AN ASSESSMENT OF THE SAFETY IQ CONTINUOUS QUALITY IMPROVEMENT PROGRAM

A SUMMARY OF KEY FINDINGS

Safety.
Improvement.
Quality.

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INTRODUCTION

Safety IQ is a community pharmacy continuous quality improvement (CQI) program developed by the College of Pharmacists of Manitoba in consultation with key pharmacy stakeholders. Safety IQ provides community pharmacy staff with the training, support, tools, and encouragement needed to enhance medication incident/near miss reporting and learning; with the overall goal of enabling community pharmacies to implement, in an open and blame-free manner, system-based changes to reduce the likelihood that similar errors happen again.

Based on definitions developed by the Institute for Safe Medication Practices Canada (ISMP Canada)[1], medication incidents and near misses are defined by Safety IQ and this report as:

- A **Medication Incident** is a preventable occurrence or circumstance that may cause or lead to inappropriate medication use or patient harm. Medication incidents may be related to professional practice, drug products, procedures, and systems, and include prescribing, order communication, product labelling/packaging/nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.

- A **Near-Miss Event** is an event or circumstance that took place and could have resulted in an unintended or undesired outcome(s), but was discovered before reaching the patient.

Safety IQ adopts various elements found in other community pharmacy CQI programs, such as SafetyNET-Rx (Nova Scotia) and COMPASS (Saskatchewan). Key elements of Safety IQ include: online reporting of medication incidents/near misses to a national database using ISMP Canada's Community Pharmacy Incident Reporting System (CPhIR); annual safety self-assessments using ISMP Canada's Medication Safety Self-Assessment survey (MSSA); quarterly meetings to discuss medication incidents/near misses and plan changes; access to summary reports of incidents occurring in community pharmacies throughout Canada; and access to training material on Safety IQ and its associated tools (e.g., CPhIR, MSSA). Safety IQ was implemented as a pilot project in 20 community pharmacies in Manitoba starting in the Fall of 2017. This report summarizes the key findings from the pilot project.

[1] ISMP Canada: Definition of Terms - https://www.ismp-canada.org/definitions.htm, Accessed July 11, 2018

STUDY METHODS & RESULTS

To explore the key outcomes of the pilot project, a survey questionnaire was developed. The questionnaire was comprised of five major sections. The first section captured basic demographic details about the respondent (e.g., position, gender, years at the current pharmacy, years of community pharmacy practice) and their community pharmacy (e.g., location, weekly script volume, medication incident reporting system prior to Safety IQ). The second section explored the extent of use of key Safety IQ tools, including ISMP Canada's CPhIR system and MSSA survey. The third section captured how the safety culture of the pharmacy may have changed during Safety IQ use. This section adopted questions from the Pharmacy Safety Climate Questionnaire,[2] a validated instrument used to assess the safety culture of community pharmacies. The safety culture of the pharmacy was captured using four constructs: (1) pharmacy working conditions; (2) blame culture; (3) safety focus; and (4) organizational learning from medication incidents. The fourth section captured the extent of Safety IQ training and the usefulness of that training. The fifth and final section of the questionnaire was comprised of open-ended questions where pharmacy staff could describe the benefits realized through Safety IQ use and the key challenges faced. Ethics approval for the survey was obtained from the St. Francis Xavier University Research Ethics Board. This board reviewed the survey's research methods and protocols following the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.*[3]

The questionnaire was mailed to 110 pharmacy staff (including pharmacy owner/manager, staff pharmacist, relief pharmacist, pharmacy technician, pharmacy assistant, and pharmacy student) in early June 2018. A follow-up round of survey mailing occurred in late June 2018. A final online survey round of deployment occurred in mid-July 2018. Fifty-two usable questionnaires were returned, yielding a response rate of approximately 47.3%. The quantitative data from the survey were analyzed using IBM SPSS Statistics 24. Following common practice in the social sciences,

[2] Phipps, D.L., De Bie, J, Herborg, H. et al (2012) Evaluation of pharmacy safety climate questionnaire in European community pharmacies, International Journal for Quality in Health Care, 24(1):16-22.
[3] Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/, Accessed July 10, 2018

[4,5] a combination of basic statistics (e.g., mean and frequencies counts) and Paired Samples T-Tests (e.g., pre- and post-Safety IQ culture differences) were used to analyze the quantitative data. The open-ended data (e.g., challenges and benefits of Safety IQ) were analysed using thematic analysis.

KEY FINDINGS

Of the 52 pharmacy staff that completed the survey, 32 (61.5%) were female, 19 (36.5%) were male, and 1 (1.9%) chose not to answer. Pharmacy staff groups represented included pharmacy owners (5 survey respondents, 9.6%) and pharmacy managers (9, 17.3%), staff pharmacists (13, 25.0%), pharmacy technicians (6, 11.5%) and assistants (17, 32.7%), and pharmacy students (2, 3.8%). The average length of time working in community pharmacy practice reported by respondents was 13.4 years, with an average of 9.9 years spent at their current pharmacy.

More staff reported working in a community pharmacy located in a city (33 survey respondents, 63.5%), than in a town (9, 17.3%) or rural setting (10, 19.2%). Survey respondents were most likely to work for an independent or banner pharmacy and least likely to work within a franchise or mass merchandiser setting. The mean number of staff pharmacists per pharmacy was 3.6, with a mean of .51 pharmacy technicians and 4.1 pharmacy assistants on staff. The average weekly prescription volume was 1,832. Over twenty percent of survey respondents indicated that no formal medication incident/near miss process existed in their community pharmacy prior to Safety IQ. For those pharmacies with a formal process in place prior to Safety IQ, process characteristics ranged from a completely manual process to a fully computerized one.

A key component of Safety IQ is reporting medication incidents/near misses to a national database using ISMP Canada's CPhIR online tool. Pharmacies represented in the study have been using Safety IQ for an average of 9 months. Pharmacy staff reported an average of .66 medication incidents/near misses to CPhIR in the past week (at time of questionnaire completion), 2.83 in the past month (at time of questionnaire completion), and 12.9 since the start of Safety IQ. Ten

[4] Willits, F., Theodori, G., Luloff, A. Another Look at Likert Scales. Journal of Rural Social Sciences, 31(3), 2016, pp. 126–139.
[5] Norman G. Likert scales, levels of measurement and the "laws" of statistics. Adv Health Sci Educ Theory Pract. 2010 Dec;15(5):625-32.

respondents (19.2%) reported no medication incidents/near misses in the past month (at time of questionnaire completion), and 5 (9.6%) reported no medication incidents/near misses since the start of Safety IQ. Twenty-seven respondents (51.9%) could not estimate the number of medication incidents/near misses that the pharmacy reported to CPhIR in the past week (at time of questionnaire completion), 26 (50.0%) could not estimate the number of medication incidents/near misses that the pharmacy reported to CPhIR in the past month (at time of questionnaire completion), and 29 (55.8%) could not estimate the number of medication incidents/near misses that the pharmacy reported to CPhIR since the start of Safety IQ.

As part of the Safety IQ initiative, community pharmacies are expected to complete an initial MSSA upon program adoption and one every year during Safety IQ use. The range of MSSA participation by the pharmacy staff in this study varied. Thirteen (25%) survey respondents did not know if their pharmacy completed the MSSA. Participation in the MSSA varied, with 20 respondents (38.5%) having been actively involved in the completion of the MSSA. Since the start of Safety IQ, 11 (21.2%) survey respondents reported that no meetings were held to discuss medication incidents/near misses. Overall, an average of 2.1 meetings had been held in the pharmacy to discuss medication incidents/near misses. When meetings were held, survey respondents were usually in attendance. Of those who were involved in such meetings, the vast majority reported feeling comfortable talking about medication incidents. However, a large number of survey respondents did not know if their pharmacy developed an improvement plan based on incident discussions or confirmed that no plan was developed. An open-ended question was presented to pharmacy staff in order to identify process or dispensing changes that have occurred as a result of discussing medication incidents and near misses. Examples of operational changes identified by survey respondents included, increasing double checking, updating files, implementing TALLman Lettering for patients with similar names, increasing interaction with patients, and slowing down.

Overall, survey respondents showed little fear and identified significant value with reporting medication incidents and near misses. For example, respondents felt that each report that they submit can make a significant contribution to patient safety (mean = 4.33, on a 5-point Likert-type scale), their professional practice (mean = 4.35), professional practice of others (mean = 4.19), and

overall contribution to the pharmacy (mean = 4.37). Respondents highlighted limited fear with reporting medication incidents and near misses. For example, fear that reporting is not anonymous (mean = 1.78), adverse consequences of reporting (mean = 1.79), and fear of telling on others when reporting (mean = 1.94) all scored low.

A variety of opportunities to learn about Safety IQ were available to pharmacy staff during the pilot period. Example training and learning opportunities included a full-day Safety IQ training workshop, half-day Safety IQ training workshop, online modules on ISMP Canada's tools, access to the Safety IQ Pilot Pharmacy Participant Manual, access to the Safety IQ webpage, and a Safety IQ newsletter (i.e., eQuipped). Despite the availability of such tools, the use of these tools by survey respondents was fairly low. When the tools were used, their usefulness for the most part, was viewed to be high. An open-ended question on the survey allowed pharmacy staff to comment on additional training that they believe would enhance their use of Safety IQ. Key themes emerging from the qualitative data include the need for increased hands-on training, more examples and reporting scenarios, and clarification on the role of the pharmacy assistant in Safety IQ.

Safety Culture

To assess the impact of Safety IQ use on the safety culture of the pharmacy, pharmacy staff were asked to indicate their agreement (i.e., 1 – Strongly Disagree to 5 – Strongly Agree) with a series of questions related to working conditions, blame culture, safety focus, and organizational learning.[4] Survey participants were asked to first answer these questions thinking of the conditions in the pharmacy before the adoption of Safety IQ (i.e., pre-Safety IQ use). They were then asked to answer the same questions again thinking of conditions in the pharmacy at the time of questionnaire completion (i.e., post-Safety IQ use).

Working conditions relate to staffing levels and working hours that might impact the level of safety at a pharmacy. Pre and post-Safety IQ perceptions of working conditions are presented in Table 1.

Table 1. Working Conditions

Working Conditions	N	Pre Safety IQ Mean	Post Safety IQ Mean	Sign. Diff (Pre-Post)	Sign.
There are not enough staff to handle the workload*	47	2.91	2.87		
Staff work in "crisis mode" trying to do too much, too quickly	46	3.50	3.33	.174	.031
Staff work longer hours than is sensible for patient care	45	2.04	2.04		
It is by luck that more serious mistakes don't happen in the pharmacy	47	2.21	2.06	.149	.007

*Reverse-coded variable

As with the other safety culture constructs presented below, to explore perceived changes in working conditions, the Likert items for working conditions were averaged to derive the Likert scale. A paired-samples t-test was then conducted on pre- and post-safety IQ working conditions to assess changes. Results of this analysis indicates a statistically significant difference in the scores for pre (M=2.7, SD=.914) and post-Safety IQ (M=2.6, SD=.900) use; t(42)=3.05, p=0.004. Specifically, working conditions improved after Safety IQ use.

Safety focus captures the commitment to patient safety in the pharmacy. Pre and post-Safety IQ perceptions of working conditions are presented in Table 2.

Table 2. Safety Focus

Safety Focus	N	Pre Safety IQ Mean	Post Safety IQ Mean	Sign. Diff (Pre-Post)	Sign.
Training in safety has a low priority and is seen as irritating, time consuming and costly	45	2.36	2.22		
Staff are seen as already trained to do their job, so why would they need more training	46	2.00	1.80	1.96	.037
"Lip service" is paid to patient safety until an actual safety incident occurs	32	2.66	2.50		

While respondents believed that their pharmacy did have a safety focus prior to implementing Safety IQ (e.g., mean responses below 3), the data also shows some improvement in the safety focus of the pharmacy during Safety IQ use. Specifically, results of the data analysis indicates a statistically significant difference in the scores for pre (M =2.4, SD =.890) and post-Safety IQ (M=2.2, SD=.806) safety focus; t(30)=2.82, p = 0.009.

Overall, pharmacy staff highlight changes in the blame and shame of reporting medication incidents and near misses (Table 3) in the pharmacy, with significant differences between pre (M =2.4, SD =1.19) and post-Safety IQ (M=2.1, SD=1.01) blame culture; t(41)=4.64, p = 0.000.

Table 3. Blame Culture

Blame Culture	N	Pre Safety IQ Mean	Post Safety IQ Mean	Sign. Diff (Pre-Post)	Sign.
There is a blame culture, so staff are reluctant to report medication incidents	45	2.36	2.09	.267	.022
Staff feel that their mistakes are held against them	44	2.45	2.27	.182	.019
When a medication incident is reported, it feels like the person is being reported, not the problem	47	2.64	2.13	.511	.000
Medication incident discussions aim to assign blame to individuals	48	2.19	1.92	.271	.002

Organizational learning is the ability and willingness of community pharmacy management and staff to proactively develop and maintain a safe working environment as presented in Table 4. Results of the data analysis indicates a statistically significant difference in the scores for pre (M =3.2, SD =.643) and post-Safety IQ (M=3.6, SD=.625) organizational learning; t(36)=-6.23, p = 0.000.[6]

[6] Given the wording of the questions, a negative t-value indicates an improvement in performance.

Table 4. Organizational learning

Organizational Learning	N	Pre Safety IQ Mean	Post Safety IQ Mean	Diff (Pre-Post)*	Sign.
Staff routinely discuss ways to prevent medication incidents from happening again	48	3.33	3.88	-.542	.000
All staff are constantly assessing risks and looking for improvements	47	3.23	4.06	-.830	.000
Staff are routinely informed about medication incidents that happen in the pharmacy	46	3.09	3.65	-.565	.000
The culture is one of continuous improvement	44	3.48	3.86	-.386	.000
The effectiveness of any changes made following a medication incident are evaluated	47	2.79	3.23	-.447	.000
The pharmacy learns and shares information about safety with staff and other pharmacies	43	2.65	3.19	-.535	.000
The team has a shared understanding and vision about safety issues; everyone is equally valued and feels free to contribute	48	3.40	3.77	-.375	.003
Following a medication incident, there is a real commitment to change throughout the pharmacy	46	3.46	3.87	-.413	.000
Staff will freely speak up if they see something that may negatively affect patient care	48	3.75	4.10	-.354	.000
Medication incident discussions are seen as learning opportunities	47	3.55	4.19	-.638	.000
Medication incident discussions aim to learn from errors and communicate the findings widely	47	3.40	4.02	-.617	.000
The pharmacy manager/owner seriously considers staff suggestions for improving patient safety	48	3.88	4.13	-.250	.001
All staff have education and training in safety	47	3.02	3.53	-.511	.000

* Given the wording of the questions, a negative difference indicates an improvement in performance.

Two open-ended questions were presented to pharmacy staff to capture the overall benefits and challenges of Safety IQ use. Key benefits from Safety IQ use include: increased discussions of medication incidents, more openness and less blame in incident discussions, perceived reduction in the number of incidents occurring in the pharmacy, and an increased awareness of individual actions and factors that may lead to incidents or near misses. Survey respondents also highlighted various challenges with Safety IQ use. The key challenge identified related to time, specifically not enough time to report all medication incidents. This resulted in not all near misses being

reported. Other challenges identified included Safety IQ having a low priority relative to other issues and initiatives in the pharmacy, challenges getting all pharmacy staff to report, challenges with training in the pharmacy (i.e., only one person received training and had difficulty training others, difficulty in training new staff), difficulty designating who is responsible for reporting an incident, staff overwhelmed with entering all near misses, multiple systems resulting in dual reporting (i.e., reporting to CPhIR and an in-store/corporate system), and various technology issues (e.g., limitations on internet capabilities slowed access to online components of the system, online components not user friendly).

Suggestions from survey respondents for things that the College of Pharmacists of Manitoba or corporate head offices (where applicable) could do to better support Safety IQ in community pharmacies include continuing with the Safety IQ program, increasing training on safety (e.g., Safety IQ continuing education units for pharmacists and technicians), enhancing contact / involvement with pharmacy assistants, improving communication/discussions of incidents (e.g., quarterly meetings with head office to discuss incidents that have happened within the chain), and increasing reporting anonymity (e.g., internal systems de-identifying those involved in a medication incident, ensuring that corporate head office does not publish incident rates by store).

SUMMARY OF SAFETY IQ OUTCOMES

To assess the completeness of Safety IQ, its key components are compared to leading pharmacy CQI programs in North America. Similar to such programs, Safety IQ contains the key components of online reporting of medication incidents/near misses to a national database, annual safety self-assessments, quarterly meetings to discuss medication incidents/near misses and plan changes, access to summary reports of incidents occurring in community pharmacies throughout Canada, and access to training material and documentation on Safety IQ and its associated tools. As a result of this comparison, it is apparent that Safety IQ is well-designed and among the top quartile in North America in terms of a comprehensive community pharmacy CQI program. The pilot data highlights the value of Safety IQ in its current form. Specifically, the pilot data identifies various improvements in the safety culture of participating community pharmacies during the pilot time-period. All four constructs of safety culture (i.e., pharmacy working conditions, blame culture, safety focus, and organizational learning from medication incidents) have improved during the

Safety IQ pilot period. In addition, the open-ended data highlight various benefits from Safety IQ use. These benefits include increased discussions of medication incidents, more openness and less blame in incident discussions, perceived reduction in the number of incidents occurring in the pharmacy, and an increased awareness of individual actions and factors that may lead to incidents or near misses. These benefits are similar to those realized in other community pharmacy CQI programs.[7]

The pilot data also highlights that community pharmacy staff realize the value of reporting and discussing medication incidents and near misses. The pilot data, for example, indicates high levels of the views that incident/near miss reporting can make a significant contribution to the pharmacy, patient safety, one's professional practice, and the professional practice of others. The pilot data indicates low levels of reporting fear, with, for example, low fear that reporting is not anonymous, low fear of adverse consequences from reporting, and low fear that "telling" on someone occurs because of reporting. Overall, it appears that pharmacy staff realize the benefits of Safety IQ and are making real gains in enhancing safety within the pharmacy.

Despite being an already well-developed program, areas for improvement were identified from the pilot data, literature review, and comparison to similar programs, and should be addressed to enhance the value, usefulness, and uptake of Safety IQ. For example, changes are recommended to enhance pharmacy assistant engagement (e.g., clarify and emphasize the role of the pharmacy assistant in Safety IQ), promote training resources (e.g., develop a dedicated training website, develop Safety IQ training cases, reorganize the existing training material), address the overwhelming volume of near-miss reporting (e.g., consider the development of a minimum bar for near miss reporting, develop a batch or hybrid manual-computerized means of recording lower impact near misses), and assess process quality (e.g., develop guidelines to allow community pharmacies to assess the completeness of their Safety IQ program and areas that may require improvement).

[7] Boyle T. A., Bishop A., Duggan K., et al. (2014) "Keeping the "continuous" in continuous quality improvement: Exploring perceived outcomes of CQI program use in community pharmacy" Research in Social & Administrative Pharmacy, 10(1), pp. 45-57.

OVERALL RECOMMENDATIONS

Medication incident and near miss reporting requirements vary across North American pharmacy jurisdictions. Such reporting requirements range from in-pharmacy documentation of the error to online reporting to a national database and various follow-up and discussion activities (e.g., quarterly meetings, annual safety self-assessments). One of the more complete medication incident/near miss reporting and learning systems in Canada was developed in 2007 through the SafetyNET-Rx project. The initial version of SafetyNET-Rx adopted, at the time, the best medication incident reporting and learning practices from across North American jurisdictions and was based on the work of Dr. David Brushwood, an early leader in establishing such programs in the United States. Since 2007, SafetyNET-Rx has been revised as new best practices and technology (especially in online systems and data analytics) have been developed. Various incident reporting and learning systems in Canada have adopted similar components found in SafetyNET-Rx.

To assess the completeness of Safety IQ, its key components are compared to SafetyNET-Rx and other leading CQI programs. Similar to such programs, Safety IQ contains the key components of online reporting of medication incidents/near misses to a national database, annual safety self-assessments, quarterly meetings to discuss medication incidents/near misses and plan changes, access to summary reports of incidents occurring in community pharmacies throughout Canada, and access to training material and documentation on Safety IQ and its associated tools.

As a result of this comparison, it is apparent that Safety IQ is well-designed and among the top quartile in North America in terms of a comprehensive community pharmacy CQI program. The pilot data highlights the value of Safety IQ in its current form. Specifically, the pilot data identifies various improvements in the safety culture of participating community pharmacies during the pilot time-period. All four constructs of safety culture (i.e., pharmacy working conditions, blame culture, safety focus, and organizational learning from medication incidents) have improved during the Safety IQ pilot period. In addition, the open-ended data highlight various benefits from Safety IQ use. These benefits include increased discussions of medication incidents, more openness and less blame in incident discussions, perceived reduction in the number of incidents occurring in the pharmacy, and an increased awareness of individual actions and factors that may lead to incidents

or near misses. These benefits are similar to those realized in other community pharmacy CQI programs.[8]

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- **Recommendation 1** - The College of Pharmacists of Manitoba rollout the Safety IQ community pharmacy continuous quality improvement program to all community pharmacies in Manitoba.

While a full provincial rollout is recommended, several issues with Safety IQ were identified from the pilot data, literature review, and comparison to similar programs, and should be addressed prior to a provincial rollout. The College of Pharmacists of Manitoba will need to identify ways to enhance pharmacy assistant engagement, promote training resources, address an overwhelming volume of near-miss reporting, and access process quality prior to a full provincial rollout of Safety IQ.

- **Recommendation 2 -** Prior to a full provincial roll-out of Safety IQ, the College of Pharmacists of Manitoba enhance pharmacy assistant engagement in Safety IQ.

- **Recommendation 3 -** Prior to a full provincial roll-out of Safety IQ, the College of Pharmacists of Manitoba enhance awareness of Safety IQ's training resources.

[8] Boyle T. A., Bishop A., Duggan K., et al. (2014) "Keeping the "continuous" in continuous quality improvement: Exploring perceived outcomes of CQI program use in community pharmacy" Research in Social & Administrative Pharmacy, 10(1), pp. 45-57.

- **Recommendation 4 -** Prior to a full provincial roll-out of Safety IQ, the College of Pharmacists of Manitoba make changes to Safety IQ to address the overwhelming volume of near miss reporting.

- **Recommendation 5 -** Prior to a full provincial roll-out of Safety IQ, the College of Pharmacists of Manitoba develop and communicate tools and a framework to assess process quality.

- **Recommendation 6** - A Safety IQ Advisory Board be established comprised of at least a representative from the College of Pharmacists of Manitoba, a staff pharmacist from Manitoba, a pharmacy technician/assistant from Manitoba, a faculty member from the University of Manitoba - College of Pharmacy, an expert in information technology (especially in the areas of data mining and online analytical processing) from a local university or college, and a member from the public at large.

CONCLUSION

Safety IQ is a community pharmacy CQI program that supports an open dialogue on medication incidents and near misses and helps community pharmacies implement system-based changes to reduce the likelihood of similar incidents occurring again. Key elements of Safety IQ include online reporting of medication incidents/near misses to a national database, annual safety self-assessments, quarterly meetings to discuss medication incidents/near misses and plan changes, access to summary reports of incidents occurring in community pharmacies throughout Canada, and access to training material on Safety IQ and its associated tools. Based on a 20-pharmacy pilot study, a number of benefits were realized, including significant changes in the safety culture of the community pharmacy. Despite the many benefits, community pharmacies faced various challenges related to Safety IQ, the most significant being finding the time to report medication incidents and near misses.