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Report by – Susan Gontaszewski – 2016 Churchill Fellow

Investigating the implementation of online prescription monitoring programs in the United States and Canada

Susan Gontaszewski 4 April 2018

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I would also like to acknowledge the support of Prof Tarun Weeramanthri, Assistant Director General Public and Aboriginal Health, and Neil Keen, Chief Pharmacist, from the Department of Health Western Australia.

KEYWORDS: prescription monitoring, prescribing, drugs of addiction, opioid prescribing, doctor shopping, medicines misuse

CONTENTS

EXECUTIVE SUMMARY

Investigating the implementation of online prescription monitoring programs in the United States and Canada | Susan Gontaszewski | Senior Policy Officer | Department of Health | Western Australia | 040 0077 331

Prescription opioid use has increased rapidly across Australia in recent years. Diversion and misuse of these medicines represent an emergent public health issue with growing numbers of fatal overdoses attributed to prescription opioids.

Prescription monitoring programs (PMP) are tools used by state regulatory agencies to track the prescribing and dispensing of controlled drugs in the community. Authorised health professionals can access patient prescription histories to inform decision making on whether to issue a controlled drug prescription. Regulators can analyse prescriber level data to identify patterns that may be non-compliant with prescribing rules or accepted standards of practice.

Western Australia has an established PMP that is used to enforce compliance with regulatory requirements for controlled drug prescribing and provide health practitioners with patient dispensing histories. The existing system requires upgrade to provide up-to-date data to regulators and practitioners at the point of care.

The aim of my Churchill Fellowship was to investigate and describe the different characteristics of established monitoring programs in the United States and Canada to inform the roll out of a best practice PMP in Western Australia and provide options for governance and administration. My Fellowship involved meetings/teleconferences with 10 PMP agencies in the United States and 4 in Canada, attending the PMP National Meeting and Congressional Briefing in Washington, DC and meeting with peak bodies involved in PMP research and policy.

Key findings and recommendations relate to three themes:

Data quality and standardisation
The utility of the PMP tool is linked to the quality of the data stored in the system. In addition to the use of establish protocols for patient entity resolution, the PMP should implement strategies to support data quality throughout the prescribing and dispensing process. Data standardisation across state PMPs supports inter-jurisdictional data sharing, national reporting and research, and streamlines development of system interfaces for cross-country roll out.

External interface and engagement
PMPs cannot exist successfully in isolation. Agencies should prioritise activities that streamline system access, integrate meaningful data into clinician workflow and support coordination of care. Working with system users and other stakeholders is critical to improve the value and reach of PMP data.

Strategies to influence prescribing
PMPs form a key pillar of clinical and regulatory strategies to influence prescribing practice. PMPs should support compliance with prescribing rules and respond to evolving understanding of the risks associated with opioid prescribing. PMP data should feed into systems that work with practitioners who may benefit from education and intervention to improve alignment with quality prescribing practices.

In the coming months I will engage with WA Health stakeholders to pursue the implementation of recommendations relating to the delivery of real time prescription monitoring in Western Australia. My findings support the need for ongoing discussions with Commonwealth, State and Territory counterparts to deliver cross-jurisdictional data standardisation. Engagement with the agencies and organisations that will be impacted by the implementation of real time prescription monitoring in Western Australia will be critical to program success.

BACKGROUND

PRESCRIPTION MONITORING PROGRAMS

Prescription monitoring programs (PMP) are tools used by state regulatory agencies to track the prescribing and dispensing of controlled drugs in the community. Authorised health professionals can access patient prescription histories to inform decision making on whether to issue a controlled drug prescription. Regulators can analyse prescriber level data to identify patterns that may be non-compliant with prescribing rules or accepted standards of practice.

PMPs are an established policy response across the United States and Canada. Whilst PMPs are ubiquitous, they are governed by diverse State or Provincial legislation, are housed within a variety of agencies, operate within different political contexts. The sector has experienced a high rate of innovation and change in recent years. These circumstances have led to the saying "if you've seen one PMP, you've seen…one PMP". Much work is currently being done to identify the elements of PMPs that would constitute best practice.[1,2]

Currently Tasmania is the only Australian jurisdiction to have implemented an online, real-time PMP. Western Australia, Queensland, South Australia and the Australian Capital Territory run prescription monitoring programs with some delays in data provision (i.e. they are not "real-time"). Victoria is currently building prescription monitoring software and a data feed sourced from prescription exchange services so that the state can commence prescription monitoring during 2018. Both the existing Tasmanian approach to prescription monitoring and model being developed in Victoria align with many of the best practice elements outlined in this report.

Since 2011 Western Australia has worked with the Commonwealth and other Australian jurisdictions on the development of a national real time prescription monitoring program. In July 2017 the Australian Government announced a $16 million investment in the development of a national approach to prescription monitoring. Under such an approach a national data feed will interface with state based prescription monitoring and regulatory systems.

PRESCRIPTION USE AND MISUSE IN THE COMMUNITY

Prescription opioid use for the treatment of chronic, non-cancer related pain became widespread from the mid-1990s. Pain was declared the "fifth vital sign" and practitioners were incorrectly counselled on the likelihood of dependence. Prescription opioid use quadrupled in Australia between 2001 and 2013[3]. In Western Australia, more than 5% of the population was dispensed an opioid prescription in 2016, with a continuous increase over recent years[4].

Most patients prescribed opioid medicines use them appropriately. Of those that misuse prescription opioids the vast majority do not transition to problematic use. However, the large quantities of medications prescribed mean that diversion and misuse of these medicines represents an increasing public health issue. Studies also suggest a link between misuse/non-medical use of prescription opioids and heroin use[5].

[1] Pew Charitable Trusts (2016), *Prescription Drug Monitoring Programs: evidence-based practices to optimise prescriber use*
[2] Beth Sproule (2015), Prescription Monitoring Programs in Canada: Best Practice and Program Review, Ottawa, ON, Canadian Centre on Substance Abuse
[3] Berterame, S et al (2016), Use of and barriers to access to opioid analgesics: a worldwide, regional and national study, *the Lancet,* Vol 387, No 10028, p1644-1656, 16.04.2016
[4] Department of Health (2017), Monitoring of Drugs of Dependence System, extracted 29.08.2017
[5] Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H. N Engl J Med 2016; 374:154-163January 14, 2016DOI: 10.1056/NEJMra1508490

The 2016 National Drug Strategy Household Survey found that almost 1 in 20 Australians reported misuse of prescription or over-the-counter pharmaceutical medicines in the past 12 months. Pain killers/opiates were the second most commonly used drug in the previous twelve months, after cannabis[6]. In a 2013 study that examined the mode by which drug treatment entrants sourced pharmaceuticals, 72% reported a medical practitioner as their usual source of benzodiazepines and 29% reported a medical practitioner as their usual source of opioids[7].

Drug induced death in Australia is at a 20 year high[8]. In 2016, the Australian Bureau of Statistics registered 1,808 drug induced deaths, with more than two thirds (71.3%) being due to accidental overdose. Benzodiazepines and prescription opioid pain-killers were present in 36.7% and 30% of drug induced deaths respectively. Heroin was present in 20% of drug induced deaths in 2016 with overdose rates increasing in recent years. Accidental deaths due to pharmaceutical opioids in Western Australia increased 2.6 fold between 2001-2005 and 2011-2015.[9]

Leakage of opioids and benzodiazepines into the illicit market, and increasing numbers overdoses associated with these medicines, indicates that health professionals would benefit from relevant information, at the time of prescribing, to support informed clinical decision making and assess risks of misuse, diversion and dependence.

PUBLIC HEALTH MEDICINES REGULATION IN WESTERN AUSTRALIA

Regulations exist to protect public health and safety through the control of the supply of medicines. Australia's national medicine scheduling process categorises medicines and poisons based on risk. State legislation adopts the national schedules and sets controls on access, storage, reporting, recording, labelling and supply that differ depending on schedule. Schedule 4 medicines are prescription medicines. Schedule 8 medicines, known as controlled drugs, are prescription medicines with a propensity for addiction and abuse.

In Western Australia, the *Medicines and Poisons Act 2014*[10] establishes a regulatory framework for Schedule 8 medicines that is designed to minimise the risks of diversion, addiction and overdose whilst allowing access to medicines where a legitimate need exists. The *Schedule 8 Medicines Prescribing Code*[11] sets out the prescribing criteria for Schedule 8 opioids, benzodiazepines, stimulants, cannabis-based products and opioid pharmacotherapy. The Act requires health practitioners to report to the Department of Health when they suspect or believe a patient is drug dependent or oversupplied. In high risk prescribing situations, practitioners must obtain Departmental approval to prescribe. Approval generally requires support from a specialist in a related area of practice. Pharmacies are required to send in monthly reports of dispensed Schedule 8 prescriptions and opioid pharmacotherapy dosing.

To monitor and enforce compliance with regulatory requirements, the Department keeps a record of information relating to the supply and prescription of Schedule 8 medicines. Information on the record is used to support the administration of the Act, prescription monitoring, compliance and case management, service planning and evaluation, reporting and research. The Department monitors prescription and dosing records against the parameters of the Code to identify non-compliant prescribing or risky patient behaviour. The

[6] Australian Institute of Health and Welfare (2017), *National Drug Strategy Household Survey 2016*, 01.06.2017
[7] Nielsen, S, Bruon, R, Dengenhardt, L, Stoove, M, Fischer, J, Carruthers, S, Lintzeris, (2013), The sources of pharmaceuticals for problematic users of benzodiazepines and prescription opioids, *Medical Journal of Australia,* 199, p696-699
[8] Australian Bureau of Statistics (2016), *3303.0 – Causes of Death, Australia, 2016*, 27/09/2016
[9] Penington Institute 2017. *Australia's Annual Overdose Report 2017*, September, Melbourne: Penington Institute
[10] *Medicines and Poisons Act (2014)*, (WA) (Austl.): https://www.slp.wa.gov.au/legislation/statutes.nsf/law_a147008.html
[11] Department of Health, (2017), *Schedule 8 Medicines Prescribing Code,* Medicines and Poisons Regulation Branch, Department of Health, Perth, Western Australia

Department runs a telephone information service that provides patient prescription histories, and other information from the record, to authorised health practitioners.

There are two major factors that limit the utility and impact of the current system:

1. Prescription data is not up to date: the monthly reporting frequency and high level of manual intervention in data matching extends the time between a prescription being dispensed and information being available in the system. This prevents prescribers and dispensers from accessing current information about patients in their care and prevents regulators from intervening in a timely manner where non-compliant prescribing is identified.
2. Information from the record is not freely available: the telephone service does not operate at all times. Prescribers and dispensers may not be able to access the information they need at the point of care.

The *National Drug Strategy 2017-2026* recommends the "implementation of real-time monitoring of prescription medications so that prescribers can prevent patients inappropriately accessing harmful and substantial quantities of medications."[12] To overcome the limitations of the current monitoring process, Western Australia has committed to implementing a system that is capable of delivering real time prescription data transfer and 24/7 online access to patient prescription histories for authorised health professionals.

CHURCHILL FELLOWSHIP

The aim of my Churchill Fellowship travels was to inform the roll out of a best practice PMP in Western Australia by investigating and describing the different characteristics of established programs and providing options for governance and administration.

My travel program was designed so that I could visit a number of different state and national agencies involved in PMP delivery, strategic planning, evaluation and support. In the United States I attended the 2017 Harold Rogers Prescription Monitoring Programs National Meeting, hosted by the Prescription Drug Monitoring Program Technical Training and Assistance Center. Over the three days of the meeting I met a number of PMP administrators who generously agreed to follow-up teleconferences whilst I was in North America.

Interviews were loosely based on the interview guide in Appendix 1, however conversations were generally free ranging and often focussed on the area of specialisation relevant to that program. I found that each program included features that would positively assist in achieving the objectives of the Western Australia PMP.

Findings are a synthesis of the data gathered throughout my travels, including observations, conversations and presented research.

[12] Department of Health (2017), *National Drug Strategy 2017-2026*, Commonwealth of Australia

PROGRAMME

Date	Engagement type	Agency	Primary contact/s
UNITED STATES			
Washington, District of Columbia			
▪ 5-8 September	Conference	Harold Rogers Prescription Drug Monitoring Programs National Meeting	Dr Patrick Knue, Director, PDMP Technical Training and Assistance Center
▪ 8 September	Congressional briefing	Congressional Caucus on Drug Abuse: PDMP Critical Decision Support Tools to Respond to the Opioid Crisis	Sherry Green, Chief Executive Officer, NAMDSL
Augusta, Maine			
▪ 18 September	Teleconference	Controlled Substance Utilisation Review and Evaluation System (CURES), State of California Department of Justice	Tina Farales, Administrator Mike Small, Program Manager
▪ 19 September	Meeting	Prescription Monitoring Program, Office of Substance Abuse, Maine Department of Health and Human Services	Johanna Buzzell, PMP Coordinator
Boston, Massachusetts			
▪ 20 September	Meeting	PDMP Technical Training and Assistance Centre, Brandeis University, Waltham	Dr Peter Kreiner, Principal Investigator
▪ 21 September	Meeting	Massachusetts Prescription Monitoring Program, Bureau of Healthcare, Safety and Quality	Len Young, Epidemiologist David Johnson, Director, Prescription Monitoring Program
▪ 21 September	Meeting	Office of Population Health, Massachusetts Department of Public Health	Dana Bergson, Assistant Director, Office of Special Analytic Projects (Chapter 55 Overdose Study)
▪ 22 September	Teleconference	Wisconsin Prescription Drug Monitoring Program, Department of Safety and Professional Services	Andrea Magermans, PDMP Managing Director
Atlanta, Georgia			
▪ 25-26 September	Meeting	National Center for Injury Prevention and Control, Centers for Disease Control and Prevention	Dr Grant Baldwin, Director, Division of Unintentional Injury Prevention Donna Michelle Putnam
Dallas-Fort Worth, Texas			
▪ 27 September	Meeting	National Alliance for Model State Drug Laws	Sherry Green, Chief Executive Officer Chad Zadrazil, Senior Legislative Attorney
Oklahoma City, Oklahoma			
▪ 29 September	Meeting	Oklahoma Prescription Monitoring Program, Bureau of Narcotics and Dangerous Drug Control	Don Vogt, Project Manager PMP

Lexington, Kentucky			
▪ 2-3 October	Meeting	Kentucky All Schedule Prescription Electronic Reporting (KASPER), Cabinet for Health and Family Services	Stephanie Hold, Director, Division of Audits and Investigations Dave Hopkins, KASPER Program Manager
▪ 3 October	Teleconference	Prescription Monitoring Program, Washington State Department of Health	Chris Baumgartner, Drug Systems Director Gary Garrett, Operations Manager
Chicago, Illinois			
▪ 5 October	Meeting	Illinois Prescription Monitoring Program, Department of Human Services, Springfield	Craig Berberet, PMP Administrator Stanley Murzynski, IT Director
▪ 6 October	Meeting	Institute for Innovations in Care and Quality, Illinois Health and Hospital Association, Naperville	Cathy Grossi, Vice President, Quality, Health Policy and Regulation Helga Brake, Assistant Vice President, Quality, Safety and Health Policy
▪ 9 October	Teleconference	Minnesota Prescription Monitoring Program, Minnesota Board of Pharmacy	Barbara Carter, PMP Manager
▪ 9 October	Teleconference	Public Health Informatics and Analytics, Tennessee Department of Health	Dr Melissa McPheeters, Director
▪ 10 October	Meeting	PDMP-Interconnect, National Association of Boards of Pharmacy, Northbrook	Dana Droz, PMP Liaison Josh Bolin, Associate Executive Director
CANADA			
Toronto, Ontario			
▪ 12 October	Meeting	Narcotics Monitoring System, Ministry of Health and Long Term Care	Angie Wong, Director
▪ 13 October	Meeting	Michael G De Groote National Pain Centre, McMaster University	Dr Norman Buckley, Director
Vancouver, British Columbia			
▪ 16 October	Teleconference	Nova Scotia Prescription Monitoring Program	Heather McPeake, Manager
▪ 17 October	Meeting	Prescription Review Program, College of Physicians and Surgeons	Dr Ailve McNestry, Deputy Registrar Joy Bhimji, Manager Drug Programs
▪ 17 October	Teleconference	Alberta Physician Prescribing Program, College of Physicians and Surgeons	Ed Jess, Director, Physician Prescribing Practices Program
▪ 18 October	Teleconference	Centre for Addiction and Mental Health, Ontario	Dr Beth Sproule, Pharmacist, Research Scientist
▪ 18 October	Teleconference	College of Physicians and Surgeons, Nova Scotia	Dr Gus Grant, Registrar
▪ 18 October	Meeting		Dr Owen Williamson, Orthopaedic Surgeon and Pain Medicine Physician

ENGAGEMENT SUMMARY

HAROLD ROGERS PRESCRIPTION MONITORING PROGRAM NATIONAL MEETING

The three days of the 2017 Harold Rogers PMP National Meeting were a fantastic way to start my Fellowship travels. It was a rapid learning experience on the current work of the various agencies tackling the opioid epidemic and emerging future trends. It became clear that illicitly manufactured fentanyl has significantly contributed to increasing opioid overdoses and requires an additional response outside of the PMP sector. The impacts of initial prescribing on long term opioid use was raised by a number of speakers. PMP interoperability and data sharing was a key focus along with growing the availability of demand reduction strategies such as medication assisted treatment.

CALIFORNIA

I started my program interviews by teleconferencing with Tina Farales and Mike Small from the Californian Department of Justice. California has had a prescription monitoring program in place since 1939 and currently runs the Controlled Substances Utilisation Review and Evaluation System (CURES). CURES processes 45 million queries per year and receives approximately 1 million prescription records per week. Data is transmitted from pharmacies on a weekly basis.

The data flowing from pharmacies to CURES is not cleaned or corrected manually. I found out through my travels that this is standard across PMPs but was something of a shock to me as information management staff in Western Australia review almost half of the dispensing transactions received in any month which is a laborious and time consuming process. In California, if there are any issues with the data the queries are referred back to the pharmacy, returning the responsibility to the original record creators.

The CURES 2.0 system runs a matching algorithm every 24 hours to create links between identities. The probabilistic matching software was implemented to improve the accuracy of alerts and makes a big difference to the risks as presented by the data.

CURES issues post-prescription alerts to prescribers where the dispensing history of a patient meets criteria relating to daily opioid dose, extended time on opioid therapy or multi-doctor/pharmacy episodes. The system also supports encrypted peer-to-peer messaging between practitioners that are involved in the same alert. Consultation mandates, with a series of exceptions, will be implemented once there is sign-off on capacity of the system to handle an increased volume of transactions and staff support is in place

CURES provides de-identified datasets for the state and each county on a quarterly basis to approved research organisations and publishes aggregate quarterly data by county on the CURES website.

MAINE

I visited the Office of Substance Abuse in Augusta, Maine, to meet with the Maine Prescription Monitoring Program. The State of Maine has recently implemented legislative rules that cover prescribing controlled drugs and the operation of the PMP.

Electronic prescribing is mandated for opioids and the legislation sets 7 day limits for acute prescription and 30 day maximum for prescriptions for chronic conditions. Prescribers are required to check the system on initial prescription of opioids or benzodiazepines and then every 90 days thereafter. Due to the high doses often prescribed for pets, veterinarians are required to query the PMP for both the person who has presented with the animal and the animal's owner; however veterinary prescriptions are not required to be reported.

There is a 100 morphine milligram equivalent (MME) maximum on all prescriptions, unless one of a series of exception criteria is met. Patients already established on higher doses are expected to taper down. Exception codes will be required to be written on the prescription and will be collected by the PMP. There are penalties for non-compliance with the prescribing rules ($250 per violation to a maximum of $5,000 per calendar year). Working on the exceptions to the prescribing cap required the program to convene a high level stakeholder group made up of health professionals and representatives from governing boards. This group met for ten months to establish the exemptions and provided a dual benefit to the program: Firstly, the involvement of the health professional groups has ensured that the exceptions support clinical workflows and good clinical practice, and secondly the members of the group played an important role in promoting the benefit of the new law to their members and colleagues.

Unsolicited reports are generated in the system for multi-provider episodes, high dose and overlapping opioid/benzodiazepines. Once an alert is generated it will be attached to the prescriber's account along with the prescribing history of the related patient so that it is visible the next time the user logs into the system.

Opioid prescribers are required to undertake 3 hours of continuing medical education (CME) every two years. The program is administered by the licensing boards and there are a variety of offerings that prescribers can access to obtain their CMEs. Prescribers can run the "My Rx" report in the system that shows their prescribing activity for an inputted date range. A "Prescribing Report" is generated quarterly and shows prescribers where they fit in comparison with their field and speciality.

Maine is part of the PMP Interconnect and currently shares data with 12 other states. Given the size of the State's border with Canada, the program is looking into sharing data with neighbouring Canadian provinces.

It has been recognised that health coverage (and the options presented) have an impact on treatment selected for patients and it is considered important that a range of treatments should be available. MaineCare (Medicaid) includes alternatives to pain medicines for the treatment of chronic pain. The Office of Substance Abuse and Mental Health Services (SAMHS) makes coverage for the uninsured in line with the Medicaid treatments and has been proactive around improving access to medication assisted treatment.

MASSACHUSSETTS

Whilst in Boston I visited the Department of Public Health that delivers the MASS-PAT (Massachusetts Prescription Awareness Tool), Chapter 55 Overdose Study and visited Brandeis University which hosts the PDMP Technical Training and Assistance Center at the Heller School for Social Policy and Management.

MASSS-PAT receives 24 hourly batch file uploads from pharmacies. MASS-Pat also receives data from out of state pharmacies that operate mail-order services to Massachusetts residents. Pharmacies are required to provide the ID number and type of the person who

picked up the prescription as well as the relationship to the person for whom the prescription was written. Pharmacists must record if the prescription was paid for by insurance or cash. When a patient obtains a high proportion of cash prescriptions it may be a sign that they are exceeding or working around the limits on prescriptions that may be in place from an insurer.

Data quality can be an issue. Where errors are identified, the prescriber can contact the Department of Public Health (DPH) who will follow up with the pharmacy. DPH has taken on this role because their intervention has been found to more effective at eliciting a change in data than when prescribers themselves followed up.

Registration is automated using reference files from licensing boards and the Drug Enforcement Agency. Law enforcement can get access to the system but only if they have had training in addiction and only for active cases. Law enforcement officers do not have the same view as health professional users. Patients can request their own prescribing history. Delegates are permitted with requests being managed by the primary account holder. Use mandates have been implemented since October 2016. Prescribers must query the system every time they write a prescription for a Schedule II or III opioid and the first time they write a prescription for a benzodiazepine. Queries spiked dramatically after implementation.

Unsolicited reports are provided based on thresholds around number of prescribers, number of pharmacies and numbers of prescriptions. The thresholds are not made publicly available.

The DPH utilises a Medical Review Group that is made up of health professionals authorised to prescribe opioids. The group reviews the profile of prescribers displaying certain behaviours (top decile of prescribers by dose, overlapping opioids/benzodiazepines or those that have doubled their prescribing rate since previous reports). This group reviews patient histories and makes recommendations on whether the health professional should be referred to their registration board. A stakeholder group meets quarterly comprising doctors, pharmacists, and government affairs staff. This group has been very useful, with the emphasis on making the system as user friendly as possible.

The DPH is a data driven team with a focus on data provision, data quality and ensuring currency of account holders. DPH receives requests for de-identified aggregate level data but is not able to share identified data. The program doesn't share data with other states at this point and is looking at secure solutions to support integration with health practitioner systems. The team is also working on communications and developing strategies to increase registration and use of the system.

MASS-PAT data is one of the datasets included in the Chapter 55 Overdose Study and I met with Dana Bergson from the department of Public Health to talk about the process and outcomes of the project to date. The study was possible due to a legislative mandate that supported the linkage and analysis of a number of datasets (mortality, claims, birth, corrections, Veterans, cancer) to improve public health outcomes related to opioid use. A key focus in the early stages of the project was establishing the structure and agreements that allowed the Department to access the datasets. We discussed the importance of long term data linkage agreements to reduce duplication of workload and support researchers in obtaining funding for larger scale long term projects that may be based on the data. The study has increased understanding of the extent and distribution of opioid use disorder and overdose in Massachusetts. The study has analysed and described the increased risks of overdose in patients who have had long term opioid prescriptions and the increased risk of fatal overdose in patients who previously experienced previous non-fatal overdose. Chapter 55 data is being used to support the implementation of prevention programs, such as Medication Assisted treatment, across the state.

Whilst in Massachusetts I travelled to Brandeis University to meet with the PDMP Training and Technical Assistance Center (TTAC). The Center acts as a national voice for PMPs and a clearinghouse for PMP information and research. The TTAC holds regional meetings, bringing PMP staff together to discuss current issues with PMP operations and share knowledge and expertise in program development. The Center also works to evaluate PMP effectiveness and has established the Prescription Behaviour Surveillance System (PBSS) which analyses multi-state PMP data against established metrics. The longitudinal data of the PBSS can serve as an early warning surveillance tool that can also be used to measure the impact of state policy and law changes. Discussions took place on the impact of a lack of universal patient identifier on data matching within PMPs and cross-jurisdictional research. State PMP diversity limits the ability to study PMPs in general but also the impact of specific practices. We discussed the differences in matching algorithms and matching thresholds, even amongst the jurisdictions that utilise the same PMP vendor.

WISCONSIN

I used a free afternoon in Boston to talk with the Wisconsin e-PDMP, part of the Department of Safety and Professional Services. The program receives dispensing data by midnight on the next business day after the transaction. Validation at the pharmacy end has been built into the system, such as checking the validity of prescriber identifiers, to improve the quality of data submitted. Matching protocols use phonetic matching and nickname matching when returning a list of patients. Patients with the same name and date of birth but different addresses are linked if there are common pharmacies or prescribers in the dispensing history. At this stage the e-PDMP do not have the ability to create links that haven't been identified by the back-end matching process.

Prescribers and dispensers have automated registration to the system using public and private information to verify the request. Law enforcement officers may be provisioned access to the system but these requests are manually approved. Individual requests for data are also required to be approved by the PDMP and these must be reasonably related to an active case. Delegates are permitted for both authorised prescribers and pharmacists.

Searches of the e-PDMP require a full surname, first name and date of birth. Users may be presented with a picklist where a search returns multiple matches. Selecting multiple records from the list will display a composite report. The prescribing profile report for an individual patient shows a map displaying the locations of prescribers and pharmacies during the report period.

Unsolicited reports are not sent to prescribers. The system generates alerts and these are attached to the patient file but correspondence to previous prescribers is not issued. Concerning patient behaviour alerts are generated for early refills (can be calculated based on number of days' supply of each prescription), dose above 90 morphine milligram equivalents, overlapping opioid/benzodiazepine prescriptions, multi-provider/dispenser episodes, long term opioid therapy with high number of providers, multiple same day prescribing or dispensing events. Current alerts are displayed at the top of the report with additional information available on click through.

The program used a number of different subject matter expert groups when developing the current layout of the patient report. At scoping and initial mock-up of layout the groups were consulted and provided valuable input. This was important as the stakeholders could "see their fingerprints" on what was eventually developed. Feedback has been positive.

Law enforcement agencies also report to the e-PDMP on either suspicion or belief of narcotic overdose, violation of controlled substances laws (illegal possession or intent to sell prescriptions), stolen or forged controlled substances prescriptions. There is no requirement to report in a particular timeframe to avoid impacting active investigations.

Prescribers are required to view the e-PDMP before issuing a controlled substance prescription (initial and any refills). There are exceptions for hospice care, emergency supply, prescriptions of 3 days or less, technical issues, where the medication is administered directly to the patient or where the e-PDMP is down.

Prescribers can view their own prescribing profile report which includes an estimate of compliance with the mandates on consultation before prescribing. A Medical Coordinator role can view prescribing profile reports for their staff but do not see identifying patient information.

In Wisconsin, different prescribing boards have written guidelines on opioid treatment. All are based on the current Center for Disease Control Guidelines but differ based on profession. It is intended that the program will be able to make referrals to the relevant professional boards where it is identified that practitioners are not meeting the Guidelines.

NEW YORK

I spoke via tele-conference with Anita Murray from the New York Bureau of Narcotics Enforcement after watching her presentation at the national PMP meeting. The Bureau is a law enforcement agency within the Department of Health that has public health investigative capacity. The Bureau runs the Internet System for Tracking Overprescribing (i-STOP) which receives daily data from pharmacies.

There is a statutory 7 day limit on the prescription of Schedule II-IV opioids for acute pain with exemptions including palliative and hospice care. There are mandates around prescriber education on pain management, addition and palliative care.

Mandates for use that require a check of the system on initial and subsequent prescriptions have been implemented in place of unsolicited reporting. E-prescribing is mandated and, although there are a list of exceptions, the current e-prescribing rate is 88%. The implementation of mandatory usage of the i-STOP system and e-prescribing mandates saw a significant reduction in multiple provider episodes in the state.

Prior to implementing use mandates, Anita recommended working with pharmacies to address data quality and get the data cleaned up. When crafting an e-prescribing mandate, it is important to consider how compliance will be audited.

i-STOP does not include alerts in the prescribing report. Whilst there have been no issues with the generation of false positives with the current algorithm, the lack of a universal patient identifier factored into this decision. Additionally, in an earlier version of the program, unsolicited reports were sent via letter which lead to a significant amount of returned mail and limited observed benefit from the intervention.

OKLAHOMA

The Oklahoma PMP is a “real time” prescription monitoring program delivered by the Bureau of Narcotics Enforcement. Data provided to the program includes number of days’ supply and the identifier number related to both the name on the prescription and the person who is collecting the medication.

Data quality issues are compounded by handwritten prescriptions. E-prescribing is not mandated at this stage. It was noted how important it is for pharmacists to understand the impact of not entering data correctly. Working with pharmacy software systems was highly recommended to improve validation and data quality at the dispensing end before the data is transmitted to the PMP. Auditing pharmacies for data quality should be part of PMP compliance, by comparing original script content to dispense system content and then again with the data sent to PMP.

Oklahoma permits a wide variety of users to access the PMP including prescribers, law enforcement, law enforcement analysts, medical examiners, medical boards, investigators at medical boards, workers compensation investigators and Medicaid investigators. Prescribers are able to create delegate accounts.

Users search the system for first name, surname and date of birth. Partial searches are permitted. A pick list will be presented when there are multiple matches to search terms specified.

Unsolicited reports are released for multi-provider episodes which has significantly reduced doctor shopping throughout the state. An email is issued to the prescriber and an alert generated in the system provides related prescribers and anyone viewing the patient report with the alert information. The program is currently working on refining the algorithm for the concurrent prescribing of opioids and benzodiazepines and high dose.

Mandates for system use require a check for first time prescribing and then every 180 days at a minimum. Enforcing compliance with the mandate is the responsibility of the licensing board. Investigators have training and a good understanding of PMP data.

A formal PMP advisory group isn't in place but the program regularly uses surveys and focus groups to engage with users. There are state specific prescribing guidelines for a variety of contexts, including emergency and primary care. These were developed using a broad group but have not been mandated at this stage.

Data is shared with 15 states via the PMP Interconnect. An agreement is in place to provide identified data to the Department of Health and Department of Mental Health. These agencies use this data to undertake surveillance activities. We discussed the importance of having epidemiologists or business intelligence resources on staff to handle complex research requests, surveillance and compliance activities.

WASHINGTON

Whilst I was in Kentucky I spoke with the Washington PMP via teleconference. The Washington PMP data is integrated with the state Emergency Department Information Exchange that is shared between all hospital emergency departments in the state and also with some in neighbouring Oregon. Users can request data via the patient file in the exchange and the report will be sent to and retained in the file. Integration is a priority for the program and staff resources are being recruited to support on-boarding of additional health record providers.

In the base system users enter full date of birth plus a partial first and surname to search. There is clustering/entity resolution in the backend but a picklist is also provided where search terms match multiple identifies in the system. Administrators have the ability to split and re-cluster records if required.

Mandates are not in place however two agencies (workers compensation and substance abuse treatment) have instigated mandates for their workforce. Unsolicited reports are not utilised by Washington as they were not observed to be effective. The program is currently working on prescriber report cards, a chief medical officer report and an overdose notification where letters are set to prescribers when data from the ED Information Exchange reveals that a patient with current opioid prescriptions has experienced a recent opioid overdose. The program does not share data with other states (aside from via the ED Information Exchange).

Washington State has comprehensive opioid prescribing guidelines that were developed by the medical directors of all health agencies in the state. Prescribing rules also cover chronic non-cancer pain. PMP data may be used in investigation of health practitioners for non-compliance with the rules or guidelines.

The program extensively uses educational videos and webinars to train health professionals in the use of the system. A training environment has been established for this purpose. County profile reports are available on the PMP website.

ILLINOIS

The Illinois Prescription Monitoring Program is a home-grown application that receives prescription data from dispensing pharmacies at the end of each business day. A fuzzy logic algorithm assists in matching/clustering records. Users are presented with a prescription history table which displays a combined report for all patients matching the search criteria entered by the user. The prescription history will display the patient name against each dispensing so that the user can see if the terms entered are returning too broad a list.

Unsolicited reports are manually verified before being pushed out to a prescriber. Alert thresholds are broad and the program doesn't concern patients or practitioners unless there's a valid reason. PMP staff will "cancel" alerts before they are sent if it is clear from the data why the prescribing has occurred (e.g. cancer treatment). Where a report is sent it appears on the welcome page for any related prescriber with a link to view the patient prescribing history. The prescriber is able to "remove" the alert so that the regulator knows it has been seen and actioned.

Registration with the PMP is mandated on renewal of medical licence. PMP integration is mandated by 2019. The program is engaging directly with hospitals and EHR vendors. The program has employed a vendor to progress integration and can develop integration modules specific for the agency or can work with in-house IT teams to facilitate the process. Hospitals decide what information they want and the manner in which it is displayed in their system. Despite the path to integration, the PMP website remains important due to the additional information hosted.

Illinois has a PMP advisory group that meets quarterly to provide advice and recommendations on PMP related policy and practice. A clinical care/peer review committee is also in place to review prescribing profiles and make recommendations for referral to the relevant board. PMP data triggers referral to this group.

Whilst in Illinois I met with Cathy Grossi and Helga Brake from the Institute for Innovations in Care and Quality, Illinois Health and Hospital Association. We discussed the evolution of PMP in the state and the challenges of integrating meaningful data into hospital systems. It's important to pay attention to the unintended consequences (as future opportunities) but don't let perfect get in the way of getting started. We discussed the importance of translating PMP data into a tool for quality improvement and making data "field friendly". It was noted that

leaving health services to design PMP integration in isolation may not necessarily be helpful unless the discussion is focussed on what is clinically useful for different audiences. Medicine reconciliation requires a single source of truth and PMP data may not provide sufficient information to manage risks. Some hospitals are integrating with e-prescribing systems to access all prescription data for their patients.

I also met with Dana Bergson and Josh Bolin from the National Association of Boards of Pharmacy (NABP) to talk about the PMP Interconnect that supports the transfer of PMP data across state lines. PMP Interconnect is vendor neutral – to participate jurisdictions sign up to the Memorandum of Understanding and build an interface with the system. Data is encrypted when passing through Interconnect.

Generally prescribers are able to select the additional states they want to search which decreases the risk of false positives and search time but is more reliant on patient recall and honesty. The Interconnect doesn't do partial searches. Matches must be exact. At the time of interview there were 42 states online with two further having signed up to the Memorandum of Understanding.

The NABP also offers the Gateway integration product that has a single connection to the PMP Interconnect and allows third party vendors to connect to PMPs without developing tailored connections for each state.

KENTUCKY

In Kentucky I spent two days with the Cabinet for Health and Family Services to learn about their Kentucky All Schedule Prescription Utilisation and Review (KASPER) system. The office is the main investigative arm of the Cabinet which has in-house investigative capacity (pharmacist investigators) and also provides support for law enforcement.

There are several ways that data may be provided: manual data entry, batch upload of a character delimited file or FTP upload through "Move It" (third party system). The ASAP standard has different record types that support error correction. A file will be rejected by the system if it contains more than 10% fatal or 20% serious errors. Once a file has been rejected the pharmacy has 7 days to resubmit. The program monitors pharmacies that have submitted rejected reports to identify whether a "fixed' prescription is subsequently recorded in the system. Where 3rd party vendors are used to send data to the PMP it can be difficult for the program to identify what has been rejected prior to PMP submission.

KASPER uses a data management platform for data matching. The platform has its own weighted system for searching and matching data. A cluster number is assigned to all the records in the system with the same cluster number linking different patient identities and addresses. A US Postal Service reference file is received quarterly which is used to verify addresses. Partial searches are not permitted but an alias list allows the user to enter multiple names and addresses to improve the reach of the search.

Mandates cover registration and use. Prescribers must query the system prior to initial prescription and no less than every 3 months and on refills for Schedule II drugs. Licensing boards set exceptions to mandates which vary by profession. Compliance enforcement rests with the licensing boards. Mandatory usage negates the need for unsolicited reporting. Over 5.5 million queries are received each year in Kentucky and a further 2 million from other states. Data is shared with 12 states, including all bordering states, with a further 5 states coming online.

Delegates are permitted with master account holders approving and deactivating delegates as required. Master account holders can request a report of all searches performed in their name which assists in monitoring delegate usage. Acute prescribing is limited to 3 days' supply with exceptions for chronic/cancer pain, hospital inpatients, end of life treatment and treatment deemed medically necessary. Approved training in pain management, addiction or KASPER use must comprise at least 7.5% of CME for prescribers.

Approximately 4% of prescription history reports are analysed by a resource management analyst prior to release to confirm the cluster is correct. This equates to approximately 600 reports per day. Reports are reviewed where the search returns multiple cluster identifiers, where a cluster contains more than one date of birth or multiple surnames.

In addition to patient dispensing history, a KASPER report displays the morphine equivalent dosage of active prescriptions. At the time of my visit the system was being upgraded to include information on drug overdose sourced via the state health information exchange. A flag in KASPER would alert prescribers and dispensers to a record for review in the exchange. The program is working to deliver an enhanced prescriber report card which will compare a prescriber's profile with others in their speciality and across the state. The report card will contain data on the percentage of patients on opioids, percentage of overlapping prescriptions, concurrent opioid and benzodiazepine prescribing and morphine equivalent dose calculations. These reports will be prepared quarterly and on an annual basis. Prescribers will be able to record that they have reviewed their report.

TENNESSEE

I met Dr Melissa McPheeters at the National PMP meeting and teleconferenced with her later in my travels to talk about her work with the Tennessee Department of Health in Informatics and Analytics. We discussed the enormous issues with data, particularly due to the reliance on hand keying and the lack of built in systems to support accurate data entry. There are issues with entity management, particularly when incorporating other datasets into the PDMP system. The emphasis across many agencies is currently on getting to the data quickly meaning the priority on entity management is often discarded. Concern was also raised with the development of risk scores and risk markers without empirical evidence that can put the trustworthiness of the data at risk. Dr McPheeters also talked about the issue with complaints based systems of prescriber compliance monitoring: if a prescriber is issuing a lot of prescriptions they may not get complaints! There are more levers for action at prescriber level than patient so the future focus of the program will be on building the algorithms of high risk prescriber behaviour and getting proactive. We discussed the importance of dissemination and translation of the PMP data. In Tennessee, data translators and educators are physically co-located with the data scientists in the team to ensure that the data can be translated into information that is useful to a range of groups.

MINNESOTA

Towards the end of my travels in the United States I spoke with Barbara Carter of the Minnesota Board of Pharmacy. The primary focus of our discussion was on data quality and the necessity of engaging with pharmacy software vendors to make improvement to the quality of data in the PMP. As pharmacy software systems have generally been established for insurance payment processing the validation systems generally cover these fields with minimal quality control mechanisms incorporated into other data elements.

In Minnesota dispensing data goes through a matching algorithm that clusters the patient list. A list is also created of patients who do not meet the threshold for clustering and these can be reviewed manually if required. There are levels of clustering in the system so the criteria can be loose (less manual matching) or tighter (more manual matching) if required. Administrators have the capacity to create manual clusters in response to external reports but this is not common practice. The system supports partial searches and will return a picklist and composite report where more than one patient cluster matches the search terms entered.

Prescribers and dispensers have direct access and registration is automated. Reference files are refreshed daily. Law enforcement and health licensing boards have indirect access and require approval for release of each patient report. Opioid substitution therapy prescribers have a mandate to consult the system. Prescribers and dispensers are mandated to have and maintain an account. Users must update their account details every 12 months. The program will forward information on non-compliant users to the relevant licensing board.

The program sends "Controlled Substances Insight Reports" for multiple provider episodes. These reports are reviewed by a pharmacist before release. The program is working on a high dose report but administrators are conscious of "alert fatigue" when sending correspondence to prescribers.

Minnesota PMP laws do not allow sharing of data, either identified or de-identified; however the program produces annual reports with aggregate data. The Board of Pharmacy has oversight of the PMP and are decision makers in issues of state-wide or strategic policy significance. An Advisory Taskforce made up of healthcare boards, medical associations, public members, health department and human services provides advice and recommendations to the PMP and promotes the PMP in the community.

ONTARIO

Whilst visiting Ontario I met with representatives of the Ministry of Health and Long Term Care Public Drug Programs and talked with Dr Norman Buckley from the National Pain Centre at McMasters University.

The Ontario Narcotic Monitoring System (NMS) was implemented in 2012. All public and private narcotic drug prescriptions are captured in the system. When a pharmacy dispenses a narcotic prescription, the NMS is queried and a real time ping back is sent to the pharmacy if the patient prescription history check reveals multi-providers (pharmacy or prescriber) within the previous 28 days. Prescribers and dispensers cannot view patient prescribing histories through the NMS and a proactive prescription monitoring program that sends information to prescribers is yet to be implemented. Investigation and analysis is taking place regarding physician report cards, academic detailing and standard reporting. E-Health Ontario is implementing a Digital Health Drug Repository to provide authorised healthcare providers with access to complete dispensing and pharmacy data. Data from the NMS may be provided to colleges on evidence of active investigation and law enforcement on subpoena. The Institute for Clinically Evaluative Sciences receives NMS data on a quarterly basis for linkage to a range of population health data sets.

I travelled around Lake Ontario from Toronto to Hamilton to meet with Dr Buckley at the National Pain Centre (NPC). The NPC was the lead agency in the development of the *2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain* and acts as a repository for best practice pain management information. Dr Buckley and I discussed the need for PMP to strike a balance in the management of opioid prescribing (think of a police officer saying, "*Would you like a driving lesson?"*). A heavy handed approach can impact patient care. Feedback

from patients is that they are now being asked to taper very quickly and resources are required to support and guide this process. We talked about developing links between PMP and working towards standardisation of practice. As in the United States, Canadian PMP are fiercely state centric. Health care is operationalised on a provincial level and can vary according to the resources, infrastructure and priorities of each jurisdiction.

I also teleconferenced with Dr Beth Sproule at the Centre for Addiction and Mental Health. I spoke with Dr Sproule about the development of PMP program and research networks to reduce siloing between agencies and improve standardisation of PMP data. The evaluation of PMP effectiveness is important and the PMP program network is developing a living document about best practice PMP in Canada. It is important to understand the evidence for PMPs overall as well as the elements which have the most impact.

BRITISH COLUMBIA

In Vancouver I met with Dr Ailve McNestry, Deputy Registrar and Joy Bhimji, Manager Drug Programs to talk about the British Columbia Prescription Review Program (PRP) run by the College of Physicians and Surgeons. I also spoke with Dr Owen Williamson, orthopaedic surgeon and pain management physician.

The PRP uses data drawn from the centralised provincial dispensing data repository known as PharmaNet to inform quality assurance processes and address physician risk. At present the PRP does not proactively analyse PharmaNet data to trigger reviews. Referrals are received from external sources which trigger an established review process. PharmaNet also has embedded rules that will alert pharmacists of patient or prescriber restrictions through interface with dispense software.

On receipt of a practitioner referral the PRP generates a practitioner profile report which provides a 3 month snapshot of prescribing and a comparator using a different time period. Analysts review reports in line with standardised procedures. When a referral is accepted the practitioner is contacted and asked to provide commentary on their profile. If concerns remain after reviewing the response, the prescriber may be asked to undertake a chart review with a medical consultant, attend a prescribing course, develop a self-reflection action plan or attend for an interview. After each step, prescribing is reviewed again. Ongoing issues will lead to a referral to a Prescription Review Panel. The Panel may elect to close the process, require another interview, refer the prescriber into the Physician Practice Enhancement Program or a complaint may be sent to an Inquiry Committee.

The PRP tracks the demographics of prescribers referred into the program and analyses common elements of complaints and PharmaNet reviews to establish common themes for intervention by the College. It is hoped that the PRP can evolve to be able to use the PharmaNet data to trigger the established review process and create prescriber report cards that may proactively influence prescribing.

Dr Williamson raised the importance of making PMP data available in a variety of formats and asking audiences and end-users what they need. PMP data custodians have a responsibility to circle back to the data when making changes to policy and practice. PMP data may also be used to demonstrate the effectiveness of related interventions that impact opioid prescribing such as prescribing practices programs. Health system reform is also required to ensure that alternative care is covered for patients outside opioid prescribing. Dr Williamson also emphasised the need to educate the broader community about opioids: they may not always be required in managing pain and function may not be improved with opioid use in comparison to managing a degree of pain or discomfort. Prescribers need education on how to undertake

a trial of opioids and how to have a fierce conversation with patients about dependency and addiction.

ALBERTA

To make the most of my time in Canada, I tele-conferenced with Ed Jess Director of Prescriber Analytics from the College of Physicians and Surgeons of Alberta to learn about the Triplicate Prescription and Prescribing Practices Programs administered by the College. The Triplicate Prescription Program (TPP) receives a daily upload of dispensing data from the Pharmaceutical Information Network. Ed spoke about the program's efforts in cleansing the data and the importance of improving data quality through engagement with pharmacies and activities to improve the practice of pharmacists. Prescribers can view dispensing histories for their patients through NetCare, the provincial electronic health record. There is a standard of practice that requires physicians to access NetCare on first prescription. The TPP sends correspondence to physicians or the relevant board where multiple provider episodes are identified. Prescribing reports are sent quarterly. The Program produces an Annual Prescribing Atlas that provides comprehensive data on patients, prescribers, drugs, doses and geographic distribution of dispensed prescription records. The Prescribing Practices Program uses trends and outliers to identify practitioners that may benefit from intervention.

NEW BRUNSWICK

In New Brunswick, Canada, PMP data is incorporated into the provincial e-health record that contains health data from multiple health sources. Authorised prescribers and dispensers are able to access the PMP view in the e-health record which contains data from multiple sources, including all dispensing of controlled drugs from community and hospital pharmacies. Work is being undertaken to incorporate PMP alert histories and register a treatment agreement that will trigger an alert if breached. The PMP is a non-punitive program. Data is used to support education on prescribing in relation to national guidelines. An Advisory Committee is mandated under legislation to look at policy, data and evaluation. A pharmacy technical group is used to provide operational, hands-on advice to the program.

NOVA SCOTIA

The Nova Scotia PMP is administered by Medavie Blue Cross and governed by a multi-disciplinary board of directors made up of registrars from the medical colleges, government officials and members of the public. I spoke with Heather McPeake, Manager of the PMP, via teleconference. Information in the PMP is pulled into the system from the provincial Drug Information System and made available to prescriber, pharmacists and law enforcement. Law enforcement access requires an active case number. De-identified, aggregate data can be shared for research purposes.

The program has developed a prescriber risk scoring tool that generates a monitored drugs prescriber risk score. The 100 prescribers with the highest score are sent a prescribing profile report annually with a detailed data break down and list of useful resources related to pain management and opioid prescribing. Risk scores are regularly reviewed by the program and are used as an intervention trigger for individualised inquiry, review by a medical consultant or referral to the Prescribing Review Committee (PRC). The PRC reviews the cases and also receives information on the number of times a prescriber has checked the PMP. The Committee can refer prescribers to a Safe Opioid Prescribing Course delivered by national

pain and addiction management specialists. Failure of interventions may lead to referral to licencing boards.

Whilst in Canada I also had the opportunity to teleconference with Dr Gus Grant, the Registrar of the College of Physicians and Surgeons, Nova Scotia. We spoke about the program elements that Dr Grant believed were successful and where there was room for improvement. Dr Grant noted that the PMP effectively targets high risk prescribers and the detailed prescribing reports give those prescribers information on the depth of the data monitored by regulators. PMPs links with the regulatory and licensing bodies can help to drive change both with the individual prescribers that may be referred and through the broader community via effective communication of the processes and outcomes. Dr Grant noted that prescribers who are directed to take a prescribing course generally change their behaviour before the course even commences – it is the oversight and intervention that effect the change. Dr Grant identified that more could be done to focus on initial prescriptions and prevent transition to chronic or high dose prescribing. The PMP has a role to play in shining the light on acute prescribing and quantities issued to opioid naïve patients. Dr Grant also identified the concurrent use of opioids and benzodiazepines as an area for future focus.

NATIONAL ALLIANCE FOR MODEL STATE DRUG LAWS

The National Alliance for Model State Drug Laws (NAMDSL) is a not-for-profit organisation that develops model drug laws, researches current and emerging best practice and provides advice, mentorship and networking opportunities for state agencies, including PMPs. I met Sherry Green and Chad Zadrazil from NAMDSL in Dallas-Fort-Wirth and covered a broad range of PMP topics, from differences in program paradigm and development to the evolving challenges in the sector. It was noted that, when establishing a PMP, a shared understanding of program objectives was important as was the understanding that the nuance of these objectives could change over time. PMPs underwent a major change when they transitioned from enforcement to health agencies, but have also shifted in recent years from simply supporting the decision on whether or not to issue a prescription to supporting holistic patient care: informing the decision not making the decision. We talked about the importance of data quality, particularly as the PMP systems are opening up to increased numbers of users and PMP data is being shared across state lines and linked into larger health datasets. Data integrity is critical; however misinterpretation is also a risk. In integrated systems it's important to preserve the content and formatting of data no matter where it's accessed. Identifying different research constituencies will assist programs in meet different data needs as providing large volumes of data may not be useful if agencies do not have the capacity to analyse and aggregate. It's important that PMP data is used to identify and evaluate the success of different program components as well as being used in healthcare research. Measures of effectiveness will link back to program purpose. If the ultimate goal of the PMP is to guide behaviour – what do we want that behaviour to be?

KEY FINDINGS

Before leaving Australia I had the somewhat naïve expectation that my travels would support a "pick and choose" approach to PMP implementation, where I could observe a number of different programs and make a choice around which PMP implementation option would fit best in Western Australia. The numerous points of difference between programs meant that this wasn't to be. My findings instead relate to elements that *all* programs incorporate albeit in slightly different ways. It's clear that there's no magic bullet for success, however, my observations were that the best programs have a clear understanding of their purpose and circle back to their objectives in evolving their policy and practice.

DATA QUALITY AND STANDARDISATION

The utility of the PMP tool is linked to the quality of the data stored in the system. In addition to the use of establish protocols for patient entity resolution, the PMP should implement strategies to support data quality throughout the prescribing and dispensing process. Data standardisation across state PMPs supports inter-jurisdictional data sharing, national reporting and research, and streamlines development of system interfaces for cross-country roll out.

- PMP in the United States use a single reporting standard and the same identifiers for prescribers and drugs. Many PMPs use the same standard for the calculation of morphine equivalence.
- Where universal patient identifiers do not exist, PMPs employ accepted matching protocols and entity resolution processes.
- PMP data is sourced from pharmacy dispensing software. Improving data quality at source was identified as an issue for a number of PMPs.
- PMPs may collect additional data to assist in entity resolution, monitoring and compliance activities. Additional fields collected include: identification number/type, phone number, diagnostic code, number of days' supply, fill type (full/partial).

EXTERNAL INTERFACE AND ENGAGEMENT

PMPs do not exist in isolation. Agencies should prioritise activities that streamline system access, integrate meaningful data into clinician workflow and support coordination of care. Working with system users and other stakeholders is critical to improving the value and reach of PMP data.

- Successful PMP have established formal and informal structures to elicit expert clinical advice and consult with system users to guide the implementation and enhancement of program activities.
- Access and use policies link back to program paradigm. Historically PMPs in the United States had links to law enforcement and this is maintained across many programs.
- Where use and/or registration mandates are in place, PMPs utilise strategies to minimise the work associated with registration and use of the system. Mandates generally have a list of reasonable exceptions. Compliance should be considered when creating mandates.
- Integrating PMP data with clinical tools streamlines use of the system and leads to significant increases in PMP engagement.
- Controlled drug prescription data is increasingly being seen as part of a broader picture of risk. PMPs are starting to collect data on a range of drugs of concern, receive additional data from external sources and are linking to other datasets for research and surveillance purposes.

- PMP data is utilised by a variety of audiences and is most impactful when made available in formats that suit stakeholder needs.

STRATEGIES TO INFLUENCE PRESCRIBING

PMPs form a key pillar of clinical and regulatory strategies to influence prescribing practice. PMPs should support compliance with prescribing rules that are responsive to evolving understanding of the risks associated with opioid prescribing. PMP data should feed into systems that work with practitioners who may benefit from education and intervention to improve alignment with quality prescribing practices.

- State agencies monitor prescribing against a number of risk factors and utilise clinical review committees to provide advice on management of outlier practice. Legislative rules may be established that set parameters for opioid prescribing and PMPs may collect related data; however agencies did not have requirements for prescribing approvals/authorities for individual patients.
- PMP data may be used to identify prescribers for referral into prescribing practices programs, generally delivered through medical Colleges, to educate and improve alignment with quality prescribing practices.
- National guidelines are assisting PMPs to set evidence based alerts and aid health agencies/medical colleges to review prescribing rules and standards of practice. Restrictions on duration of initial/acute prescriptions are being implemented to reduce the likelihood of dependence and transition to long term therapy. Additional guidance may be required on alternatives to opioid prescribing, tapering and managing complex patients.

FINDINGS

PROGRAM OBJECTIVES

PMPs aim to influence the prescribing of controlled drugs but the specific objectives of each program will influence design and policy development. Early PMPs aimed to provide enforcement officers with information on diversion and fraud. They were housed in investigation and law enforcement agencies, only looked at the drugs with the highest abuse potential and weren't "open" to the prescribers and pharmacists they monitored.

Over time PMPs have evolved to be tools to support quality prescribing. They may be housed within regulatory agencies that license health professionals and used as the basis for educational intervention and support.

PMPs have further developed to assist health practitioners identify patients that may be at risk of overdose or dependence. The program may monitor all drugs of concern and may issue or display alerts for prescribers to flag patient risk. PMPs support research, epidemiology and surveillance – using their timely data to identify trends and hotspots for intervention. They are often located in Health or Public Health agencies and are starting to accept and link to other data sources to provide a full clinical picture of prescribing risk.

Depending on the objectives of the program, there may be key differences in:

- Monitored drugs
- Timeliness of data provision
- Data sharing
- Access and use

State based prescribing approvals were not part of the system of controlled drug regulation in the jurisdictions I visited in the United States or Canada however, in Australia, PMPs are generally associated with state health agencies that assess and issue approvals to prescribe controlled drugs. At present, the Western Australian PMP has a dual purpose:

1. Monitoring prescribing compliance against the Act, Regulations and Code.
2. Providing information to health practitioners about patients in their care.

There may be tension between the needs of clinicians and the needs of regulators in implementing the PMP. Given the dual purpose of the program in WA, it is important that a realistic balance is struck between patient care/clinical workload and the information needs of regulators to monitor compliance and manage the risks associated with prescribing. The purpose of the PMP should be clearly documented and understood by all stakeholders as it will influence the law, policy and practice required for program implementation.

GOVERNANCE AND PROGRAM ORGANISATION

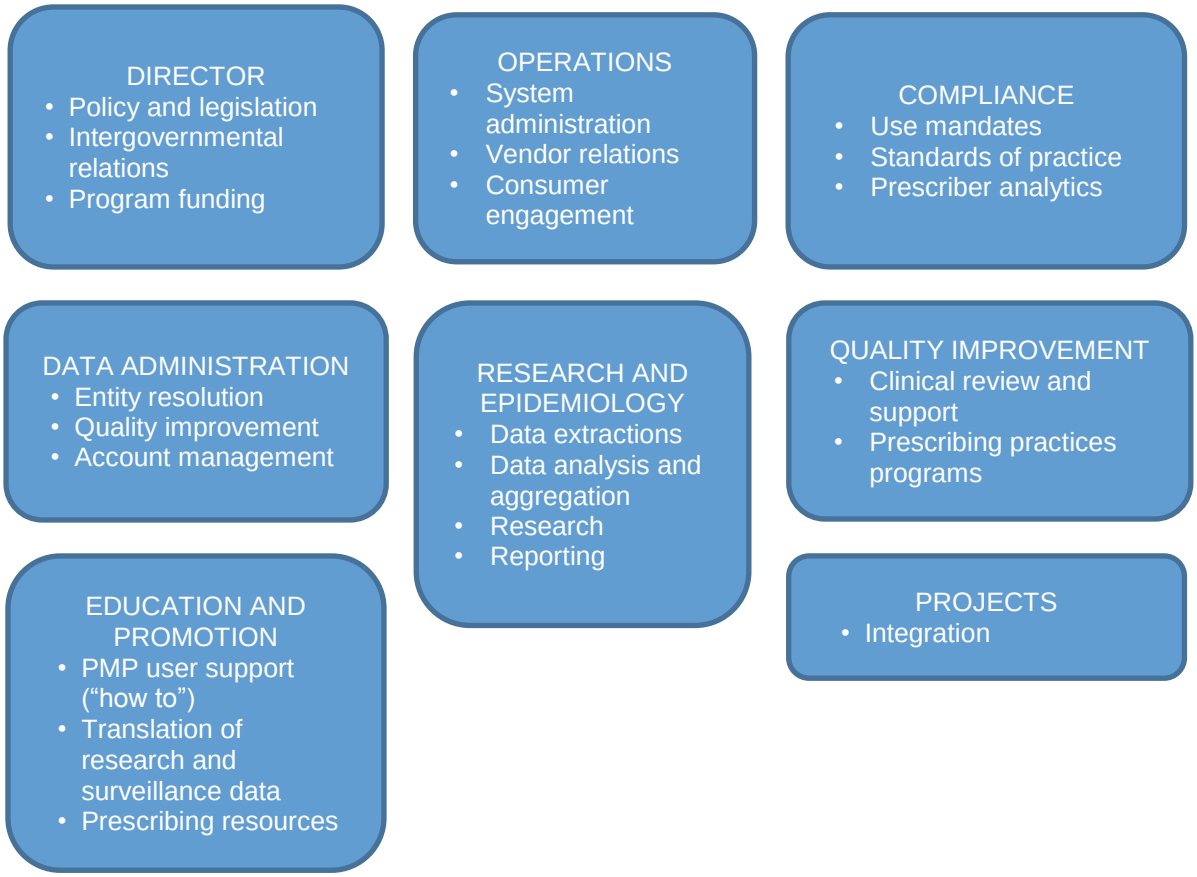
PMPs in the United States have dedicated legislation that sets out the data to be collected, reporting frequency, format and mechanism for data transmission, fields to be provided and types of users that may be authorised. The National Alliance for Model State Drug laws (NAMSDL) have developed a Model PMP Act that sets out a legislative structure to establish a PMP, defines roles and responsibilities in reporting and establishes sanctions for non-adherence and protections for the use of program data[13].

[13] *Model Prescription Monitoring Program Act*, Revised May 28, 2015, National Alliance for Model State Drug Laws (NAMSDL): http://www.namsdl.org/library/A72D4573-0D93-65C4-281BD9DB01418276/

Some PMPs may report to a governing board, whilst other jurisdictions have advisory committees, established in legislation, that provide advice and recommendations to the PMP agency on policy and program implementation. Whether or not the use of such groups was mandated, I found that the majority of programs had access to an expert group that provided high level strategy and policy input to the program.

PMP administrators reported that these groups were of great value in ensuring the policy and implementation of the systems were not in unnecessary conflict with existing work practices and were successful at improving buy-in from the agencies around the table. These groups were often utilised to craft exceptions to mandatory legislative components of the program and provide guidance on thresholds for monitoring and alerts. Many jurisdictions also utilised smaller, less formal groups to test out new ideas or operational changes. These groups were more likely to be subject matter experts: the people "with their hands on the keys" who could be heavily involved in particular projects.

The organisational structure of PMP operational teams was lean. PMP staff were not involved in the provision of clinical advice or guidance to health practitioners, processes were automated and, as stated above, there was no system for issuing approvals to prescribe. A common theme of discussion on organisational structure was that it was the ideal practice to split the policy/strategy and operations of the system. A comprehensive PMP structure is illustrated below. This is synthesised from my many meetings and discussions rather than being representative of any one program.



In small teams, the culture and skills of the team can influence the way the program develops and many successful PMPs had a particular focus to their expertise (e.g. investigations, epidemiology or IT). I observed that, where PMP teams didn't have the capacity to offer a particular "service" in-house, many had developed strong links or formal relationship with external agencies to maximise the impact and reach of the program.

ACCESS AND AUTHORISED USERS

AUTHORISED USERS

A variety of registered health professionals with a role in the prescribing and dispensing process may be authorised to access the system including medical practitioners, specialist nurses, pharmacists and veterinarians. Access to PMP data is linked to the objectives of the program.

Law enforcement has had a long-standing association with PMPs in the United States and many systems were established with the primary objectives of identifying fraud and criminal behaviour. Whilst this has evolved over time, many PMPs continue to permit law enforcement officers to have access to PMP data. Access may be direct, where the user can request and receive prescribing reports automatically, or indirect, where a PMP administrator is required to approve each request. Law enforcement access to the system is predicated on an active case, with probable cause, that is related to the PMP. Massachusetts requires law enforcement officers accessing the PMP to undertake training prior to use. Some PMPs will only provide data to law enforcement on provision of a warrant or grand jury subpoena.

Other agencies that may be authorised to access the PMP include:

- Medicare/Medicaid investigators
- Professional licensing board investigators
- Workers compensation investigators
- Medication assisted treatment services
- Veterans Affairs
- Judges, probation or parole officers
- Medical examiners/Coroners

Different user groups may only be permitted a limited view of the system. For example, professional licensing investigators may see prescriber level rather than patient identifying data. The data provided to each group and type of access provided (direct/indirect) is related to their role and the objectives of the program.

In Western Australia, current legislative provisions permit access for health professionals and health regulators only. Access to PMP data for additional groups, particularly professional licensing investigators, may be aligned with program objectives and should be considered where appropriate.

AUTOMATED REGISTRATION

To increase PMP access and use, many programs have implemented a number of strategies to streamline enrolment processes. Health professional users may be automatically enrolled in the program when they register or renew their professional licence. More commonly, users register by completing an online form. Automated registration processes verify application data against reference files which are generally obtained from professional licensing agencies. Both public (e.g. prescriber licence number) and private information (e.g. tax file number or social security number) are used to confirm identity. Streamlined enrolment processes are often implemented in line with registration or use mandates. Automating enrolment simplifies the process for health professional users but also means that scarce PMP resources are not spent manually verifying and approving applications. This is only possible where the PMP has access to the relevant data files and these are regularly updated. For other user types, the verification of credentials and approval is undertaken manually.

DELEGATES

Delegates are non-licensed staff working in a healthcare setting that may be provisioned access to a PMP to streamline the workflow processes associated with PMP use. Delegate accounts are generally approved by the authorised health professional user and linked directly to their account. Generally a deeming provision is in place so the authorised user is responsible for the activities of their delegate. Authorised users may be able to identify searches that have been made in their name so they can provide some monitoring to the delegate activities. In Maine, authorised users are required to verify their delegate list annually.

In the United States, PMP data is provided in the form of a static report which is requested and returned to the practitioner (rather than the practitioner both searching and viewing records via a user interface). Delegates may request reports for patient lists prior to the patients attending the surgery – reports are then printed or attached to the patient file so they are ready when the prescriber sees the patient. In California, delegates can request reports but these are sent directly to the prescribers account. In other states, delegates have full access.

Benefits to health professional workflow provided through the use of delegate accounts should be balanced against any potential risks to patient privacy that may arise through expanded system access.

MANDATES

Mandates written into law or policy require prescribers or dispenser to register with the PMP and/or query the system in particular circumstances. Registration and use mandates are promoted as a best practice tool for increasing prescriber and dispenser utilisation of the PMP.

When PMPs were first developed, they weren't particularly user friendly and registering for the system was a manual, multi-step process. Practitioner utilisation of PMPs in these circumstances was relatively low and so legislative mandates were considered necessary for clinicians to engage with the system.

REGISTRATION MANDATES

Registration mandates have been associated with a 9-10% reduction in doctor shopping[14]. Registration mandates require specified health professional groups to enrol and activate a PMP account.

PMPs use a variety of strategies to manage the implementation of registration mandates, including the linking of registration to practitioner licence renewal or automatically registering the health professional with the PMP when they register for state/provincial based Health Information Exchanges.

Having an account with the PMP is of limited value if the practitioner forgets their log-in or changes details. Minnesota requires medical practitioners to hold and maintain an account with the PMP. Annual checking of account details is required. Non-compliance is reported to the licensing board.

USE MANDATES

[14] Wen, Hefei et al, (2017) States with prescription drug monitoring mandates sae a reduction in opioids prescribed to Medicaid enrolees, *Health Affairs*, Vol 36, No 4, https://doi.org/10.1377/hlthaff.2016.1141

Use mandates require the practitioner to log into the PMP and view a patient prescribing history in certain circumstances. Use mandates are now in place in almost two thirds of PMP states and they have been shown to increase use of PMPs, with associated changes in prescribing practice (reduced multiple provider episodes and prescribing of certain drugs).[15]

Mandates range across a wide spectrum: from requiring PMP use only if it is suspected or believed that there may be deceptive or illegal behaviour to requiring a check every time a controlled drug prescription is issued. Many jurisdictions require an initial check when first prescribing, with additional checks required at a particular frequency or when there are concerns. Most mandates have a list of exceptions.

Streamlined PMP registration processes are generally utilised by states that have implemented use mandates to ensure that the PMP can accommodate increased registration requests. Even with streamlined registration, additional resourcing may be required to educate and support prescribers in registering and using the system. Enhancements may also be required to PMP infrastructure and operation to accommodate increased use of the system.

Jurisdictions generally did not undertake proactive monitoring against use mandates. Instead, where complaints were received or a case was under review, information on a prescriber's history could form part of the investigation. Wisconsin, which has a broad mandate in place requiring a review of the system prior to writing each prescription, is able to estimate the percentage of prescriptions written in compliance with the mandate. This information is made available to prescribers and medical directors via prescribing profile reports.

In Western Australia, the *Schedule 8 Medicines Prescribing Code* states that prescribers should contact the Department for information when first treating a patient with Schedule 8 medicines or when "warning flags" are present that would warrant additional caution when prescribing. The Code does not require further checks with any specified frequency.

Whilst mandates may become less necessary as PMPs become more aligned with the needs of health practitioners, it is appropriate that work with stakeholders takes place to define a set of circumstances where PMP information would be considered an integral part of the requirements for quality prescribing. Compliance and enforcement need to be part of the conversation when crafting mandates.

DATA COLLECTED

PMPs collect the following data from the records of dispensed prescriptions:

- Patient information (name, address, date of birth, healthcare identifier)
- Prescriber information (name, practice address, health professional identifier)
- Pharmacy information (name, address, business identifier/registration number)
- Date prescribed and dispensed
- Drug (drug identifier, name, strength, formulation)
- Quantity

Data is entered into the dispensing system by pharmacists from hard copy prescriptions or created at the point of issuing an electronic prescription, which is then pulled to the dispensing software at the time of dispensing. The dispensing pharmacist may be required to add additional elements that are required by the PMP. A number of the PMPs require the collection of additional data that may have merit in the Australian context.

[15] PDMP Center of Excellence, 2016, *COE Briefing: PDMP Prescriber Use Mandates: characteristics, current status and outcomes in selected states*, Brandeis University

INCLUSION OF A BROAD RANGE OF DRUGS OF CONCERN

Medicines are broken into five schedules in the United States based on medical use and potential for abuse. Schedule I drugs are not considered to have an accepted medical use and have high potential for dependence and abuse. Schedules II through V have accepted medical uses with decreasing abuse potential. It is considered best practice for PMPs to collect data on all drugs in Schedules II-V[16]. This practice sees PMPs collecting data on a number of different medicines that are not currently collected by Australian PMPs including, all codeine preparations, tramadol, all benzodiazepines, steroids, testosterone and carisoprodol (Soma). State PMPs may also require reporting of medicines that are not currently scheduled but are recognised as drugs of concern or abuse in that jurisdiction. Kentucky has commenced collecting data on gabapentin prescriptions which has revealed extensive use within the community. Whilst there are workflow implications of additional data collection, the broader range of drugs reported will assist clinicians in making informed healthcare decisions.

NUMBER OF DAYS SUPPLY

The number of days' supply field is entered at the time of e-prescribing or dispensing and is calculated or validated by the pharmacist based on the quantity and daily dose on the prescription. Collection of the number of days' supply for each dispensed prescription allows for the computation and display of the daily dispensed dose in morphine milligram equivalents (MME), flag early refills and overlapping opioid/benzodiazepine prescriptions and identify whether the patient has an "active" prescription. MME above 90mg and concurrent use of opioids and benzodiazepines has been demonstrated to increase overdose risk[17], whilst a pattern of early refills may indicate a patient has escalated their dose or is diverting dispensed medication. In Western Australia, the daily MME prescribed for a patient will determine whether authorisation from the Department (and mandated specialist review) is required.

RECIPIENT IDENTIFICATION

Many PMP collect identification number and type for both the person collecting the prescription and the intended recipient. In the early stages of the opioid epidemic in the US script runners would ferry patients to "pill mills" to obtain high quantity/dose prescriptions which the script runner would then fill themselves. Collecting identification details of the persons collecting the prescription assists the PMP and law enforcement in identifying persons that may be involved in this type of behaviour. Confirming patient details by sighting identification may improve data quality and patient matching in the system.

SOURCE OF PAYMENT

Insurers have checks in place to prevent prescription fraud, including restrictions on maximum quantities prescribed and refill frequency. Private/cash prescriptions have been utilised to avoid these rules. Analysis of PMP data in a veteran population found that persons sourcing

[16] PDMP Training and Technical Assistance Center (2017) *Tracking PDMP Enhancement: The best practice checklist,* Brandeis University

[17] Sun Eric C, Dixit Anjali, Humphreys Keith, Darnall Beth D, Baker Laurence C, Mackey Sean et al. Association between concurrent use of prescription opioids and benzodiazepines and overdose: retrospective analysis BMJ 2017; 356 :j760

both insurance and private prescriptions had increased odds of risky opioid therapy.[18] Whilst it's is not known whether this translates to the Australian context, targeted monitoring is possible when payment type is collected at the pharmacy.

PARTIAL DISPENSING

Partial filling of prescriptions may be used to reduce the risk of diversion, misuse or overdose by restricting the amount of medication provided to a patient at one time. Opioid contracts or authorities to prescribe may require a patient to attend the pharmacy for dosing or be issued with small quantities of medication. Monitoring against these requirements is not possible when the PMP does not receive data to indicate whether a supply is for the full prescribed quantity or for a partial fill. Recording information on partial filling of prescriptions would allow for monitoring against requirements on limited dispensing and daily dosing rules.

DATA PROVISION

TIMELINESS

Timeliness of data provision is recognised as being part of a best practice PMP as it provides health practitioners with up to date patient histories at the point of care. Most PMP in the United States require a dispensing event to be reported within 24 hours or at the end of the next business day. Dispensing data is currently required to be provided to the Western Australian PMP in monthly batch files. Tasmania is the only Australian jurisdiction with a real time reporting system. Victoria is building a real time monitoring system that is expected to be operational during 2018.

PMP systems need to be able to identify issues with data upload (which could indicate a breach of data provision requirements) and differentiate this from pharmacies that simply have not dispensed any reportable drugs during the period. To address this, several jurisdictions, including New York, have implemented a requirement for pharmacists to report zero dispensings in any 24 hour period. Real time systems require a method to flag and action potential breaks in dispensing data upload stream.

QUALITY

PMP administrators identified the need to improve the accuracy and completeness of data entered in dispensing software systems. Ongoing engagement with software providers is critical to support improved validation at the time of e-prescribing or entering dispensing data.

Error identification and correction is critical to ensuring that PMP data meet an appropriate level of quality and reliability. The PMP will set thresholds that may lead to individual records or whole report files being rejected. On uploading a report a confirmation may be sent to the pharmacy identifying the number of errors in the data. PMPs are working to streamline processes for record correction however monitoring for compliance with this requirement can be complicated and is particularly problematic where data is received via a third party provider. If dispensing data is rejected by the third party system before sending on to the PMP, the state agency cannot determine if the data file received is complete. Physical audits of pharmacy dispensing records may be required to confirm the completeness of the PMP data set.

[18] Becker, WA, Fenton, BT, Brandt, CA et al (2017) Multiple Sources of Prescription Payment and Risky Opioid Therapy Among Veterans, *Medcare*, Jul 2017: 55 Suppl 7 Suppl 1 533-536

DATA MATCHING

In the United States, as in Australia, the lack of state managed patient identifiers leaves state-based PMP without a clear path to ensuring that the records in the patient and prescriber tables of the database are representative of the "real world" truth. Whether it is intentionally deceptive conduct or an artefact of manual data entry processes across multiple settings, patients that move between providers may be represented multiple times in the system.

Entity resolution processes are typically used to connect disparate data silos and are critical to the success of the PMP and act to ensure:

- practitioners view an accurate and complete prescribing history of their patients,
- users maintain trust in the system for alerts/breaches
- epidemiological analysis of the data doesn't misrepresent the number of patients or risk factors of the cohort.

Research has shown the impact of matching on the creation of alerts within the PMP system. Multi-provider episodes increased by approximately 450% in California after a probabilistic matching process was implemented to clean up and link patient records in the system. (compared with the exact matching protocol used previously).[19]

Factors impacting on data matching and observed solutions are outlined below:

Manual data entry is prone to error

- Electronic prescribing of scheduled substances is mandated in New York, Minnesota and Maine. Electronic prescribing minimises manual data entry, particularly in the creation of patient files. At a medical practice patient records are usually created and updated by dedicated practice administrators so initial record creation may be more accurate.
- Pharmacists as a group are high users of the PMP, indicating that they see the value of the system in informing their healthcare decisions. Educating pharmacists in how their data entry impacts on the flow of information to prescribers, and its role in the healthcare process, may be a useful strategy in improving practice.

Software systems have minimal validation

- Many PMPs raised the issue of limited dispensing system validation as a hindrance to the creation of accurate PMP records. It was strongly recommended that PMPs engage with prescribing and dispensing software vendors to ensure that the systems support the entry of accurate data at the time of patient/prescriber file creation.

Lack of universal patient/prescriber identifiers

- The utilisation of a national healthcare identifier for patients and practitioners that can be recorded at the time of prescribing and dispensing, with subsequent transfer to the PMP, would assist in patient/prescriber entity resolution.
- The collection of other identifying data fields (licence number, social security number, mobile phone number) may assist in improving the accuracy of data matching.

Unsophisticated matching processes within the PMP

- Without the availability of a universal patient identifier, rigid, deterministic matching processes may lead to the creation of too many patient files. Many jurisdictions employ fuzzy logic or probabilistic matching processes when matching data.

[19] Kreiner, Peter (2017) Approaches to Patient Record Linking: How Much Difference Can It Make? Presentation to East regional PDMP Meeting, Burlington VT: http://www.pdmpassist.org/pdf/26-C_Kreiner.pdf

- PMPs cluster records that are not exact matches but meet certain thresholds. For example, a patient that matches on full name and date of birth but not on address. Clustering may happen at the time of record creation or on a set frequency (California clusters every 24 hours). In some cases jurisdictions could de-cluster if required, although most took a hands off approach to data matching.
- Phonetic or nickname matching processes were used by a number of jurisdictions to account for differences in patient details between practice and pharmacy.

Patient searching

- There was variation in the patient search protocols when a user searched for a patient in the PMP. Some PMPs required entry of full name and date of birth, some allowed partial searches, some allowed multiple alias searches or expanded date of birth range.
- Many PMPs offered the user a list of search responses (a "pick list") with the ability to select one or more records which would be complied in a composite report. The user can differentiate between the entities linked to each dispensing.
- In Kentucky clusters may be reviewed manually prior to sending out a PMP report, to ensure the cluster is a likely match.

Consistency

- It was observed that there may be differences between the patient search protocol between website and integrated search processes. A number of jurisdictions gave the user the option to undertake partial searches (with or without a pick-list) via the website but integrated searches were exact match only. Clinicians treating a new patient need confidence that there is no existing data in the system that would indicate a risk when opioid prescribing. Differences between search protocols should be discouraged.
- Where possible, data matching and search protocols should be consistent across jurisdictions if data is to be shared or reported collectively. If significant differences are in place, this should be communicated to end users.
- The need for rapid access to information may limit the ability to undertake entity resolution. Process and results may differ for day to day access compared with data used for surveillance or linked to other data sources.

Australian States and Territories do not issue or manage state-wide patient health identifiers (such as those in place across Canadian Provinces). Commonwealth managed patient identifiers such as the Individual Healthcare Identifier (IHI) and Medicare number are not captured on prescriptions or through existing PMP. Victoria is developing a prescribing data feed that will deliver IHI enriched data to the PMP and assist in entity resolution within the system.

Current Western Australian practice utilises manual intervention to create new records or undertake matching/clustering where the base matching criteria is not met. This is a resource intensive and time consuming process that keeps prescription records out of circulation for some months after dispensing, denying regulators and health professional access to up-to-date data. In an online system practitioners rightly have an expectation of 24 hour access to current data.

PMPS need a method to manage the trade-off between prescription data flowing into the system with minimal intervention against the risk of providing incorrect data (either too much or too little) to a system user that could be the basis of a poor clinical decision. The quality and sophistication of the matching algorithm/entity resolution process utilised by the PMP can directly influence this and should follow established and contemporary protocols.

STANDARDS AND REFERENCE DATA

PMPs in the United States utilise a number of standardised approaches across programs. Master and reference data in PMPs may be sourced from, enriched by or validated against data from external agencies, where appropriate agreements are in place.

PMP REPORTING STANDARD

Every PMP in the United States uses the American Society for Automation in Pharmacy (ASAP) Standard for Prescription Drug Monitoring Programs. The Standard ensures that the same information is collected at the dispensary and reported in the same manner to the PMP. The standard supports batch file and real time prescription processing. Use of a standard improves data quality and patient matching, and supports cross jurisdictional data linkage. All states adopt a particular version of the Standard as being the required format for data provision for the program. Not all states require the collection of all elements specified in the ASAP and will develop a local data submission guide that sets out the ASAP fields required for submission. The Medicines and Poisons Regulations require a record to be kept of the administration or supply of Schedule 4 and Schedule 8 poisons and this record must be provided to the Department in a specified manner, form and time. A document such as ASAP would provide the basis for such a specification.

MASTER DATA

Master data is standardised and shared across different PMP organisations.

DRUGS

The National Drug Code (NDC) uniquely identifies all over the counter and prescriptions medicines in the United States. The NDC identifies labeler (manufacturer, distributor, repackaged), product information (product formulation, formulation and strength) and pack size for each product. PMPs access NDC files (updated daily) which are uploaded into the system and used to match against dispensing data.

HEALTH PROFESSIONALS

The National Provider Identifier (NPI) is a unique number identifying different healthcare providers in the United States. NPI is available to state agencies as a download file or via application programming interface (API). This is the primary health professional identifier used by PMP.

The Drug Enforcement Agency (DEA) Number is issued to those health practitioners approved to prescribe controlled drugs. This information is used by the PMP in data matching and registering prescribers for use of the system.

MORPHINE EQUIVALENCE

Many PMP compare dispensed opioid doses across formulations by using a conversion factor to calculate a morphine milligram equivalent (MME) dose for each prescription. MME over time can be used to identify patients at risk of overdose. MME is calculated in the PMP and used in alert thresholds or to display in prescription history reports. The MME conversion formula is:((Drug strength)*(Drug quantity)*(MME Conversion factor))/(Days' supply)[20].

[20] PDMP TTAC Technical Assistance Guide No. 01-13 *Calculating daily Morphine Milligram Equivalents*, Revised November 2017

The Centers for Disease Control and Prevention (CDC) developed a conversion reference table for opioid medications, organised by National Drug Code. This data can be incorporated into a PMP and used to compute MME. CDC also has a mobile app and tool for software developers to calculate MME based on PMP data.

National consensus on MME will increase consistency in reporting and streamline development of other tools for practitioners and PMP developers. A similar approach to stimulants and benzodiazepine dosing may also be of assistance.

REPORTING FRAMEWORK

The use of a standard to define reporting measures that will be implemented across jurisdictions supports national level data analysis whilst recognising that jurisdictions may have different systems and different priorities or capacity for reporting. The Prescription Behaviour Surveillance System (PBSS), based out of the PDMP Training and Technical Assistance Center at Brandeis University, has defined measures for PMP reporting across participating states that may be considered as the basis for commencing discussions in Australia.[21]

WHAT'S PROVIDED TO A HEALTH PRACTITIONER

Health practitioners are the primary users of a PMP. In the United States, when an authorised user logs into the PMP, they can request a static report related to a patient in their care. Canadian systems generally allow a practitioner to view records via a user interface that may be part of the provincial health information portal.

Minimum report content is a patient prescribing history for a designated period of time (usually 12 months). The minimum information provided in the patient dispensing history is:

- prescriber and pharmacy name,
- date prescribed and dispensed,
- drug information and quantity.

Where the report contains multiple patient entities it is generally possible to identify which record is associated with each dispensing. More sophisticated reports contain graphics, analytics and quick view indicators of patient risk. In Kentucky, KASPER reports display the MME figure prominently on the report with additional warning flags when the daily dose is above 90MME.

The APRISS PMP system, an off-the-shelf-product used by the majority of PMPs in the United States, has a module called NarxCare that displays a risk score for opioid prescribing with a higher score indicating higher overdose risk.

Wisconsin e-PDMP uses a map to display prescription history locations, including both prescribers and dispensers. This can be a quick way of discerning patients that may travel to multiple locations to access prescriptions. This would also allow differentiation between patients that attend multiple prescribers at the same practices and those that move between practices.

Overlapping opioid and benzodiazepine prescriptions present an increased risk of overdose. A graphical display can illustrate where prescriptions have overlapped and provide a useful tool for prescribers when talking with patients about the risk of concurrent medication use.

[21] http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/Definitions%20of%20PBSS%20Measures.pdf

Similarly a graphical display may be used to show the patient's MME over time which may be useful in identifying unauthorised dose escalation.

Current alerts may be provided in the patient prescribing report so that they are visible to prospective prescribers rather than solely on a retrospective basis. Alerts may be represented by graphics with additional detail on alert definition and meaning available via mouse-hover or click through.

Patient reports may also include external sources of information relevant to controlled drug prescribing including police reports or prescription fraud or misuse, overdose reports and treatment contracts.

COORDINATED CARE

In recent years, as PMP have transitioned away from enforcement to the health environment, they are increasingly being used to support coordination of care between disparate health providers or settings.

Wisconsin e-PDMP and the Californian CURES program allow a health practitioner to register a "treatment compact" (exclusivity contract) with a patient and post this to the PMP. Treatment compacts may link the patient to a prescriber or pharmacy, set a particular regimen or establish a dispensing frequency. Treatment compacts may be viewed by other PMP users and may be incorporated into alerts. The compact may provide guidance to other health practitioners on where a patient should be referred if they present at a different practice for opioid prescriptions.

Some PMPs support encrypted peer to peer messaging within the system. Californian health professionals that are the subject of the same alert in the system can communicate via the PMP. This communication is secure and not visible to regulators. Some PMP display phone number of prescribers and pharmacies on patient reports to facilitate communication between practitioners involved in a patient's care.

A number of systems are recording or linking to additional information considered relevant to opioid prescribing risk. Recording episodes of opioid overdose is the primary area of activity in this space.

Consulting the PMP is aimed at assisting practitioners to identify patients that are at risk of dependence, but what does the clinician do when they make such an assessment? A number of the program administrators I spoke with voiced concern about prescribers believing they had no choice but to "fire" a patient when problematic use or dependence was identified. Increasing availability of drug treatment and improving referral pathways is becoming a priority across the sector and the PMP may play a role in supporting this transition. Kentucky PMP is developing a tool, which will be available via the PMP website, for real time drug treatment placement service and availability.

The PMP web portal may also house information to support quality prescribing, including referral details for pain or addiction specialists, MME calculators, opioid guidelines and patient resources.

ALERTS AND BREACHES

One of the best known features of PMP is the ability of the system to issue alerts to prescribers when prescribing or dispensing patterns meet certain thresholds. Alerts are generally configured in alignment with:

- State based prescribing rules
- CDC or National Guidelines
- Advice from PMP steering groups.

Research is also being used to establish risk markers that are then incorporated into alert thresholds (e.g. prescription after recorded overdose).

Common alerts include:

- Multi-prescriber and/or multi-pharmacy
- High MME
- Overlapping opioid and benzodiazepine prescriptions

Alerts may trigger a dispensing report to be sent to the related health professionals by email (known as unsolicited reporting), attached to the health professionals accounts in the PMP (so they can log in and view alert history) and appear on a prescription history report or the patient file in the PMP interface.

Formal evaluations of the impact of unsolicited reporting show mixed results. The Massachusetts PMP found that sending unsolicited reports was associated with a significant reduction in a number of risk measures (number of prescriptions, prescriber, pharmacies, days' supply and MME)[22]. However other studies haven't shown a significant difference in behaviour change between alert and control groups[23].

Not all jurisdictions use alerts/unsolicited reporting. Where use mandates are in place practitioners should, in theory, be receiving information on patient dispensing history by reviewing the PMP prior to prescribing. Sending multiple alert types by email may create alert fatigue. The effectiveness of alerts can be reduced if there are concerns about data quality or accuracy. A number of jurisdictions I spoke with have rolled back the type of alerts sent to prescribers or have oversight prior to issue to provide real world perspective (to prevent, for example, alerts being sent to prescribers treating palliative patients or prescribing medication assisted treatment).

Alerts sent solely to the prescribers involved in a triggering prescription event miss the opportunity of providing the data to the next prescriber down the line. Alert information may be displayed on the patient profile in the PMP and included in PMP dispensing reports. Wisconsin e-PDMP has different alert types which are displayed prominently in the dispensing report. If the user clicks on the alert icon they are taken to additional information explaining how the alert is calculated.

A number of jurisdictions provide unsolicited advice to health professionals in relation to reports from external sources (such as overdose reports from hospitals) and law enforcement. This provides health practitioners with an additional indicator of patient risk when considering the prescription of controlled drugs.

Whether the information is communicated to the prescriber after the prescribing event (as per unsolicited reports) and/or incorporated into the patient data displayed in the PMP (as per the alerts functionality) communicating markers of elevated risk was common to most PMPs.

Alerts will be linked to the program paradigm. In Western Australia, monitoring activities are also directed towards identifying breaches of the Act, Regulations and Code. In this context, alerts may be patient or prescriber related and ideally the system should be able to

[22] Leonard D. Young, Peter W. Kreiner, Lee Panas; Unsolicited Reporting to Prescribers of Opioid Analgesics by a State Prescription Drug Monitoring Program: An Observational Study with Matched Comparison Group, PAIN MEDICINE, , pnx044, https://doi.org/10.1093/pm/pnx044

[23] Douglas McDonald, ABT and Associates. Presentation to the Harold Rogers National Meeting of Prescription Monitoring Programs, September 2017.

differentiate between the two types of alerts on this basis. Health professional alerts may advise future prescribers of risky patient behaviour. Prescriber based alerts would be used by regulators and be related to non-compliance with prescribing rules. Implementing this functionality in the PMP should be part of discussions with practitioners and regulators. Alerts should be configurable, so that thresholds can change in response to resourcing capacity, data quality and evolving evidence.

DATA SHARING

Most PMPs in the United States have legislation that supports data sharing with authorised out-of-state practitioners. Two platforms exist to support interstate data sharing (PMP-Interconnect and RxCheck). Use of a third-party provider means that each jurisdiction must maintain only a single connection and the system facilitates communications between multiple state PMP databases. So whilst there is not a single national prescription monitoring system in the United States, there is a network of sharing states that provides coverage across the country.

In line with their established role in preventing fraud and diversion of medications, many PMPs share data with Medicare/Medicaid insurance providers. Medicaid/Medicare investigators may be authorised users of the PMP system but the agencies may also receive regular raw data downloads for analysis and operational use.

Where law enforcement are not authorised users of the system, PMPs may still release data on receipt of warrant or grand jury subpoena.

Many PMPs are exempt from public records laws. California allows a practitioner to share a PMP report with patients, provided this is documented in the patient record. Certain PMPs allow patients to request their PMP report. In Massachusetts patients may also request information on the practitioners that have requested their PMP dispensing history report.

INTEGRATION

PMP integration brings PMP data into external systems, in particular patient health records in prescribing, dispensing and hospital applications. It can be as simple as a link to the PMP web portal in a patient's electronic medical record (EMR) (with the associated log in and search processes still required). It can offer a single sign on to the PMP with or without the associated patient search and entity selection process. Or it can pull records from the PMP that appear in the patient's e-chart.

Many states utilise an off the shelf product that is compatible with the predominant PMP software in use in the US. Others have built their own integration modules so that they can achieve parity with the look and content of the reporting available via their website. And others let the health agency or EMR vendor take the lead on what PMP data to include in the record and how it should be displayed.

Illinois has mandated PMP integration to roll out by 2018. The PMP has a dedicated integration project officer that works with health organisations or health software providers to develop integration modules. The program has developed a generic application programming interface (API) to the PMP but will also engage with vendors or health services directly for bespoke development. The PMP has worked with the Illinois Health and Hospital Association to successfully integrate the PMP with large hospital providers in the state.

Support and advocacy from frontline users was observed as being the most successful way to get institutional integration projects off the ground. The users influence the executive who, in turn, influence the IT department. PMP integration projects have to compete with other IT

projects, some of which have financial incentives or direct financial benefit to the facility. When discussing integration it is important to demonstrate the time/cost savings involved for the institution in question. PMPs have generally been in place for some time before they start looking at integrating with electronic health records can draw on data on current system use to support these discussions.

An advantage of using clinical systems as the launch point for PMP access is that users only have access to the PMP information of patients that exist in their clinical record. However ensuring that integrated systems restrict access to data in line with PMP access and use policies may be a challenge.

Integration is often seen as a way of offering a workable solution to mandated PMP use. However it is important to consider how system use would be tracked in fully integrated systems to monitor compliance with mandates.

If the patient search process is different between the PMP website and the integration module (e.g. exact match vs fuzzy logic search), it may mean a clinician receives different information depending on the method they use to access the PMP.

Jurisdictions that were pursuing integration worked with vendors that operated across multiple states. If integration projects can work with multiple PMPs it reduces the burden on software providers.

PMP web portals may continue to have a role even as integration gains momentum. PMP data is increasingly being viewed as only part of the picture and maintaining a website that can gather and host additional information and offer other services to stakeholders (including those outside the healthcare space) is likely to become more, not less, important.

When considering integration from an Australian perspective, it is important to understand that there may be additional information that may impact on prescribing. In Western Australia, the decision to prescribe is influenced by clinical and regulatory factors that may be based on more than dispensing history. Direct integration may need to include markers of patient risk (such as a flag of drug dependence) that are relevant to the decision making process. Establishing integration standards and a minimum dataset for incorporation into integrated systems will streamline the integration pathway.

REPORTING, RESEARCH AND SURVEILLANCE

RESEARCH

PMP datasets are increasingly being used for research and surveillance purposes, including:

- tracking the impact of PMP policy and interventions over time
- monitoring changes in prescribing behaviour
- linking PMP data to other datasets to gain a broader understanding of risk and identify areas for intervention.

The Institute for Clinical Evaluative Sciences (ICES) is a not-for-profit research institute that works with a range of linked population level health data sets in Ontario, Canada, to evaluate health policy, programs and outcomes. Data from the Narcotics Monitoring System of Ontario is provided to ICES and linked on a quarterly basis. Longitudinal data has been used to

identify the impact of prescription monitoring and other activities designed to influence opioid prescribing.[24]

The Kentucky Injury Prevention and Research Center (KIPRC) is a partnership between the Kentucky Department of Public Health and University of Kentucky College of Public Health. The Center undertakes surveillance and research as well as direct intervention and education, to increase awareness and reduce prevalence of injury in the state. KIPRC used data from the Kentucky PMP and linked it to patient data in the Drug Overdose Surveillance System database that contained death certificate data, autopsy reports, toxicology and coroner's investigation reports. The data is analysed at a state and local level to identify overdose trends, inform interventions and education initiatives. The data from the system was used to inform the decision to include gabapentin in routine toxicology testing from 2014 and again in the decision to include it in the list of monitored drugs after toxicology data showed increasing presence of the substance in overdose deaths. [25]

In August 2015, Massachusetts created the Chapter 55 overdose study, which links and analyses government held data sets, including the Massachusetts PMP, to gain an understanding the opioid overdose epidemic in that state. The initiative attempts to address key questions relating to overdose including multiple provider episodes, co-prescription of benzodiazepines and opioids, proportion of overdoses where the person had access to a prescription at the time of death, the impact of access to treatment for drug dependence. The analysis has found that any instance of 3 or more prescribers was associated with a 7 fold increase in opioid related overdose. Concurrent opioid/benzodiazepines prescriptions were associated with a 4 fold increase, 83% of overdoses had illicit or likely illicit substances in their system at the time of death.[26] The Chapter 55 report includes analysis and recommendations for action based on the data.

Differences in data elements collected and field format/meaning can make cross jurisdictional analysis difficult. In Canada, a prescription monitoring program research network has been established through the Canadian Research Initiative in Substance Misuse Program to evaluate the outcomes of PMP in that country. A key first step is to establish a list of common indicators across programs.

SURVEILLANCE

PMPs are increasingly working to develop the business intelligence and analytics capabilities of the systems. This may involve utilising off-the-shelf products that can be customer for state/provincial needs or developing analytics engines in-house. The Prescription Behaviour Surveillance System project is a joint effort of the Bureau of Justice Assistance, Centres for Disease Control and Food and Drug Administration to develop a tool that can provide early warning, comparative reporting across jurisdictions and evaluation of interventions. This system can deliver reports against 43 agreed measures drawn from the state data. Reports can be prepared for states that set out risk measures and compared with other PBSS states to identify local trends and areas for intervention. [27]

REPORTING

[24] Gomes T, Juulink D, Yao Z et al, (2014) Impact of legislation and a prescription monitoring program on the prevalence of potentially inappropriate prescriptions for monitored drugs in Ontario: a time series analysis, *CMAJ Open,* 2014:2(4), E256-61 EPub 2014 Oct 1

[25] Hargrove SL, Bunn TL, Slavova S, et al, Establishment of a comprehensive drug overdose fatality surveillance system in Kentucky to inform drug overdose prevention policies, interventions and best practices, *Injury Prevention* Published Online First: 24 July 2017. doi: 10.1136/injuryprev-2016-042308

[26] Massachusetts Department of Public Health, (2016) An Assessment of Opioid Related Deaths in Massachusetts 2013-2014

[27] http://www.pdmpassist.org/pdf/COE_documents/Add_to_TTAC/PBSS_summary_handout_20150325.pdf

Many PMPs are mandated, under their enabling legislation, to provide annual reports to the legislature or governing body. PMPs must also report to the source of grant funding such as the CDC or Bureau of Justice Assistance.

Alberta Triplicate Prescription Program releases an annual Data Atlas that provides comprehensive data on patients, prescribers, drugs, doses and geographic distribution of dispensed prescription records. Data is broken into opioids and benzodiazepines and is drawn from the Alberta PIN. It's an excellent example of a comprehensive PMP report.[28]

COMPLIANCE AND QUALITY IMPROVEMENT

PMP data can be used to assist prescribers in understanding their prescribing profile or identifying prescribers that would benefit from education or intervention to improve prescribing practice. Canadian agencies working with PMP data were established for the purpose of quality improvement rather than enforcement. PMPs associated with quality improvement tended to be located within or have strong links to professional licensing boards.

PRESCRIBER REPORTS

PMPs allow prescribers to generate a report of their own prescribing history. This can be useful to assist in identifying fraud or data errors.

Prescriber profiles or "report cards" compare a prescriber to their peers or other set benchmarks (such as daily morphine equivalent dose) and are an emerging area to assist with quality improvement[29]. Report cards contain comparative data that displays a practitioner's prescribing profile compared to the average for their speciality and/or the jurisdiction of prescribing. The report card may also list individual patients that have met or exceeded certain risk thresholds. Report cards may also contain information or links to relevant resources such as morphine milligram equivalent calculation, good prescribing practice or drug treatment referral.

In Alberta, Canada, more than 50% of the 8,200 physicians that were sent a report card in 2016 felt that the document was valuable and that they would make a change in prescribing practice on that basis. [30]

The comparative data used in generating report cards may also be used in referral to clinical management groups. These queries may identify the top percentage of prescribers in a particular category (e.g. MME prescriber or patients with overlapping opioid/benzodiazepine prescriptions) or those that fall a certain number of standard deviations away from the mean.

MEDICAL COORDINATOR ROLE

Some PMPs can create a role for a medical coordinator that can be linked to other health professional accounts. The medical coordinator cannot view patient histories through the PMP, but can view the prescriber reports for their linked health professionals to assist in providing oversight on prescribing practice. Wisconsin's e-PDMP Medical Coordinator report contains prescribing practice metrics that illustrate where the practitioner sits in the percentile

[28] Ellehoj E, Niruban SJ, Oreopoulos A, McDermott C, Samanani S. 2016 Alberta Triplicate Prescription Program Atlas. Edmonton, Alberta: The College of Physicians & Surgeons of Alberta; 2017. 40 p

[29]PDMP Training and Technical Assistance Center (2016) Technical Assistance Guide: Prescriber report Cards, Bureau of Justice Assistance: http://www.pdmpassist.org/pdf/Report_Card_TAG_20160315_final.pdf

[30] Alberta Triplicate Prescription program, (2017)Annual Report 2016-2017, College of Physicians and Surgeons Alberta

for a number of measures, the total number of concerning patient history alerts related to a prescriber and an estimate of the prescribers e-PDMP usage.

PEER REVIEW COMMITTEES/PRESCRIBING PRACTICE PROGRAMS

A clinical review committee (CRC) often consists of representatives from various health professional fields, health regulators and investigators. The CRC will provide advice or recommendations for further action in response to PMP data presented to the group.

The British Columbia Prescription Review Program (PRP) has a documented process for the triage, assessment and staged interventions to improve prescribing practice. The Program may require prescriber interviews, written commentary on specific cases, mentorship for the management of a difficult case, undertaking an approved prescriber training course or entering into an agreement to restrict prescribing. If the group isn't able to effect change to prescribing practice, escalation or referral into an investigation/complaints management process may be considered. The PRP may also receive requests from prescribers to restrict their prescribing of certain substances – this information is recorded in the PharmaNet and will generate an alert to a pharmacist if dispensing a prescription for a restricted substance.

The Alberta College of Physicians and Surgeons operates a competence program intended to identify regulated members whose competence may require assessment and improvement through further education." The Prescribing Practices Program monitors the prescribing practices of members in line with risk parameters that are set by a Competence Committee.[31] Educational interventions are offered to prescribers and remediation processes are implemented where improvement is not observed through education alone.

HEALTH PROFESSIONAL EDUCATION AND TRAINING

Education and training focusses on how to use PMP systems, quality prescribing and treatment referral.

The Californian CURES system utilises short videos to provide "how to" support for system users. Kentucky PMP administrators have worked with universities to teach medical students about how to use and interpret the system. Washington State PMP utilises webinar for training purposes and has established a training environment for this purpose. This means that use of the system can be demonstrated in real time rather than relying on static slides or screen shots. CDC is working to support the delivery of care in concordance with the national opioid guideline through the development of online training modules and working with universities to ensure curricula align with current best practice.

PMPs that are part of or linked to formal quality improvement programs have established educational programs to support prescribers. British Columbia Prescription Review Program (PRP) has developed a self-audit tool to assist with reflection and education on a prescriber's alignment with College endorsed prescribing guidelines. The PRP also maintains a list of safe prescribing courses that may be mandated as part of a prescribers participation in the program process.

PMP legislation in a number of jurisdictions requires that prescribers complete mandatory continuing medical education (CME) activities that relate to opioid pain management, PMP use and identifying and treating dependency. Compliance with the mandates is generally

[31] Physician Prescribing Practices Program (2015) Rules for Member Participation, College of Physicians and Surgeons of Alberta

administered by the relevant health professional licensing board. PMP staff generally do not deliver training modules except those that focus on PMP utilisation and interpretation.

PRESCRIBING RULES AND GUIDELINES

PMP agencies in the United States are not generally directly responsible for setting prescribing requirements for controlled medicines. Some jurisdictions have established "prescribing rules" that set the regulatory requirements for prescribing of controlled drugs. State or provincial based rules may have been developed locally or may reference the relevant national guidelines.

Washington State has adopted rules for the management of chronic non-cancer pain. Rules developed by the Medical Quality Assurance Commission[32] require the physicians to obtain, evaluate and document patient history and physical evaluation when considering the use of opioids in the treatment of non-cancer pain. A treatment plan and evidence of informed consent is required. A treatment contract is required for high risk prescribing. Prescriptions for episodic care (such as emergency or urgent care) require the diagnosis be documented (by International Classifications of Diseases (ICD) code) on the prescription. Consultation with a pain management specialist is required when writing prescriptions above 120 MME per day unless specific circumstances are met.

Maine has implemented rules that establish a maximum MME of 100mg per day[33]. The PMP will be used to monitor compliance with these rules by collecting dose and, for any scripts where the dose is above 100MME, the prescriber must select an exception code that explains prescribed dose. One of the exception groups is "palliative care". Where palliative care is the selected exception group, the prescriber must record a diagnostic code on the prescription. Exception and diagnostic code data will be transferred to the PMP which will both monitor compliance with the requirements and analyse the conditions most associated with high dose PMP prescribing. The exceptions to the 100MME rule were crafted in conjunction with a specialist clinical advisory group to ensure that the rule did not act as a barrier to care.

The United States and Canada have both developed national opioid prescribing guidelines in recent years. The CDC built upon an existing literature review and used the GRADE process (Grading of Recommendations, Assessment, Development and Evaluation) to review evidence and develop a set of draft recommendations for the Guideline. The team worked with a group of key stakeholders to carefully craft these into the current set of 12 recommendations which were released in March 2016 in the *CDC Guideline for Prescribing Opioids for Chronic Pain*[34]. The *CDC Guideline for Prescribing Opioids for Chronic Pain* contains recommendations covering the decision to initiate or continue opioids; treatment regimen, follow-up and discontinuation; and assessing risks and addressing harms of opioid use. Many opioid prescribing resources reference a 90-100MME dose threshold in terms of opioid prescribing. Evidence reviews for the CDC Guideline found that overdose risk factors increased 1.9-4.6 when comparing opioid doses of 50-<100MME compared with doses of 1-<20 MME.

The Michael G DeGroote National Pain Center (NPC) at McMaster University was the lead agency in the recent update and release of the *2017 Canadian Guideline for Opioids for Chronic Non-Cancer Pain*[35]. The Canadian Guidelines provide recommendations for opioid

[32] Washington Administrative Code, Department of Health, Medical quality assurance commission, Pain Management: WAC 246-919-850 through WAC 246-919-863

[33] Public Law, Chapter 488, *An Act to Prevent Opiate Abuse by Strengthening the Controlled Substances Prescription Monitoring Program*, Sec. 13. 32 MRSA SS2210

[34] Dowell D, Haegerich TM, Chou R. *CDC Guideline for Prescribing Opioids for Chronic Pain* — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1

[35] Jason W. Busse, Samantha Craigie, David N. Juurlink, D. Norman Buckley, Li Wang, Rachel J. Couban, Thomas Agoritsas, Elie A. Akl, Alonso Carrasco-Labra, Lynn Cooper, Chris Cull, Bruno R. da Costa, Joseph W. Frank, Gus Grant, Alfonso Iorio,

initiation and dosing and opioid rotation and tapering for patients with chronic non-cancer pain. Recommendations in the Guidelines have been categorised as either strong or weak. Strong recommendations can be adopted as policy, practice standard or performance indicator. The Guidelines strongly recommend using non-opioid pharmacotherapy or non-pharmacological therapy instead of a trial of opioids, restricting prescribed doses to less than 90MME, recommend a formal multi-disciplinary program for patients on prescribed opioids who are experiencing difficulties in tapering and strongly recommend against the use of opioids in patients with chronic non-cancer pain and an active substance use disorder.

The CDC is now focussed on the development of relevant education materials and the promotion of guideline concordant care. Whilst the Guideline is not mandated, many PMPs have adopted CDC recommendations as their thresholds for unsolicited reporting (e.g. prescribing above 90MME/day) or restrictions on acute prescriptions (e.g. prescribing less than 7 days' supply). Recommendations are also being translated into practice through incorporation into Medicaid and Medicare programs (e.g. support for non-pharmacological treatments for chronic pain) that have the potential to influence practice through the type of services they will fund. There is capacity for PMPs to support/interact with clinical guidelines and they also serve to focus the community on what quality opioid prescribing looks like.

Areas for development of further guidance and assistance for health professionals include alternatives to opioid prescribing, tapering and prescribing in acute settings.

ALTERNATIVES TO OPIOIDS

Both the CDC and Canadian opioid guidelines identify that non-opioid treatments should be explored as first line treatments for chronic non-concern pain. State health agencies are developing resources for practitioners that support the use of alternative therapies.[36] Health agencies are working with insurance providers to increase the coverage for non-prescription based therapies for pain.

TAPERING

Tapering was identified as a particular issue on several occasions throughout my travels. The CDC and Canadian opioid guidelines do not recommend prescribing doses above 90MME per day however many patients may be already established at significantly higher doses (many without a commensurate improvement in function). "Firing" these patients or pushing them through a speedy withdrawal may have serious adverse consequences. It is important that community prescribers have the skills and tools to manage tapering safely. To support these patients and the health professionals involved in their care, both prescribing guidelines and practical support are being developed for tapering. Oklahoma recommends re-consideration of opioid therapy for patients on doses above 50MME/day without benefit, when opioids are combined with benzodiazepines, if pain and function is not clinically improved by opioid treatment[37]. Slow tapering is recommended.

ACUTE PRESCRIBING

An area of emerging policy interest is the regulation of acute prescribing. Increased duration of initial opioid prescriptions has been associated with an increased risk of long term opioid

Navindra Persaud, Sol Stern, Peter Tugwell, Per Olav Vandvik, Gordon H. Guyatt CMAJ May 2017, 189 (18) E659-E666; DOI: 10.1503/cmaj.170363

[36] https://www.ok.gov/health2/documents/Nonopioid_Treatments.pdf
[37] https://www.ok.gov/health2/documents/Pocket_Guide_Tapering.pdf

prescribing[38]. The CDC Guidelines for Prescribing Opioids for Chronic Pain recommend that prescriptions for acute pain be restricted to 7 days or less[39]. Kentucky, Massachusetts, Maine and New York are amongst states that place limits of the number of days that can be supplied when prescribing for a patient for the first time or when prescribing for an acute condition. PMP can be used to monitor adherence to any rules if the number of days' supply field is collected at the time of dispensing.

FENTANYL

The influx of fentanyl from China and Mexico, cut into heroin or pressed into illicitly manufactured opioid analgesics, is driving overdoses skyward. At the National meeting of PMPs it became clear that illicitly manufactured fentanyl (IMF) is a major driver of the overdose increase in North America and supply reduction efforts are focussing on disrupting the IMF supply chain in addition to prescribing related strategies. The Prescription Behaviour Surveillance System used PMP data compared with overdoses from synthetically manufactured opioids (primarily fentanyl). It was identified that, whilst prescription rates remained steady over the study period, overdoses associated with this type of drug increased and overdose deaths involving synthetic opioids tripled.[40] The potency of fentanyl provides a new incentive to prevent the transition to opioid dependency with a diminished window to provide access to treatment. Australia's fentanyl overdose rate increased 7.6 fold between 2001-2005 and 2011-2015.[41]

[38] Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1.

[39] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1.

[40] Prescription Behaviour Surveillance System (2017), Issue Brief, July 2017, CDC National Center for Injury Prevention and Control and Brandeis University

[41] Penington Institute 2017. *Australia's Annual Overdose Report 2017*, September, Melbourne: Penington Institute

RECOMMENDATIONS

Western Australia has an established prescription monitoring program and the Department of Health has committed to improving the current system through the timeliness of data provision and increasing health professional access to information. WA Health continues to work towards a national approach to prescription monitoring.

On the basis of investigation and analysis of prescription monitoring programs in the United States and Canada I recommend the Department of Health consider the following to facilitate the development of a best practice PMP in Western Australia.

DATA QUALITY AND STANDARDISATION

- Engage with stakeholders and external agencies to:
  - establish validation requirements for approved prescribing and dispensing systems and ensure those systems support quality data provision to the PMP
  - obtain health professional identifier reference data to facilitate streamlined PMP registration
  - educate pharmacists and implement strategies that improve the accuracy of patient record creation, including the collection of patient identifiers.
- Engage with the Commonwealth, States and Territories to:
  - develop and endorse a PMP reporting standard
  - establish a PMP data sharing framework
  - adopt a central drug reference set for controlled drugs that support state specific variance where required
  - develop or adopt a list of agreed morphine equivalent values for opioid medicines
  - establish a shared reporting framework for PMP data.
- Enhance local PMP systems to:
  - accommodate automated registration of health professional users
  - utilise established patient record matching practice and minimise manual intervention required for linking and record creation
  - receive additional patient and prescriber identifiers that improve matching as above
  - support alert types for both patient and prescriber risk.
- Establish a regulatory framework to support integration of PMP data into electronic medical records, including the development of minimum standards for data matching and data fields for display. Prioritise the development of an application programming interface that will facilitate integration with approved health IT systems.
- Investigate the regulatory impact of mandating electronic prescribing of controlled drugs and the following changes to reporting:
  - expanded reporting of all drugs of concern
  - number of days' supply
  - partially filled prescriptions.

EXTERNAL INTERFACE AND ENGAGEMENT

- Establish a PMP Advisory Committee to provide the Department with advice and recommendations on the implementation, operation and evaluation of a real time, online prescription monitoring system in Western Australia.
- Proactively engage other agencies to amplify the use of PMP data and achieve program objectives.
- Consider how access for different user types (perhaps with limited views of the system) may be aligned with the objectives of the program.

- Consider whether external data sources could be linked to the PMP to provide a broader picture of patient risk when considering the prescription of controlled drugs.
- Engage PMP stakeholders to determine how data may be used in various settings (clinical care, health service planning, research and evaluation) and how data should be received and displayed for each intended audience. Work with prescribers and dispensers to improve the utility of PMP data via web portal display and enhance PMP systems as required.
- Enhance PMP systems to:
    - incorporate additional features that improve communication and coordination of care, including lodgement of treatment contract and
    - ensure PMP data is made available in a variety of formats, including unit record level and aggregate data.

STRATEGIES TO INFLUENCE PRESCRIBING

- Establish a PMP use mandate and outline associated exceptions. Automated registration, education and training materials should be in place prior to any such mandate taking effect.
- Establish a protocol where PMP data is used to identify prescribers that may benefit from education and assistance in complying with the requirements of the *Schedule 8 Medicines Prescribing Code*. Utilise PMP data in evaluating the impact of such interventions.
- Establish a clinical support and review committee to provide the Department and prescribers with assistance in managing complex cases.
- Review the Schedule 8 Medicines Prescribing Code to:
    - ensure appropriate clinical-regulatory oversight where prescribing exceeds 50mg MME/day.
    - consider the impact of implementing restrictions on the prescribing of opioid medicines for acute conditions.

NEXT STEPS

The outcomes of my fellowship travels directly relate to my role with the Medicines and Poisons Regulation Branch of the WA Department of Health. The Department has already committed to replacing the existing prescription monitoring program, known as the Monitoring of Drugs of Dependence System, with a system capable of real time prescription monitoring and online health practitioner access. In the coming months I will work with WA Health colleagues to pursue the implementation of recommendations relating to the delivery of real time prescription monitoring in Western Australia. Further development of regulation, policy, systems and practice will be required to maximise the gains made through the implementation of a contemporary software solution.

Engagement with the agencies and organisations impacted by the implementation of real time prescription monitoring in Western Australia will be critical to program success. I intend to undertake a “PMP roadshow” to meet with different stakeholder agencies to discuss my Churchill Fellowship travels and the findings relevant to each group.

My findings support the necessity of ongoing discussions with Commonwealth, State and Territory counterparts to deliver national PMP data standardisation. A central data store that utilises advanced patient matching protocols and national health identifiers will provide benefit to individual State and Territory PMPs and also streamline cross-jurisdictional data-sharing and national surveillance, reporting and research.

APPENDIX

INTERVIEW GUIDE
Name of Agency
Agency type • *Health, drug enforcement, professional registration*
Contact name/title
Program name
Data collected • *List of data fields*
Frequency of data submission
Data quality • *Known issues and measures in place to prevent /address*
Authorised users • *Authorised user types* • *How are users provisioned access to the system* • *Auto-registration/streamlined registration?*
Delegate accounts • *Does the system allow authorised users to register other users/delegates* • *Impact?*
Information provided in a requested report • *How does a user request a report?* • *Format?* • *Fields?* • *Caveats to data use?*
Information provided in an unsolicited report • What triggers the creation of an unsolicited report? • Format? • Fields?
Prescribing profile reports • *Issued or on request?* • *Format?* • *Impact?*
Mandate • *Is system registration/ use mandated?* • *Limits?* • *Impact?*
Data sharing • *How is data used by other agencies?* • *Legislative/policy support*
Integration • *Does the system interface or integrate with other systems?* • *Data and format?* • *Impact?*
Prescribing guidelines • *Are there opioid prescribing guidelines that are applicable in the jurisdiction?* • *Are any of these mandated?*
Governance structure • *How is the program governed?*

INTERVIEW GUIDE
• *Oversight/steering committee or clinical reference group in place?* • *How are clinicians engaged with program development?*
Organisational structure • *Clinical vs administrative staff?* • *Investigators/case managers?*
Training/education/support for users • *Use of system?* • *User support?* • *Opioid prescribing and case management?* • *Engagement methodologies*
Program evaluation/research • *Assessing program impact* • *Research*
Challenges, successes, champions
Next steps