

Using human factors and FMEA methods to evaluate labelling of injectables drugs

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Executive Summary

Poor labelling of injectable medications can be a contributing factor to medication errors leading to adverse drug events. We sought to address some of the issues with the labelling of ampoules and vials. The first phase of the project involved comparing a sample of existing labels on drug ampoules and vials with the 1999 Canadian Standards Association International standard (CAN/CSA-Z264.2-99) and with the relevant Canadian (Health Canada) Food and Drug Regulations (C.R.C., c.870). The adherence rate to the 23 mandatory requirements in the CSA Standard was 59%. The average proportion of the inner labels for ampoules and vials that did not adhere to one or more of the requirements in the Canadian Food and Drug Regulations was 35% but a large portion of the non-adherence resulted from not including both the English and French versions of the word sterile and for not including the manufacturer address on the label. However, 1 % of the samples did not display the common name properly and 2% of the samples did not display the route(s) of administration. In the cases of improperly displayed common name, it appears that there was preferential emphasis placed on the manufacturer's branding.

The second phase of the project involved conducting a Failure Mode and Effects Analysis (FMEA) with 7 healthcare professionals with previous experience with FMEA in order to identify the critical information needed on an ampoule or vial for safe medication use. Failure modes related to reading brand name, common name, concentration, total amount of drug ingredient(s) per total volume and route(s) of administration were rated with higher than the average criticality in the FMEA. The third phase of the project involved conducting a human factors experiment with a group of 24 nurses. This experiment demonstrated the superiority of black lettering on a white background over printing directly on ampoules (or on a clear substrate that is adhered to ampoules). The findings in this report have implications for those involved in

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designing drug labels and for those involved in providing recommendations for the design of drug labels (i.e. Health Canada, the Canadian Standards Association, and ISMP Canada).

The following diagram makes it clear why, in our experiment with 24 nurses, we found that the newly designed labels were read more quickly than the existing labels in current use.

Participants were given as much time as they liked to read the labels in a quiet room with no distractions. The improved performance with the new labels would likely be more exaggerated in a stressful workplace environment.



Existing labels (3 left) and the new labels (3 right).

Based on the results of this three-phased study, several suggestions are made regarding the improvement of guidelines, standards and recommendations related to drug labelling:

1. When the CSA standard and the government regulations are under review, consider
 - performing user testing regarding the interpretation of the guideline or regulations;

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- including an explanation (evidence) of the rationale for particular recommendations or requirements;
 - examining the failure modes (or errors) related to the brand name, common name, concentration, total amount of drug ingredient(s) and route of administration;
 - evaluating the necessity of the information required in regulations, such as “address of manufacturer,” which takes valuable space on the label.
2. Study the feasibility of using larger-sized ampoules and vials for small volumes to increase surface area for label information.
 3. Prohibit the use of printing directly on glass or a clear substrate in the labelling of ampoules or vials containing medications.

The following are recommended reading:

Cohen, M.R. (Ed.). 2007. *Medication Errors, 2nd Edition*. Washington, D.C.: American Pharmacists Association.

Institute of Medicine of the National Academies. 2007. *Preventing Medication Errors*, Quality Chasm Series. Washington, DC: The National Academies Press.