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Regulatory and other responses to the pharmaceutical opioid problem

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Introduction

In the last twenty years there have been substantial increases in the use of pharmaceutical opioids in many countries, including Australia which has one of the highest levels of opioid utilisation globally ¹. Almost 15 million opioid prescriptions were dispensed in 2015 and our use of high-potency opioids has also increased ². One of the main drivers is the increased use of prescription opioids for chronic non-cancer pain (CNCP) ³. In parallel to escalating use, opioid-related harms have also increased. Since 2000, there has been a shift in both hospitalisations due to opioid poisonings and opioid-related deaths, from predominantly heroin to pharmaceutical opioids⁴. Use of pharmaceutical opioids for non-medical purposes is also relatively common, reported by 4.8% of the Australian population⁴.

A range of possible strategies to minimise unnecessary opioid exposure and adverse events were highlighted in the National Pharmaceutical Drug Misuse Framework for Action (2012–2015) ⁵ including: coordinated medication management systems (prescription drug monitoring programmes (PDMPs)); improvement of access to pain and addiction services; development of resources, and workforce development. To date, few of these strategies have been implemented. We summarise recent and emerging responses in Australia that aim to minimise harms from pharmaceutical opioids.

Regulatory responses aimed at reducing aberrant opioid prescribing and restricting opioid supply

Codeine rescheduling—In 2016, the most common analgesics used for non-medical purposes by Australians were over-the-counter (OTC) codeine products⁴. There have been several attempts to reduce extra medical use and harms from OTC codeine. In May 2010, OTC codeine products were up-scheduled from Schedule 2 (Pharmacy Medicine) to Schedule 3 (Pharmacist Only Medicine). This change, however, had no meaningful impact on codeine poisonings ⁶. They were subsequently up-scheduled again in February 2018 to Schedule 4 (Prescription-only medicines). The impacts of this decision remain to be seen ⁷.

Prescription drug monitoring programmes (PDMPs)—PDMPs (programs designed to track prescribing and dispensing of prescription drugs of potential non-medical use) are being introduced in Australia, although their characteristics remain unclear, and there are likely to be jurisdictional differences, with potentially different outcomes. Differences may include whether the program is: voluntary vs. mandatory; monitors S8 opioids only vs. S8 opioids and benzodiazepines; fully automated vs. requires specific actions from the prescriber or pharmacist (e.g. requesting a record); and real-time vs. time-lagged.

International research on the impacts of PDMPs indicate mixed findings, with effectiveness varying according to programme features⁸. For example, some US states with PDMPs report reductions in prescription opioid poisonings, with stronger protective effects where PDMPs monitored more schedules or required more regular reporting⁹. Less clear is how PDMPs will impact upon other aberrant behaviours (such as injection), other substance use (prescribed or illicit), and opioid use disorders. Other unintended consequences have also been suggested, including stigmatisation of patients and a “chilling effect” where prescribers underuse opioids due to fear of repercussions, rapidly reduce opioid doses or cease opioids altogether, leading to inadequate pain relief or opioid withdrawal¹⁰. Whilst PMPs have intrinsic face validity – in practice there remain many unanswered questions.

An alternative approach to establishing stand-alone PDMPs is the impending expansion of My Health Record (MHR). Many aspects of PDMPs can be incorporated into MHR, however the focus of MHR is to more broadly enhance co-ordination and quality of healthcare, efficiency and patient safety, rather than an emphasis upon medications only, as is the case of PDMPs. This is likely to be less stigmatising and offer better integration into routine healthcare than stand-alone PDMPs requiring their own infrastructure. Medical and consumer groups will need to consider how MHR will address S8 medications – the ability for a patient to ‘opt out’ – or for a doctor to require access to MHR prior to opioid prescribing beyond emergency presentations.

Reponses to minimise harmful patterns of use and harm

Abuse-deterrent formulations—Abuse-deterrent opioid formulations are intended to minimise extra-medical use by targeting use involving unintended routes of administration. Examples include making tablets tamper-resistant or including naloxone to deter injection. In Australia, available evidence from convenience samples suggests most individuals tampering pharmaceutical opioids take these drugs via injection, on an infrequent basis, and use a variety of pharmaceutical opioids and heroin¹¹. Australian post-marketing surveillance studies show reductions in use and tampering amongst people who inject drugs following introduction of abuse-deterrent formulations, with no evidence of switching to other pharmaceutical opioids or heroin¹¹. However, these formulations have not eradicated tampering and injection, and appear to have had limited impacts on overall opioid utilisation and population-level harm¹¹. Unlike the Food and Drug Administration in the US, the Australian Therapeutic Goods Administration is yet to adopt an abuse-deterrent framework to enable the development and propagation of abuse-deterrent formulations over higher-risk opioid formulations.

Other responses to reduce pharmaceutical opioid-related harms

Greater availability of multidisciplinary pain services for people with CNCP and addiction treatment services for opioid dependent people are necessary to direct patients to more effective and safer treatment approaches than a reliance on opioid medications for CNCP.

Access to multidisciplinary services—Contemporary guidelines regarding the management of CNCP emphasise the importance of multidisciplinary approaches that integrate medication, psychological approaches, and physical therapies. Many such services are most effectively and efficiently provided in MDTs, however, few non-medical services are funded by Medicare in the community, and hence out-of-reach for the majority of patients requiring their assistance. There continues to be unmet capacity to deliver MDT approaches within state-funded Local Health District or private health services, and much more needs to be done to enhance access. The inability to access effective non-medication-based treatments likely contributes to an overreliance upon opioid medications.

Access to Opioid Substitution Therapy (OST)—Despite increasing concern about pharmaceutical opioid dependence in Australia, the number of patients (per population) in OST (methadone/buprenorphine) has remained static for more than 15 years⁴. In a recent Australian study, few patients with concurrent chronic pain and opioid dependence¹² reported lifetime enrolment in OST, with participant's indicating significant stigma associated with OST. The study highlighted the need to better integrate primary health, specialist pain and specialist addiction services.

Both methadone and buprenorphine are effective in the treatment of pharmaceutical opioid use disorders^{13,14}. High dose buprenorphine/buprenorphine-naloxone is proving a useful approach for patients with chronic pain and opioid use disorder¹⁵. Yet few Australian general practitioners – estimated at no more than 5% - prescribe methadone or buprenorphine/naloxone, despite the recent relaxation in training and credentialing requirements in most jurisdictions. Concerted efforts are required to enhance the uptake of effective treatments by general practitioners, and address many of the perceived barriers. Expansion of specialist addiction services will be required as PMPs begin to identify patients with opioid use disorders (OUDs).

Naloxone availability—Interest in the use of 'take home naloxone' (THN) as a strategy to reduce opioid overdose deaths has grown in recent years¹⁶, and supported by the World Health Organization. In Australia, THN programs are now incorporated in a range of services targeting people who inject drugs, including peer-based, needle and syringe programs, and Alcohol and other Drug (AoD) treatment services¹⁶. However, THN programmes have been less widely established outside of these settings¹⁶. Services targeting people with a history of injecting opioid use reach few CNCP patients, and efforts are required to engage doctors who prescribe opioids to also consider THN interventions for their patients.

Since 1st February 2016, naloxone was re-scheduled to Schedule 3, and is now available OTC, although there has been limited uptake and strategies are urgently needed to improve pharmacists' knowledge and confidence in educating customers regarding opioid overdose

and effective use of naloxone. Importantly whilst THN is important in reducing opioid-related overdoses, it will not impact on overall levels of opioid utilisation.

Education and advocacy for consumers and health care providers

In recent years, various government and non-government organisations have undertaken initiatives to promote education on the quality use of opioids and also an increasing awareness about opioid-related problems through various organisation-based websites and position statements. Examples include the NSW Agency for Clinical Innovation's Pain Management Network which provides information for consumers and health professionals on the management of chronic pain. Scriptwise is a not-for-profit organisation that aims to prevent non-medical use of prescription medications and overdose fatalities in Australia. Within the pain management sector, there has also been growing emphasis on the need to 'deprescribe' opioids and adopt multidisciplinary non-medication-based approaches to managing pain, as outlined in The Australian Pain Society's Guiding Principles for Pain Management.

Actions for the future

It is important to reduce harms associated with pharmaceutical opioid use, but equally important that we do not prevent access for those who may benefit from opioid treatment. Our emphasis should be upon enhancing patient outcomes and safety – and recognise that regulatory responses such as rescheduling drugs, introducing PDMPs or abuse deterrent medicines are merely a means to achieve that end, and inadequate on their own. We need better education of health provider and consumers, better communication between providers through electronic clinical information systems, and increased availability of specialist pain and addiction services that work collaboratively with primary care providers. We must address the stigma of addiction that prevents patients and their doctors from effectively addressing this issue – much in the same we have made inroads in countering the stigma of mental health problems in the community over the past two decades. As a society we need to reverse our over-reliance on medications as solutions for chronic health problems.

The vastness of the problem and the breadth of required approaches suggests we need to revisit the role of a national policy with clear targets, implementation and evaluation strategies – absent from the last National Framework. Many of the solutions were identified a decade ago but have not been implemented. There are too many Australians experiencing opioid related harms for us to neglect this issue for another decade.

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