

Medication Safety Issues - 1

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ABSTRACT

Preventing medical or medication errors is pivotal in quality patient care and safety. Significantly, error prevention activities are multifactorial. These include, (i) enlisting staff creativity in improving safe practices, (ii) patient education, (iii) provision of information leaflet, (iv) clarity in instructions, (v) application of failure mode and effects analysis, and (vi) care in approving access to medications.

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INTRODUCTION

Medication and medical errors are serious problems throughout the world. It has been estimated that between 44,000 and 98,000 Americans die each year as a consequence of medical errors, with the annual financial cost estimated at approximately US\$40 billion (1-3). In Australia, the direct cost to the acute care system due to medication errors have been estimated to be between AUD\$867 million to over AUD\$1 billion annually (4,5). Importantly, a large proportion of medical errors or adverse drug events are preventable errors (1-3, 6-9).

Accordingly, the purpose of this series of articles is to increase the awareness of health professionals in Malaysia on preventable medication or medical errors. The issues highlighted in this article are drawn primarily from *ISMP Medication Safety Alert!*, and are used with permission from the Institute for Safe Medication Practices, Pennsylvania, USA (www.ismp.org). It is our hope that this contribution will result in safe medication or medical practices and improved patient care.

Systems thinking; Tap into staff creativity to unleash innovation (10).

A letter to the editor was published in the *New England Journal of Medicine* from a physician

who suggested using metal detectors to prevent the risk of injuries from metal objects during magnetic resonance imaging (MRI) (11). Unfortunately, his suggestion was spurred by the recent tragic death of a six-year-old child in New York who suffered a skull fracture and intracranial haemorrhage after an oxygen tank was pulled by the magnet into the machine at high speed.

As noted by the author, injuries from undetected or misplaced metal objects (e.g. IV drug poles, sandbags containing metal filings, defibrillators, wheelchairs, etc.) brought into MRI exam rooms are not uncommon. Yet, staff training and patient questionnaires to detect metal implants remain the most common methods used to prevent such incidents.

In fact, education has been healthcare's bread and butter for preventing errors and injuries. And while education may prevent some errors, its success is limited because it relies heavily upon human memory and vigilance. More to the point, education alone fails to change the system in a way that would make it impossible for people to make mistakes.

More effective solutions require systems thinking. The suggestion to use highly sensitive

walkthrough metal detectors (which are available commercially for about US\$2,000-\$5,500 and require minimal maintenance) to prevent accidental introduction of a metal object into a MRI exam room is an excellent example of systems thinking. This coupled with staff education and patient screening has a high likelihood of *preventing* injuries. But how did the physician come up with such a powerful suggestion? In retrospect, it seems so obvious. Yet systems thinking is not as easy as it seems.

Our history of errors with potassium chloride concentrate for injection in patient care units demonstrates this very well. Until systems thinking prevailed, many organizations relied upon staff education and manufacturer label warnings to prevent administration of potassium chloride concentrate without proper dilution. Although lessened, errors persisted until the pharmaceutical industry manufactured premixed solutions, physicians standardized potassium replacement therapy to maximize use of commercially available solutions, and vials of potassium chloride were removed from patient care units. Unfortunately, it took years for the healthcare industry to come up with and implement such an effective system-based solution that now seems so simple and intuitive.

To become more proficient at systems thinking, multidisciplinary teams must openly discuss medication errors and refuse to settle for old familiar (and ineffective) ways of solving problems. If education is identified as an error reduction strategy, we can't stop there. Instead of just building inspections into processes to detect errors before they reach patients, we need to find ways to actually *prevent* them. We must always ask, "Are there ways to make it impossible, not just unlikely, for people to make such a mistake?" Systems thinking is the key needed to bridge the gap between understanding the causes of errors and selecting error reduction strategies that have the greatest likelihood of success. With practice and a little creativity, we can become more skilful and innovative in identifying system-wide strategies that work *continuously* and *automatically* to prevent errors and injuries.

Educating the patient – key to patient safety (12).

Education provided to patients while in the physician's office can arm them with the information needed to prevent errors. A patient

was to receive methotrexate IV followed in an hour by fluorouracil IV as part of a treatment regimen for breast cancer. To reduce methotrexate toxicity, her oncologist prescribed oral leucovorin rescue to be started 24 hours after the methotrexate. He wrote the order as "leucovorin 25 mg, one every 6 hours x 6 *doses* starting 24 hours *after* chemotherapy." The pharmacy provided the correct medication, but the directions typed on the label were to "Take one tablet every 6 hours for 6 *days* starting 24 hours *before* chemotherapy." The patient remembered what she'd heard in the doctor's office and called her physician for clarification. Had she taken the drug as directed on the label, she would have negated the therapeutic effect of the chemotherapy.

Failure mode and effect analysis can help guide error prevention efforts (12).

Too often, marketing efforts, contractual agreements with purchasing groups or vendors, and cost serve as primary sources of information when making decisions about which medical products to purchase and use. Evaluation and input from those who would be using the products may not be sought and error potential may not be considered ahead of time. Later, this may lead to unforeseen problems in the hands of clinical users.

These pitfalls can be avoided by using a process known as Failure Mode and Effects Analysis (FMEA) to examine the use of new products and the design of new services and processes to determine points of potential failure and what their effect would be – *before any error actually happens*. In this regard, FMEA differs from Root Cause Analysis (RCA). RCA is a *reactive* process, employed *after* an error occurs, to identify its underlying causes. In contrast, FMEA is a *proactive* process used to look more carefully and systematically at vulnerable areas or processes. FMEA can be employed *before* purchase and implementation of new services, processes or products to identify potential failure modes so that steps can be taken to avoid errors *before* they occur.

How can FMEA be used to reduce the risk of medication errors? To cite just one example, an interdisciplinary committee could use FMEA to assess new drugs being considered for the formulary. Here's how the process would work.

- Step 1: The committee would explore how

the intended product would be procured and used, from acquisition through administration. Who would prescribe the drug and for what type of patient? Where would the drug be stored? Who would prepare and dispense it? How would it be administered?

- Step 2: Potential failure modes (how and where systems and processes may fail) would be identified while considering how the product would be used. Could the drug be mistaken for another similarly packaged product? Does the label clearly express the strength or concentration? Does the name sound or look like another drug on the formulary? Are dosing parameters complex? Is the administration process error prone?
- Step 3: Once failure modes have been identified, staff would determine the likelihood of making a mistake and the potential consequences of an error. What would happen to the patient if the drug were given in the wrong dose, at the wrong time, to the wrong patient, by the wrong route, at the wrong rate?
- Step 4: Staff would identify any preexisting processes in place that could help detect the error before it reaches the patient, and evaluate their effectiveness based upon knowledge of human factors.
- Step 5: If failure modes could cause errors with significant consequences, actions would be taken to prevent the error, detect it before it reaches the patient, or minimize its consequences. A few examples include using an alternative product; preparing the drug in the pharmacy; standardizing drug concentrations, order communication and dosing methods; using auxiliary warning labels or computer alerts; and requiring entry of specific data into computer systems before processing orders.

Care with what you write! (13).

A hospital reported mix-ups between two different “rubicin” products (anthracyclines). A nurse called the pharmacy to report that the colour of the idarubicin dispensed from the pharmacy was different than the colour of the dose she had given the day before. Further investigation revealed that the patient had received daunorubicin instead of idarubicin on the previous day because staff thought they were both the same drug. With five different “rubicin” products on the market, each with similar names, and two with

liposomal forms, mix-ups are not surprising. To avoid confusion, prepare a chart for the pharmacy and the oncology unit that displays all the anthracycline products by generic name, brand name(s), investigational drug name/identifier, and liposomal forms if available. Include dosing information if desired. By the way, we heard that the “Rubicin” family does not like to be identified by first name only. So don’t use Val, Ida, Donna or Epi. Doc’s full name should also be used.

Care with what you use and who has access to medications (14).

TIMENTIN® (ticarcillin and clavulanate potassium) 3.1 grams IV was ordered for a patient after the pharmacy had closed. A nursing supervisor went into pharmacy, but could only find the pharmacy bulk package which contains 31 grams. She selected two vials and brought them to the patient care unit. A staff nurse assumed that each vial contained one dose. She gave the patient one vial at 1 am and another at 5 am. The patient developed seizures, acute renal failure, congestive heart failure, and eventually died. When questioned, both the supervisor and nurse said that they had misread the 31 grams as 3.1 grams. For a time, a shortage of 3.1 gram Timentin vials resulted in availability of only the 31 gram bulk containers in the pharmacy. Lesson to be learned: Patients are at risk when non-pharmacists have complete access to a pharmacy after hours. With current technology, planning, and cooperation from medical and nursing staff, night access to the pharmacy can be eliminated, even in rural hospitals. If there’s any chance that medications packaged in pharmacy bulk packages might somehow reach patient care areas, make sure that extra warnings are affixed to the containers.

Drug information leaflets in error prevention (15).

Drug information leaflets handed to patients can help prevent errors. A verbal order was given to a pharmacist for **NOROXIN** (norfloxacin) 400 mg bid x 5 days. However, the pharmacist heard, transcribed, and dispensed **NEURONTIN** 400 mg instead. When the patient got home, he read the leaflet and called the pharmacy to ask why he’d been given medicine for seizures instead of the anticipated antibiotic for a urinary tract infection. The prescription was clarified with the patient’s physician and the error was corrected. While there are many ways that errors like this

can be prevented, it's important to point out the value of patient information leaflets as a backup when other systems fail. Instruct patients about the importance of seeking counselling from

pharmacists when obtaining prescriptions and reading leaflets when they are provided. Armed with proper information, patients can be a strong defence against errors.



REFERENCES

1. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health care system. Washington DC: National Academy Press; 2000.
2. Leape LL, Brennan TA, Laird NM, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients. *N Engl J Med* 1991; 324: 377-84.
3. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH. Incidence of adverse events and negligence in hospitalized patients. *N Engl J Med* 1991; 324: 370-76.
4. Australian Health Minister's Advisory Council. The final report of the Taskforce on quality in Australian health care. Canberra: Australian Government Publishing Service; 1996.
5. Australian Council for Safety and Quality in Health Care. Safety First – Report to the Australian Health Ministers' Conference. Canberra: Australian Government Publishing Service; 2000.
6. Lesar TS, Briceland L, Stein D. Factors related to errors in medication prescribing. *JAMA* 1997; 277: 312-317.
7. Roughead EE, Gilbert AL, Primrose JG, Sansom LN. Drug-related hospital admissions: a review of Australian studies published 1998 – 1996. *MJA* 1998; 168: 405-408.
8. Hayward RA, Hofer TP. Estimating hospital deaths due to medical errors. *JAMA* 2001; 286:415-420.
9. Bates D, Spell N, Cullen DC, Burdick E, Laird N, Petersen LA, Small SD, Sweitzer BJ, Leape LL. The costs of adverse drug events in hospitalised patients: adverse drug events prevention study group. *JAMA* 1997; 277: 307-311.
10. ISMP Medication Safety Alert! 2nd October 2001.
11. Landrigan C. Preventable deaths and injuries during magnetic resonance imaging. *N Engl J Med*. 2001;345:1000-1001.
12. ISMP Medication Safety Alert! 17th October 2001.
13. ISMP Medication Safety Alert! 31st October 2001.
14. ISMP Medication Safety Alert! 23rd Jan 2002.
15. ISMP Medication Safety Alert! 6th Feb 2002.