

Opioids Roundtable Outcomes Statement

Key points

- Regulation of opioids should support and encourage best clinical practice and the quality use of medicines.
- Psychosocial factors influence a patient's experience of pain, their chance of developing chronic pain and their risk of opioid misuse. Psychosocial factors should be assessed at every presentation to identify patients' vulnerability.
- Patients should be managed under a comprehensive treatment plan that considers psychosocial factors and includes multimodal strategies for pain management.
- Better system pathways and linkages between health professionals are needed to facilitate this shared care approach.
- All patients with chronic non-cancer pain should undergo a trial treatment period of 1–3 months to assess their responsiveness to opioid therapy.
- Data are needed on the effectiveness of opioids to inform best practice and support evidence-based decision making.
- Although it is important to reduce the regulatory burden on prescribers, any relaxation of regulatory control should not make it easier for patients to obtain, and thereby potentially misuse, opioids.
- An online authority system would reduce regulatory burden. It should include prompts to encourage quality use of opioids, and mandatory data fields to assist with data collection and inform policy development.
- It is unlikely that the current 12-month review is effective, as this time frame is too long to ensure quality use of opioids.
- Real-time prescription monitoring systems are an excellent tool to support quality use of opioids. Tasmania's system has demonstrated the potential impact of these tools, but additional support may be needed to allow all states and territories to implement similar systems.
- Prescribers need more education and training about opioids.
- The language used to describe opioid-associated behaviour (such as misuse, aberrant behaviour and prescription shopping) can be pejorative and may contribute to stigmatisation of patients.

Background

On 27 May 2015, an Opioids Roundtable was held in Canberra as part of the Post-market Review of Authority Required Pharmaceutical Benefits Scheme (PBS) Listings (the Review). The Review aims to improve patient safety and care by reducing administrative burden for health professionals, and with regard to PBS listed opioids, to continue to manage the risk of misuse and diversion.

The purpose of the Opioids Roundtable was to obtain stakeholder views on the PBS listings and restrictions for opioids (excluding listings on the Palliative Care Schedule). Whilst the focus was on PBS listings, discussion was held in a broader context and covered a range of issues associated with opioid use. Roundtable participants included representatives from consumer groups, industry, government and health professionals (see Appendix 1).

The outcomes of the Opioids Roundtable will be used to assist the Pharmaceutical Benefits Advisory Committee (PBAC) to form recommendations to the Minister for Health on the PBS authority and restrictions for opioids.

Current PBS listings for opioids

Most opioids are listed on the PBS as Restricted Benefits for the treatment of moderate to severe disabling pain, with quantities limited to about 14 days of treatment. Prescribers may telephone the Department of Human Services (DHS) to obtain an authority to prescribe larger quantities and/or repeats for patients who need long-term medication. For patients who require more than 12 months of treatment, another practitioner must review the patient before further authorities may be granted by DHS.

The PBAC initially considered that a review after 1–2 months of therapy would be clinically appropriate; however, this was changed to 12 months in recognition of system issues that would make an earlier review difficult. These include a lack of access to pain specialists and other specialists, and the burden of referring patients, which are particularly problematic for rural practitioners and patients.

In 2014, there were more than 2.3 million authority approvals for opioids (36% of all authority approvals), including requests for increased quantities and/or repeats, and requests to prescribe Authority Required opioid listings. Although this represents a substantial regulatory burden for clinicians and patients, increasing access to opioids may lead to poor quality use of these medicines.

Issues for discussion

Issues for discussion at the roundtable included:

- the quantity and number of repeats permitted without authority
- the requirement and timing of pain management reviews for ongoing prescription of opioids
- the appropriateness of compliance activities
- real-time monitoring of opioid prescriptions and dispensing
- whether a distinction should be made between the availability of opioids for cancer pain and non-cancer pain.

National Pharmaceutical Drug Misuse Framework for Action (2012–15)

The National Pharmaceutical Drug Misuse Framework for Action (2012–15) aims to reduce the misuse of pharmaceutical drugs and associated harms, and improve the quality use of medicines without stigmatising patients or limiting accessibility of medicines for therapeutic use. The Framework includes nine priority areas with specific associated actions. Responsibility for implementing the actions in the Framework is shared by the Australian Government, state and territory governments, industry and consumers, recognising that members will undertake actions in line with their own priorities, timing and resources. The Framework includes the following actions: progressing implementation of a nationally based and jurisdictionally consistent real-time prescription monitoring system; providing education for prescribers, such as relevant guidelines; and providing advice about non-pharmacological options for pain management.

Utilisation of opioids

In 2014, almost 3 million people in Australia were prescribed at least one opioid under the PBS or Repatriation PBS (RPBS). The most common prescriptions were for paracetamol with codeine (more than 1.7 million patients), followed by oxycodone (around 1 million patients). Utilisation is highest in older age groups. Since the end of 2009, there has been a general increase in prescriptions, from around 2.5 million per quarter to around 3.5 million per quarter. Defined daily doses (DDDs, as defined by the World Health Organization) have increased approximately 20-fold since 1987. However, utilisation of morphine decreased by more than 40% between 2004 and 2014.

DDDs do not necessarily reflect the recommended or average prescribed dose in Australia. Analysis of utilisation by oral morphine equivalents, to adjust for potency, results in an increase in DDDs over the period 2009 to 2014 from around 15–20 DDDs per 1000 population per day to around 30–35 DDDs per 1000 population per day; oxycodone also becomes the most highly used opioid, followed by tramadol.

Around 95% of authority approvals were requested by vocationally registered GPs, non-vocationally registered GPs (including non-specialists) and GP trainees. Variation in prescribing among practitioners is high, with a small number of prescribers making a large number of authority requests. Authority requests for opioids were predominantly for increased quantities.

Pharmaceutical opioid use, illicit use and misuse in Australia

Data from the National Drug and Alcohol Research Centre show that up to 50% of people who inject drugs use opioids, but that this use comprises a small minority of prescribed opioids (e.g. less than 5% of prescribed oxycodone). The trends in deaths from opioids have reversed since 2000, when 70% of opioid-related deaths were due to heroin and 30% were due to prescribed opioids. In 2011, 70% of deaths due to opioids were related to pharmaceutical opioids.

The Pain and Opioids in Treatment (POINT) study examines the patterns of opioid use in a cohort of people prescribed opioids for chronic non-cancer pain. The study aims to identify demographic and clinical predictors of adverse events (including dependence, non-adherence and diversion), as well as predictors of poor pain relief and other clinical outcomes. The cohort of 1514 people was recruited from community pharmacies across Australia, and more than 80% of patients have been followed up for 12 months. Around 60% of the cohort were using oxycodone, and 63% were also taking over-the-counter opioids. The median duration of prescribed opioid use was 4 years, at a median oral morphine equivalent dose of 75 mg per day (although 9% of participants were taking more than 200 mg of oral morphine equivalents per day). Non-adherent behaviours in the past month were reported by 38% of participants, primarily relating to underuse or overuse of opioids relative to their doctor's advice. Diversion or selling was uncommon, with only 4% of participants reporting that they had ever diverted opioids.

The Prescribed Opioids Difficulties Scale (PODS) was used to assess concerns about controlling opioid use and related psychosocial problems. Participants who scored higher on this scale were more likely to be younger, have current mental health problems, be using oxycodone, and be using Schedule 4 opioids. Increasing opioid use (i.e. higher oral morphine equivalent doses per day) was associated with increasing dependence, increasing non-adherence and a higher PODS score. Psychosocial problems relating to pharmaceutical opioids were common among patients with chronic pain.

Treatment for opioid dependence varies by state and territory, but a proportion of people commencing opioid substitution therapy (OST) in all states and territories do so as a result of dependence on pharmaceutical opioids rather than heroin. Of these, only 25% reported that their

first use of pharmaceutical opioids was via prescription, and 71% usually obtained opioids from non-prescribed sources, suggesting that substantial diversion occurs somewhere else within the supply chain. The Pharmaceutical Opioid Users seeking Treatment (POUT) study showed that people entering treatment for pharmaceutical opioid dependence were more likely to be older, less likely to inject opioids and more likely to have used opioids for pain management.

Opioid management in Australia: a pain medicine physician's perspective

Pain is a complex experience, with high variability between people. Poor management of acute pain may lead to neurophysiological sensitisation and chronic pain. Opioid use can lead to altered nociception, producing tolerance (higher doses required to achieve the same effect) or hyperalgesia (decreased pain threshold). There is a lack of high-quality studies on the effects of long-term or high-dose use of opioids. The available studies indicate that opioids decrease pain intensity in around 30% of people, but have no benefit or elicit adverse effects in the remaining 70% of people.

People with chronic pain tend to have depression and disability, as well as psychosocial characteristics such as lower education and employment. Patients should therefore be assessed early according to the injury (severity, acute pain control, nerve injury, effect on function) and the person (childhood pain experience, level of education, psychosocial stress, anxiety, catastrophising, history of addiction)—this can help predict outcomes of long-term opioid use, including the risk of aberrant behaviour or dependence.

Pain management should include detailed review and consideration of a range of biopsychosocial factors for each patient, and use multimodal strategies, including non-pharmacological options such as cognitive behavioural therapy and exercise. Opioids should be carefully selected, trialled and reviewed for each patient (including in combination with other medications), and any adverse effects or development of tolerance should be actively managed. However, it was acknowledged that psychological and social support, and pain specialists can be difficult to access in some areas, and effective management requires a relationship with a regular practitioner, which may not always exist. GPs also require education and support on how to identify people who may be at risk of developing chronic pain after acute injury (e.g. using risk assessment tools such as the Screener and Opioid Assessment for Patients in Pain), and how to develop effective coordinated care strategies.

Department of Human Services and opioids

DHS administers the PBS, including providing PBS subsidies to eligible patients, granting authority approvals for Authority Required PBS listings and providing payments to prescribers. It undertakes opioid compliance activities to identify inappropriate prescribing, incorrect prescribing, fraud or offence. Monitoring the use of Schedule 8 (Controlled Drugs) opioids by patients and prescribers is the responsibility of state and territory governments.

Authority requests can be managed either over the telephone (limited to 1 month's supply) or in writing (up to 3 months' supply). DHS is considering developing an online channel for authority requests, which would be integrated with GP practice software and include authentication of the prescriber, as well as questions about prescribing that are currently asked during phone authority requests. Issues relating to privacy are under consideration; however, participants felt that patient safety should come first when deciding on the level of information available through this channel. It was also noted that phone authorities are an important opportunity to provide real-time advice to the prescriber, such as on reasons for rejection of an authority.

DHS also runs the Prescription Shopping Programme (PSP), which can identify whether a patient is potentially being oversupplied. A potential 'prescription shopper' is identified as someone who, in the past 3 months, has received one of the following:

- prescribed pharmaceutical benefits from six or more different prescribers
- 25 or more target pharmaceutical benefits (which includes all PBS-listed opioids)
- 50 or more pharmaceutical benefits.

Clinicians and pharmacists can contact the PSP to find out whether a patient meets these criteria.

Many patients who require complex management would meet one of the criteria in the legitimate course of their management. However, it was noted that, if the patient maintains relationships with the same group of prescribers, the prescribers would be aware of the patient's history and would not contact the PSP. The PSP aims to help prescribers make decisions about their patients but does not prevent them prescribing.

It was noted that any changes to PBS listings or authority approvals to increase quantities or repeats, may allow patients to avoid meeting the PSP criteria (e.g. it may be possible for a person to visit fewer doctors, or require fewer prescriptions, to receive the same quantity of medication). This would also need to be considered by the Review.

Roundtable participants felt that the term 'prescription shopper', as well as other terms such as 'misuse' and 'aberrant behaviour', are pejorative and inappropriate. It is important to avoid stigmatising these patients by using such language, and remember that these are people with complex care needs who require support.

Real-time prescription monitoring

In response to an increase in prescription opioid overdoses and deaths, Tasmania implemented the DAPIS Online Remote Access (DORA) system in 2011. DORA is a decision support tool for prescribers that provides secure, real-time access to objective information about:

- supplies of Schedule 8 medications by Tasmanian pharmacies for a particular patient
- authorities issued to the GP to prescribe Schedule 8 medications (including the indication)
- the patient's history of drug dependence or drug seeking
- the patient's past or current treatment for opioid dependence.

DORA assists prescribers with quality assurance and timely, evidence-based decision making, and includes data about PBS and non-PBS medicines. Since DORA was implemented, opioid-related deaths in Tasmania decreased from 32 in 2007 to approximately 20 in 2013 and 2014. The system can be scaled up to suit states with larger populations, and can be used to identify areas of high prescribing to guide targeted actions. The success of the system has relied on clinical and policy support from drug and alcohol services, and pain services, as well as highly skilled and energetic pharmacists and addiction medicine specialists who champion the system and discuss issues with prescribers.

Real-time prescription monitoring systems support prescribers by providing them with the key information they need to be able to prescribe opioids in a way that is safe, clinically appropriate and in the best interests of the patient. They can be used as a framework to identify problems of poor medication adherence, misuse, dependency, forgery and prescription shopping. However, the

monitoring system itself is only a tool. Broader changes in regulation and clinical practice are required to ensure quality use of medicines, including:

- undergraduate and postgraduate medical education and training to support prescribers to make evidence-based decisions and to have timely, meaningful and thorough conversations with their patients
- supporting prescribers to assess the benefits, risks and harms of medications, and consider non-pharmacological approaches to pain management
- linking GPs with addiction and pain specialists, as well as other specialists, to better assess, diagnose and quickly manage the primary medical problem, based on the best evidence relevant to that condition, as well as the psychosocial aspects
- leadership and integration in clinical practice, clinical governance and policy.

States and territories other than Tasmania are at different stages of implementing real-time prescription monitoring systems:

- Queensland has a monitoring and reporting system for PBS and private opioid prescriptions, but there is a 1-month time lag to update the information.
- New South Wales is in the process of migrating its authority database to compatible software, then will scope and cost the implementation of a real-time system.
- The Australian Capital Territory has a web portal where prescribers can upload information every month. This results in a 1-month time lag for information, but software vendors were not willing to make changes to software to allow real-time reporting.
- Victoria is beginning to scope the implementation costs of a real-time system.
- South Australia collects data from pharmacies but has a long time lag; it is in the process of developing an initial business case for real-time reporting.
- Western Australia has a prescription monitoring system with a 1-week time lag, and an advice line that prescribers can call.

Note: The Northern Territory was not represented at the roundtable.

Once implemented, systems in different states and territories may be able to communicate and share data, depending on the system used.

Options to reduce regulatory burden

Participants were asked to consider options to reduce the regulatory burden of PBS opioid prescriptions, including advantages, disadvantages and implementation issues. Specific issues to be considered included:

- timing of pain management reviews
- differential PBS listings for cancer pain and non-cancer pain
- appropriateness of the current PBS listings, including:
 - subsidised indications and eligibility criteria
 - quantities available
 - number of repeats
 - type of benefit (e.g. unrestricted, Restricted Benefit, Authority Required (STREAMLINED) or Authority Required).

Participants considered that the main issue was not how to reduce regulatory burden, but how to ensure that the regulations support the quality use of opioids. For example, participants felt that the advice received from DHS via telephone authority requests was valuable, but phone requests provide only up to 1 month's supply, whereas written requests (where immediate advice is not available) provide longer periods of treatment, usually up to 3 months' supply. Participants considered that written requests for opioids should be abolished, so that all requests include immediate advice, which would also facilitate faster patient access to medicines.

The potential for online PBS authority requests was welcomed as an opportunity to improve the efficiency of the system, and also to build in mandatory fields to support quality use of opioids. For example, the system could calculate the oral morphine equivalent dose, and, when a certain threshold is reached, prescribers would need to complete additional steps in the authority process, such as telephoning for advice. This could also incorporate a prompt to consider other methods of pain management once this threshold is reached.

Greater integration between state and federal levels of regulation would reduce the regulatory burden and assist prescribers to provide better care. The burden of having two sets of regulation to govern opioid use (the PBS, and the states and territories medicines and poisons regulation) could be reduced by adjusting the way opioid prescriptions are controlled. For example, where authority has been granted by a state or territory, it may be unnecessary for DHS to undertake some of their current checks.

Participants noted that the data indicate that doubling the PBS quantity available without an authority would substantially reduce the regulatory burden. However, it should also be made clear to prescribers that smaller quantities can be prescribed, if clinically appropriate. It was noted that prescription software generally defaults to the largest quantity and number of repeats available, which reduces the likelihood that smaller quantities will be prescribed. Participants suggested that conservative access should be maintained for methadone in terms of the quantities and repeats available, with the exception of PBS listings for palliative care. They suggested that access to modified-release opioids could be increased, but there were some concerns about increasing access to immediate-release opioids.

Participants considered that opioids should be treated as a class in the PBS, with consistent restrictions and quantities available, and only minor variations between listings. The utility of the descriptor 'severe pain' in the restrictions was queried, and participants suggested that 'significant pain with impact' may be more appropriate.

Participants agreed that the lack of data on the effectiveness of opioids in chronic pain was a significant issue, and that data should be reviewed and further research carried out to better inform evidence-based prescribing. A review of over-the-counter use of codeine is also warranted, as these patients are not assessed by a prescriber, but long-term use can be harmful.

Participants discussed the timing of the patient review, currently set at 12 months. Most participants considered that this time frame is too long to be of best use to the patient. Within 3 months of initiation of opioids was suggested as a more appropriate time for review, and the review should be done by an appropriately skilled practitioner (not necessarily a pain specialist). Some participants queried whether it would be possible for patients to access a relevant specialist in this time frame, and it was suggested that telephone consultation would be sufficient. Some participants felt that the review requirement should be removed, as it removes personal responsibility from the prescriber. Consumer representatives indicated that patients using opioids long-term are concerned that their medication will be removed.

It was suggested that all patients should undergo a trial period to assess their responsiveness to opioid therapy before any long-term maintenance therapy starts. The length of the trial period should be between 1 month and 3 months. The trial should assess not just the patient's level of distress but, more importantly, the impact of the pain on the patient's functioning. The prescriber may need to adjust the dose within the trial period.

Specific education and training of prescribers (and dispensers) about opioids should be provided, as prescribing patterns suggest that some prescribers do not have a clear understanding of the pharmacology and toxicology of these medicines, particularly when used in combination with other medications. It was noted that doctors who prescribe methadone for OST are required to undergo specific training and pass an examination, but this is not required for other opioids. It is important that prescribers are also trained to recognise when opioid treatment is not working effectively, and to consider alternative pain management strategies.

Prescribers should also be trained and supported to consider use of opioids as part of a comprehensive treatment plan. In a similar way to prescribing medication as part of a plan for smoking cessation, this treatment plan does not need to be specific or prescriptive. A requirement that the patient needs a comprehensive management plan may prompt prescribers to consider all relevant issues, seek advice from other professionals where appropriate, and ensure that they are providing the best care for the patient.

Some participants felt that cancer pain and non-cancer pain should be differentiated because the duration of treatment for cancer pain is generally shorter than for non-cancer pain, and the current regulatory burden of authority requests for opioids on cancer patients and oncology specialists is substantial. In addition, cancer pain is often progressive, and medications require more frequent review. It was suggested that there be Authority Required (STREAMLINED) listings for all opioids (except tramadol, which is used minimally in the management of cancer pain) that provide access to 1 month's therapy for cancer pain. However, other participants felt that cancer pain and non-cancer pain should not be differentiated.

Any changes to PBS restrictions should also consider the potential effect on patients who are long-term opioid users, and ensure that they have adequate support and services to help them reduce their use.

Consensus was not reached regarding an appropriate level of regulation for the prescribing of opioids: some participants felt that more regulation was necessary; others, less. However, participants agreed that quality use of medicines and good patient care are the critical issues, and that policy and regulation have significant roles in enabling these. Regulation needs to be appropriate to the risk at both the individual patient level and at the population level.

Next steps

Participants were advised that the draft Outcomes Statement would be circulated for comment. The final statement would be presented to the Review Reference Group and the PBAC, which would then make recommendations to the Minister for Health, if required.

Appendix 1 Roundtable participants

Chair: Dr Tony Hobbs, Principal Medical Adviser, Strategic Policy and Innovation Group, Australian Government Department of Health

Deputy Chair: Professor Chris Baggoley, AO, Chief Medical Officer, Australian Government Department of Health

Name	Organisation, committee or specialty
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Mark Anns	Indivior
Susan Ballantyne	Queensland Department of Health
Vivien Bevan	ACT Health Protection Service
Peter Boyles	Tasmanian Department of Health and Human Services
Dr Paul Brent	Chair, Advisory Committee on Medicines Scheduling
Naomi Burgess	SA Health
Patrice Cafferky	Australian Primary Health Care Nurses Association
Elizabeth Carrigan	Australian Pain Management Association
Professor Milton Cohen	Faculty of Pain Medicine, Australian and New Zealand College of Anaesthetists
Soëlily Consen-Lynch	Medicines Australia
Professor Jon Currie	Addiction medicine specialist
Professor Louisa Degenhardt	Drug and alcohol research
Lisa Dive	Royal Australasian College of Physicians
Professor Michael Dooley	Society of Hospital Pharmacists of Australia
Danielle Dowell	bioCSL
Herbert Down	Australian Commission on Safety and Quality in Health Care
Julie Ellis	A. Menarini Australia
Amy Faden	Drug and Alcohol Nurses Australasia
Professor Michael Farrell	Addiction psychiatry, drug and alcohol research
Kent Garrett	Member, Council of Australian Therapeutic Advisory Groups
Sophie Glover-Koudounas	Janssen
John Green	Medical Software Industry Association
Ben Guthrie	Sandoz & Generic Medicines Industry Association
Ruth Hay	Queensland Department of Health
Margo Hickman	Registered nurse
Dr Malcolm Hogg	Anaesthetist and pain specialist
Dr Elspeth Hutton	Australian and New Zealand Association of Neurologists

Name	Organisation, committee or specialty
Dr Walid Jammal	General practice
Dr Marianne Jauncey	Public health physician
Neil Keen	Western Australian Department of Health
William Kelly	Australian Health Practitioner Regulation Agency
Suvir Khanchandani	Cipla Australia
Associate Professor Brian Le	Palliative care specialist
Denis Leahy	Pharmacy Guild of Australia
Dr Martyn Lloyd-Jones	Addiction medicine specialist
Michelle Lynch	Pharmaceutical Society of Australia
Judith Mackson	New South Wales Department of Health
Matthew McCrone	Victorian Department of Health
Carter Moore	Consumers Health Forum of Australia
Dr Mandy Nielsen	Chronic Pain Australia
Jane Orr	Mundipharma Australia
Vincent O'Sullivan	Pharmacy Guild of Australia
Associate Professor Adrian Reynolds	Addiction medicine specialist
Associate Professor Gary Richardson	Oncology
Debra Rowett	Member, Drug Utilisation Sub-Committee of the PBAC
Dr Tracey Soh	Australian Medical Association
Lynn Weekes	NPS MedicineWise
Dr Sam Whittle	Rheumatology
Fiona Wynn	Member, Intergovernmental Committee on Drugs (IGCD)

Australian Government representatives

Department of Human Services

Name	Position
Dr Jo-Anne Benson	Chief Medical Advisor and National Manager, Practitioner Review Program
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Karen Hebditch	A/g National Manager, Pharmaceutical Benefits Branch
Christopher Lake	Compliance Section
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Department of Veterans' Affairs

Name	Position
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Therapeutic Goods Administration

Name	Position
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Department of Health

Name	Position
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Julie Cutts	Director, Post-market Review Section
Anne Jackson	Assistant Director, Post-market Review Section
Chris Killick-Moran	Member, IGCD National Pharmaceutical Misuse Working Group
David Pearson	Director, Pharmaceutical Access Specialised Supply Section
Adriana Platona	Assistant Secretary, Pharmaceutical Evaluation Branch
Dr Alicia Segrave	Director, Drug Utilisation Sub-Committee Secretariat
Dinusha Vithanachchi	Drug Utilisation Sub-Committee Secretariat
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