Medication error reporting and learning, and pharmacovigilance systems at the national and organizational level

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ISMP Error Reporting Programs

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ISMP National Medication Errors Reporting Program

— Started in 1975, the first and only voluntary, practitioner-based medication error-reporting program

— The objectives of the ISMP MERP are:
  • Learn the underlying causes of reported medication errors or hazards
  • Disseminate valuable recommendations to individuals and organizations to prevent future errors
  • Provide guidance to the healthcare community, regulatory agencies, and pharmaceutical and device manufacturers
  • Provides narratives, photos, computer screen shots.
ISMP National Medication Errors Reporting Program

- National Medication Error Reporting Program
- National Vaccine Error Reporting Program
- Consumer Error Reporting Program
Why we operate the program

— Capitalize on provider and consumer altruism
— Reporters need to trust in identity non-disclosure
— To provide a personal response to reporting errors (how we use the information)
— To demonstrate we are non-critical of individuals
— To provide expert and credible analysis of reported errors
Why we operate the program

— To share de-identified reports with the US Food and Drug Administration (FDA), the United States Pharmacopeia (USP), drug manufacturers, etc.

— Program operates independent of regulatory/accrediting bodies

— Impact is visible; changes based on reports (“Thanks to your reporting”)

— Program not operated for commercial gain
Safety requires a state of Mindfulness (Part 1)

In an effort to make healthcare safer, many healthcare organizations have adopted a variety of strategies to improve patient outcomes. One such strategy is mindfulness, which involves being present and focused on the present moment. Mindfulness is particularly important in healthcare settings, where it can help providers stay calm and focused, which can ultimately lead to better patient outcomes.

The origins of mindfulness can be traced back to ancient India, where it was practiced as a method for achieving spiritual enlightenment. Over time, mindfulness has been adapted for use in various settings, including healthcare, where it has been shown to be effective in improving patient outcomes.

Mindfulness is a practice that involves being present and focused on the present moment. It is a way of being that can help providers stay calm and focused, which can ultimately lead to better patient outcomes.

In healthcare, mindfulness can be practiced in a variety of ways. For example, providers can practice mindfulness by taking deep breaths before addressing patients, or by focusing on their breath while performing a procedure. Mindfulness can also be practiced in a more structured setting, such as a meditation session, where providers can learn to quiet their minds and focus on the present moment.

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Mix-ups between the influenza (flu) vaccine and COVID-19 vaccines

Since the 2021-22 influenza (flu) vaccine became available last month, the Institute for Safe Medication Practices (ISMP) has received 16 cases of accidental influenza and coronavirus disease 2019 (COVID-19) vaccine mix-ups. All reports were sent by consumers or healthcare practitioners via one of the ISMP national error reporting programs (www.ismp.org/report-medication-errors). Most of the mix-ups occurred in patients who consented to a flu vaccine but received one of the COVID-19 vaccines instead. In three cases, patients received the flu vaccine instead of the intended COVID-19 vaccine. All the events occurred in community/ambulatory care pharmacies.

In the October 7, 2021, ISMP Medication Safety Alert! (www.ismp.org/node/278679), ISMP reviewed several errors with vaccine mix-ups and noted several possible contributing factors. Given that flu season is a busy time for vaccinations, many pharmacies are facing an increased demand for vaccination services. Since many of the errors were reported by consumers, details about the contributing factors were not provided in many cases. However, the possible causative factors we have gleaned from the reports include the following:

- **Increased demand and coordination of the vaccines.** Flu season is already a busy vaccination time for community pharmacies. And, with the approval of the Pfizer-BioNTech vaccine booster and the surge in COVID-19 cases, pharmacies can barely keep up with the vaccination demand. Also, the ability to administer the flu and COVID-19 vaccines during the same visit (www.ismp.org/eval/786) may be a contributing factor.

Syringes near each other. Two vaccine providers indicated that they had picked up a COVID-19 vaccine instead of the flu vaccine syringe, which were right next to each other in the vaccination area. Brining both vaccines into a patient vaccination area when they are not needed sets the vaccine provider up for a possible mix-up.

Unlabeled syringes. While many vaccine providers purchase the flu vaccine in manufacturer filled syringes, which are labeled, COVID-19 vaccines are available in multiple-dose vials and must be prepared in a syringe for administration to patients. It is possible that these prepared COVID-19 vaccine syringes were not labeled. Also, COVID-19 vaccine doses may be prepared in an unlabeled syringe by one healthcare provider and administered by another; as a result, the person who administers the vaccine may not visually verify the empty vial if it remains with the person who prepared the dose.

Distracted. After a vaccine mix-up, one vaccine provider told the patient that he had become distracted by their conversation. Interruptions and other distractions in a busy pharmacy could also lead to mix-ups.

Staffing shortages. Because most healthcare providers are experiencing staffing shortages, it is possible that current vaccine providers are multitasking and are hurried/rushed, even when patients are scheduled for vaccinations. For example, a pharmacist who was working alone in a busy pharmacy recently told us that she needed to administer more than 50 vaccinations during her shift, in addition to dispensing prescriptions.
IMSN CVSIG issues Recommendations for Global Implementation of Safe COVID-19 Immunization Practices

During the fall of 2020, as the world waited in anticipation for the emergency use/conditional marketing authorization of COVID-19 vaccines, members of the International Medication Safety Network (IMSN) began to discuss safety issues that might impact global immunization roll out efforts with regard to the knowledge on vaccination errors already gathered by the IMSN.

With the goal of sharing experience and learning from member countries to address COVID-19 vaccine safety issues, the IMSN Executive Committee formed the IMSN COVID-19 Vaccine Safety Interest Group (CVSIG) in February 2021.