MEDINFO 2007
HISA Ltd Australia
© 2007 The authors. All rights reserved.

Identifying Potential Human Errors in the Medication Label Reading Process using FMEA

Jennifer Jeon [a], Sylvia Hyland [b], Catherine M. Burns [a], Kathryn Momtahan [c]

[a] *Department of Systems Design Engineering, University of Waterloo, Canada*
[b] *Institute for Safe Medication Practices Canada, Canada*
[c] *The Ottawa Hospital, Canada*

Abstract

Poor labelling is a contributing factor of medication errors. To predict potential human errors in the process of reading the container labels for injectable medications, Failure Mode and Effects Analysis (FMEA) was applied to the label reading process. The implementation of FMEA involved various challenges including difficulties in representing a context-sensitive process, defining the failure modes, their causes and effects and developing rating scales for criticality. The identified failure modes were rated via a focus group of healthcare professionals. The results of the FMEA will be applied to improve existing label designs to prevent potential medication errors that may result from human errors in the label reading process.

Keywords:

medication errors, drug labelling, risk assessment, FMEA

Introduction

Medication errors leading to harm are a significant cause of adverse medical events [1, 2]. Poor labelling of injectable medications can be a contributing factor to medication errors. According to a survey of 687 anesthesiologists in Canada, the misidentification of the drug ampoule or vial was cited as one of the most common causes of medication error (46.8%) [3]. To identify potential human errors that can arise in the label reading process, their causes, their effects and possible interventions, modified process Failure Mode and Effects Analysis (FMEA) was applied to the label reading process. FMEA is a proactive technique designed for predicting potential system failures, their causes and effects for developing mediations to prevent the failures.

Methodology

The research team consisted of a pharmacist, a nurse/ human factors psychologist, a human factors engineer, and a graduate student in human factors engineering.

The FMEA methodology developed by the Institute for Safe Medication Practices Canada (ISMP Canada), for use in healthcare, was selected as the basic framework. First, the label reading process was defined and flowcharted. There is no single established procedure for optimal reading of labels by healthcare professionals, and the process is fluid depending on the context. Therefore, an "ideal" label reading process was developed in consultation with practicing nurses. Secondly, the research team identified failure modes and their effects. The failure modes were defined as any failure in the human user's perception/cognition when reading the labels, and their effects were defined as potential types of medication errors that could result from the failure modes. Plausible causes of the failure modes were then identified with a focus on the users and existing label designs. To prioritize the failure modes, the failure modes were ranked by a focus group of 9 healthcare professionals: 6 pharmacists, 1 registered nurse, 1 educator in medication safety and 1 administrative staff in healthcare. The failure modes were rated in terms of their severity, frequency, and detectability, the rating scales for which were derived by integrating the rating scales from the Health Care Failure Mode and Effects Analysis [4] and a medication error category index [5]. For each failure mode, the median value of each type of the criticality ratings was calculated from the aggregated participant results. The three median values were multiplied together to derive a Risk Priority Number (RPN) value for each failure mode. The higher the RPN value, the more critical is the failure mode.

Results and discussion

A total of 24 failure modes were identified for the label reading process. The criticality ratings from two participants were excluded from the analysis; one pharmacist's ratings were incomplete, and the administrative staff's expertise was inadequate for the purposes of the study. The criticality ratings from the remaining 7 participants yielded RPN values ranging from 12 to 45 with an average of 30.

The process of reading the drug brand name, common name, concentration, total amount of drug ingredient per total volume and route of administration had associated failure modes with relatively high RPN values (30 or

higher) as shown in Table 1. The standard for Labelling of Drug Ampoules, Vials, and prefilled syringes developed

Table 1 – Failure modes with RPN values of 30 or higher

Failure Mode Description	RPN
User misperceives the brand name of a wrong drug as the common name of the correct drug.	45
User misperceives a different common name as the correct common name.	45
User misperceives the concentration as the total amount of the drug ingredient or vice versa.	45
User misperceives the values of the concentration/ total amount of the drug ingredient.	45
User does not read the route of administration.	45
User does not read the common name.	36
User does not read the multi-dose information.	36
User does not read the formulation type.	36
User does not read non-medicinal ingredient	36
User cannot read the concentration or the total amount of the drug ingredient.	30
User cannot read the route of administration.	30

by the Canadian Standards Association International defines the first three items as 'critical information', and a large portion of the standard is devoted to ensuring the legibility of these label contents [6]. Although not defined as critical information in the standard, route of administration is important for injectable drug use. Medication errors involving wrong route of administration were found to be the second-highest type of medication errors causing harm in the USP MEDMARX analysis of reported medication errors in 2003.[7].

In general, the participants found it difficult to rate the failure modes without a specific scenario. The detectability of failure modes, in particular, is highly dependant on the stage in the medication use process (e.g. dispensing, administration) where the failure mode occurs.

Conclusion

Applying FMEA to predict potential human errors in the process for reading the container labels for injectable pharmaceuticals required the use of a combination of several existing FMEA frameworks. Defining the failure modes, their causes and their effects was challenged by the cognitive/perceptual nature of the reading process and the fact that it is only a small link in the complex chain of events in the medication delivery process. Nevertheless, the criticality ratings of the failure modes collected via a focus group of healthcare professionals identified contents on the label that are important to end users in order to safely deliver medication to patients. The results of the analysis are being applied to improve existing label designs as interventions to reduce the likelihood of medication errors that may result from the identified critical human errors.

Acknowledgement

This study is funded by the Canadian Patient Safety Institute. We would like to thank Professor John Senders, members of ISMP Canada and the nurses at the University of Ottawa Heart Institute for their valuable time and expertise.

References

[1] Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, Barnes BA, Hebert L, Newhouse JP, Weiler PC, Hiatt H. The nature of adverse events in hospitalized patients. Results of the harvard medical practice study ii. N Engl J Med 1991 Feb 7: 324 (6); 377-84.

[2] Aspden P, Wolcott JA, Bootman JL, Cronenwett LR, editors. Preventing medication errors. 1st ed. Washington, DC: INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES; 2006.

[3] Orser BA, Chen RJB, Yee DA. Medication errors in anesthetic practice: A survey of 687 practitioners. Can J Anesth 2001 February 1: 48; 139-46.

[4] DeRosier J, Stalhandske E, Bagian JP, Nudell T. Using health care failure mode and effect analysis™: The va national center for patient safety's prospective risk analysis system. Joint Commission Journal on Quality and Patient Safety 2002 May: 28 (5); 248-67.

[5] National Coordinating Council for Medication Error Reporting and Prevention. Ncc merp index for categorizing medication errors. 2001 [cited 2006 Nov. 26]; Available from: http://www.nccmerp.org/medErrorCatIndex.html

[6] CSA International. Labelling of drug ampoules, vials, and prefilled syringes. Etobicoke, Ontario, Canada: CSA International; 1999.

[7] Hicks RW, Santell JP, Cousins DD, Williams RL. Medmarx 5th anniversary data report: A chartbook of 2003 findings and trends 1999-2003. Rockville, MD: USP Center for the Advancement of Patient Safety; 2004.

Address for correspondence

Jennifer Jeon
Department of Systems Design Engineering
University of Waterloo
200 University Ave West, Waterloo ON, Canada N2L 3G1
Email: hwjeon@uwaterloo.ca