Michael G. DeGroote National Pain Centre

Nova Scotia Prescription Monitoring Program

Review and Recommendations

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Executive Summary

The Prescription Monitoring program in Nova Scotia is recognized nationally as a good example of a targeted program supported by quality educational interventions. It is a nationwide leader in such programs, and has sufficient experience now to initiate modifications in process and possibly governance to enhance its pursuit of its mission.

The goal of a Prescription Monitoring Program (PMP) is to ensure that there is appropriate monitoring of substances that have the potential to cause harm, including abuse and misuse, so that people who require such substances therapeutically still have the means to access these substances, while minimizing access to those who do not. In order to maximally achieve this goal, PMPs need to have all monitored prescriptions recorded electronically in an accurate fashion, and have historical data (information pertaining to patient, prescriber, pharmacy) available in this database. This information should be complete and available for dissemination amongst appropriate users who can analyze the information in a systematic yet swift manner. The format of the database should be simple to interpret, reproducible and standardized. The steps toward achieving these standards require resources and time, however they can be implemented through gradual refinement of current processes. If steps are not taken periodically to address gaps in the program, there is the potential for individuals to take advantage and circumvent the system for abuse and personal gain.

A significant case that was not expeditiously managed by the Nova Scotia Prescription Monitoring Program (NS PMP) prompted a review of current practices. An analysis of this case was undertaken internally, as well as seeking external consultation, prompting this written review by Dr. Norman Buckley, Vikas Parihar Pharm.D and Dr Ramesh Zacharias from the National Pain Centre (NPC) at McMaster University. Upon analysis of the index case, several areas of improvement were identified in this review. These recommendations include increasing transparency and consistency by permitting all PMP staff to see notes attached to case files electronically, escalating cases to the medical consultant earlier when medical expertise and interpretation are required (i.e. when doses are increased beyond a reasonable amount even when justified by the prescriber), instituting stricter practices around picking up prescriptions from pharmacies, and lastly increasing the number of staff so that rotation of cases can occur between staff members in order to mitigate unintentional confirmation biases and workload constraints.

Beyond the examination of the index case, this review prepared by the National Pain Centre has evaluated the current practices of the NS PMP and compared them to 40 best practice principles published by Clark et al, 2012. Out of the 40 best practice recommendations (Table 2), the Nova Scotia PMP adheres to 22 of the recommendations, 5 were partially adhered to, 12 were not adhered to and for one recommendation the status of adherence was unknown. Overall the program is adequate at detecting many areas of potential abuse and has made recent strides to refine monitoring practices, through the incorporation of new algorithms aimed at identifying high risk prescribing practices. Further

improvements to the NS PMP have been identified in this review by the NPC which include: measuring health related outcomes as opposed to surrogate outcomes, closing the controlled prescription loop by tracking individuals who pick up prescriptions from their pharmacy, mandating usage of PMP Data by physicians and pharmacists when making clinical decisions and monitoring non-controlled drugs and substances.

Further recommendations advocated by this review include discontinuing the monitoring of drugs not implicated in abuse, such as Acetaminophen and Acetylsalicylic Acid in drug utilization reports, to ease workload constraints. Additional refinements to the new prescriber risk scoring initiative can be made, such as measuring the overall change (percentage increase) in high risk prescribers rather than looking at static figures at a certain point in time. Lastly interpretation of prescriber risk scoring data must incorporate more critical analysis, such as impacts on rates of overdoses (fatal and non-fatal), abuse and addiction rates.

One simple recommendation which could have the effect of reducing or eliminating the risk of patient alteration or duplication of prescriptions as a source of diversion would be to permit direct faxing of prescriptions to pharmacies from physician offices. This would effectively eliminate paper 'hard copies' from the prescription process, pending introduction of a fully integrated e-prescribing program. Such a practice would also create a more direct communication between the physician office and the pharmacy as it would be necessary to establish the fax connection by having the patient identify the pharmacy with which they wished to work. It is our understanding that permitting faxed prescriptions would require simultaneous cooperation of the provincial regulatory bodies for pharmacy and medicine.

In terms of governance, it may be the case that prescribers will respond more assiduously to communications from the PMP if the PMP is governed under the auspices of the College of Physicians and Surgeons of Nova Scotia. As other Regulated Health Care Professionals enter the prescribing process for restricted substances, their Colleges will also need to be engaged.

This report, and the work of the PMP to date, has focused on high prescribers, but arguably very low prescribers are also part of the problem as their patients are driven to seek care in other practices where opioids are more available, possibly inappropriately.

Overall any suggestions made in this report will have to be taken in the context of current funding and available human resources, as implementing any of these reforms would require input from other parties, research and support from other government officials. We believe that this is an important program which should be continued.

Introduction

Nova Scotia is recognized nationally for an enviable program of prescription monitoring which incorporates a medical consultant and is supported by a province wide mentoring program for management of addictions and pain. The mentoring program has been linked with a similar program in Ontario to provide supplemental resources. Such programs fit well into the national strategy addressing abuse of opioids, the First Do No Harm (FDNH) strategy initiated and managed by the Canadian Centre on Substance Abuse. This strategy identifies among other things the lack of knowledge and awareness of optimal pain management as a root cause for inappropriate opioid prescribing. Additionally this strategy identifies the need to have readily accessible information about patient pharmacotherapy in order to avoid adverse drug interactions, accidental and deliberate multiple prescribing, inappropriate prescribing practice on the prescriber side, as well as prescription fraud on the patient side. The Nova Scotia PMP focuses on restricted drugs to the exclusion of other pharmaceuticals.

The following review of the Nova Scotia Prescription Monitoring Program (NS PMP) has been conducted by Dr. Norman Buckley, Chair of the Department of Anesthesia and Director of the Michael G DeGroote National Pain Centre at McMaster University, Vikas Parihar Pharm.D., Clinical Pharmacist at the Michael G. DeGroote Chronic Pain Clinic and Dr. Ramesh Zacharias, Medical Director of the Michael G DeGroote Pain Clinic. The goal of this review is to recommend modifications to the NS PMP to modify monitoring protocols, reduce harms from the use of controlled substances and reduce the risk of diversion of controlled substances. An analysis of the index case which prompted the review of the NS PMP, a critique of current elements of the program as well as additional recommendations to best practice principles will be discussed.

Current Operational Process of the Nova Scotia PMP

In order to appropriately analyze the process by which prescriptions and physicians are monitored by the NS PMP, a process map outlining the case recognition and resolution of such cases by Drug Utilization Reports (DUR) in Figure 1, and the newly instituted prescriber risk scoring algorithm in Figure 2. At the end of this report, we include Figure 3 which represent our suggested modifications of these processes to incorporate best practice recommendations.

Figure 1 – Current Process Map for DUR Generated Case Reviews

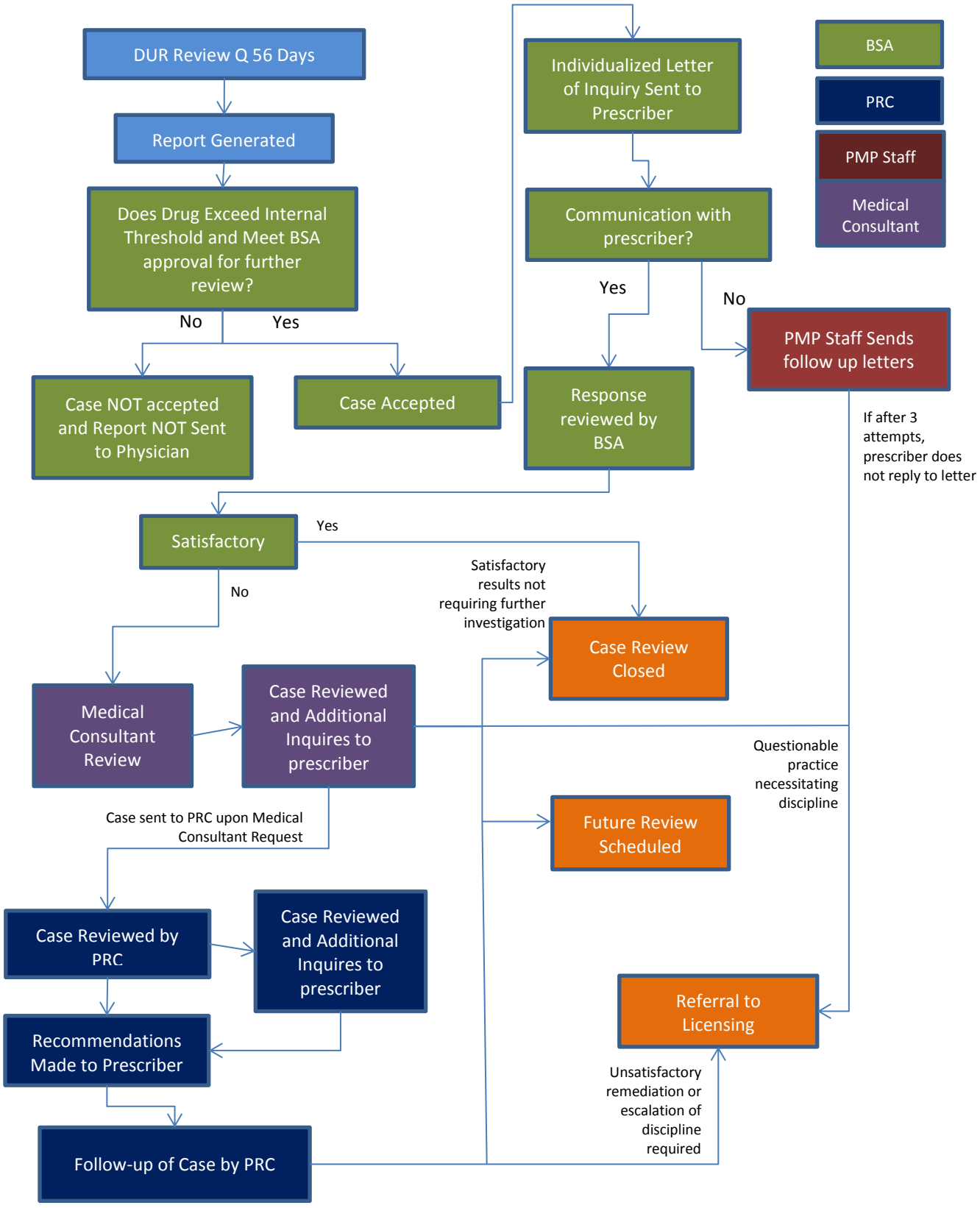
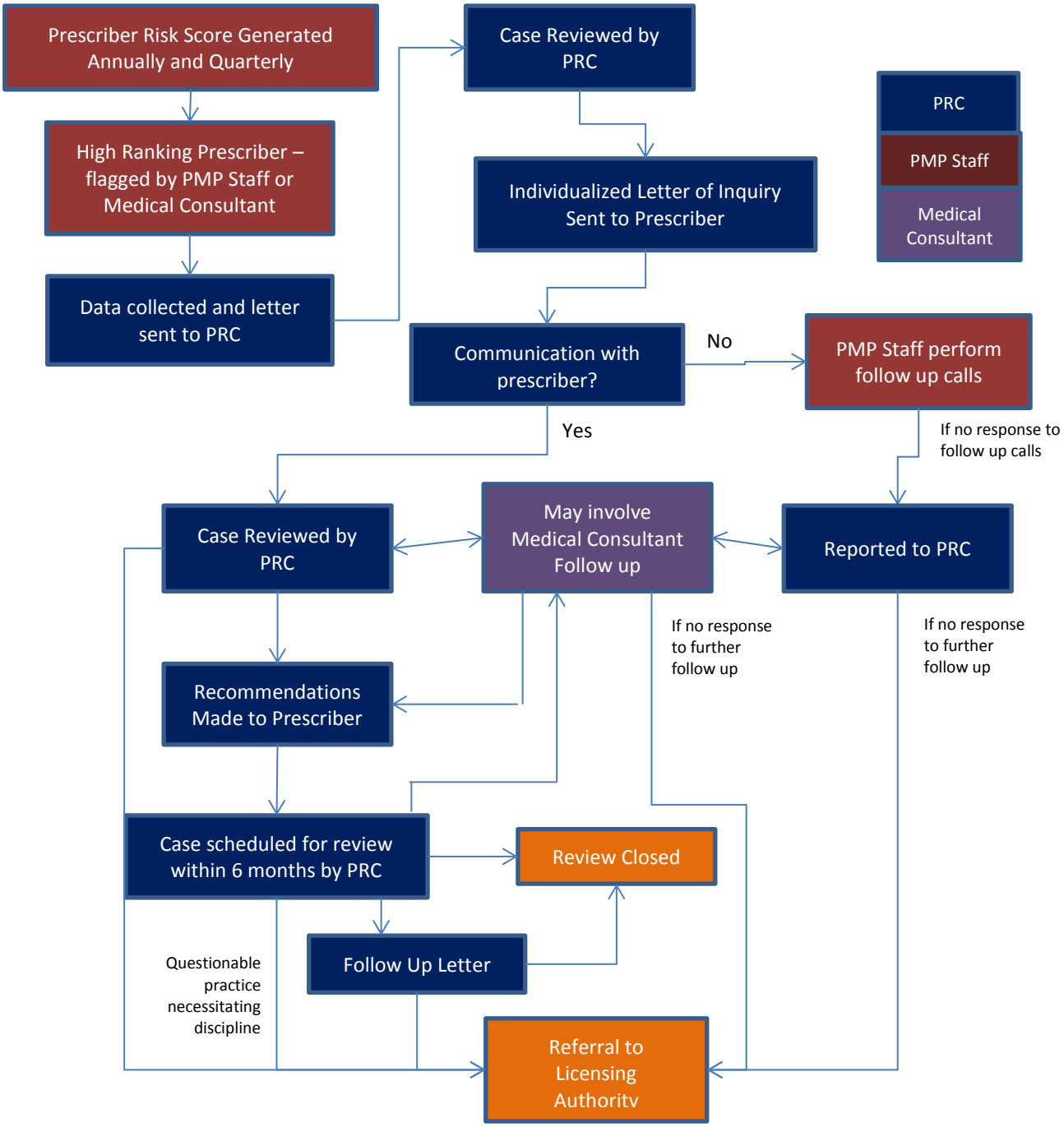


Figure 2 – Current Process Map - Prescriber Risk Scoring Monitoring and Case Reviews



Review of Index Case Prompting PMP Review

The case involving a physician diverting prescription opiates from 2010-2016 has been summarized in Table 1, for ease of interpretation and to demonstrate the chronological flow and interventions proceeded.

Table 1 – Timeline of Index Case			
Date	**Report(s)**	**Intervention**	**Findings**
Jan 26 2010	Physician in question identified on "Multiple Prescriber Report."	Letter sent to physician regarding patient being identified on report.	
October 21 2010	**Medical Consultant** contacted by College of Pharmacists of Nova Scotia in regards to the physician in question delivering patient`s medications.	**Medical Consultant** communicated to physician that it is not advisable to deliver medications – provided options of blister packing or daily prescriptions as suitable alternatives.	Notes were recorded in medical consultants note book. ***Not recorded in PMP Intervention System for future reference.***
July 16 2011	Physician is first identified on a Drug Utilization Report (DUR).	Not accepted as a case.	
April 27 2012	Subsequent identification on a second DUR Report.	Accepted as a case for review. Letter sent to physician by PMP regarding the rationale behind the escalation in prescribing of narcotics.	Retrospective finding – **630 tablets/month** were prescribed for the patient from October 2011 to March 2012.
June 14 2012	Physician provided feedback to PMP staff.	Case Closed – not escalated to **Medical consultant.**	Physician provided rationale for escalation – the patient had multiple co-morbidities, being closely monitored, patient/physician agreement in place, recently weaned off of benzodiazepines.
December 2012	Number of tablets prescribed **exceeded 1000/month.**		
December 2013	Subsequent identification on DUR report.	Accepted as a case for review for a second time. Letter sent to physician by PMP regarding the rationale behind the escalation in prescribing of narcotics.	The patient was receiving **2,580 tablets per month.**
February 2014	Physician provided	Case closed – not escalated	Physician provided an

	feedback.	to **Medical consultant.**	outline of steps taken to monitor patient, and reported that patient had no indication for misuse/abuse/diversion. Increase in prescribing volume had resulted in increased quality of life.
March 31 2014	Pharmacist dispensing medication to patient sent a report to the PMP regarding physician delivering medication to the patient and increases in doses of medications.	Concern was recorded and file remained closed due to recent correspondence on file by prescriber. Not escalated to the Medical Consultant.	
February 25 2016	Physician was charged with several crimes related to trafficking of monitored drugs.		

An internal review of this case and NS PMP operations were performed, which resulted in several preliminary recommendations being made:

1. Adjustment of systems and resources to ensure all information available to support case reviews are documented in the PMP system for future reference.
2. A step-wise process is required for review of individual files.
3. The staff members processing DUR reports should be alternated each 56 day period to support an additional layer of analysis added to the process.
4. Change the DUR and related intervention reporting recommendations (e.g. pill count volume reporting).
5. Additional resources should be added to support more in depth case analysis and increased medical consultant involvement in case reviews.
6. The overall mandate and role of the PMP should be reviewed in collaboration with the PMP Board and DHW.

National Pain Centre Critique of the Index Case & Root Cause Analysis

Upon analysis of this case, there are several keys points in time at which interventions could have taken place that would have prevented the final outcome or could have resulted in the identification of diversion much sooner. Proceeding in chronological order, it was noted that the medical consultant upon initial review of the case in October 2010, made notes and recommendations that were kept in a private notebook and not recorded in a centralized database. Had this information been accessible to PMP staff at subsequent points in the investigations that followed, it is likely that the Business Support Analyst (BSA) would have escalated the case to other individuals, higher in the chain of

command at an earlier time point (after the first DUR report) once the same prescriber and patient were flagged again for the same reason. A solution to this issue would be to develop a centralized record system where cases and affiliated notes made about a prescriber or patient by PMP Staff and the Medical Consultant are available to all parties, in a chronological order. This would be analogous to the customer service record or log instituted by companies with call-centre service processes, when clients call and request assistance over a series of interactions.

Secondly, although the responses provided to the BSA and other PMP staff concerning patient characteristics (i.e. increased pain control with increased doses/quantities of medication) and procedures in place to monitor the patient were well documented by the physician, such escalation in doses/volume of pills is in contradiction to what is currently believed to be optimal pain management. Escalating doses, particularly from 600 tablets to approximately 2600 tablets indicates that this patient's pain is not under control, and rather than prescribe the same medication at higher doses, alternate medications should have been instituted. In order to correctly identify and assess such a discrepancy from a physician's report, whenever a notable change (200-300% increase) in dose/quantity prescribed is noted, such cases should be referred to the medical consultant rather than dealt by the BSA or other PMP staff (i.e. in reference to events on June 2012 & Feb 2014). The Medical Consultant would be responsible for being aware of the most up to date recommendations, such as the prescribing guidelines available at the National Pain Centre (the Canadian Opioid Guideline, National Opioid Use Guideline Group- [NOUGG], 2010) and Centers for Disease Control (CDC) which advocate that escalating doses do not necessarily equate to safer or better outcomes.

Thirdly, it is highly unusual for a patient to designate their physician as their contact to pick up and deliver prescriptions. The vast majority of pharmacies are capable of delivering medication at a low or no cost to patients. In addition, some pharmacies operate by mail order if locales are distant. Concerns were raised on two separate occasions (October 21st, 2010 as well as March 31st, 2014) by pharmacists. In order to prevent such a situation from happening again, either a warning should be given or a flag should be raised if a prescriber appears to be the one ordering and picking up for the patient as controlled substances have a high likelihood of being diverted for personal use if an individual is involved in the process of ordering/dispensing/delivering of medications. Additionally, banning the practice altogether (i.e. physician delivery of medications) would ensure that such an occurrence will not be repeated in the future. Instituting a system to identify persons picking up prescriptions (through the presentation of government issued ID at the pharmacy) would also serve as a means to enforce such a ban.

Lastly it is likely that had the prescriber risk scoring initiative been implemented sooner, the program would have identified this prescriber earlier as needing an investigation and the case would have been forwarded to the PRC for a comprehensive review. We also feel that is prudent to have additional staff members (most importantly a second medical consultant) so that rotation of cases can occur to provide a fresh perspective on a case that has already been flagged before and reviewed by another medical consultant. It would also allow for more cases to be reviewed, and mitigate potential backlogs created by time needed to be taken off by having one medical consultant on board. This would also eliminate the systemic risk of having a key program dependent upon a single individual who may become ill, move practice or be on vacation.

Best Practice Recommendations

In order to ensure that the Nova Scotia Prescription Monitoring Program is as effective as possible in achieving its mandate, a systematic comparison of current practices to PMP best practice principles was conducted. A review of the literature by the NPC identified several guidelines outlining best practice recommendations, however a publication by Clark et. Al, 2002 was selected as the primary source material for this review due to its detail and comprehensiveness. Out of the 40 best practice recommendations advocated by this review (refer to Table 2 for specific recommendations), the Nova Scotia PMP adheres to 22 of the recommendations, 5 were partially adhered to, 12 were not adhered to and 1 recommendations adherence to best practice was unknown.

I. Areas of compliance to best practice recommendations

The Nova Scotia Prescription Monitoring Program does adhere to a majority of these best practice principles as outlined by Clark et. al 2012. The collection of prescription data on all controlled drugs and substances listed under the Controlled Drugs and Substances Act (with the exception of benzodiazepines) is a noteworthy example. As patterns of prescribing, dispensing, utilization by patients (legitimate & illegitimate) changes over time, it is critical that any program should monitor all drugs with the potential for abuse and misuse as well as make adaptions to the program based on these trends. We advocate the addition of monitoring benzodiazepines (which is projected to be included as a monitored medication approximately in Sept 2016), as these are medications that are liable to abuse and diversion as well as implicated as a causative agent in overdoses (both fatal and non-fatal).

Other positive aspects of the program includes the linking of patient identifiers to prescription records at multiple access points (physician's office and/or pharmacy), which allows for tracking both specific patient use and prescriber use patterns. Security measures such as serialized prescription pads, pharmacy audits, and the generation of DUR reports/prescriber risk scoring initiatives all culminate in preventing fraudulent activities. Lastly, promotion of the program through bulletins on the PMP website and educational sessions emphasize the importance of the program and why it is relevant, which facilitates usage of data by end users (i.e. physicians and pharmacists) to incorporate this information into their prescribing and dispensing practices.

II. Areas of partial compliance to best practice recommendations

Although the program adheres to a majority of best practice recommendations, some areas can be improved upon. Partial adherence refers to incomplete implementation of a best practice recommendation. We identified four such examples.

A. Collection and Submission of Data

The program collects prescription information throughout the day at the pharmacy level, which is accumulated before it is sent to the PMP. This occurs 5 times per day. However, if the system were to send information more frequently with a closer approximation to real time submission and analysis, this would reduce the lag time during which suspicious activity would

go undetected. For example, fraudulent prescriptions if rejected by one pharmacy can be taken back by a patient and presented at another pharmacy and filled if the second pharmacist is unaware that it has previously been rejected. In addition, this second pharmacy can inform law enforcement or the physician of such activities if made aware sooner, increasing the likelihood of apprehending the individual. Therefore steps made to increase the throughput and analysis of real time information from the pharmacy level to the PMP is important in identifying fraud in a timely fashion.

B. Determine valid criteria for questionable activity- both prescriber and patient

The impact of the prescribing risk scoring initiative by the NS PMP in the reduction of the quantity of tablets prescribed, as well as days supplied amongst high risk prescribers, is an indication that implementation of such a program has net benefits in the reduction of the amount of controlled substances being prescribed at a single time to a patient, which can be overused or misused. Currently the NS PMP does not have defined criteria for the development of an analogous algorithm to score/flag patients who are heavy users of controlled substance(s) who would be at risk of harmful outcomes (such as overuse or misuse).

We suggest the development of such an algorithm, based upon epidemiological data which identifies patients at high risk for abuse and misuse within the province (i.e. age, gender, geographic area, medical conditions etc.) supported by evidence from healthcare literature. The implementation of a patient specific algorithm would allow the PMP to detect users who have unusually high or otherwise risky usage, rather than solely using prescribing patterns amongst physicians and nurse practitioners as the source of identification and intervention in monitoring controlled substances. Once a patient is identified, unsolicited reports could be sent to the primary care providers to address these concerns.

C. Develop expert systems to guide analyses

The use of expert systems and algorithms to identify problematic situations from review of data sets has the potential to sort through large amounts of data while minimizing the use of personnel time and individual decision making, or the potential impact of human error. Although the startup costs to develop such systems can be significant, once such a system is developed and refined dividends are realized. For example a successful expert guided system can allow for redeployment or even reduction in some staff levels, increased surveillance and detection of suspicious persons (prescribers/pharmacies/patients) and overall net decrease in population level misuse and abuse of controlled drugs and substances.

It was apparent in the past that such systems at the NS PMP would lead to high numbers of cases being flagged for review. This can be avoided in part by the continuous refinement of the expert guided systems or changing the thresholds (i.e. the top 10% of prescribers vs top 15% prescribing benzodiazepines) at which point the cases flagged would require manual review by a staff member. Collaboration with other PMP programs across Canada or in the U.S. can also serve as a means to learn from others' experience and determine what automated systems have either worked or not worked, so as prevent "reinventing the wheel."

D. Conduct promotional campaigns

Promotion of the NS PMP's mandate, surveillance methods, activities and successful impact on prescribing behavior is an important aspect that could be further elaborated in practice. Promoting the NS PMP's impact factor and mandate can serve as a means to preserve funding and even to obtain more funding from other (perhaps non-traditional) sources. Currently promotional information is posted on the program's website and in an annual report, which is a passive form of promotion. Active promotion includes the use of outreach initiatives, such as promotional information at professional association conferences (i.e. information booth), as well as education seminars at continuing education events. It can also take the form of ads (on buses, billboards, posters at pharmacies, television, radio, internet) aimed at the general public, so as to make them aware how such activity is of benefit to them and also to serve as a deterrent to those wishing to abuse the system. The role of social media in such instances is less clear to us, but any information which would be deemed suitable for release to the public in the form of reports, news releases, information bulletins to health care professionals etc. would certainly also be suitable for promulgation through social media channels.

III. Areas of non-compliance to best practice recommendations

A. E-Prescribing, EHR & PMP Database linkages

There exist several recommendations that cannot be put into practice at this time, due to the unavailability of e-prescribing initiatives in Nova Scotia. These include linking e-prescribing to the PMP database, which would allow real time information flow from the PMP to the prescriber or the prescriber/pharmacy to the PMP. Such a linkage would allow prescribers at the point of prescribing (or the pharmacist at the point of dispensing) to see an alert generated by the PMP on their screen if a patient were to have additional controlled substances prescribed. Additionally, if the prescriber were to electronically order a controlled substance, this would send the prescription information in real time to the PMP for monitoring, as well as the pharmacy, thereby preventing delays where action can take place. Overall this form of integration of technology can allow physicians to avoid prescribing controlled substances to patient's with questionable history, minimize the amount of inappropriate medication ordered and dispensed, as well as reduce the 'back end workload' in prescription monitoring and running reports at the PMP (i.e. DUR, multiple prescribers etc.).

Another area of benefit from integrating EHR and the PMP database is to inform other prescribers or pharmacies of the previous or current disciplinary status of prescribers/pharmacists who have been or who are involved in the care of the patient (through automated alerts when a prescription is being written or the patient's electronic file is being accessed). This would allow these healthcare professionals to use their clinical judgment to determine whether a prescription should be given or not in such circumstance.

Future initiatives at modernizing prescribing practices and generating a universal system will likely be undertaken by provinces across the country. However when such systems are built, a cornerstone to ensuring safe and effective prescribing and monitoring of controlled substances would be to have it interfaced with the PMP database from the start, rather than build an e-prescribing system and then have it interface with the PMP database at a later time point. Ultimately the single largest initiative that can be instituted to improve the NS PMP would be to develop an e-prescribing/EHR interface to support the prevention of abuse of controlled substances.

B. Collect Positive ID on persons picking up prescription

One area of improvement to the NS PMP that can be implemented to minimize diversion is to have a mechanism by which the person to whom the prescription is prescribed is verified as the individual who picks up the prescription at the pharmacy, forming a closed loop. Such a system serves as a deterrent to persons whose aim is to pick up another person's prescription for the sole purpose of diversion (i.e. friend, or family member). Furthermore, it allows the pharmacy to send this information to the prescriber, so that if a patient reports their prescription was lost in transit, it can be verified to whom the prescription was given to.

The index case which prompted the review of the program, in part had issues in which the physician was both prescribing the medication to be dispensed and also was the agent who was picking up the prescription, which appears to have enabled the physician to divert medications for personal use. To avoid such a specific scenario, a provincial standard that prescriptions for controlled substances should not be picked by the individual prescribing them would need to be established, which can be enforced by having a system to collect the ID of any person picking up a prescription.

C. Mandating Utilization of the PMP Database prior to prescribing & delegating access.

The surest way any system can enforce compliance to standards is to build them in such a way that they become a forced function. Mandating that all (or all new) prescriptions for controlled substances first require an online check of the PMP database at the prescriber's end or pharmacy's dispensing end, would ensure that the information necessary for a physician or pharmacist to avoid the inappropriate ordering and dispensing of controlled substances to questionable patients is made available. E-prescribing interfaced with the PMP database would further support this goal, as alerts would be generated to physicians/pharmacists without having to log on to the online PMP database or call the PMP to request this information.

However, as e-prescribing & electronic health record initiatives require significant time to build, in the interim mandating that all (a majority) or a random selection of prescriptions for controlled substances require a database check, can be instituted to prevent double doctoring.

As it can be cumbersome for a physician or pharmacist to access the online PMP database for every prescription, allowing these professionals to delegate access to other staff members involved in the circle of care of the patient (i.e. physician assistants, nurses, secretarial staff, pharmacy technicians/assistants) would also increase compliance to this standard.

D. Enact interprovincial data sharing among PMPs

Individuals who are likely to abuse controlled substances may go to great lengths to find ways in which they can obtain prescriptions from multiple prescribers. Due to the fact that Nova Scotia is in close proximity to several provinces (i.e. New Brunswick and PEI), individuals can travel between provinces and bypass the NS PMP by seeking out prescribers in other provinces to prescribe controlled substances to them. This is especially problematic in bordering townships, where access is much easier to out of province prescribers and pharmacies.

Coordination with other provinces, although difficult, ultimately would prevent such occurrences of doctor shopping/access to multiple prescribers/dispensers across provincial borders. In order to facilitate such a process, uniform reporting standards would need to be agreed upon amongst PMPs and health agencies in all collaborating provinces. Once a formalized information sharing agreement is agreed upon between provincial jurisdictions, this information would then be accessible to a patient's health care providers, who can in turn make informed decisions and take corrective actions to prevent further abuses from occurring.

E. Measuring Clinical Outcomes with Changes to NS PMP Standards

The prescriber risk scoring initiative enacted recently assessed the impact of sending Unsolicited Reports to prescribers deemed at high risk of prescribing medications in a potentially unsafe manner. The outcome of this initiative was a decrease in the total number of tablets prescribed at a given time, as well as the duration for which a prescription was ordered (prescriptions lasting more than 30 days). Although these measurements seem meaningful, these are considered surrogate outcomes of abuse and misuse of controlled substances. Measuring longitudinally (either prospectively or retrospectively) changes enacted by the NS PMP with clinical outcome measurements (i.e. rates of prescription opioid addiction, non-fatal and fatal overdoses) would provide legislators with valuable concrete information regarding the impact produced by the NS PMP (as well as documenting the increased need for surveillance as advocated by the NS PMP). Such data would ultimately serve to demonstrate to government officials that the funds expended upon these further programs, staff and surveillance measures had real value in terms of healthcare outcomes.

F. Collect data on non-scheduled drugs implicated in abuse

Monitoring non controlled drugs implicated in abuse, such as dimenhydrinate or dextromethorphan, as well as substances used to manufacture controlled substances (pseudoephedrine) is another area in which the NS PMP can be effective at preventing drug abuse. Recording sales of such medications or having patients provide a health card number if they were to purchase these drugs in large quantities, from behind the counter at a pharmacy

(i.e. dimenhydrinate in quantities above 100 tablets), would permit the NS PMP to collect information on drugs often overlooked by monitoring systems but which may be used in drug cocktails and implicated in adverse health outcomes (overdose & hospitalization).

Additional Recommendations

A. Modification of categories on the DUR Intervention Report

Acetaminophen, Acetylsalicylic Acid and Codeine are available as OTC products, and do not explicitly require a prescription. As individuals are able to obtain these drugs from alternate sources (i.e. non-pharmacy sources such as corner stores, service stations etc.), the true scope of usage is confounded and the significance of monitoring these drugs is diluted. Hence, it would be more appropriate to invest the limited resources available to monitor drugs or products in monitoring those drugs or products that are uniquely obtained via prescription that can cause harm, such as benzodiazepines and pseudoephedrine as examples.

B. Modifications to the prescriber risk scoring tool

The introduction of the prescriber risk scoring algorithm to rank prescribers at highest risk of unsafe practice and sending detailed Unsolicited Reports is a method incorporated into various PMPs in other jurisdictions. Our observation of the data that was sent to the NPC suggests that it appears to have been an effective measure for reducing the number of high volume prescriptions (prescriptions of large quantities of tablets and/or for long periods of time).

Although the net number of prescriptions for tablets greater than 540 and between 360-539 decreased 31.9% & and 24.9% respectively after the introduction of prescriber risk scoring, it should be noted that this figure may be misleading. Prescribers identified by the Risk Scoring Initiative may adapt their methods to prescribe alternate drugs, with the same potential for harm or diversion that are not under surveillance. This has been seen during analogous monitoring system changes in the US (Hartzema, 1992; Weintraub, 1991). In order to evaluate the overall impact of the prescriber risk scoring algorithm, the PMP would need to track changes in trends in prescribing – both decreases and increases of various different medications - to assess both the intended and unintended consequences of this intervention.

Furthermore, prescribers may adapt their prescribing to still prescribe high volume of tablets, but with shorter intervals. For example a prescriber flagged for providing a patient with 400 tablets over 60 days may opt to change the prescription to 200 tablets over 30 days, which over a 60 day period is the same amount of tablets prescribed, but the prescriber or patient would not be flagged by the current risk prescriber algorithm. A recommendation to reduce this risk is to track the cumulative or aggregate number of pills prescribed to an individual patient over a 6 month or 12 month period.

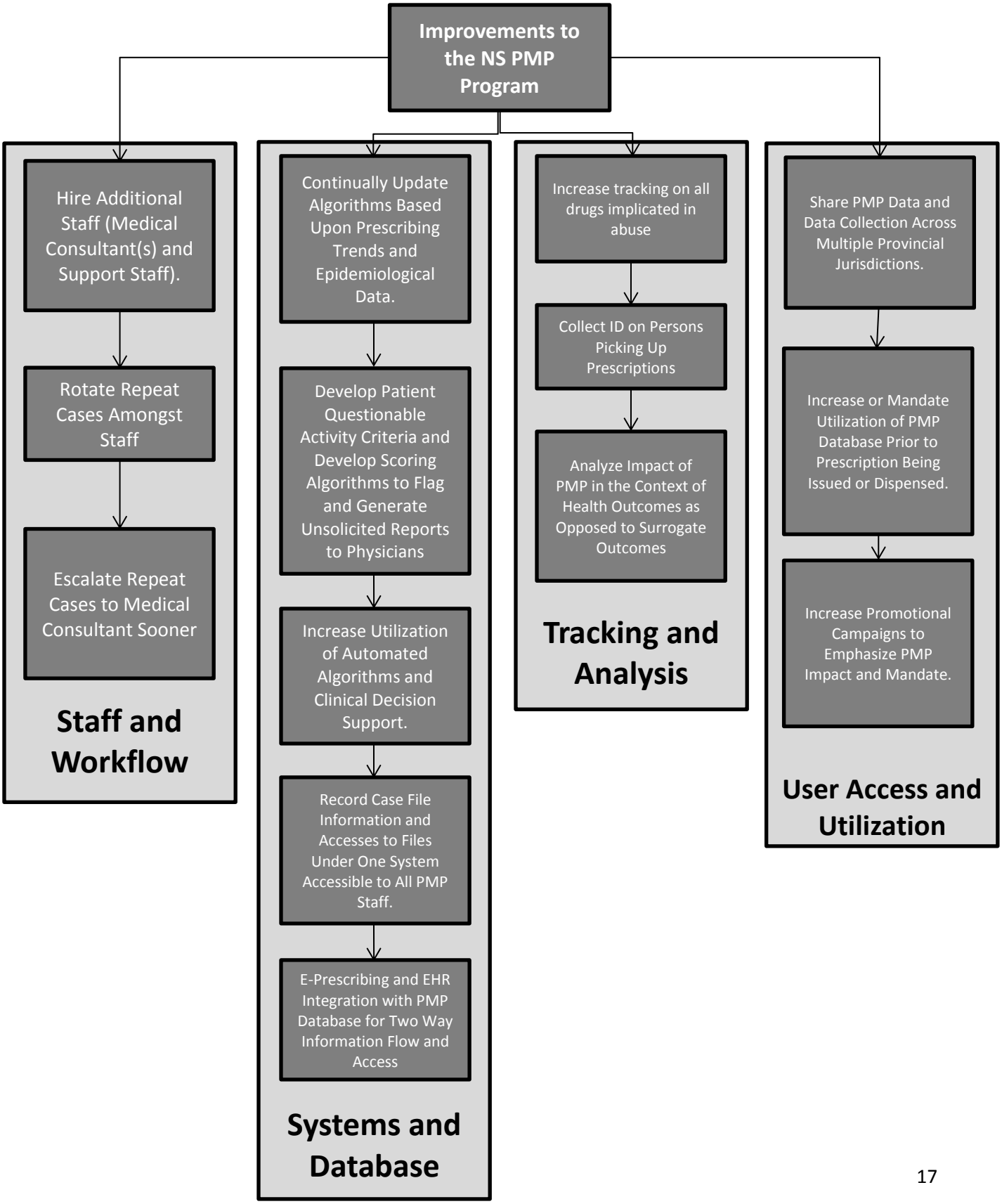
Lastly assessing the number of tablets does not accurately represent the risk of prescribing high dose narcotics. For example if a prescriber were to provide Morphine 50 mg, as 5 tablets x 10 mg but change the prescription to 1 tablet x 50 mg, the dose is still the same but the prescriber has reduced the overall pill count 5 times. Therefore the prescription which was flagged by the risk scoring algorithm can

be modified to still provide the same dose but, would not trigger a report unless the data were analyzed manually and the total dose noted. To mitigate this effect, it would be prudent to track the total daily dose per prescription rather than numbers of tablets, before and after the introduction of unsolicited letters sent to high risk prescribers, as well as adjusting the weighting of the morphine equivalent total to a higher impact on the risk scoring algorithm.

An additional area in which there seems to belittle or no focus (either in the Nova Scotia PMP or literature in general) is on the very low prescribing cohort. Little data is available to address this, but there will be some patients who do require opioid therapy, who benefit and who are using medications appropriately, in virtually every practice setting. Thus it seems inappropriate to find a prescriber who has little or no opioid prescribing in their profile. Some practices go so far as to post signs indicating that they do not prescribe opioids at all, which is outside of any understanding of management of patients in primary care. Perhaps this is seen as a low risk cohort form the standpoint of overdose, but to some extent non-prescribing will drive a portion of patients from that practice into other practices which may already be overburdened, or perhaps may represent a cohort with less appropriate overall attention to the care of the patients in question. In all likelihood this area of monitoring and intervention is a complex problem, but should not be ignored.

In summary, periodic analysis and refinement of the risk prescriber scoring tool should be undertaken to account for factors which may have been missed or deemed less significant upon its creation. This would result in a dynamic risk scoring tool that adjusts to changes in demographics, prescribing habits and drug usage over time while maintaining appropriate surveillance.

Figure 3 – Proposed Recommendations to NS PMP Based on Best Practice.



Conclusion

As noted at the outset of this report, Nova Scotia has an enviable program for prescription monitoring and the medical oversight of prescribing of restricted substances. Despite many successes in its operation, a significant case of active deception carried out by a physician escaped detection over a period of time until ultimately the fraud was detected when a change in patient status led to detection of the prescribing fraud. The fraud was apparently made apparent when application of the system (review of patient prescribing status) was carried out by a second prescriber/emergency department and the fraud was detected. There were several points prior to this when the system might have detected the fraud earlier, had slightly different practices been in place.

We have reviewed the case in question and made comments, and in addition carried out a review of the PMP itself, comparing to what is suggested as best practice in a PMP. The work supporting that best practice archetype comes from work done to support the First Do No Harm strategy of the Canadian Centre on Substance Abuse, a national strategy directed against prescription drug misuse and abuse, which has been led in part by representatives of the Nova Scotia Department of Health.

Very specific recommendations are contained in the tables included in the report, comparing the Nova Scotia system to the archetypal best practice system. Some recommendations arise from a systems vantage point- for example, it would be very wise to have more than one medical consultant involved. Even if there was no increase in total time commitment (although there is a case for increasing time dedicated to the program) it is always problematic to be dependent upon a single individual for an important program. Having two or three individuals who each provided part time support to the program would spread the responsibility, provide for a ‘sounding board’ for difficult issues, and eliminate the risk that the program would founder should the single consultant become ill, or move their practice.

It is our belief that no system is immune to the deliberate deceptive practices of a skilled and knowledgeable individual who sets out to commit fraud, and in this case it must be said that in the end the fraud was detected by the system. However it is also the case that as always there are improvements which can be made to make the system more effective and responsive to changes in best practice as this becomes known through research and education.

We hope that this report is of assistance in the review of the program and thank you for the privilege of carrying it out.

Appendix A

Table 2 – Current Adherence to Best Practice Recommendations (Clark et al 2012)				
Category	**Recommendation**	**Rationale**	**Currently adopted by NS PMP**	**Barriers to Adoption**
Data collection and Data Quality	1. Collect data on all schedules of controlled substances	A variety of drugs have the potential for abuse. Not tracking multiple drugs that can be abused underestimates the rates of doctor shopping. Therefore prescribers may not be alerted of hazardous use of prescription medications.	Yes - Monitors all drugs listed as controlled under the CDSA, with the ***exception*** of testosterone (compounded) and benzodiazepines (projected to begin monitoring Sept 30, 2016)	Cost of monitoring many drug classes.
	2. Adopt a uniform reporting standard (i.e. standardized template)	Allows for collaborations with other facilities (public and private agencies), inter-provincial programs, easier collection, use and analysis of prescription history data.	Yes a reporting standard is present, however specific to the prescription monitoring program (and not other agencies).	Upgrading costs and additional staff resources
	3. Collect data on non scheduled drugs implicated in abuse	Certain drugs classified as unscheduled or schedule II & III are used as drug cocktails or used to produce illicit drugs. For example, pseudoephedrine used for the production of methamphetamine. Additionally dimenhydrinate (gravol) is a drug of abuse when consumed in large quantities.	No – there is no tracking of non-controlled medications indicated in abuse or of substances used to manufacture controlled substances.	Patient privacy concerns, regulatory measures would require alterations, increased restriction to unscheduled medications, opposition by pharmaceutical manufacturers and pharmacies.
	4. Collect Positive ID on person picking up prescription	A large degree (cited as upwards of 38%) of prescriptions have the potential to be picked up by a person other than the one being prescribed. Therefore this opens up the opportunity for	No – the PMP does not track if a delegate receives the prescription on behalf of whom the	Costs to establish and electronic database and collection program of government issued ID,

		diversion. Implementation of this standard can decrease diversion, particularly for private and cash paying individuals.	prescription was prescribed.	increase wait time for prescriptions at the pharmacy and physician's office.
	5. Collect data on method of payment	Individuals who pay for cash for the controlled prescriptions (i.e. cash vs. credit, debit, insurance plan or pharmacare program) have a higher likelihood of doctor shopping and prescription diversion.	No – the PMP does not receive information on whom the payer is at point of sale.	Patient privacy
	6. Reduce data collection interval; real-time data collection	Real time data compared to data submitted once weekly or bi-weekly decreases the turnaround time and increases the speed at which questionable prescribing or diversion can be detected and acted upon.	Partially – data sent 5 times per day. In the future this will be increased to hourly submission to the PMP.	Cost, staff time, information technology upgrades
	7. Institute serialized prescription forms	Unique prescription pads sent to prescribers have a propensity to reduce prescription fraud, as a particular pad can be reported if stolen from the prescriber and all subsequent prescriptions can be canceled/tracked.	Yes – potential for discontinuation pending e-prescribing or other methods being implemented.	Increased screening for serial numbers (staff time), increased printing costs
	8. Integrate e-prescribing with PMP data collection	At the point of prescribing, data would be visible to the prescriber to alert them of any additional controlled substances prescribed. If the prescriber were to electronically order a controlled substance, this would send the prescription information in real time to the PMP for monitoring, as well as the pharmacy. Overall integration of technology to minimize increase in back end workload in prescription monitoring and running reports (i.e. DUR, multiple prescribers etc.)	No – e-prescribing is not currently available, hence integration with PMP not possible as of yet.	Costly implementation province wide, uniform standard of e-prescribing would need to be initiated and agreed upon by many parties.
	9. Improve data quality	Accurate collection of data (inputted and submitted information from the pharmacy and physicians office to the PMP), allows the PMP to analyze a closer representation of the actual	Yes – pharmacies are audited at least once every two years of monitored prescriptions	Increased cost of surveying data collection practices, establishing a set of

		prescribing patterns and use of medications. Poor data collection practices can produce misleading and misrepresentation of the true state of prescription abuse/misuse, i.e. 'garbage in = garbage out,' therefore making reports (whether they be unsolicited or solicited) based on poor quality information less meaningful.	to the PMP, in regards to accuracy of the data submitted and what is written.	uniform standards for reporting.
Data linking and analysis	10. Link records to permit reliable ID of individuals	Linking records of unique individuals increases accuracy of identification.	Yes	Establishing a linking algorithm, identifying which form(s) of ID would need to be collected that would be the most convenient and apply to the majority of the population.
	11. Determine valid criteria for questionable activity	The NS PMP has determined several criteria for questionable prescriber activity and performed validation measures. No identified questionable activity measures were noted in this review in regards to identifying at risk patients. Several studies have indicated that male gender, ages 18-34, filling four or more opioid prescriptions, filling prescriptions from 2 or more pharmacies, early refills, escalating doses, were best predictors of a patient's opioid abuse potential. Unsolicited reports would then be generated and sent to the prescriber from this information.	Partially – Prescriber defined questionable activity has been implemented, however no patient defined questionable activity has been established.	Lack of agreed upon standards to formulate ideal questionable activity criteria.
	12. Conduct periodic analyses of questionable activity	Periodic analyses of patients and prescribers rates of prescribing and use of opioids.	Partially - Measures prescribers questionable activity, through the use	Lack of program resources

			of prescriber risk scoring and DUR reviews.	
	13. Conduct epidemiological analyses	Collection of geographic data (county, postal code, town, pharmacy etc.) and linking this data to opioid/controlled substance use/abuse.	Yes	Lack of resources, Lack of familiarity with conducting such analyses, Communication amongst many agencies
	14. Develop expert systems to guide analyses	The use of automated systems (decision making algorithms) to identify and sort questionable activity, prescribing trends. Such systems can efficiently sort through and partially analyze large volumes of prescribers/patients.	Partially –Last auditor general's report (2014) identified the need to reduce manual review and optimize cases that are accepted for review. Proposals have been made to DUR redesign.	Development costs and operating costs.
	15. Record data on prescriber disciplinary status and patient lock ins	Linking prescription record data on prescribers' death or disciplinary status (i.e. College of Physicians) electronically. Allows for real time intervention at the pharmacy as well as referral to colleges for discipline.	No	Lack of resources
User access and report dissemination	16. Provide continuous online access to automated reports	Online access for prescribers and pharmacies to access patient/prescriber/pharmacy data in regards to prescriptions dispensed, dates of dispensing, interventions etc. This increases the use and impact of the PMP. This practice has been adopted largely in most U.S. jurisdictions.	Yes – Online access is available to prescribers and pharmacists.	Privacy concerns, costs and technological support issues.
	17. Optimize reporting to fit user needs	The display of information in reports can be highlighted and suppressed depending on the end user. This can emphasize information pertinent to the user and make it more meaningful, therefore likely to be acted upon.	Yes – Standardized reports are available online. Individualized reports can be sent by the PMP by mail or fax based on the user's needs.	Development and implementation costs.

	18. Integrate PMP data with health information exchanges, EHR	Integrating PMP data retrieval with health information exchanges, electronic health records, pharmacy dispensing systems reduces the amount of time required by end users to find and sort information.	No – EHR not fully implemented.	Privacy and security concerns, Implementation costs.
	19. Send unsolicited report (URs) and alerts	Informs prescribers and pharmacists that patients may be abusing or diverting controlled substances; helps prescribers make better decisions about prescribing controlled substances. Serves as an incentive to maintain appropriate patient records and improve prescriber patterns.	Yes – reports sent to prescribers for risk scoring and flagged drug utilization. ***However*** reports not sent to pharmacies.	Legislative prohibitions and lack of program resources.
	20. Publicize use and impact of PMP	Publicizing the impact of the PMP serves to justify the need for monitoring and secures funding/support.	Yes – through bulletins online and annual report each year that describes the core activities of the program. Two members of the PMP Board are representatives of the Department of Health and Wellness and provide updates to government agencies.	Staff resources required to build reports, presentations and maintain websites.
PMP recruitment, utilization and education	21. Enable access to data by appropriate users	Enable access to users other than healthcare professionals that are in the circle of care of the patient and require access to PMP data. Such examples include law enforcement officials (involved in the area of drug trafficking/monitoring), professionals in drug abuse programs, medical examiners etc. This would further cement the support for PMP data use and monitoring as well as provide more efficient results to end users.	Yes – prescribers and pharmacists are able to access information from the PMP via phone and fax as well online access.	Legislative prohibitions on PMP data access by potential users, concerns about misuse of data by law enforcement and substance abuse treatment agencies, lack of awareness of PMP.
	22. Proactively identify and conduct	Identifying high end users, sending unsolicited reports serves to address users most likely	Yes	Lack of resources

	outreach to potential high end users	responsible for the bulk of prescribing of monitored substances and potential poor prescribing practices.		
	23. Conduct recruitment campaigns	Enrolling practitioners (practitioners who may not otherwise be monitored by the program), conducting outreach presentations on the need for monitoring increases the overall impact of prescription monitoring programs.	Yes - All physicians, NPs and Dentists enrolled ***except*** veterinarians.	Lack of resources, and little evidence on who is best to approach for enrollment
	24. Streamline certification and enrollment processing	Providing easier, yet secure access to PMP information so that high utilization of PMP data occurs, resulting in positive impacts. For example, while notarization prevents fraudulent individuals claiming to be a healthcare provider, it serves as a barrier to enrollment and usage of the system.		Lack of information systems and validated processes that would facilitate certification and enrollment
	25. Mandate enrollment	Mandating enrollment increases provider utilization of PMP, as well as monitoring.		Need for legislative/regulatory change, provider resistance to mandates, and lack of program resources to implement mandate.
	26. Conduct promotional campaigns	A reiteration of the above – promotional campaigns and prescriber education may increase utilization.	Partially – promotion made through the PMP website.	Lack of resources for outreach and prescriber education.
	27. Improve data timeliness and access	Moving from a paper of fax based system to continuous online access, dramatically increase the ease and probability of providers making voluntary queries or solicited reports to the system.	Yes – Online access is available.	Lack of resources to implement online systems.
	28. Conduct user education	Education seminars/webinars on how to effectively use the PMP system further strengths the PMP initiative for safer utilization of controlled substances.	Yes through traditional presentations regarding the role of the PMP and availability of information. .	Lack of resources and lack of evidence on which educational approaches produce the greatest changes in

				prescriber and other end user behavior
	29. Mandate utilization	Mandating that all prescribers enrolled/monitored by the PMP utilize a PMP report prior to prescribing may improve prescribing, patient safety and drug treatment.	No	Provider resistance to mandates, need for legislative/regulatory reform, lack of program resources to monitor compliance
	30. Institute financial incentives	Incentives (such as lower medical malpractice premiums), encourages the use of PMP data and improvement of prescribing practices.	No	Lack of evidence for effectiveness and lack of precedents
	31. Delegate access	Delegation of access to office staff (secretarial staff) can improve compliance in regards to accessing PMP information.	No	Concerns about data security and patient confidentiality, the need to monitor delegate account users by master account holders.
Inter-organizational best practices	32. Enact interprovincial data sharing among PMPs	Doctor shopping and other forms of prescription drug diversion occurs across provincial jurisdictions (i.e. NS resident doctor shopping in NB or PEI). Sharing data amongst provinces aims to reduce such practices.	No – data is de-identified when it is made available. Data on prescription filled in NS are monitored only. However prescribers registered with the NS PMP who are out of province are able to access information from the PMP upon request.	Standardization of collection, reporting and disseminating data across provinces and territories.
	33. Collaborate with other agencies/organizations	Coordinate with public & private payers, as well as other government entities to provide coordination of PMP data collection and utilization thereby reducing overall public and private costs.	Yes – significant collaboration with public agencies occur but ***limited*** with private, 3rd party agencies.	Regulatory and organizational barriers to adoption.
Evaluation of	34. Conduct satisfaction	Satisfaction and utilization surveys of PMPs	Yes	Lack of staff time and

PMPs	and utilization surveys of end users	provide important feedback for the purpose of program enhancement and to increase user by in.		expertise to design and filed surveys as well as interpret data
	35. Conduct audits of PMP system utilization for appropriateness and extent of use	PMP utilization audits show how often prescribers will query the database and download reports. If a PMP audit reveals high utilization, it would follow that the impact of such a program is large. If it is underutilized through the conduction of an audit, improvements can be identified and acted upon.	Yes – PMP tracks and reports data requests/profile requests to the PMP board.	Staff time required to extract and examine data
	36. Use PMP data as outcome measures in evaluating program and policy changes	Tracking the number of patients possibly engaged in abuse and diversion can be measured by a PMP, and serve as a proximate measure of health outcomes. Such data can be used to manipulate policy changes.	No	Limited PMP resource affect the extent o which data analyses and outcome measures can be constructed/carried out.
	37. Analyze other outcome data (e.g. overdoses, deaths, hospitalizations, ER visits) to evaluate PMP impact	Linking PMP data (unsolicited reports, lowering questionable prescribing rates) to outcome measures (overdose cases, hospitalizations) and tracking trends can help to identify the meaningfulness of the program and impact on a population level.	No	Specific resources would be required to map and collate this data on a routine basis
Funding PMPs	38. Secure funding independent of economic downturns, conflicts of interest, public policy changes and changes in PMP policies	In order to ensure viability, an effective PMP requires secure funding. Funding can be obtained from federal and provincial grants, however these are for specific initiatives. Licensing fees can be alternate source, whereby part of the prescriber or pharmacist licensing fee is used to fund the program. General revenue – specific funds made available through federal and provincial budgets. Private donations, Insurance fees, private	Yes – Funding is provided by the NS Department of Health and Wellness on an annual basis. For the Prescriber Risk Scoring Initiative funding was secured from the Canadian Centre on Substance Abuse.	Opposition from those wanting to limit prescription monitoring, lack of PMP leadership to spearhead funding initiatives, failure to include all stakeholders in advocating for PMP supports, lack of public awareness of the benefits of MPs, lack of resources and expertise

		donations, settlements, forfeiture funds (obtained through seizure by the RCMP or provincial police).		to apply for grants.
	39. Enact legislation to maintain sufficient funding over time	To ensure that a PMP is adequately funded, provinces can draft legislation that mandates specific funds, for what they can be used and what alternate sources of funding can be obtained.	Unknown	Requires political support from lawmakers.
	40. Conduct periodic review of PMP performance to ensure efficient operations and identify opportunities for improvement.	The purpose of the review is to assess the effectiveness of the program, evaluate the current performance, staffing levels, technological capabilities and areas of improvements.	Yes	Revenue shortfalls (public and private), and negotiating legislative changes.

References

1. Beth Sproule. (2015). *Prescription Monitoring Programs in Canada: Best Practice and Program Review,* Ottawa, ON, Canadian Centre on Substance Abuse. Pg. 1-40
2. Clark, T., Eadie, J., Kreiner, P., & Strickler, G. (2012). *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices.* Waltham, MA: Prescription Drug Monitoring Program, Center of Excellence, Brandeis University. Retrieved from www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report.pdf.
3. Hartzema A.G., Porta M.S., Tilson HH, Zullich, S.G., Grasela, T.H., Fiedler-Kelly, J.B., & Gengo, F.M. (1992). Impact of triplicate prescription program on psychotropic prescribing patterns in long-term care facilities*. Annals of Pharmacotherapy*, *26*(4), 539–546.
4. Weintraub, M., Singh, S., Byrne, L., Maharaj, K., & Guttmacher. L. (1991). Consequences of the 1989 New York State triplicate benzodiazepine prescription regulations*. Journal of the American Medical Association*, *266*(17), 2392–2397.
5. *First Do No Harm: Responding to Canada's Prescription Drug Crisis*- retrieved from **/www.ccsa.ca/resource%20library/canada-strategy-prescription-drug-misuse-report-en.pdf**