ISMP Canada is an independent Canadian non-profit agency established for the collection and analysis of medication error reports and the development of recommendations for the enhancement of patient safety.

The Healthcare Insurance Reciprocal of Canada (HIROC) is a member-owned expert provider of professional and general liability coverage and risk management support.

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Enhanced Sterile Water Label Paves Way for National Standard

The recently announced changes to sterile water product labels by Baxter Canada demonstrate an interest in enhancing overall patient safety. ISMP Canada and Baxter Canada have worked together to design label improvements within the limitations of manufacturing equipment. This bulletin will discuss some of the enhancements that were made to the sterile water for injection product based on learned principles of human factors engineering. The "usability" of a label depends on a combination of factors, including (i) use of colour to convey and draw attention to information, (ii) use of redundant cues and (iii) ensuring that critical information is clearly displayed.[1]

The dangers of sterile water are not new to the healthcare community. ISMP Canada has previously warned of inadvertent intravenous administration of sterile water for injection and the resultant patient harm that can occur.[2] Sterile water is hypotonic and therefore hemolytic. ISMP (U.S.) published additional reports of errors with sterile water including a fatal patient outcome.[3, 4, 5] Sterile water products marketed in flexible plastic bags (e.g., Viaflex®) have a similar appearance to IV solutions which are predominantly marketed in flexible plastic bags (Figure 3). This can contribute to substitution errors. Preventing errors with sterile water requires a multi-pronged approach that includes careful review of available products for hospital inventory selection, as well as purchasing, storage and labelling procedures that clearly identify water products and their intended use. It is not enough to caution healthcare providers to be more careful and to read labels three times.[6]

Use of colour

Studies indicate that the colour red conveys the

Figure 1. Before - Sterile Water for Injection label.

Figure 2. After - New Sterile Water for Injection label combines colour, information display and redundant cues to help differentiate the product from IV solutions.

Figure 3. An IV solution, 0.9% Sodium Chloride Injection, and the former Sterile Water for Injection product, both had labels with black print.

highest level of perceived hazard, followed by orange, black, green and blue.[7] The change from black print to all **red** print on the label shown in Figure 2 sends a message of warning to the health care professional. A survey to identify user expectations in relation to products supplied in flexible plastic bags revealed that "red conveys danger; red is like a stop sign".[8] There is an emerging consensus that sterile water products marketed in flexible plastic bags should have predominantly red print. This consensus stems from an evaluation of the product within the context of its use and storage in the hospital setting.

Prominence of Critical Information

The words "Not for Direct Infusion" have been given prominence on the new label (Figure 2). As well, varied font size and varied use of lower case and upper case lettering help to distinguish information. The word "WATER" is in larger print size, and upper case lettering. The official USP name "sterile water for injection" can, in fact, mislead a healthcare practitioner to believe that the product could be administered intravenously. Since the official USP name is a requirement, the new label design de-emphasizes the words "for injection" by printing these words in smaller size and lower case lettering.

Use of Redundant Cues

The use of the international chemical H_20 symbol adds a "redundant cue" to the label, assisting the user in identifying the product as water. Ideally, the use of multiple redundant cues, such as a unique size and shape of container, can further assist the user in differentiating products. Based on human factors engineering principles, a product that is not intended for IV use would also not be compatible with IV tubing. Future goals for the healthcare industry are to devise and implement systems that incorporate additional safeguards designed to help prevent human error. Improving the label design is a first step.

ISMP Canada encourages the use of product safety techniques such as failure mode and effects analysis (FMEA) and the application of human factors engineering principles in naming, labelling and packaging design of pharmaceutical products. The label enhancements described above have inspired an interest in the development of a nationally recognized standard or guideline for labelling of sterile water products. Abbott Laboratories is planning to change the label of their sterile water for injection product. The new label in the design stage has red print and includes the H_2O symbol. Pharmaceutical labelling and packaging can speak a universal language and standardization can be an effective strategy for error-reduction.[9] Health Canada has expressed an interest in a coordinated effort together with ISMP Canada and pharmaceutical manufacturers to develop a recognized standard, or guideline, for sterile water products.

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 or (ii) email us at 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.

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1 Gosbee LL, MASc, Human Factors Specialist. Written communication June 11, 2003.
2 Sentinel Event with Sterile Water – Lessons Shared. ISMP Canada Safety Bulletin. Volume 2, Issue 4, 2002.
3 Water, water, everywhere, but please don't give IV. Medication Safety Alert! Volume 8, Issue 2, 2003.
4 More on Sterile Water for Injection. Medication Safety Alert! Volume 8, Issue 5: 2003.
5 Even More About Sterile Water. ISMP Medication Safety Alert! Volume 8, Issue 6: 2003.
6 Senders J. PhD, Prof. Emer., Faculty of Applied Sciences, University of Toronto. Personal Communication May 28, 2003.
7 Human Factors Perspectives on Warnings, Selections from Human Factors and Ergonomics Society Annual Meetings, 1994-2000 Santa Monica, CA: Human Factors and Ergonomics Society. Volume 2, 2000; page 276.
8 Survey conducted by ISMP Canada. 2002-2003.
9 Cohen M. Editor. *Medication Errors.* Washington DC: American Pharmaceutical Association; 1999:13.21

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