Vaccine Medication Incidents in the Community

A MULTI-INCIDENT ANALYSIS BY ISMP CANADA

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INTRODUCTION

The value and global impact of vaccinations on public health cannot be overstated. The World Health Organization acknowledges that vaccinations are only second to clean water in reducing the burden of infectious diseases.[1] A 2015 report from the C.D. Howe Institute highlighted policy changes that could ameliorate immunization coverage in Canada.[2] One such recommendation is that a further expansion on pharmacists' scope of practice concerning vaccine administration will improve overall immunization rates by reducing costs and barriers associated with accessing immunization services.[2,3] Patient-reported accessibility and convenience of pharmacist-administered vaccinations can be further evidenced by a 2015 national survey which revealed that nearly 4 in 5 of Canadians would consider a pharmacist-administered vaccination.[3,4] Considering (1) the pressure exerted on the Ontario Government to incorporate additional vaccines to pharmacists' scope of practice, (2) the increasing public acceptability of pharmacist-delivered vaccinations, and (3) the rapidly changing landscape of pharmacist-delivered immunizations in other provinces, it would be prudent for Ontario pharmacists to begin establishing system-based error prevention models that go above and beyond exercising individual vaccine vigilance.[5,6,7,8]

According to the United States Vaccine Adverse Event Reporting System (VAERS) 2015 statistics, the most common type of vaccination errors are related to scheduling (27%), storage/dispensing (23%), and vaccine type (15%).[9] The data also suggests that while errors do occur during the prescribing and dispensing stage, the most common stage of the medication system during which vaccination errors occur is administration.[10] This is particularly important as Ontario pharmacists' role in vaccine administration continues to grow and evolve. When taking into consideration the increasing complexity of provincial immunization schedules and the ever-expanding array of available vaccine products, left unchecked, these factors could potentially compound the number of vaccine errors in the future.[11,12]

On a small scale, vaccination errors may potentially lead to patient harm, inconvenience related to patient recall, increased costs, wasted time and vaccine, and possible unwanted media attention.[9,13,14] Furthermore, such an error can diminish or eliminate the immunological effectiveness of the vaccination.[15] On a large scale, this translates into both compromised patient care and, through herd immunity, public protection against serious infectious diseases.[15] Considering the ongoing public concern regarding adverse effects of vaccines, minimizing vaccination errors is paramount in maintaining confidence in the healthcare system.[9]

Reports using US vaccination error data have been published in abundance (i.e. ISMP's Vaccine Error Reporting Program (VERP) and CDC's and FDA's VAERS).[9,10,15] The paucity of reports using Canadian data is the justification for this multi-incident analysis (MIA). The following are the primary objectives of the analysis: (1) to foster a greater comprehension for the scope and impact of vaccination errors on

patient safety in Canada, (2) to expose specific stages throughout the medication use system that are considered high-risk for generating system-based errors, and (3) to propose recommendations that aid in pharmacist's vigilance for potential violations in the "rights" of vaccine administration.[13]

MULTI-INCIDENT ANALYSIS OF VACCINE MEDICATION INCIDENTS

The Community Pharmacy Incident Reporting (CPhIR) Program (available at http://www.cphir.ca) is designed for community pharmacies to report near misses or medication incidents anonymously to ISMP Canada for further analysis and dissemination of shared learning from incidents.[16] CPhIR has allowed the collection of invaluable information to help identify system-based vulnerable areas in order to prevent future medication incidents.16 This article provides an overview of a multi-incident analysis of medication incidents involving vaccine errors reported to the CPhIR program. Incidents were extracted using vaccine brand names and their corresponding abbreviations and infections from the Public Health Agency of Canada's "Types and Contents of Vaccines Available for Use in Canada" (http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php) as search terms. A total of 839 incidents were retrieved from April 2010 to September 2015. From this, 707 incidents were excluded from the analysis because they fulfilled any one or more of the following criteria: (1) incident report did not provide sufficient detail or narrative for subsequent theme classification, (2) incident was unrelated to the topic, (3) incident report was a duplicate incident entry, or (4) underlying problem in the incident was not specific to vaccines (e.g. third party billing issues, refills, etc.). Consequently, 132 incidents contained relevant and sufficient narrative description and were included in the analysis. These medication incidents were analyzed and categorized into 7 main themes and further divided into subthemes. The main themes in this analysis are intended to represent violations of "The 6 'Rights' of Vaccine Administration" which originate from nursing literature.[13] These themes were adapted from an administration focus to expand and include common errors found in storing, preparing, and dispensing of vaccines. This accurately represents the unique environment of a community pharmacy which includes nearly all stages of the medication-use system.

For the purposes of this article, the following definitions will be used for "selected" and "dispensed". A vaccine is "selected" when it is chosen from the pharmacy inventory, during either the order entry or the prescription preparation stage. A vaccine is "dispensed" when it is released from the pharmacy to the patient or the patient's agent. (Note: The "Incident Examples" provided in Tables 2 to 8 were limited by what was inputted by pharmacy practitioners to the "Incident Description" field of the CPhIR program.)

TABLE 1. Themes and Subthemes of the Vaccine Multi-Incident Analysis

Themes	Subthemes
Wrong Vaccine/Drug Product or Incomplete Vaccine	Wrong Vaccine or Drug Product Prescribed
	Wrong Vaccine or Drug Product Selected at Pharmacy
	Wrong Formulation Selected at Pharmacy
	No Diluent Dispensed
Wrong Dosage	Wrong Dosage for Age Prescribed
	Wrong Dosage for Age Selected at Pharmacy
Wrong Time	Inappropriate Dosing Schedule Prescribed or Vaccine Dispensed too Early/Late
	Expired Medication Dispensed/Administered
Wrong Storage	Wrong Storage in Patient's Home
	Wrong Storage in Pharmacy
Wrong Patient	(No subthemes identified)
Wrong Documentation	(No subthemes identified)
Wrong Manner/Route	(No subthemes identified)

TABLE 2: Theme One – Wrong Vaccine/Drug Product or Incomplete Vaccine

Subtheme: Wrong Vaccine or Drug Product Prescribed

Incident Example	Possible Contributing Factors	Commentary
A physician prescribed polio vaccine (Imovax® Polio) for a patient. The patient's mother came to the pharmacy and realized that it was the incorrect vaccine by the difference in cost of the polio vaccine compared to the cost of the rabies vaccine (Imovax® Rabies) that she expected to be picking up.	Unfamiliarity with the vaccine, particularly its indications.[9] Failure to check or verify the indications or appropriateness of the vaccine.[9] Confusion due to look-alike/sound-alike vaccine or drug product names.[9]	Differentiate the appearance of similar vaccine/medication names on computer screens by highlighting dissimilarities (e.g., Imovax® **POLIO** vs. Imovax® **RABIES**).[9] *[Simplification/standardization]* Place Public Health Agency of Canada's "Table 1: Types and Contents of Vaccines Available for Use in Canada" hardcopy near – or a desktop link on – the prescriber computer as a readily accessible reference. (http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php) *[Education & Information]*

Subtheme: Wrong Vaccine or Drug Product Selected at Pharmacy

Incident Example	Possible Contributing Factors	Commentary
A prescription was brought into the pharmacy for Havrix® Junior. It was entered as Havrix® Junior but Twinrix® Junior was selected from the fridge and labeled. The error was discovered by the pharmacist upon checking.* *Note: Havrix® is Hepatitis A vaccine; Twinrix® is Hepatitis A and B vaccine.	Unfamiliarity with the vaccine, particularly its indications.[9] Failure to check or verify the indications of the vaccine.[9] Confusion due to look-alike/sound-alike vaccine/drug product names and ambiguous labeling and packaging.[9] Unsafe storage arrangements (e.g., stored too close to similar-looking vaccines).[9]	Implement barcode scanning at prescription preparation which requires scanning of the vaccine barcode to prevent inadvertently labeling the wrong vaccine. *[Automation/computerization]* To prevent potential order-entry errors, differentiate the appearance of similar vaccine/medication names on computer screens by highlighting dissimilarities (e.g., TALLman lettering: HAVrix® vs. TWINrix®).9 *[Simplification/standardization]* Separate/segregate vials and syringes into bins or other containers according to vaccine type and formulation. Never store different vaccines in the same containers.[9] *[Simplification/standardization]* Store vaccines with similar packaging or names on different shelves within the refrigerator/freezer, or in separate refrigerators/freezers, to lessen the risk of errors.9 *[Rules & policies]* To prevent potential order-entry errors, inquire about/confirm the indication for the vaccine with the patient at prescription drop-off or pick-up. *[Rules & policies]* To prevent potential order-entry errors, place Public Health Agency of Canada's "Table 1: Types and Contents of Vaccines Available for Use in Canada" hardcopy near – or a desktop link on – the order-entry computer as a readily accessible reference. (http://www.phac-aspc.gc.ca/publicat/cig-gci/p01-14-eng.php) *[Education & Information]*

Subtheme: Wrong Formulation Selected at Pharmacy		
Incident Example	**Possible Contributing Factors**	**Commentary**
A prescription was written for and entered as Gardasil® 9, but was filled and dispensed as Gardasil®. The error was discovered by the physician when the vaccine was brought in to be administered.* *Note: Gardisil® – protects against 4 types of HPV; Gardisil® 9 – protects against 9 types of HPV.	Unfamiliarity with the vaccine, particularly its new formulations.[9] Failure to check or verify the potential formulations of the vaccine.[9] Confusion due to look-alike/sound-alike vaccines and their formulations.[9]	Implement barcode scanning at prescription preparation which requires scanning of the vaccine barcode to prevent inadvertently labeling the wrong vaccine formulation. *[Automation/computerization]* To prevent potential order-entry errors, differentiate the appearance of vaccine formulations on computer screens by highlighting dissimilarities (e.g. Gardasil® **ORIGINAL** vs. Gardasil® **9 VALENT**) .[9] *[Simplification/standardization]* Separate/segregate vials and syringes into bins or other containers according to vaccine type and formulation. Never store different vaccine formulations in the same containers.9 *[Simplification/standardization]* Store vaccine formulations with similar packaging or names on different shelves within the refrigerator/freezer, or in separate refrigerators/freezers, to lessen the risk of errors.[9] *[Rules & policies]*
Subtheme: No Diluent Dispensed		
Incident Example	**Possible Contributing Factors**	**Commentary**
A pharmacy dispensed Zostavax® II to a patient who subsequently brought the vaccine to their physician for administration. The physician then called the pharmacy to inform them that the diluent was not dispensed along with the vaccine. The pharmacy delivered the diluent to the physician's office.* *Note: Not all vaccines are available as a prepared, ready-to-inject, pre-filled syringe. Many have two vials that require mixing prior to administration: one containing the concentrated vaccine powder, and a second, which is the diluent.	No system to ensure co-dispensing of both vaccine and diluent.[9]	Establish barcode scanning during dispensing that requires scanning the barcodes of both the vaccine and corresponding diluent. *[Automation/computerization]* Affix or dispense labels with illustrated mixing directions to the outside of the designated vaccine storage baskets in the fridge to remind staff to dispense/mix the vaccine with its corresponding diluent (http://www.cdc.gov/vaccines/recs/storage/guide/vaccine-storage-labels.pdf). *[Reminders, checklists, double checks]* Label the specific locations where vaccines are kept to remind staff to combine the contents of vials as indicated.9 *[Reminders, checklists, double checks]* Dispense the products together in a bag (or attached with rubber band) with an auxiliary label to remind staff to include both vials. *[Reminders, checklists, double checks]* Establish a process to store vaccines and their corresponding diluents in the pharmacy together if storage requirements do not differ (e.g. attached using rubber band or label tape).[9,15] *[Rules & policies]* Establish ongoing education of staff involved in dispensing and administering vaccines, which includes discussion of safety issues with vaccines and specific diluents.[9] *[Education & Information]*

TABLE 3: Theme Two – Wrong Dosage

Subtheme: Wrong Dosage for Age Prescribed

Incident Example	Possible Contributing Factors	Commentary
Upon checking, the pharmacist noted that the adult Havrix® dose that was prescribed was not indicated for the 17 year old patient. The pharmacist contacted the prescribing physician and recommended Havrix® Junior.* *Note: Patients aged 1-18 year(s) require Havrix® Junior.	Unfamiliarity with the vaccine, particularly its dose and age specifications.[9] Failure to check or verify the vaccine age indication and the patient's age.[9]	Prior to prescribing a vaccine, verify the patient's age by asking the date of birth (if the patient is available) and referencing the patient's health record, or immunization record, and verifying the indicated age range for the vaccine.[9] *[Rules & policies]* Place easily accessible links to vaccine manufacturer monographs or a chart with vaccine brand names, age-specific formulations, and corresponding indicated ages at/near prescriber computer as an accessible reference. *[Education & Information]*

Subtheme: Wrong Dosage for Age Selected at Pharmacy

Incident Example	Possible Contributing Factors	Commentary
A prescription was brought into the pharmacy requesting Twinrix®. The patient's age, 18 years old, was explicitly written on the prescription. The pharmacy filled and dispensed Twinrix ® adult strength. The error was discovered by the physician before the vaccine was administered.* *Note: Patients aged 1-18 year(s) require Twinrix® Junior.	Unfamiliarity with the vaccine, particularly its dose and age specifications.[9] Failure to check or verify the vaccine age indication and the patient's age.[9]	Work with pharmacy software developers to create a pop-up reminder that appears when the patient's age does not fall within the indicated age range for the prescribed vaccine. This pop-up should only be bypassed with a free-text entry of the reason along with the staff's identifier (e.g. scanning of personal barcode). *[Automation/computerization]* Investigate purchasing differing age-specific formulations of the same vaccine from different manufacturers to help distinguish them (where applicable).[9] *[Simplification/standardization]* To prevent potential selection errors, affix auxiliary labels to the vaccines and/or storage areas to draw attention to the specific ages for these vaccines.[9] *[Reminders, checklists, double checks]* Separate/segregate the storage areas of pediatric and adult formulations of vaccines (e.g. use of baskets or bins).9 *[Rules & policies]* Prior to dispensing a vaccine, verify the patient's age by asking the date of birth (if the patient is available) and referencing the patient's health record, or immunization record, and verifying the indicated age range for the vaccine.[9] *[Rules & policies]* Make immunization schedules easily available to both clinicians/staff and patients/caregivers.[15] *[Education & Information]* Place easily accessible links to vaccine manufacturer monographs or a chart with vaccine brand names, age-specific formulations, and corresponding indicated ages at/near the order-entry computer as an accessible reference. *[Education & Information]*

TABLE 4: Theme Three – Wrong Time

Subtheme: Inappropriate Dosing Schedule Prescribed or Vaccine Dispensed too Early/Late

Incident Example	Possible Contributing Factors	Commentary
A patient's third dose of Twinrix® was given at the prescribed 6 months, but not after the necessary 5 months from the second dose. The error was discovered after the vaccine was administered by the physician. The pharmacist contacted the physician regarding the error, and the physician opted to test the patient to ensure adequate seroconversion.* *Note: The standard dosing schedule for Twinrix® is 3 doses given at 0, 1, and 6 months. Doses must never be given too early or too close together to ensure adequate seroconversion.	Unfamiliarity with the vaccine, particularly its dosing schedule.[9] Failure to check or verify the vaccination schedule and the patient's age, health record, or local immunization information system.[9]	If possible, link the immunization schedule to the pharmacy system and/or vaccination record.[9] *[Automation/computerization]* For frequently administered vaccines, establish standard, pre-printed order sets or protocols, which include: • Information regarding any required follow-up doses.[9] *[Simplification/standardization]* Build an alert into the vaccination record to remind staff to discuss prior immunizations with the patient or caregiver.9 *[Reminders, checklists, double checks]* Prior to prescribing or dispensing a vaccine, consult the manufacturer's dosing schedule (e.g. standard, rapid, or alternate schedule) to verify appropriateness with respect to patient's age. *[Rules & policies]* Prior to prescribing or dispensing a vaccine, verify the patient's current immunization status by checking the patient's health record, pharmacy profile, and vaccination record to avoid invalid doses administered too soon.9 *[Rules & policies]* Post up-to-date, easy-to-read immunization schedules for infants, children, teens, and adults that staff can quickly reference in clinical areas where vaccinations may be prescribed, dispensed, or administered (available from the Canadian Immunization Guide http://www.phac-aspc.gc.ca/publicat/cig-gci/p03-eng.php).[9] *[Education & Information]* Encourage patients, or their caregivers, to track their vaccination status using ISMP Canada's MyMedRec app or Immunize Canada's app to record and store vaccine information and to access vaccination schedules (https://itunes.apple.com/ca/app/mymedrec/id534377850?mt=8 http://www.immunize.ca/en/app.aspx). [Education & Information]

Subtheme: Expired Medication Dispensed/Administered

Incident Example	Possible Contributing Factors	Commentary
A pharmacy filled a prescription for Menjugate® that had been expired for over one month. The physician noticed the error prior to injecting the child. The mother contacted the pharmacy to request an exchange for a valid vaccine.	Unsafe storage conditions (e.g. expired vaccines).[9] Failure to check vaccine expiration date prior to dispensing or administering.	Implement barcode scanning at prescription preparation and configure pharmacy software to prompt user to enter expiration date of vaccine once scanned. *[Automation/computerization]* Use a standardized vaccination documentation form that includes a prompt to document vaccine expiry prior to the dispensing and administration of vaccine. *[Simplification/standardization]* Check for expired vaccines weekly and when vaccines are removed from stock. Rotate the stock based on the expiration date to prevent unnecessary waste by placing vaccines first to expire in the front.9 [9] *[Rules & policies]* If an expired vaccine has been administered in error, revaccination with a valid dose is advised.[9] *[Rules & policies]*

TABLE 5: Theme Four: Wrong Storage

Subtheme: Wrong Storage in Patient's Home		
Incident Example	**Possible Contributing Factors**	**Commentary**
A physician contacted the pharmacy stating that they would not administer the vaccination because Twinrix® was left unrefrigerated by the patient for over 7 hours. The patient claimed that the pharmacy failed to inform the patient's agent that the vaccine is to be refrigerated. The pharmacy only asked if the agent was going home immediately, but did not ask to place the product in the refrigerator.	Patient/Patient's agent not counseled/informed of the storage requirements for the vaccine.	Have the checking pharmacist place indicators/ reminders on prescription bag to remind dispensing staff to counsel regarding storage conditions (e.g. different coloured bag clips or stickers that indicate "fridge"). *[Reminders, checklists, double checks]* Place an auxiliary label directly onto the vaccine carton that brings attention to the storage conditions of the vaccine (e.g. "This medication must be stored in the refrigerator"). *[Reminders, checklists, double checks]* Have the pharmacy system print out a specific vaccine information sheet that includes storage conditions each time the vaccine is processed; this is to be dispensed along with vaccine. *[Rules & policies]* Where possible, inform patients to fill their vaccines on the day it is to be administered so as to avoid the need to take the vaccine home and store it in the fridge. *[Education & Information]*
Subtheme: Wrong Storage in Pharmacy		
Incident Example	**Possible Contributing Factors**	**Commentary**
A patient presented to the pharmacy to pick up their Twinrix® vaccine. The technician went to retrieve the receipt from the drawer and discovered that the vaccine had also been stored unrefrigerated with the receipt. A new vaccine was labelled and dispensed.	No system or protocol to ensure proper storage of vaccines that have been checked by the pharmacist	Use different coloured baskets for refrigerated and frozen items to alert checking pharmacist, pharmacy technician, and pharmacy staff to the appropriate storage conditions of the vaccine. *[Rules & policies]* Delegate the responsibility of storing the checked vaccine into the dedicated "dispensing" fridge to the checking pharmacist/pharmacy technician. *[Rules & policies]*

TABLE 6: Theme Five – Wrong Patient

Incident Example	Possible Contributing Factors	Commentary
A patient presented to the pharmacy to pick up their vaccine for Havrix®. The pharmacy dispensed the incorrect patient's vaccine. This vaccine was also Havrix® with the same patient first name but different last name. The error was discovered by the physician when the vaccine was brought in to be administered.	Failure to check or verify the vaccine and other prepared contents with corresponding patient or patient name.	Arrange to have refrigeration and freezer units large enough to store and organize checked prescriptions.[9] *[Simplification/ standardization]* Store checked vaccines in their own dedicated basket in the designated fridge according to last name (e.g. one basket each for last names A-F, G-N, O-Z). *[Simplification/standardization]* Highlight the patient's name on both the prescription receipt and label in order to draw attention to the patient's name after dispensing. *[Reminders, checklists, double checks]* At prescription pick-up, verify or double-check at least one other patient identifier (e.g. address), in addition to the patient's first and last name, prior to releasing the prescription. *[Reminders, checklists, double checks]*

TABLE 7: Theme Six – Wrong Documentation

Incident Example	Possible Contributing Factors	Commentary
A patient presented to the pharmacy with a prescription for Zostavax® to be administered by the pharmacist. It was discovered by the pharmacist shortly before the vaccine was to be administered that the patient had lymphoma.* *Note: The administration of Zostavax®, a live-attenuated vaccine, is contraindicated in patients with lymphoma.	Failure to check or verify the vaccination schedule and the patient's health record or local immunization information system.[9]	For frequently prescribed/administered vaccines, establish pre-printed standard order sets or protocols, which include: • Criteria for screening patients to determine the need for vaccination, indications, contraindications, and precautions.[9] *[Simplification/standardization]* To avoid omissions, duplicate vaccine doses, and administration of inappropriate or contraindicated vaccines: • Inquire about the patient's medical conditions at prescription drop-off. • Document any conditions into the pharmacy software's dedicated "Medical Conditions" section so that a drug-disease interaction check is performed when the vaccine is processed. • Check the patient's health record, pharmacy profile, and vaccination record (if applicable or available). *[Rules & policies]*

TABLE 8: Theme Seven – Wrong Manner/Route

Incident Example	Possible Contributing Factors	Commentary
A pharmacist was researching into Zostavax® for a patient and discovered that it is given subcutaneously. The pharmacist then remembered administering Zostavax® to a previous patient intramuscularly. Upon checking the documentation, the pharmacist did indeed administer the vaccine intramuscularly.	Unfamiliarity with the vaccine, particularly its protocol and route of administration.[9] Failure to check or verify the vaccine administration protocol.	For frequently administered vaccines, establish pre-printed standard order sets or protocols, which include: • Directions for administering the vaccine, including the route and any special procedures required to enhance safety.[9] *[Simplification/standardization]* Highlight the route of administration on vaccine carton labels by circling or using boldface type or colour to bring attention to the information as necessary.[9] *[Reminders, checklists, double checks]* Post a quick reference for clinicians to verify the route of administration for all vaccines. A chart is available from the Immunization Action Coalition (IAC) (http://www.immunize.org/catg.d/p3085.pdf).[9] *[Education & Information]* Place easily accessible links to vaccine manufacturer monographs, or a chart with multi-dose vaccine dosages, at/near administration area. *[Education & Information]*

CONCLUSION

Vaccinations are a vital component of preventive healthcare on both the individual and population level. Therefore, even relatively benign mistakes (e.g. administration of an expired vaccine) can expose individuals and communities to deadly infectious diseases. As healthcare professionals, it is our duty to protect the public by preventing immunization-related errors by exercising vaccine vigilance. This is especially true for pharmacists as our scope of practice expands and permits administration of an increasing number of vaccines in addition to our traditional dispensing role. Considering the complexity of the provincial immunization schedule, the abundance and variety of vaccines and their individual specifications, and the increasing responsibilities of pharmacists, vaccine vigilance on its own is not a sufficient mechanism to protect against vaccine-related errors.

This multi-incident analysis has provided the means to implement a system-based error prevention model intended to supplement vaccine vigilance exercised by the pharmacy team. It has highlighted the majority of vaccine-related errors in community pharmacy practice, and has facilitated the development of effective, yet practical, recommendations. Such recommendations vary greatly in their impact to current workflow, ranging from improvements that may be implemented immediately (e.g. staff/patient education and re-organization of vaccine storage area) to those that require time and resources (e.g. installation of barcode scanning devices). By utilizing both individual and system-based error prevention models, pharmacists can refine their contribution to immunization coverage in Canada.

ACKNOWLEDGEMENTS

The authors would like to acknowledge Roger Cheng, Project Lead, ISMP Canada, for his assistance in conducting the incident analysis of this report.

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 (http://www.cphir.ca). The CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (http://www.ismpcanada.org/cmirps.htm). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings. The incidents anonymously reported by community pharmacy practitioners to CPhIR were extremely helpful in the preparation of this article.

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