

## Human Factors and Substitution Errors

Approximately 45-50% of medication errors reported to the USP-ISMP Medication Error Reporting Program (MERP) are related to problems with product labelling, packaging and nomenclature.<sup>1</sup> Although many of these problems involve original manufacturer products, they can originate from hospital in-house manufacturing and packaging. ISMP Canada has received two error reports involving in-house packaging practices that contributed to substitution errors and resulted in patient harm. The reporting hospitals indicated a desire to share information about their respective errors with others for learning purposes.

In the first case a patient diagnosed with methanol overdose was transferred from another facility and prescribed “continue IV ethanol drip at 100 mL/h” and “ethanol to dialysate as per protocol”. The Pharmacy initially supplied pre-packaged 100% ethanol for addition to the dialysate and, after clarification with the physician, prepared an intravenous infusion solution of 10% ethanol. Both items were prepared in similar sterile bottles as shown in Figure I. Although the bottles were correctly labelled, the 100% ethanol intended for addition to dialysate was inadvertently administered intravenously. The patient initially developed renal impairment as a result of the error. The patient also required skin grafts to repair necrotic wounds, resulting from injection of 100% ethanol. Fortunately, the patient made a full recovery.

The hospital identified the following possible contributing factors to the error:

- Written order - the order for IV ethanol infusion did not specify the drug concentration.
- Accessibility of information - the hospital manual describing parenteral administration policies listed ethanol information under ‘alcohol’. The nurse attempted to search for information under ‘ethanol’ and was unable to locate information.
- Packaging of products - the 100% ethanol was supplied in a clear glass evacuated bottle with stopper. This bottle can be spiked and is compatible with intravenous administration sets.
- Label design - although the 100% ethanol product was labelled with a computer-generated warning: “For Dialysis Use Only, Not for Injection”, the warning was not distinct from other label information.

As a result of the hospital's in-depth review of the event, the following system changes were recommended and instituted:

1. Development of a pre-printed treatment order set for the management of methanol overdose.
2. The manual describing intravenous medication policies has been modified to include a cross-reference for ethanol and alcohol.
3. 100% ethanol prepared for addition to dialysate is now prepared in amber glass bottles with screw caps that are incompatible with IV sets, to prevent inadvertent IV infusion. See Figure II.
4. The amber bottles containing 100% ethanol are labelled with bright orange auxiliary warning labels, stating “Not For Injection”.



**Figure I:** Similar packaging and labelling of an IV solution and a solution intended for addition to dialysate.



**Figure II:** Changes implemented to better differentiate an IV solution from a solution intended for addition to dialysate.

The second error report involved inadvertent administration of a topical solution into a patient's eye instead of the intended ophthalmic preparation. A specialty ophthalmic solution had been prepared and dispensed in a wide-mouthed container to facilitate pouring the solution into an eyecup. The container was similar to bottles used for in-house manufactured topical solutions, Figure III. A bottle of the topical solution was inadvertently included in a supply of ophthalmic solutions to the nursing unit's floor stock. The topical solution was administered and resulted in eye damage that required aggressive corrective treatment. The label information describing the topical product as intended "For External Use Only" went unnoticed by three individuals separately handling the product.



**Figure III:** Topical product and ophthalmic solution manufactured and dispensed in similar containers.

The following system changes have been implemented by the hospital:

1. Physician ordering practices were changed to correspond with marketed ophthalmic products, thus eliminating the need for in-house manufacturing of this ophthalmic product.
2. Mandatory addition of a bright orange "For External Use Only" auxiliary label to all in-house prepared external use products.
3. Review of all packaging used for in-house manufactured products to identify risk potential for dangerous look-alike/feel-alike substitution errors.

#### References:

1. Cohen M, President and CEO of ISMP (U.S.). Personal communication - May 26, 2003
2. WebWord.com: What is Human Factors? Available at <http://webword.com/whatishumanfactors.html>; accessed May 26, 2003.
3. Sawyer D. Do It by Design: An Introduction to Human Factors in Medical Devices. U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Devices and Radiological Health. December, 1996. Available at <http://www.fda.gov/cdrh/humfac/doitpdf.pdf>; accessed May 28, 2003.
4. Senders, J. Prof. Emer. Faculty of Applied Sciences, University of Toronto, Personal Communication. May 28, 2003.

*ISMP Canada is a national voluntary medication incident and 'near miss' reporting program founded for the purpose of sharing the learning experiences from medication errors. Implementation of preventative strategies and system safeguards to decrease the risk for error-induced injury and thereby promote medication safety in healthcare is our collaborative goal.*

*To report a medication error to ISMP Canada: (i) visit our website [www.ismp-canada.org](http://www.ismp-canada.org) or (ii) email us at [info@ismp-canada.org](mailto:info@ismp-canada.org) or (iii) phone us at 416-480-4099. ISMP Canada guarantees confidentiality and security of information received. ISMP Canada respects the wishes of the reporter as to the level of detail to be included in our publications.*

4. A new label software and printer were purchased to enhance labelling capabilities for manufactured and batch products. The new labels offer flexibility in format, font, size and boldface in order to highlight and differentiate salient information.

These errors illustrate the importance of 'human factors' considerations in designing and selecting packaging and labelling for the safe use of drugs. The central approach of human factors engineering is the application of relevant information about human characteristics and behaviour to the design of objects, facilities and environments that people use.<sup>2</sup> There are four dimensions of human abilities basic to understanding human factors: physical and sensory capabilities, perceptual and cognitive capabilities, expectancies, and mental models.<sup>3</sup> For instance, expectancies (or user expectations) can give rise to incorrect perceptions and this phenomenon has been named "confirmation bias". Confirmation bias leads an individual to "see" information that confirms their expectations, rather than to see information that contradicts expectations.

Users rely on multiple cues to help distinguish among objects, such as the size and shape of packaging, the colour and formatting of a label. The "usability" of a label or package depends on a combination of factors, such as prominent display of critical information and appropriate size, shape and colour to convey and draw attention to information.<sup>4</sup> It is not enough to caution healthcare providers to be more careful and to read labels three times. The described hospitals' error reports and resultant system changes illustrate how scrutiny of labelling and packaging based on human factors can enhance product safety.

As a result of the errors, the hospitals not only evaluated the individual products, they evaluated products within the context of their use. This is critical to designing system improvements based on human factors. ISMP Canada recommends that all medications in a hospital should, as time permits, be continuously reviewed for similar potential product confusions and the possible interventions that can enhance safety.