Alcohol and Drug Foundation: Position Paper

Prescription Drug Monitoring Programs.

What is it?

Prescription drug monitoring programs (PDMPs) are databases utilised by governments that aim to monitor and reduce some prescription drug use.

PDMPs are designed to track prescribing and dispensing of prescription drugs of potential extra-medical use and/or drugs with a high risk of dependence or overdose, such as opioid-based pain relief. A number of PDMPs have been introduced internationally, most with jurisdictional differences and thus different outcomes.[1] Differences may include: whether the program is voluntary or mandatory, which drugs are monitored (S8* opioids, S8 opioids and benzodiazepines), whether it is fully automated or requiring specific actions from prescriber or pharmacist and if it is real-time vs. time-lagged.

International research on the impact of PDMPs shows mixed results thus far with effectiveness varying according to the programs' features.

Real-time prescription monitoring

A *real-time prescription monitoring* (RTPM) system is designed to monitor the prescribing and dispensing patterns of prescription medications and provide medical practitioners and/or pharmacists with accurate and timely information regarding their patient's medication history at the *point of recommending or dispensing medication*, i.e. in 'real-time'.

Real-time monitoring of prescriptions improves prescribers and pharmacists' knowledge of, and control over, their patient's access to scheduled, high-risk medications. The main aim is to identify people who may have, or may be, developing a substance use disorder relating to their prescribed pharmaceuticals and to provide appropriate care in a timely manner. In addition, RTPM can help to identify risky combinations (such as between opioids and benzodiazepines) and assist as part of a regulatory process enabling feedback to prescribers who may be suggesting risky combinations of medications or providing a person with more medication than recommended.

* S8 refers to the category of medicines known as Controlled Drugs. Medicines that are given an S8 classification are considered to be drugs of dependence and possession of these medicines without authority is an offence. In states doctors require a permit to prescribe medicines from this schedule (inc. opioids and some amphetamine type medicines). Some medicines covered under a RTPM may be S4 (some benzodiazepines).

Why?

The non-medical use of pharmaceutical drugs is a major drug problem.

Pharmaceutical non-medical use is the consumption of a prescription drug other than as directed by a registered healthcare professional or for non-therapeutic purposes.

Non-medical, or extra-medical use, is use of pharmaceuticals without a valid prescription, the prescription of excessive quantities or at excessive frequencies, non-adherence to prescription or due to a drug dependence that has developed following medical treatment. (NB: misuse is a term no-longer used to describe the behaviours of people due to the potential to stigmatise. The term however is still used in data collection reports.)[2,3]

According to the 2016 National Drug Strategy Household Survey, 4.8% of the population aged over 14 years (one million Australians) 'misused' a pharmaceutical in the past year.[4] Over one-quarter of this group reported doing so weekly or daily. Pain-killers/analgesics and opioids were the most frequent pharmaceuticals used extra-medically (second to steroids), accounting for 29% of those that had used extra-medical pharmaceuticals. Ten per cent of those that had recently used painkillers/analgesics and opioids reported they had difficulty cutting down or stopping their use.[4] Benzodiazepines and opioids are the pharmaceutical drugs most commonly used extra-medically in Australia.[2]

The scale of the problem represented by prescription drugs is most easily illustrated by its contribution to premature mortality. Prescription drugs are now responsible for more deaths in Australia than illicit drugs. In 2016, 1608 people died from drug-induced deaths (including both accidental and suicide and illicit, pharmaceutical and non-medical pharmaceutical use).

Of these 1608 deaths, coroners' reports show:

- 663 reported presence of benzodiazepines
- 550 had presence of opioids (oxycodone, codeine)
- 276 showed unspecified antidepressants
- 234 reported synthetic narcotics (fentanyl, tramadol, pethidine).[5]

It is important to note that over half of all acute drug deaths had two or more substances identified on their toxicology report at death. At times, a pathologist may provide information on the main drug contributing to the death, but no further information on additional substances identified at toxicology.[5] Further to this, there are cases where individual drugs are present in toxicology findings but may not be the individual cause of death.

In the decade between 2006 and 2016, the number of deaths where opioids or benzodiazepines were present rose, by 127% and 168% respectively.[2] In over 96% of cases where benzodiazepines were present they were taken in conjunction with other drugs, including alcohol.

In Victoria, statistics from the Coroners Prevention Unit, cited in the Deloitte Regulatory Impact Statement,[6] told a similar tale: overdose deaths that involved pharmaceutical medicines rose from 295 in 2009 to 372 in 2016; an increase from 5.5 to 6.0 deaths per 100,000 people. They indicated that 87% of the deaths in 2016 involved benzodiazepines, while 62% involved pharmaceutical opioids.

Multiple prescribing

There are a range of reasons that people may seek prescribed medications from more than one doctor. This can include:

- being under the care of more than one doctor for multiple complex medical conditions
- patients may not be aware of the type of medication each doctor is prescribing and may be unaware they are receiving the same medication multiple times
- some people may be unable to get sufficient medications from one doctor or be seeking medication in excess of initial therapeutic need
- seeking excess for personal consumption, or in some cases to supply others[1]
- for diversion or for re-selling purposes.[7]

Extra-medical use and/or dependence on pharmaceutical medication may in some cases be associated with what is reported as 'prescription' or 'doctor shopping', whereby a patient seeks multiple prescriptions from different health providers.[8] A patient who receives multiple scripts in that way cannot be supervised responsibly by medical professionals and is at risk of taking an incorrect, or excessive, dose or taking medications and drugs that interact dangerously with each other.[9]

Accessing multiple prescriptions can increase the risk of consuming an incorrect dose, of consuming inter-acting drugs[9] and increase the opportunity for illicit sale and sharing of pharmaceuticals. It is important to note, however, that much of the access to pharmaceutical drugs for non-medical use is not typically from consumers visiting multiple prescribers but rather from non-prescribed sources such as family members, dealers or online.[10]

Risk of dependence

Patients who attend a single prescriber are not necessarily protected from the risk of dependence or later harm.

Dependence and overdose can occur when a patient receives their prescriptions from a single prescriber. Data presented in Melbourne in 2017 showed that most of 838 persons who had died from pharmaceutical overdose in Victoria in 2011–13 had attended one general practitioner.[11] This data suggests that a real-time prescription monitoring program in some cases may not provide complete additional protection at the provider level but may enable greater oversight by regulators of risky prescribing practices.

Programs that have adopted a 'best practice' model, such as real-time reporting and proactive provision of patient reports to providers may reduce multiple prescribing as well as reduce the overall supply of prescription opioids available for diversion.[1]

Dependence on pharmaceuticals can develop from a range of different circumstances including:

- therapeutic dependence develops due to a valid prescription and treatment of a medical condition
- inappropriately managed pain leading to the over-consumption of prescribed medication
- self-treatment of pain
- self-treatment of opioid dependence (e.g. pharmaceutical opioids being used to manage withdrawal symptoms amongst opioid dependent persons)
- drug substitution, when the availability of other drugs is irregular or low
- polydrug use. Some people may use pharmaceuticals if they are available as part of mental health self-management or if they are entrenched in illicit drug markets and dependence
- perception that pharmaceuticals are 'safer alternatives' than illicit drugs.[10]

Medical practitioners are an important source of pharmaceuticals – both for legitimate and extra-medical use, however research is showing that they are not the main source of prescription opioids for those who seek treatment.[10] PDMPs and RTPM programs are important mechanisms to intervene and understand when a person with a legitimate prescription may be developing a dependence or is at increased risk due to polydrug use, excessive use or changes to their patterns of use. The extra-medical use or non-medical use that may result due to diversion of pharmaceuticals will continue to be a challenge to monitor but RTPM may help to identify illegal and inappropriate prescribing and reduce supply.[1]

Models for delivery

Prescription Drug Monitoring Programs operate extensively in the US and Canada and increasingly in Australia, but their structure and systems vary around the frequency of reporting, drugs monitored, systems to support patients and practitioners and the patient populations included.

Frequency of reporting

Globally, the number of mandated prescription monitoring systems has grown since the early 2000s, with 49 out of 50 states in the US having implemented PDMPs in an effort to mitigate prescription drug extra-medical use, diversion, inappropriate prescribing and dispensing.[7] The US systems, however, are generally not real-time systems, or the data may not be accessible in real time, to allow for immediate changes to prescribing or dispensing medications.

Norway has a nationwide prescription database covering all drugs dispensed in community pharmacies. However, information is transmitted each month and the system's aim is to improve prescribing practices and provide data for research rather than for the purposes of the RTPM systems now in place in some states in Australia.[12]

Medications monitored

Some PDMP systems propose only monitoring S8 medications whilst others argue they should include other opioids (e.g. tramadol and codeine) and all benzodiazepines.

Concerns have been noted of the potential of a 'chilling effect', whereby when only some opioids are monitored a shift may occur to increasing prescriptions/use of unmonitored drugs which may leave patients under-treated or seeking help elsewhere for licit or illicit management.[7] In Canada, the nature of drugs monitored varies, particularly those in the Schedule 4 categories.[12]

Limiting access to prescription medication can result in increased use of illicit drugs, as occurred with the 2014 United States Drug Enforcement Administration's rescheduling of hydrocodone combination products, which: 'coincided with a statistically significant, sustained increase in illicit trading of opioids through online US cryptomarkets'.[13] Risks may be mitigated by timely referrals of identified at-risk patients to appropriate health services or to drug treatment services, as required. Ensuring health professionals are informed about relevant services and that the services have capacity to attend to new clients will also help to mitigate this risk.

Settings in which patients may be excluded

Some models (e.g. Victoria, Australia) consider excluding palliative care patients, cancer patients, people in aged care residential facilities, hospital inpatients, emergency department patients, prisoners and patients in police custody. Patients supplied with seven days or less medicines are excluded in some PDMP systems in the US.[6]

Some considerations for variability of inclusion/exclusion:

Limited supply patients	Patients who receive a supply of seven days' medication or less may be excluded from a RTPM system. This may, however, jeopardise the integrity of the program as it is still possible for a patient to attend multiple prescribers within a period of seven days or less to obtain a greater supply, and to risk and experience severe harm as a result.
Cancer patients	Consideration of cancer patients' exclusion from a RTPM system is valid. However, as many people make a full or lasting recovery from cancer appropriate prescribing is still prudent to avoid potential adverse effects such as developing a dependence.
Palliative care patients	There is an argument that palliative care patients may be excluded from a RTPM system: when they are suffering from an incurable disease that is progressive and far advanced; when the prognosis of a limited lifespan is due to that disease or medical condition; when supply of the restricted medication is aimed at providing palliative treatment.
Patients in residential care settings	Patients in residential care settings should not be excluded from a RTPM system as there remain benefits to informing prescriptions within these settings.

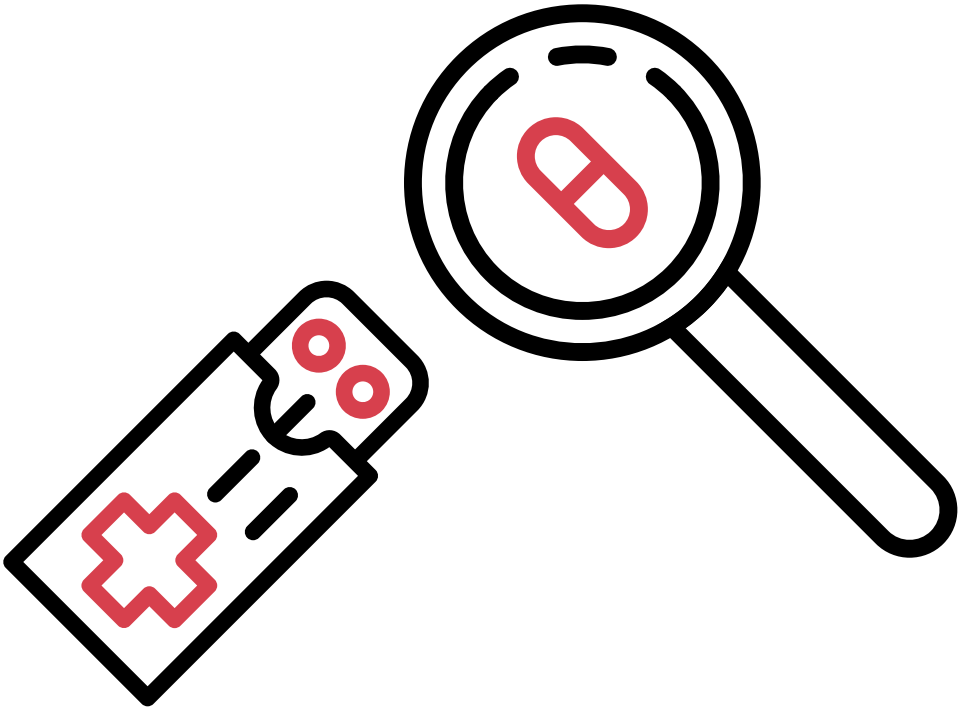
Current status in Australia

In 2013, the Australian Government funded the development of the Electronic Reporting and Recording of Controlled Drugs (ERRCD) system to assist state and territory governments to improve their monitoring and regulation of controlled medicines. The Government's expectation was that the original Drugs and Poisons Information System (DORA), developed in Tasmania, should be adopted by all jurisdictions to provide a consistent approach.[14] In 2017, the Australian Government announced a further $16 million to assist that process.

Currently, DORA is voluntary and does not include S4 codeine products or benzodiazepines other than alprazolam.[15] The Victorian Government developed SafeScript, which is now mandatory for prescribers and dispensers and incorporates all Schedule 8 drugs and several Schedule 4 drugs (including opioids and benzodiazepines).

A key reason for the bespoke model in Victoria was the desire to have the system integrate with clinical workflow software, not possible with ECCRD.[16] The SafeScript system is intended to have minimal interruption to clinical workflow and will provide pop-up notifications in real time to provide information about whether warnings relating to the patient exist in the SafeScript system, enabling further investigation and informing clinical decision making.

In April 2018, the Council of Australian Governments (COAG) Health Council agreed to progress with an approach based on SafeScript's design principles to assist in ensuring all systems are interoperable and data can be shared between systems.[16]



Evidence

Prescription Drug Monitoring Programs

PDMPs have been used as a critical tool to better inform clinical care, identify illegal prescribing and reduce prescription opioid-related morbidity and mortality.[1] Programs across the United States and Canada operate under different regulatory bodies, collect different types of data, require data to be updated at different time variables and allow access to different groups of people.

Evidence that PDMPs decrease non-fatal or fatal overdose is currently insufficient, mostly due to the variations in programs and designs.[1] Studies have shown however, that PDMPs are associated with reductions in supply,[17] diversion[18] and non-medical use[19] of prescription opioids and as such they are valuable in reducing harm.[1]

Mortality from oxycodone declined by 25% after the implementation of Florida's PDMP. Whilst other policy changes were introduced at a similar time (tamper resistant packaging, enforcement crackdowns, closure of a number of Florida's pain management clinics) the effect was seen independent of these factors.[20]

A systematic review by Fink et al[1] found that there is insufficient evidence that PDMPs increase or decrease nonfatal or fatal overdoses. One exception to this was a low-strength evidence reduction in fatal overdoses after implementation of PDMPs that have the following aspect:

- mandatory provider review
- authorised providers to access PDMP data
- updated frequently
- monitoring of non-scheduled drugs.

The same systematic review reported unintended consequences of PDMPs including three studies that reported an increase in heroin-related overdose post implementation.

Studies in the US have identified a potential risk of transition from pharmaceutical use of opioids to use of illicit drugs such as heroin. One study of heroin dependent people undergoing drug treatment found that 75% were introduced to heroin via the initial use of prescription opioids and that they eventually preferred heroin because it was less expensive and more accessible than prescription drugs.

Of this group, nearly 94% indicated they used heroin because prescription opioids were far more expensive and harder to obtain.[21]

The Center for Disease Control and Prevention (CDC) advised that the best way to decrease heroin dependence was to decrease the extra-medical use of pharmaceutical opioids.[22] There is no evidence of this occurring outside of the United States, to date.

Finley et al[7] evaluated the impact of PDMPs and highlighted significant gaps in research across four key domains specifically related to opioid-related outcomes:

- opioid prescribing
- opioid diversion and supply
- opioid misuse
- opioid-related morbidity and mortality.[7]

Real-time prescription monitoring

There is limited evidence on the impact of RTPM to date, specifically as many of the studies have been conducted in the US where prescription monitoring programs usually do not provide real-time information, and the frequency of reports varies from daily to monthly. As these models are not consistent in many aspects with the real-time model being implemented in Australia, not all outcomes are generalisable to the Australian context.

Pros, cons and considerations relating to real-time prescription monitoring

The benefits of a RTPM system include:

- prescribers having more information available to them to make safer clinical decisions
- supports patient safety
- may help to reduce the development of dependence
- reduction in overdose – non-fatal and fatal
- reduction of diversion of pharmaceuticals to illicit market.

The introduction of real-time monitoring carries its own risks.

- Where some opioids are monitored, and others are not there may be a risk that people will shift to less efficacious medications which may reduce their quality of care.
- There is a danger that individuals who are dependent on prescription drugs will seek a supply of illicit alternatives unless they have access to other methods of relieving physical and mental distress.[1,21]
- There are legitimate concerns with the impacts RTPM may have on an already overloaded treatment sector.
- If a prescriber doesn't access the database at point of prescription but the pharmacist does, this may place the pharmacist in a difficult position.
- If a person is on pharmacotherapy there is potential that someone who may have a dependence and attempts to obtain a script via accessing multiple prescribers may be removed from the pharmacotherapy prescribers list, putting the individual at significantly increased risk.[23]
- Patients who live in regional or remote areas, who fit into the category for extra-medical use due to multiple prescriptions at the same time, may not have any access to alternative treatment options and thus seek relief in other ways.
- Current alcohol and other drug (AOD) support services are geared towards dependence on illicit drugs and alcohol. Many people with pharmaceutical dependence may be uncomfortable accessing the same AOD services that people who use/inject illicit drugs access.
- There is a stigma around access to services.[23]
- Current treatments, including daily pharmacotherapy dosing at pharmacies, are often unavailable/unsustainable for people who have jobs, live remotely, have family responsibilities, etc.
- Concerns over cross border issues that arise when different systems are used have also been raised, reinforcing the need for a national system that picks up individuals who may move between states and territories.

Where risk is identified there is a requirement to address this within the system in order to ensure there are no inadvertent barriers to services and treatment.[23]

Other issues to consider include:

1. **Potential stigmatisation:** training is needed for medical practitioners and providers to ensure that the programs do not further stigmatise people who are at risk of, or are using, pharmaceutical drugs extra-medically.
2. **Patient needs:** there is a lack of evidence to describe how patients who are impacted view the introduction of RTPM. The absence of the voice of patients in the design of the system and supporting mechanisms may mean opportunities to strengthen the approach have been lost.
3. **Privacy concerns:** people concerned about their health data being shared too widely.
4. **It is important to ensure that the system remains a health-focused system** with the aim to maximise optimal care and safe prescribing habits and does not become a mechanism for law enforcement (such as the pseudoephedrine monitoring system) over the opportunity to provide quality care.

5. **Cost:** the system is considered to be cost effective. The Deloitte Regulatory Impact Statement cost-benefit analysis of SafeScript over ten years predicted a saving of 500 lives, with a net benefit to Victoria of $2 billion; while a worst-case scenario, in which SafeScript proved to be less effective and less efficient, would lower the net benefit to around $500,000.[6] In either case, SafeScript is predicted to provide a material improvement in the physical and mental health of Victorians.[6]
6. **Legal liability for pharmacists and medical practitioners** if, for example, RTPM data is missed and a patient suffers an overdose. Further to this, if people are identified as high risk there is a duty of care to assist the person to a less risky situation and not just decline a service.

There is no data to show the effects of RTPM on treatment facilities yet, although modelling is being undertaken through the 2018/19 SafeScript trial in Victoria.

ADF position

- A national, real-time prescription monitoring scheme is required to improve the quality of clinical care for patients and to reduce the extra-medical use of prescription pharmaceuticals.
- A RTPM scheme should monitor all Schedule 8 drugs and codeine, all benzodiazepines, z-drugs and quetiapine and consider other drugs, in a timely manner, where evidence of harm is emerging (e.g. pregabalin).
- Effective real-time prescription monitoring requires training and resourcing of medical staff and pharmacists. Appropriate training and resourcing will ensure they can:
  - identify patients at risk of excessive use at an early stage and provide suitable care (i.e. before they would reach threshold for MBS 'prescription shopper' warnings
  - identify potential risky combinations
  - provide non-pharmacological care or advice for patients where they are first line, rather than prescribe a pharmaceutical medication in the first instance
  - ensure they can refer pharmaceutical dependent patients to an appropriate health or drug treatment service when necessary
  - avoid stigma for patients who need help for extra-medical use of prescribed medication.
- Effective real-time prescription monitoring requires substantial consumer education about appropriate use of prescribed medications and about non-pharmacological treatments for common mental and physical health conditions, particularly pain, anxiety and sleep disorders.
- Considerations should be given to the availability of support services including treatment options.
- Data should be collected to monitor the ongoing impacts and success of RTPM systems on consumers, medical practitioners and pharmacists.

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