

Challenges with applying FMEA to the process for reading labels on injectable drug containers

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As a part of a study that aims to evaluate and improve the labelling of containers for injectable drugs, Failure Mode and Effects Analysis (FMEA) was applied to the label reading process. Implementing a FMEA on a small-scale cognitive process involved various challenges including difficulties in representing the process, defining the failure modes, causes and effects, developing the rating scales for criticality, and rating the criticality of the failure modes. The failure modes were rated via two focus groups of healthcare professionals. The results highlight complexities and potential pitfalls with applying FMEA to the label reading process.

INTRODUCTION

Harm from medication errors is the most common type of adverse medical events (Leape et al., 1991). Poor labelling has been identified as a major contributing factor of medication errors. Thirty-three percent of the medication errors reported to the United States Pharmacopoeia (USP) Medication Errors Reporting (MER) program during a period of one year (between 1996 and 1997) cited labelling as a contributing factor (United States Pharmacopoeia, 1998). Injectable drugs, in particular, were involved in more than half (50.5%) of the medication error reports submitted by hospital pharmacists to the USP Drug Product Problem Reporting program between 1995 and 1999 (United States Pharmacopoeia, 2000). We are currently conducting a study that aims to evaluate and improve the labelling of ampoules and vials for injectable drugs. A key objective is to identify potential human errors that can arise in the label reading process, the underlying causes for errors, and label design improvements to reduce likelihood of errors.

Statistical predictions of medication error from analysis of reports collected through reporting programs, such as the USP MER and the U.S. Food and Drug Administration (FDA)'s MedWatch are limited due to the voluntary nature of the reporting programs. There is also no universal taxonomy for medication error reporting limiting the ability to aggregate and compare data from various reporting programs (Senders, 2004). Case studies by the Institute for Safe Medication Practices (ISMP), the FDA, the USP and individual researchers do provide insights to causes of errors (for examples, see articles from ISMP Medication Safety Alert[®] Newsletters, USP Quality Review, USP CAPSLink[™]). Human errors are the result of interactions of various causes, both environmental and perceptual/cognitive/neurological in origin. Predicting human errors is complex and it is impossible to predict human errors (failures) precisely.

Failure Mode and Effects Analysis (FMEA) is a prospective technique to identify known and potential failures and their sources from the system and develop interventions to prevent or minimize the effects of the failures. FMEA is used synonymously with Failure Mode Effects and Criticality

Analysis (FMECA) in healthcare (Krouwer, 2004). Since the U.S. Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has required its accredited hospitals to conduct an annual proactive risk assessment such as FMEA (Rich, 2001), FMEA is becoming more widely adopted in healthcare organizations.

Several variations of FMEA have been developed in healthcare. The Department of Veterans Administration (VA) National Center for Patient Safety (NCPS) has developed the Health Care Failure Mode and Effect Analysis (HFMEA[™]). To overcome difficulties in directly applying traditional FMEA from engineering, HFMEA[™] uses different definitions and algorithms adopted from the FDA's Hazard Analysis and Critical Control Point (HACCP) method, as well as its Root Cause Analysis (RCA) method. ISMP Canada, which provides training to healthcare professionals on FMEA, has developed its own version of FMEA (Institute for Safe Medication Practices Canada, 2006). JCAHO also has its own version of FMEA. These frameworks, however, were not designed for analyzing a small sub-process at the human cognition level such as reading medication container labels.

Most applications of FMEA in healthcare have been on organizational and/or procedural processes (Bonnabry et al., 2005; Burgmeier, 2002; Esmail et al., 2005) or complex medical devices (Fechter & Barba, 2004; Zapanta et al., 2005) that involve a large number of sub-processes and more than one user. The process of reading the manufacturer's label on an ampoule or a vial involves a single user and a rather simple sequence of perceptual and cognitive processes. To the best of the authors' knowledge, there has not been any study applying FMEA to such a small cognitive process.

This paper describes a modified process FMEA applied to the label reading process. The resulting criticality ratings are discussed. Challenges encountered implementing FMEA and recommendations for applying FMEA in healthcare are also provided.

METHOD

ISMP Canada's FMEA framework was used as a basis for this study. 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 procedure used for this study was as follows:

1. Define the process of interest.
2. Generate a flowchart of the process and its sub-processes.
3. Brainstorm for potential failure modes and their effects.
4. Identify causes of failure modes.
5. Rank each failure mode in terms of severity, frequency, and detectability.
6. Calculate Risk Priority Number (RPN) for each failure mode. RPN is defined as the product of a severity, frequency and detectability rating and determines the impact of the failure mode on the patient or the system.
7. Develop interventions to minimize the occurrences and/or effects of the failure modes with high RPN values.

The failure modes were ranked through two focus groups of healthcare professionals. The first group consisted of 6 pharmacists, 1 registered nurse, 1 educator in medication safety and 1 administrative staff in healthcare (9 participants in total). The second focus group consisted of 1 clinical nurse educator, 1 quality manager, 2 pharmacy technicians, 1 registered nurse and 1 physician (6 participants in total). The first focus group was considered as a pilot study, and its results were used to revise and improve the materials for the second focus group.

In both focus groups, each participant was given an information package that explained the purpose of the study, the FMEA methodology, a description of the rating scales and a questionnaire. Each participant was provided with a flowchart of the process being analyzed as well as a partially completed FMEA table. The first focus group participants were given, for their reference, a copy of the cross-tabulation analysis results of ‘type of medication error’ and ‘harm from medication error’ as identified by USP MEDMARX from reports collected during 2003 (Hicks, Santell, Cousins, & Williams, 2004).

The moderator explained the contents of the focus group information package and answered questions during the session. Participants were asked to complete the questionnaire and rate the identified failure modes in terms of their severity, frequency and detectability. In addition, the first focus group participants were asked to determine if there is an effective control measure that could reduce the likelihood of the failure modes.

There were a total of 24 failure modes and 31 failure modes provided for ranking consideration by the first focus group and by the second focus group, respectively. The larger number of failure modes in the second focus group was due to the addition of failure modes related to injectable drugs provided in powder for reconstitution, as well as failure mode 5 that was inadvertently omitted in the first focus group materials. Although the participants were encouraged to determine the rating individually, they were permitted to

engage in discussion with the other participants. The participants were given as much time as needed to complete the tasks.

RESULTS

Defining failure modes and their effects

There is no single definition for failure modes in FMEA. Similarly, there is no single definition for effects of failure modes. Adverse drug events are often the result of a series of failures in the chain of causes and effects. Depending on the scope and the purpose of the analysis, one causal link could be considered an effect of the preceding link(s) or a cause of the following link(s). For example, the effect of a pharmacist misreading the total amount of a drug ingredient contained in a vial may be defined as a ‘wrong dose’ dispensing error. On the other hand, the effect of the error could include patient death depending on the drug and/or dose and/or patient factors. For this study, the failure mode was defined as any failure in the human user’s perception/cognition when reading the labels. The effects were defined as potential types of medication errors that could result from the failure modes. Thirteen medication error types used in the USP MEDMARX program were used for the error types (Hicks, Santell, Cousins, & Williams, 2004).

Defining rating scales

Defining appropriate rating scales for severity, frequency and detectability is crucial for obtaining meaningful RPN values. The traditional 10-level scale used for FMEA in engineering is not necessarily suitable for processes in healthcare. For example, many failures in healthcare could potentially lead to patient death or injury (level 10). This is the reason the VA NCPS came up with modified severity and frequency rating scales for its HFMEA™ (DeRosier, Stalhandske, Bagian, & Nudell, 2002). The cognitive nature of the process in this study suggested a need for a further modification to the usual scales in existing FMEA frameworks for healthcare. For severity, the 5-level scale of ISMP Canada’s FMEA (No effect, Slight, Moderate, Major and Severe/Catastrophic) was considered to be simple yet comprehensive for this study. The definitions were derived from the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)’s index for categorizing medication errors (National Coordinating Council for Medication Error Reporting and Prevention, 2001) of which ISMP is a member. The severity rating scale from the HFMEA™ (DeRosier, Stalhandske, Bagian, & Nudell, 2002) was used. Table 1 shows the finalized severity rating scale.

Table 1 – Severity rating scale

Severity Description	Score	Patient Outcome
No effect	1	No injury nor increased length of stay nor increased level of care
Slight	2	Monitoring to confirm no patient harm and/or

		intervention to preclude harm required
Moderate	3	Temporary lessening of bodily functioning (sensory, motor, physiologic, or intellectual) and intervention required
Major	4	Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) or disfigurement, surgical intervention required, increased length of stay or increased level of care
Severe / Catastrophic	5	Death or major permanent loss of patient function (sensory, motor, physiologic, or intellectual)

For frequency, the 5-level scale of ISMP Canada’s FMEA (Yearly, Monthly, Weekly, Daily and Hourly) was not considered appropriate for estimating the frequency of human errors in the current task. The VA’s HFMEA™’s 4-level probability rating scale (Remote, Uncommon, Occasional and Frequent) better reflects the probability of human errors. However, it covers only a limited frequency range for human cognition failures. Therefore, an additional higher frequency level was added to the scale, and the definitions of the original scale were modified to arrive at the frequency rating scale shown in Table 2. For detectability, the 4-level scale of ISMP Canada’s FMEA framework was adopted without modifications; score of 1 for always detected, 2 for likely detected, 3 for unlikely detected and 4 for never detected.

Table 2 - Frequency Rating Scale

Frequency Rating	Frequency Description	Score
Remote	May happen some time in 3 to 5 years	1
Uncommon	May happen some time in 1 to 2 years	2
Occasional	May happen several times in a year	3
Frequent	May happen several times in a month	4
Very frequent	May happen several times in a day	5

Findings - first focus group

The data from one pharmacist was incomplete and therefore was excluded from the analysis. Also, the administrative staff’s expertise was inadequate for the purposes of the study, and the data from the participant was excluded. Therefore, the data from 7 participants from the first focus group was analyzed.

To calculate the RPN values, the median value of the ratings across the participants for each of severity, frequency and detectability was derived for each failure mode (see

Figure 1). Then, the three median values were multiplied together to calculate a RPN value for each failure mode. There was relatively small variance in the median values of the ratings across the failure modes for frequency and detectability compared to the variance for severity as shown in Table 3. Consequently, the variances in the RPN values were largely influenced by the variances in the severity median values. In particular, the severity ratings for the failure modes 1 to 10 had high median ratings with relatively small variances across participants as shown in Figure 2.

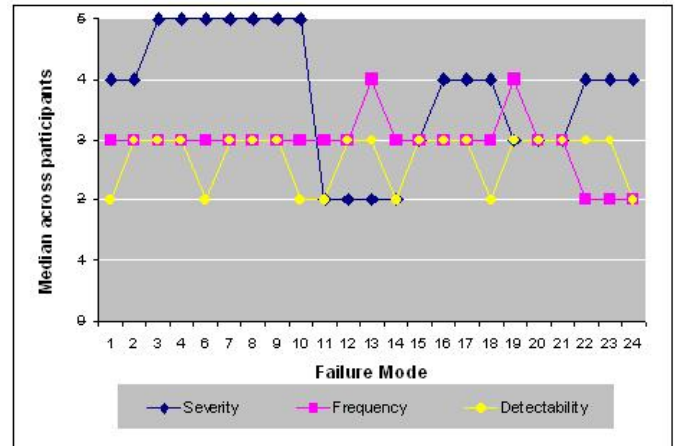


Figure 1: Median values of severity, frequency and detectability ratings

Table 3: Statistics on the median values of the ratings

	Severity	Frequency	Detectability
Variance in the median values across failure modes	1.18	0.23	0.22
Average	3.78	2.96	2.70

Findings - second focus group

The ratings from the second focus group could not be used for calculating meaningful RPN values. Except for one participant, all participants gave the failure modes the severity rating of 5 or did not give a rating. Moreover, the participants expressed difficulties estimating the likely frequency of the failure modes. Three participants gave all the failure modes the frequency rating of 3, 2 participants did not give any frequency rating, and only 1 participant gave varying frequency ratings. Similarly, 3 participants gave all failure modes the detectability rating of 3, one participant did not give any rating and only two participants gave varying detectability ratings.

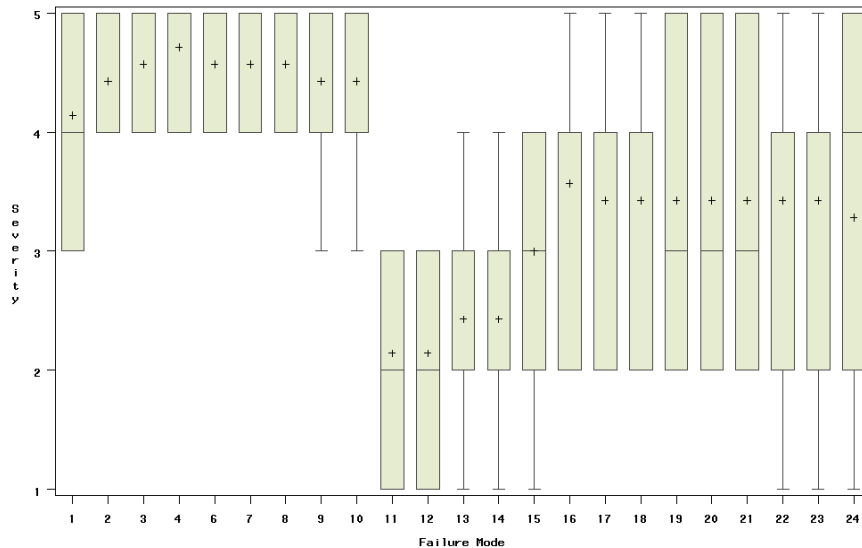


Figure 2: Severity ratings

DISCUSSION

The difficulties that the second focus group participants expressed demonstrate challenges that human factors practitioners may face when conducting a FMEA in a multidisciplinary team involving healthcare professionals due to their lack of exposure to a prospective approach. Although the second focus group was conducted with improved materials based on the results from the first group, the second group did not yield meaningful data while the first group did. The first focus group participants all had previous knowledge of FMEA related to medication errors; six of them teach FMEA. In contrast, one participant from the second group had a single FMEA project experience.

An additional challenge in conducting the FMEA was the loosely defined concepts in FMEA which necessitated developing unique definitions for failure modes, effects, and causes for our study. Limited availability of healthcare professionals makes it difficult to provide them with sufficient education and training on FMEA. A successful FMEA requires a multidisciplinary team including end users who understand and appreciate the methodology (Wetterneck, Skibinski, Schroeder, Roberts, & Carayon, 2004). This is especially important considering the subjective nature of how the criticality of failure modes is determined in a FMEA.

Analyzing a small context-sensitive process using a FMEA framework was challenging. Compared to rather solidly defined processes in manufacturing, chemical and nuclear power industries, the processes in healthcare often directly involve multiple types of end users and are variable and fluid. There is no single established procedure for reading labels for healthcare professionals. Depending on the end user's profession, the patient's condition, the type of medication, the prescription, and the medication delivery system encasing the label reading process, the condition in which the label is read differs. The consequences of potential errors in the medication label reading

process differ as well depending on how the medication is prescribed, dispensed or administered. To the best of the authors' knowledge, there is no guidance in the literature on how to represent a context-sensitive process such as this in a FMEA. Defining a separate process for each potential scenario would make the scale of the analysis unwieldy. The approach taken for this study was to develop a single general process that includes all the potential steps. This was a plausible approach since the order in which the label contents are read is of less concern than capturing all potential failure modes. Moreover, the addition or omission of a step was not expected to alter the potential failure modes related to other steps in the process. However, participants found it difficult to rate the failure modes without a specific scenario. For example, the severity of a failure mode highly depends on the type of medication. For other studies, defining a single general process may not be possible, and doing so may obscure context-sensitive failure modes.

Despite these challenges, the results satisfied the main objective of constructing a framework for improving existing label designs to prevent potential human errors. Due to small variances in frequency and detectability ratings across the failure modes, the RPN values from the first focus group did not have sufficient variance to prioritize individual failure modes. Nevertheless, the RPN values revealed which pieces of information on the labels are important and which ones are of less importance to end users. Except for one failure mode, all the other failure modes that are related to reading the brand name, common name, concentration, total amount of drug ingredient(s) and route of administration (failure mode 1 to 4 and 6 to 10) had high severity ratings and small variance, and consequently high RPN values (higher than the average RPN value of 30). The first three items are defined as critical information in the standard for the labelling of drug ampoules, vials and pre-filled syringes developed by Canadian Standards Association International (CSA International, 1999). A large portion of the standard is dedicated to ensuring the legibility and salience of critical information. The fourth item is recognized

to be critical for injectable drug use. For example, 'wrong route of administration errors' was the second highest type of harmful medication errors according to the analysis of the medication errors reported to the USP MEDMARX during 2003 (Hicks, Santell, Cousins, & Williams, 2004).

CONCLUSIONS

The outcome of this study highlights complexities and potential pitfalls with applying FMEA to the label reading process, and these may be applicable to other processes in healthcare. It is difficult to represent a small-scale process that can be encased in many larger processes within the FMEA framework. In this study, the problem was further complicated by the cognitive nature of the process. Generalizing the process such that it encompasses many potential contexts is one approach. However, such an approach makes it difficult to assess the criticality of potential failure modes in terms of their frequency, severity and detectability.

Although there are generic FMEA frameworks developed for healthcare, adopting these frameworks may be problematic. Depending on the nature of the process and purpose of the analysis, the definitions for failure modes, causes and effects will vary. Consequently, the criticality rating scales in the generic frameworks may not be directly applicable and would require customization as was the case for this study. Furthermore, when involving healthcare professionals for rating the failure modes, it should be ensured that they have a good understanding of the FMEA method and feel comfortable with extrapolating their knowledge in a prospective analysis paradigm. Given the limited availability of healthcare professionals and time-consuming nature of FMEA (Burgmeier, 2002; Esmail et al., 2005; Fechter & Barba, 2004; Wetterneck, Skibinski, Schroeder, Roberts, & Carayon, 2004), it is recommended that healthcare organizations consider developing, at a minimum, a dedicated group of healthcare professionals to perform FMEA on high risk processes.

The study yielded RPN values that identify information on the label that are important to end users. The results give direction to the next phase of research in which existing label designs will be redesigned as an intervention to reduce opportunities for identified failure modes.

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