Identifying potential human errors in the medication label reading process using FMEA

Jennifer Jeon
Department of Systems Design Engineering
University of Waterloo

Catherine M. Burns
Department of Systems Design Engineering
University of Waterloo

Sylvia Hyland
Institute for Safe Medication Practices Canada

Kathryn Momtahan
The Ottawa Hospital

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L'Hôpital d'Ottawa

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Medication Errors

- Drug complications are the most common single type of adverse medical events [1]
- Adverse drug events are estimated to cost a teaching hospital in the U.S. **$5.6 million** annually [2]

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Poor labelling – a contributing factor

- Cited by **33%** of the medication errors reported to the United States Pharmacopoeia (USP) from 1996 to 1997 [3]

- A standard for Labelling of Drug Ampoules, Vials, and Pre-filled Syringes developed by the Canadian Standards Association International to address poor labelling issues [4]

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Objectives

- Identify potential human errors in the process of reading the container labels for injectable pharmaceuticals
- Prioritize potential failures in terms of their criticality
- Address critical failures by redesigning existing labels

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Method - FMEA

- Prospective analysis technique to identify and avoid potential failures from a system or a product
- A reliability engineering technique
- Becoming widely accepted in healthcare

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Method

1. Define & flowchart the label reading process
2. Brainstorm for potential failure modes and their effects.
3. Identify causes of failure modes.
4. Rate & prioritize the failure modes
5. Develop mediations for failures modes with high priority.

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Results

- 24 failure modes identified
- Severity, frequency, and detectability ratings for each failure mode from a focus group of healthcare professionals
- Risk Priority Number (RPN) values derived from the criticality ratings

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Results

Table 1: Failure modes with the highest RPN value

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

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Discussion

Label contents related to high RPN values

- Brand name
- Common name
- Concentration & total amount of drug ingredient

Defined as critical information in the CSA Standard [4]

- Route of administration → **Critical for proper administration**

Discussion

Challenges with applying FMEA

- Difficulties in
  - representing a context-sensitive process
  - defining the failure modes, and their causes & effects
- Customized rating scales developed from an existing FMEA framework & a medication error category index

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Conclusions

- Applying FMEA to a cognitive/perceptual process such as the label reading process can be challenging
- Identified the label contents for injectable pharmaceuticals that are important to the end users
- Results being applied to improve existing label designs.

References

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Contact

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