



Medication Safety Alerts

This column draws on US and Canadian experience and includes, with permission, material from the ISMP Medication Safety Alert! biweekly bulletin, published by the Institute for Safe Medication Practices (ISMP), Huntingdon Valley, Pennsylvania, USA.

News

Medication System Incompatibility Reported

ISMP Canada recently assisted many Canadian hospitals who were faced with an unforeseen medication system problem. Both Abbott Laboratory Canada and Baxter Inc. also provided assistance to hospitals and made significant efforts to resolve the issue. The two manufacturers displayed commitment to investigating the root causes of the incompatibility of the Abbott Lifeshield prefilled syringes with the Baxter Continu-Flo I.V. ports. When the new pre-filled syringes from Abbott appeared in Canadian hospitals, it became evident during education sessions, that the new Abbott syringe needles were pulling the Baxter ports from the Continu-Flo tubing. There was a demonstrated risk that the “closed IV system” could become “open” when the new syringe was removed from the tubing.

As an interim measure and short-term solution, Abbott Laboratory Canada has shipped the regular Abboject product lines into Canada via the Special Access Program.

All updates on this issue are posted in ISMP Canada's website: www.ismp-canada.org

A National Medication Error Reporting System

ISMP Canada participated in an invitational workshop in Ottawa, entitled "National Medication Error Reporting and Prevention: A Shared Responsibility". The invitational workshop was co-sponsored by CSHP and Health Canada. One important consensus reached by the participants was the need for a voluntary medication error reporting system for Canada. ISMP Canada's vision is to promote and work collaboratively to achieve such a system. The two-day workshop resulted in the establishment of a coalition, whose mandate is to prepare and submit a business plan to the Federal/Provincial Territories Committee. The business plan will seek funding to implement a national medication reporting and prevention program in Canada. The coalition members are: Health Canada, ISMP Canada, CSHP, CPhA, CMA, CNA, Rx&D, CHA, as well as, a consumer representative. Bruce Roswell, Director of Drug Surveillance of the Bureau of Therapeutic Product Programs, Health Canada, is coordinating this important effort. The target timeline for submitting the business plan is April 2001. ISMP Canada will keep you posted.

Safety Briefs

Reported Error with Expired Flu Vaccine

ISMP Canada has received a report of inadvertent administration of last year's flu vaccine (expiry date July 2000) to 12 patients.

The root cause analysis of the event has yielded the following contributing factors:

- 1) The multidose vial with an expiry date of July 2000 had been distributed in the spring of 2000. This product was dispensed after the 'flu vaccine injection campaign' because of the extended duration of the 1999-2000 flu season. The multidose vial was different from the pre-loaded syringes used in the vaccine injection campaign.
- 2) The multidose product was stored in a department, which was not on the list for quality inspections by the Pharmacy Department.
- 3) The health care professional administering the product had remembered using the pre-loaded syringes, made by an alternate manufacturer, during the 'flu campaign' of the previous year, 1999-2000. It was therefore, incorrectly assumed that the vials in the fridge were new (for the 2000-2001 year).

ISMP Canada is sharing this information since it is felt there is potential risk of this happening in other clinics, doctor's offices and hospitals.

Safe Medication Practice Recommendations:

- i) Communicate to all Clinics, Nursing Units, Doctor's Offices and Departments, the need to check refrigerators for expired flu vaccine.
- ii) Ensure the checking list for expired products cover all nursing units, and consider expanding the quality assurance inspection process. It is recognized some areas are not checked by Pharmacy due to accessibility and/or hours of service and/or Pharmacy staffing.
- iii) Ensure refrigerated products are included in the inspection processes. It is recognized that cassette exchanges, or procedures for non-refrigerated drugs may differ from those for refrigerated products. Sometimes the refrigerated items are easily missed.
- iv) Each year, during the process of ordering a new supply of flu vaccine, send a 'Reminder Notice' to all areas serviced by your Pharmacy to "check for expired flu vaccine". Make the reminder notice a part of your yearly protocol.**

ISMP Canada expressed great appreciation to the health care professional for notifying us of the error.

Concentrated Potassium Chloride Injection

Many Canadian hospitals are following the lead of our American counterparts by taking serious efforts to eliminate concentrated potassium chloride (KCl) injection from Nursing Unit floorstock medications. There is ever-increasing awareness that concentrated KCl availability on Nursing Units is one of the “root causes” of errors which involve mistaking KCl for normal saline or sterile water or furosemide.^{1,2,3} ISMP Canada is planning an information blitz to highlight the issue and to further encourage Canadian hospitals to address this risk-management issue. ISMP in the U.S. has reported that the majority of hospitals in the U.S., have taken the initiative to remove this hazardous substance from patient care areas. Adverse drug events causing death, due to KCl concentrate, have thereby, been reduced from a previous reported high, of twelve deaths in one year, to one death in one year. It is recognized this is still one death too many.

Currently, in Canada, there is an increasing array of pre-mixed IV solutions, containing KCl, available. The pre-mixed solutions are competitively priced and offer a practical alternative to the need to mix solutions in patient care areas. The Hamilton Health Science Corporation, the University Health Network (UHN) in Toronto, Hospitals in Saskatoon and The Sault Area Hospitals have shared their initiatives to remove KCl concentrate from floorstock. William Osler Health Care Corporation is also in the process of developing a project plan. ISMP Canada is interested in learning of the successes and challenges occurring in your hospital related to this issue. [Make this important medication system improvement your patient safety initiative for the year 2000/2001!](#)

References are noted at the end of this column.

(The special feature described below is taken directly from ISMP Medication Safety Alert! Volume 5, Issue 11, May 31, 2000. It is included in this issue of the Canadian Journal of Hospital Pharmacists because of the discussion and ongoing debate pertaining to voluntary vs mandatory reporting programs)

Mandatory reporting programs:

Why we can't "look the other way"

Since the release of the Institute of Medicine (IOM) report, the issue of mandatory vs. voluntary medical error reporting has been actively debated, with individuals and professional organizations widely divided on the issue. Now, months later, many otherwise staunch supporters of voluntary reporting programs have suggested that we simply “look the other way” and allow - even support - the inevitable progression of mandatory reporting programs, citing a need to respond to the public's distrust in healthcare. Yet, such misguided support, or even “looking the other way,” carries a high price tag.

Mandatory reporting programs have infiltrated healthcare – subtly at first, but potentially dangerous in the end. As we struggle to embrace a blame-free culture within our

organizations, external mandatory reporting programs unravel our best efforts. We work hard to make it safe for practitioners to report errors within our organizations. But we can do little to protect them (and the organization) from the typical effects of disclosure to mandatory reporting programs – fear, financial penalties, punitive actions concerning licenses, and legal and public scrutiny. How can we truly make it safe to disclose errors internally when we are forced to report the most serious errors to external mandatory reporting programs that have punishment at their core? The IOM report leaves us to struggle with this conundrum by recommending both nonpunitive systems for reporting and analyzing errors within our organizations as well as external mandatory reporting programs designed to hold providers “accountable” and make errors “costly.”

At best, mandatory reporting programs promise large numbers of reported errors (despite evidence to the contrary). But will the data be useful when it lacks insightful narratives from front line practitioners? Will large numbers and the variety of reports overrun the program’s ability to provide expert analysis and use data effectively? Will the number of reported errors be held out to be a true reflection of patient safety when underreporting is rampant and many errors go undetected? Will it lead to a false sense of security and tacit acceptance of errors? Perhaps it is not the “mandatory” component of reporting programs that is most problematic, for reporting is fundamental to all error reduction efforts. Rather, it’s the punitive intent of mandatory reporting programs, its harmful effect on nonpunitive error reduction efforts, and its ineffective use of data.

On the other hand, voluntary reporting systems have been much more successful in bridging the patient safety gap. Their intent is to learn about errors and disseminate the knowledge at the first sign of a problem, not to enforce standards or hold providers accountable through threats of punishment. The driving force for reporters is a deep sense of altruism and concern for patients, not compliance with a mandate that may result in sanctions. The programs’ usefulness lies not in the volume of reports received, but in the quality and contextual richness of practitioners’ narrative reports that represent a sampling of errors. In fact, voluntary programs do not wait until a numerical threshold has been exceeded or multiple patient deaths have been reported to learn from errors and suggest system-based action. Because of clear successes with voluntary reporting programs, more must be done to expand voluntary reporting. The major barrier to reporting is the potential loss of legal protection for the insightful analysis contained in reports. Practitioners do not need mandates to force error reporting. They just need to feel safe doing so. Until healthcare embraces such a culture and protects error reports from legal discovery, error reporting will continue to be an untapped resource. Don’t make the situation worse by supporting mandatory reporting, either passively or actively. Such support can only serve to hinder our efforts to improve patient safety.

References:

1. [Sentinel Event Alert. Joint Commission on Accreditation of Healthcare Organizations. Issue One. February 27, 1998. http://www.jcaho.org](http://www.jcaho.org)

2. USP Quality Review. Intravenous Potassium Predicament. The United States Pharmacopeial Convention, Inc. October, 1996. <http://www.usp.org>
3. Cohen, Michael. editor. Medication Errors- Chapter: High-Alert Medications: Safeguarding Against Errors.1999. Published by the American Pharmaceutical Association, Washington. <http://www.aphanet.org>

