Analysis of Medication Incidents Associated with Patient Harm in Saskatchewan using the Medication Safety Culture Indicator Matrix (MedSCIM)

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Background

Many provinces are mandating pharmacy participation in anonymous medication incident reporting programs as a key component of their medication safety initiatives. These initiatives strive to improve patient safety through promoting continuous quality improvement and the analysis of medication incidents for the purpose of shared learning.

As pharmacy participation in incident reporting programs shifts from a voluntary practice to one that is mandatory, there must also be a shift in the culture of reporting. Organizations must strive to move from a "blame and shame" culture which emphasizes individual fault, to a culture that focuses on system factors and is generative of solutions that can improve patient safety.

To support Saskatchewan's commitment to improving patient safety, the Community Pharmacy Professionals Advancing Safety in Saskatchewan (COMPASS) program was launched. This initiative was developed by the Saskatchewan College of Pharmacy Professionals (SCPP) in partnership with the Institute for Safe Medication Practices Canada (ISMP Canada).[1] The COMPASS program consists of three main initiatives: medication incident reporting, proactive safety assessments and quality improvement meetings. As of December 2017, all 384 community pharmacies in Saskatchewan have been participating in the COMPASS program.[1]

The objective of this analysis was to examine the medication safety culture demonstrated by Saskatchewan community pharmacy professionals using the Medication Safety Culture Indicator Matrix (MedSCIM).

Methods

Medication incidents from all COMPASS pharmacies are reported to the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program. CPhIR is an online medication incident reporting and continuous quality improvement platform.[2] During the incident reporting process, there are mandatory fields that users must include in their reports such as: type of medication incident, medications involved, and a description of the medication incident. The information from these mandatory fields is combined with information from optional fields such as contributing factors and actions at the store level and then used for the purpose of incident analysis and shared learning.

During the reporting period from December 1, 2017 to January 31, 2019, there were incidents that were retroactively reported, dating back to May 2017. During this time, 267 incidents associated with patient harm were reported by COMPASS pharmacies. Upon further evaluation, 12 of these incidents were omitted for varying reasons: four incidents were deemed to have resulted in "no harm", three incidents were assessed to be "near misses", two incidents were concluded to be adverse drug reactions instead of medication incidents, and three incidents were determined to be duplicate reports. Therefore, a total of 255 incidents were included in this analysis.

Analysis of the dataset was performed by two independent analysts using the Medication Safety Culture Indicator Matrix (MedSCIM) tool. The MedSCIM framework allows for the qualitative assessment of an organization's patient safety culture by evaluating narrative information contained in medication

incident reports. The medication incidents were then categorized and given an alphanumeric score based on the two dimensions of the MedSCIM tool:[3]

1. **Core Event: Degree of Documentation** evaluates incident reports based on their clarity and completeness. This includes whether readers can understand *what* the medication incident was, and *why* the incident may have occurred (i.e. underlying contributing factors). Ratings on the "Core Event" domain can range from 1 to 3 (Table 1).[3]
2. **Maturity of Culture to Medication Safety** evaluates incident reports based on the reporter's perceived approach to patient safety culture. This includes the reporter's ability to view medication incidents from a system-based perspective, rather than one focused on individual fault. Ratings on the "Maturity of Culture to Medication Safety" domain can range from A to D (Table 1).[3]

Results

COMPASS pharmacies varied in the degree of documentation present in their incident reports (Figure 1). The majority of the incident reports (142 of 255) were deemed to be "semi-complete" (i.e. Level 2), as their level of documentation allowed for an understanding of what medication incident had occurred. A large portion of the incidents (105 of 255) were deemed to be "fully complete" (i.e. Level 1), as the details of the medication incident were clear, and potential contributing factors were suggested. Few of the incidents (8 of 255) were deemed to be "not complete" (i.e. Level 3). In these cases, details of the medication incident were unclear.

COMPASS pharmacies were also highly variable in their maturity of culture to medication safety (Figure 2). Nearly half (n = 120) of the analyzed incidents were characterized as having a "reactive" (i.e. Grade C) culture. These reports treated incidents as isolated events and did not approach the incidents from a system-based perspective or offer a solution. A "blame and shame" or "pathological" (i.e. Grade D) culture was the next most prominent culture displayed within the data, with 51 of the reports displaying this approach. These reports emphasized human behaviours and individual fault in their description of events. Many of the reports went beyond a "reactive" or "pathological" approach, with 39 of them being assessed as "calculative" (i.e. Grade B) and 45 as "generative" (i.e. Grade A). For these 84 incidents, the reporters have gone beyond blaming others or simply resolving medication incidents as they occur. They have considered how the medication system may have allowed the incident to occur, and sometimes also offered solutions to identified system flaws.

The most commonly assigned MedSCIM ratings were: 2C, 2D, and 1A (Figure 3). Incident examples of varying MedSCIM ratings are illustrated in Figure 4. Additionally, there was a group of similar reports identified where the reporter would describe system-factors relevant to the incident as well as a potential solution (indicative of a "Grade A" culture) but also emphasized individual fault as a factor (indicative of a "Grade D" culture); incident #2 (Figure 4) is an example of one of these reports. These incidents were assigned a "Grade C" rating to capture an average of their "Grade A" and "Grade D" qualities, and to reflect room for improvement in medication safety culture.

Discussion

Within the CPhIR incident reporting program there are multiple optional fields where users may share more details about a medication incident. Additional information provided in these optional fields is

then used in our analyses. Information contained in three optional fields, in particular, is important when conducting a MedSCIM assessment:

1. "Contributing Factors of This Incident";
2. "Actions at Store Level"; and
3. "Shared Learning for ISMP Canada to Disseminate".

To determine the degree of documentation relating to a medication incident (i.e. the number rating in MedSCIM assessment), the optional fields describing "contributing factors", "actions taken by the pharmacy", and "shared learning" are assessed as well as the incident description (Figure 5). The majority of reports assigned a Level 1 rating had more than one of the optional fields completed. As more optional fields are included in an incident report, it is more likely that the reporter will allude to potential contributing factors to the incident, which is indicative of a Level 1 rating. This is best exemplified by the fact that incidents which included all three optional fields of interest comprised the largest number of Level 1 reports (44 of 105) (Figure 5). Based on this data, it also appears that "actions taken by the pharmacy" and "contributing factors" entries are particularly important to achieving a complete incident report, with the "shared learning" section supplementing information reported in these fields. Documenting medication incidents to the level where both the incident itself and potential contributing factors are clear is crucial to improving our medication-use system. It is through the analysis of common themes and contributing factors that organizations, such as ISMP Canada, are able to generate potential recommendations and best practices to improve our medication-use system and prevent patient harm.

In determining a reporter's perceived approach to patient safety culture or a pharmacy's maturity of culture to medication safety (i.e. the letter rating in MedSCIM assessment), the optional fields describing "actions taken by the pharmacy" and "shared learning" are also often assessed in addition to the mandatory incident description field (Figure 6). Almost all Grade A reports were documented with "actions taken by the pharmacy" or completed with both "actions taken by the pharmacy" and "shared learning" optional fields. A single incident in the Grade A category (1 of 45) (Figure 6) filled in the "shared learning" optional field alone. This is likely due to the fact that few reports will have learning to share without having actions taken at the pharmacy level. Reports with only the mandatory incident description field completed were never assigned a "Grade A" rating. These results emphasize the importance of reflection in response to medication incidents. Taking the time to consider what system-based factors may have allowed the incident to occur, what solutions could be implemented to solve similar incidents at the local level and sharing this learning with the broader pharmacy community was indicative of a highly developed and generative culture towards medication safety.

In our assessment of the factors that differentiated highly rated medication incident reports, we chose to examine reports that scored well on either domain of the MedSCIM tool, degree of documentation (i.e. Level 1) or maturity of culture to medication safety (i.e. Grade A), rather than reports that scored highly on both dimensions (i.e. Grade 1A). This approach allows for the data to be viewed from the perspective of COMPASS pharmacies who may excel in one element of medication safety culture but need improvement in the other.

However, it is important to note that completing all optional fields does not by itself ensure a high rating or an excellent approach to patient safety culture. It is, instead, the narratives of the medication incident report that best exemplify an organization's approach to medication safety culture. Figure 5 and Figure 6 show that producing a well-documented incident report or an incident report with a

desirable patient safety culture requires additional effort. COMPASS pharmacies must take the time to reflect on, implement, and monitor the actions that these optional fields outline.

Limitations

A MedSCIM assessment relies on the qualitative interpretation and analysis of narrative data within incident reports. The different categories within the Core Event: Degree of Documentation and Maturity of Culture to Medication Safety domains are not mutually exclusive to one another. It is possible that some incidents may fall between two or more alphanumeric categories in the MedSCIM framework. The assessment and trends presented in this report were derived from the individual interpretations and subsequent consensus generated between the two Medication Safety Analysts at ISMP Canada.

Conclusions

Overall, COMPASS pharmacies have demonstrated many areas of strength with respect to their patient safety culture. Nearly all incidents associated with patient harm were reported with a sufficient level of detail to describe what medication incident occurred, and many reports also specified potential contributing factors to the incidents (Figure 1). Additionally, many COMPASS pharmacies went beyond a "reactive" approach and considered what system-factors may have allowed the incidents to occur and offered solutions to the identified problems (Figure 2).

However, these positive approaches to patient safety culture were not demonstrated by all COMPASS pharmacies. A majority of the incident reports were characterized as displaying a "reactive" approach to medication incidents (Figure 2). This approach is characterized by resolving medication incidents as they occur, rather than proactively seeking system-based improvements to prevent similar medication incidents. Many reports also displayed a "pathological" culture, including some reports that may otherwise have been classified as "generative".

To improve their patient safety culture, COMPASS pharmacies should focus on fostering an environment where incident reporting is valued as a means to prevent patient harm. Practitioners should be encouraged to report not only medication incidents, but also near misses or potentially risky practices that could result in medication incidents. Community pharmacies that embrace a just culture and provide psychological safety to their staff are well positioned to be leaders in patient safety.

COMPASS pharmacies should also be encouraged to use the CPhIR incident reporting platform to its fullest extent. Pharmacies who thoroughly document medication incidents using the relevant optional fields are likely also implementing their suggested patient safety improvements in their own practices. Going forward, all COMPASS pharmacies should strive to achieve a stronger patient safety culture.

Acknowledgements

ISMP Canada would like to acknowledge support from the Ontario Ministry of Health and Long-Term care for the development of the Community Pharmacy Incident Reporting (CPhIR) Program. The CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS). A primary objective of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety across all healthcare settings. The incidents

anonymously reported by COMPASS pharmacies to CPhIR were extremely helpful in the preparation of this analysis.

References

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3. Poon C, Kawano A, Yoo L, Cheng R, Ho C. *Medication Safety Culture Indicator Matrix (MedSCIM): Going Beyond the Numbers and Using Incident Reports to Assess Medication Safety Culture* [poster]. 2016. Available from: https://www.ismp-canada.org/download/posters/PPC2016Poster_MedSCIM.pdf.

Table 1 – Definition of MedSCIM Dimensions and Outcomes[3]

MedSCIM Index	OUTCOME	DEFINITION
Core Event	Level 1: **Report fully complete**	The medication incident provides sufficient information to describe the medication incident and contributing factors.
	Level 2: **Report semi-complete**	The medication incident provides sufficient information to describe the medication incident. No information is provided about contributing factors.
	Level 3: **Report not complete**	The medication incident provides insufficient information to allow meaningful qualitative analysis.
Maturity of Culture to Medication Safety (Modification of Ashcroft et al.[2])	Grade A: **Generative**	The medication incident uses a systems-based approach to describe the root cause and develop possible solutions to prevent future recurrence.
	Grade B: **Calculative**	The medication incident uses a systems-based approach to describe the root cause. No solutions are offered to prevent future recurrence.
	Grade C: **Reactive**	The medication incident is treated as an isolated incident. No solutions are offered to prevent future recurrence.
	Grade D: **Pathological**	The medication incident focuses on human behaviours instead of a systems-based approach.

Figure 1 – Core Event: Degree of Documentation (*n* = 255)

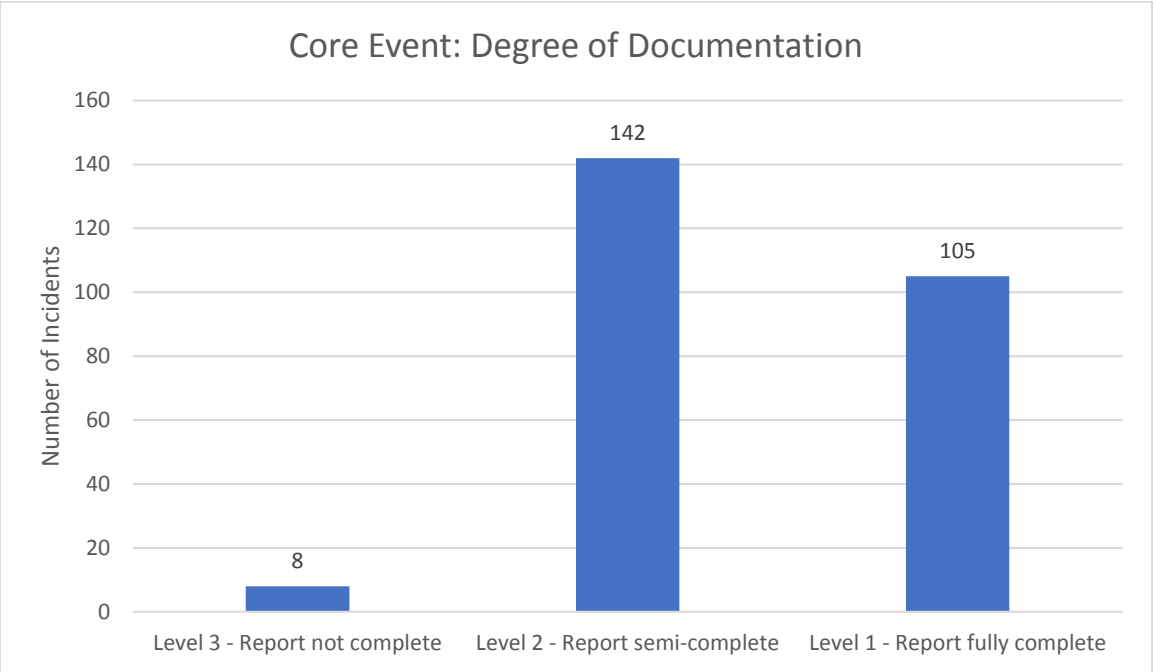

Figure 2 – Maturity of Culture to Medication Safety (*n* = 255)

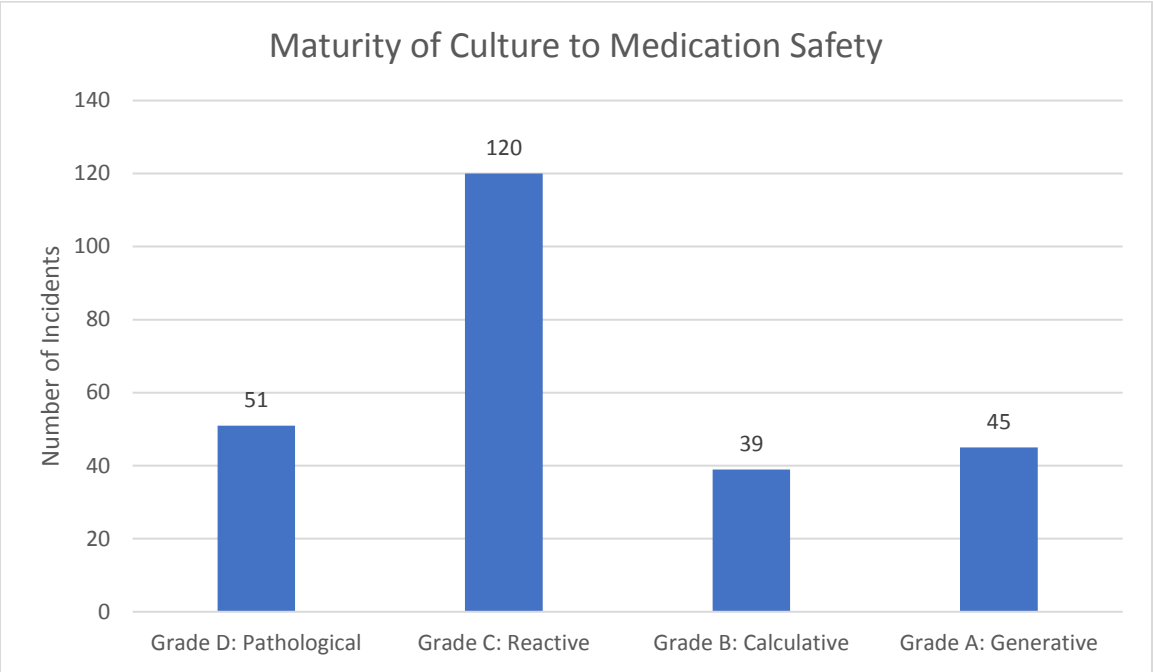

Figure 3 – MedSCIM Assessment (*n* = 255)

	Grade D: Pathological	Grade C: Reactive	Grade B: Calculative	Grade A: Generative
Level 1: Report fully complete	**16**	**28**	**29**	**32**
Level 2: Report semi-complete	**34**	**86**	**9**	**13**
Level 3: Report not complete	**1**	**6**	**1**	**0**

Figure 4 – Incident Examples of Varying MedSCIM Ratings

Incident Examples		Core Event: Degree of Documentation	Maturity of Culture to Medication Safety
#1	A pharmacist had entered a prescription for Quetiapine 25 mg. When the drug was being filled, a technician accidentally changed the strength to 300 mg when modifying the prescription. The medication was continued for the next 6 months. When doing a patient assessment, it was realized that the patient has been having problems with coordination and was unsure why. The error was then discovered. ***Actions at Store Level***: No technicians are allowed to do brand changes; it will always be pharmacists now.	2	D
#2	We run a pharmacy located in a large nursing home. We serve 2 different residents from different floors on Methadone. Our pharmacy mixed up Methadone doses and sent Methadone for patient A to the floor of patient B and vice versa. However, the products were labelled correctly. […] Patient A received Patient B's Methadone dose - an overdose of 15 mg of Methadone**. A nursing student gave the medication and did not check the label correctly prior to administration.** Patient B did not receive the incorrect dose and the dose was replaced. Patient A was monitored for side effects by the nursing team. A local incident report was made, and the prescriber was informed of the error. ***Actions at store level***: A team meeting occurred to discuss this error and prevention strategies. We decided to label each dose with a floor number in large block letters on each vial (i.e. either #1 or #2 representing floor 1 or floor 2).	1	C
#3	A parent contacted the pharmacy to inquire if there had been a change to their child's Amantadine prescription as they didn't recognize it. We confirmed on the compliance packaging that it should be the same as previously, as the drug identification number (DIN) was circled in verification. The pharmacist asked the parent to email the pharmacy a picture. The medication picture appeared to be Amiodarone 100 mg. Pharmacy manager contacted parent and notified them of error. […] Pharmacy manager asked parent not to give any more medication until physician could be contacted. Pharmacy manager went to patient's home and delivered 7 days of correct medication in blister package, picked up incorrect medication, and counseled on possible adverse effects. Pharmacy manager asked parent to take child for full assessment at clinic, and parent agreed. Pharmacy followed up later tonight. ***Actions at store level***: Pharmacy manager has requested IT to turn on UPC packaging verification for nursing home/compliance pack patients. The previous process of having the packager print compliance pack list and circle DINs did not prevent this error from occurring. […] As of recently, it appears that all blister pack medications now require verification by UPC scanning before a label can be printed.	1	A

Figure 5 – Breakdown of "Level 1" Documentation Ratings by Optional Fields Entered (*n* = 105)

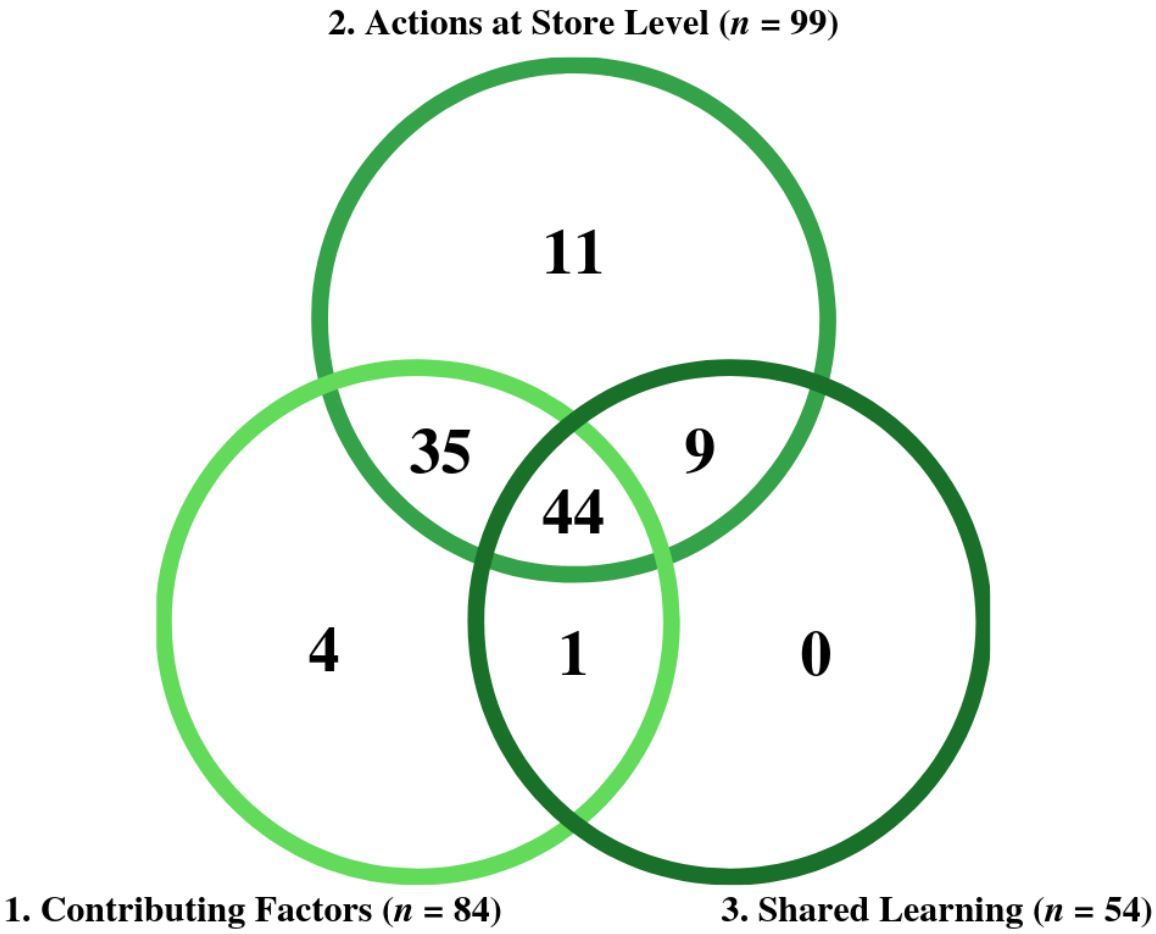

Figure 6 – Breakdown of "Grade A" Culture Ratings by Optional Fields Entered (*n* = 45)