognising that each procedure has its own unique skill-set, and ensure credentialing processes are adequate (for examples see^{32,33}).

Support participation by clinicians in CPD and peer review activities. Monitor and periodically review individual and service performance against accepted quality indicators and ensure under-performance is addressed promptly and effectively.

Ensure practitioners who provide sedation or anaesthesia for these procedures meet a defined standard of competency for sedation or anaesthesia (see quality statement 4).

Where relevant to the health service organisation, implement and ensure compliance with policies and procedures for the safe supervision of trainees.



Quality statement 7:

Procedural performance

Clinicians identify and adhere to current best-practice guidelines for performing the specific procedure, adapting the technique to safely accommodate anatomical variation in the patient.

Purpose of this quality statement

To ensure patients receive procedures that conform to best-practice standards to maximise positive patient outcomes and minimise adverse events.

What this quality statement means



For patients

Pain medicine procedures differ from pain medications that you might take by mouth. Procedures are much more complex and their outcomes depend on the skill of the proceduralist and the technique they use. You can be confident that the doctor performing your procedure will know and follow the guidelines for how best to perform your specific procedure.

Because a procedure targets a specific part in your body, the technique needs to be adapted to your individual anatomy and health. Your doctor will follow guidelines in the use of imaging (ultrasound or x-ray pictures recorded during the procedure) to help see your anatomy and guide the procedure accurately (see also Quality statement 5).



For clinicians

Base your procedural technique on the best-available evidence to maximise patient outcomes and safety. Evidence sources might include practice guidelines for diagnostic and treatment procedures developed by lead national or international professional organisations in the field^{30,34}, and/or rigorous scientific papers reporting techniques that clearly deliver improved patient outcomes with equivalent or improved safety.

Ensure immediate pre-procedure patient checks are completed. These include checking consent, patient identity, current health, and confirming procedure, side and site³⁵. Ensure routine and rescue staffing and equipment are ready and appropriate for the procedure and any sedation/anaesthesia planned.

Having identified the relevant current best-practice guideline for the specific procedure, adhere to the published technique, adapting only to accommodate patient anatomical variation. Use best-practice imaging (see Quality statement 5) and documentation (see Quality statement 8). Note: Experimental variations in technique or technology should be firstly limited to registered, ethics-approved, research studies undertaken with appropriate consent, and then may be generally available after a peer-reviewed approval process that meets professional standards (for example see³⁶).

If the procedure involves surgery or the implantation of a device, follow relevant surgical guidelines and manufacturers' instructions to protect patient safety.

If adverse events occur during the procedure or recovery, inform the patient of the nature of the incident, its consequences, implications and management³⁷.

Ensure that the number of patients booked on each list/session enables the proceduralist to undertake all procedures safely.



For health services

Provide systems and equipment that facilitate the safe and appropriate performance of these technically skilled procedures.

Require and support proceduralists to maintain accurate records of the procedure including all diagnostic and therapeutic interventions, procedure duration, and details of any adverse events (see also Quality statement 8).

Ensure complications or adverse events of a procedure are reported in the health service organisation's incident management system, monitored and reviewed as part of quality monitoring and clinical quality improvement activities (such as morbidity and mortality reviews).



Quality statement 8:

Documentation and communication

Relevant, accurate, complete and timely information about a patient's care is documented in the healthcare record, including key images acquired during the procedure. Patients receive discharge instructions. Relevant information is communicated with the clinicians involved in care.

Purpose of this quality statement

To ensure good quality medical records inform the ongoing care of patients.

What this quality statement means



For patients

Your doctor and other clinical staff are required by law to record key information about your assessment, and about the advice and care given. Some x-rays or other images taken during your procedure may be stored on hard-copy x-ray films or digitally in your record.

Information about your health is both personal and sensitive, and there are safeguards to restrict the way this information can be used. Your doctor and the facility will store your information securely, according to privacy regulations. Your doctor will share your information with the clinicians who are directly involved in your care, and seek your consent for any disclosure of information for purposes other than providing direct care.

Before discharge home, you should be provided with a copy of your discharge information outlining the procedure and related care that you received, and any ongoing care or follow-up instructions. If your procedure was performed to implant a medical device that is intended to remain in place after the procedure, then you will also be given a patient information leaflet and a patient implant card. The card contains information about your implanted device, and should be carried with you at all times in case this information is needed to assist in emergency or routine medical care.



For clinicians

Explain to patients and carers how patient information is collected, used and disclosed, and the safeguards that apply. Record clinical information contemporaneously.

Before the procedure record: assessment findings; the rationale for recommending the given procedure; risks for the individual patient and risk mitigation advice; material discussed in the process of obtaining informed consent; and pre-procedure checklists completed. During or immediately after the procedure record: details of the procedure conducted including sedation or anaesthesia; images and radiation screening time; adverse events that occurred and open disclosure; immediate patient outcome and ongoing monitoring plan; and discharge care instructions.

Not all images acquired need to be permanently recorded. Key images are those that show the position of the hardware when significant events occurred – such as the injection of a contrast agent or drug, application of thermal energy, final position of a lead, or the position when an adverse experience was reported. Images should be

recorded in sufficient planes to allow a third party to determine where exactly the hardware or contrast medium was located³⁸.

If a catheter or lead is partially inserted and intended to remain in place after the procedure, record the length that remains deep to the skin, its course (for example whether tracked subcutaneously and the spinal level at which it enters the spinal canal) and the location of the tip.

Whenever the skin is opened surgically, comply with relevant standards for the recording of instruments and accountable items³⁹. If a device is fully inserted and intended to remain in place after the procedure, record the device specifications and unique identifier in the patient's healthcare record and, with patient consent, in any relevant device registry. Ensure the patient has understood the consumer device information leaflet and has been given a patient implant card that complies with standard specifications prior to discharge⁴⁰.

When sedation or anaesthesia is used, comply with standards for recording these activities^{13,41}. Ensure patients are given a copy of their discharge instructions, and told when it will be safe to drive⁴². Explain the pathway for seeking advice and care for any post-procedural concerns.



For health services

Develop and implement systems to support the contemporaneous documentation of pain medicine procedures and relevant imaging in the healthcare record. Implement in the context of broader standards and policies that apply to healthcare record documentation (see Appendix 1).

Make the organisation's documentation policies available to relevant personnel. Ensure relevant personnel understand their roles and responsibilities for documentation.

Establish robust systems for reporting and investigating adverse incidents and outcomes as part of clinical governance and improvement. Have in place systems to enable recall of patients should their implanted devices be subject to manufacturer warnings or recalls.



Quality statement 9: Outcome assessment

Patients who undergo diagnostic blocks have real-time recording of pain intensity and function throughout recovery from local anaesthesia. Patients who undergo therapeutic procedures complete patient-reported multidimensional outcome measures at intervals relevant to the procedure. Beneficial and adverse outcomes are communicated with patients and referrers.

Purpose of this quality statement

To ensure that a multidimensional evaluation of procedural outcome informs ongoing patient care and quality improvement.

What this quality statement means



For patients

Your doctor or nurse will follow your progress after the procedure and record the outcome, including any positive and negative experiences. This assessment will differ depending on the type of procedure you have had:

- Diagnostic procedures – Involve injecting local anaesthetic near a nerve or tissue to see if it temporarily improves your pain and function. You may, or may not, get temporary relief. You will be asked to report your pain experience regularly over the first hours or days after the procedure. Any negative experiences should also be recorded. This information is vital to making an accurate diagnosis and helping plan future management.
- Therapeutic procedures – Are intended to relieve pain longer-term, so it is important to track your outcomes over many months or years. Your doctor or care team will ask you to answer some questions before the procedure, and at various times afterwards, to measure the effect on your pain, and how you feel and function. Any negative experiences should also be recorded. This information will help you and your doctor plan your ongoing care, both procedural and non-procedural.

Your outcome information will be shared with you and your referring doctor (see also Quality statement 8). It may also be de-identified (specific information that identifies you is removed) and sent to a national outcomes registry that is used to help monitor the effects of pain medicine procedures and other pain treatments in the Australian and/or New Zealand population. This helps clinicians and planners improve the care patients receive.



For clinicians

For diagnostic blocks, record pain scores using a validated measure before and after the intervention and any functional improvement that accrues^{43,44}. The diagnosis and any therapeutic implications should be considered and recorded. For therapeutic procedures, evaluate patients at follow up intervals relevant to each procedure, to assess the sensory outcome and multidimensional pain experience. Supplement clinician assessment with patient-reported outcome measures. Pain score, medication intake, and functional capacity relevant to the patient's goals form part of the multidimensional assessment expected to be recorded as well as any complications.

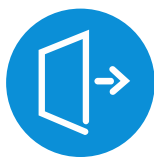
If the proceduralist is not the doctor coordinating the patient's care, outcome information should be communicated in a timely fashion to the coordinating doctor, and arrangements made for hand-over of responsibility for longer-term outcome follow up.

Specialist pain medicine physicians who undertake procedures are expected to engage in FPM-approved clinical outcome audits as a component of their CPD¹². Participation in case-mix-adjusted benchmarking and clinical improvement are encouraged (for example⁸).



For health services

Health services should support clinicians to record and audit the clinical and patient-reported outcomes of their pain medicine procedures. Encourage participation in national provider de-identified, case-mix adjusted benchmarking, where this is feasible. Ensure robust systems for reporting and investigating adverse incidents and outcomes as part of clinical governance and improvement.



Quality statement 10: **Post-procedure care**

Following completion of a procedure, patient progress is monitored closely and any complications are quickly recognised, managed and followed up. If the procedure has been performed by a clinician who is not involved in the patient's ongoing care, a high-quality handover to the treating doctor or team is given to facilitate ongoing care.

Purpose of this quality statement

To ensure that practitioners structure their practice in such a way as to guarantee a safe system of care surrounding the patient that extends to the post-procedure period.

What this quality statement means



For patients

Your doctor will ensure that your care is able to continue after the procedure even if there are unexpected complications such as infection or incomplete recovery. Referrals to other specialists may be required, and should be available promptly if the need arises. Your doctor should have procedures in place to enable rapid reporting and management of complications arising from care.

If the procedure has had a beneficial outcome, it is likely that you may still need some further input to get the best possible result. If your procedure was done by a doctor who is not your usual doctor, then they will communicate with your usual doctor or team to ensure all necessary follow-up and ongoing care is organised.

Information fed back to the treating doctor or team should include the reason for the procedure, operative details (operation report if possible) and advice about what to look out for that might suggest you need to be seen urgently within the first days – weeks after the procedure. Your usual treating doctor or team will also monitor your progress and help you to plan your ongoing care.



For clinicians

Doctors undertaking procedures should ensure appropriate follow-up and ongoing management or handover of care.

Separate to risk mitigation practices in the immediate perioperative period, risk of unexpected complications such as infection or haematoma, or even simply a dramatic increase in pain in the days after a procedure, require adequate provision to be made for appropriate management.

Referral networks that might include the patient's general practitioner, general surgery or infectious disease specialists, and inpatient or emergency care should be developed for assessment and appropriate management of complications.

Procedures which can potentially breach the dura require the availability of neurosurgical referral within an appropriate time frame.

Proceduralists who are not part of the referring pain team need to have provision for high-quality clinical handover including the operative particulars and details of advice for aftercare and follow-up (see also Quality statement 8).



For health services

Health services should ensure policies and processes for responding to unplanned care needs following procedures. This includes alarm and response systems in the event of rapid deterioration requiring resuscitation, and systems to facilitate communication with, and care of, patients who experience serious complications emerging post-discharge.

Serious complications are thought to be uncommon or rare, but may include paraspinal or epidural abscesses, haematomata or dural leaks. Health services should ensure that clinicians performing procedures have systematic follow-up arrangements and referral networks that enable them to provide appropriate aftercare to patients.

Health services should monitor quality and safety of procedures, including systems for reporting serious incidents, adverse events, and open disclosure³⁷ according to clinical governance standards (see Appendix 1).

Appendix 1: Using the clinical care standard

Implementation in context

Implementation of this standard should be undertaken within the context and requirements of national standards and other relevant guidelines for health service organisations and clinicians providing pain medicine services.

OVERARCHING NATIONAL STANDARDS

Australian National Safety and Quality Health Service (NSQHS) Standards

The NSQHS Standards were developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in collaboration with the Australian Government, state and territory governments, clinical experts, patients and carers⁴⁵.

The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision. They provide a quality-assurance mechanism that tests whether relevant systems are in place to ensure expected standards of safety and quality are met.

In Australia, all hospitals and day procedure services, where the majority of pain medicine procedures are performed, are expected to implement the current [NSQHS Standards](#) in a manner that suits the services provided and their associated risks.

Pain medicine procedures that do not involve any surgery, intravenous sedation or anaesthesia, local anaesthetic doses that risk systemic toxicity, or penetration of the spinal canal or cranium, might be exempt from being performed in registered hospitals or day procedure services.

It is nevertheless advisable to implement, as a minimum, the current [Standards for general practices](#)⁴⁶.

Individual standards within the NSQHS Standards that are particularly relevant to the safety and quality of pain medicine procedures are as follows:

- The Clinical Governance Standard, including actions related to:
 - Governance, leadership and culture (for example, action 1.1).
 - Safety and quality monitoring, including incident reporting systems (1.8 and 1.11).
 - Policies and procedures (for example 1.7).
 - Credentialing and scope of clinical practice (1.23 and 1.24).
 - Evidence-based care (1.27).
 - Variation in clinical practice and health outcomes (1.28).
 - Safe environment (1.29) including for Aboriginal and Torres Strait Islander people (1.33).
- The Partnering with Consumers Standard, including actions related to:
 - Informed consent (2.4).
 - Information for consumers (2.9).
 - Communication of clinical information (2.10).
- The Preventing and Controlling Healthcare-Associated Infection Standard, including actions related to:
 - Infection prevention and control systems (3.5 to 3.13).
 - Reprocessing of reusable medical devices (3.14).
- The Communicating for Safety Standard, including actions related to:

- Communication of critical information (6.9 and 6.10).
- Documentation of information (6.11).
- The Recognising and Responding to Acute Deterioration Standard, including actions related to:
 - Responding to deterioration (8.10 to 8.13).

Standards New Zealand

The New Zealand Ministry of Health, Manatū Hauora, has developed equivalent standards with the same aim—to provide safe and reasonable levels of service for consumers²⁰. All hospitals, day procedure services and rooms/offices where pain medicine procedures are performed are expected to implement the NZ Ministry of Health Standards in a manner that suits the services provided and their associated risks. Individual standards that are particularly relevant to the safety and quality of pain medicine procedures are as follows:

- NZS 8134.0:2008 Health and Disability Service (General) Standard.
- NZS 8164:2005 Day-stay surgery and procedures.
- NZS 8165:2005 Rooms/Office-based surgery and procedures.

Related FPM/ANZCA professional documents

FPM fellows and trainees are expected to be familiar with and guided by [FPM and ANZCA professional documents](#). The following are relevant to the planning, conduct or documentation of procedures, and procedural sedation or anaesthesia:

PS02 Statement on credentialing and defining the scope of clinical practice in anaesthesia

PS03 Guidelines for the management of major regional analgesia

PS04 Statement on the post-anaesthesia care unit

PS07 Guidelines on pre-anaesthesia consultation and patient preparation

PS08 Statement on the assistant for the anaesthetist

PS09 Guidelines on sedation and/or analgesia for diagnostic and interventional medical, dental or surgical procedures

PS15 Guidelines for the perioperative care of patients selected for day care surgery

PS18 Guidelines on monitoring during anaesthesia

PS26 Statement on informed consent for anaesthesia or sedation

PS28 Guidelines on infection control in anaesthesia

PS31 Guidelines on checking anaesthesia delivery systems

PS37 Guidelines for health practitioners administering local anaesthesia

PS41 Guidelines on acute pain management

PS45 Statement on patients' rights to pain management and associated responsibilities

PS54 Statement on the minimum safety requirements for anaesthetic machines and workstations for clinical practice

PS55 Recommendations on minimum facilities for safe administration of anaesthesia in operating suites and other anaesthetising locations

PS56 Guidelines on Equipment to manage a difficult airway during anaesthesia

PS58 Guidelines on quality assurance and quality improvement in anaesthesia

Radiation certification by jurisdictions

FPM fellows and trainees who operate radiographic imaging equipment are expected to be aware of relevant standards²⁹ and to hold the required radiation safety licence for the jurisdiction(s) in which they practise (listed alphabetically):

ACT: www.health.act.gov.au/businesses/radiation-safety/apply-radiation-licence

QLD: www.health.qld.gov.au/system-governance/licences/radiation-licensing/licence-application

NSW: www.epa.nsw.gov.au/your-environment/radiation/radiation-user-licence

NT: <https://nt.gov.au/industry/licences/radiation-licences-for-medical-and-dental-practitioners>

NZ: www.health.govt.nz/our-work/radiation-safety/users-radiation/licensing-radiation-users

SA: https://www.epa.sa.gov.au/business_and_industry/radiation

TAS: <https://www.dhhs.tas.gov.au/publichealth/radiation>

VIC: www2.health.vic.gov.au/public-health/radiation/licensing

WA: www.radiologicalcouncil.wa.gov.au/Pages/Licensing.html

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Faculty of Pain Medicine Professional Documents

POLICY – A document that formally states principle, plan and/or course of action that is prescriptive and mandatory.

STATEMENT – A document that describes where the college stands on a particular issue. This may include areas that lack clarity or where opinions vary. A statement is not prescriptive.

GUIDELINE – A document that offers advice on a particular subject, ideally based on best practice recommendations and information, available evidence and/or expert consensus. A guideline is not prescriptive.

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