Preventing Medication Errors with FMEA

by Thomas T. Reiley

Medical errors are a subset of medical adverse events. Adverse events are defined as injuries caused by medical management rather than by the underlying disease or patient condition. Not all adverse events, such as adverse drug reactions, are the result of errors. An adverse drug reaction would be the result of error only if such a reaction had occurred before or could have been reasonably predicted in an individual patient. This discussion addresses preventable medication accidents, commonly known as medication errors.

Medication accidents have been found to occur in two percent of hospitalized patients. These errors increase the average length of stay by 4.6 days and the average cost of hospitalization by $4,700 per admission, or $2.8 million per year for a 700-bed teaching hospital.[1]

In 1993, 7,395 patients died from medication errors. Outpatient deaths due to medication errors rose eightfold from 1983-93, as compared to a 2.3-fold increase for inpatients.[2]

The problem of medical systems, like all human systems, is that humans err. A human error becomes an accident and has the possibility of causing harm when the preventive, error-proofing processes within a system are inadequate. Sanford E. Feldman and Douglas W. Roblin refer to these processes as "latent system faults."[3] These faults have a delayed impact on the system and are propagated by persons whose activities are removed in space and time from accidents that occur.

Types of Medication Errors

- Drug omission
- Wrong drug
- Wrong dose/concentration
- Unordered drug
- Extra dose
- Wrong formulation/dosage form
- Wrong route/administration technique
- Wrong time
- Deteriorated drug
- Patient compliance/monitoring error

A specific tool used to achieve comprehensive and rapid improvement in safety in non-healthcare industries is failure modes and effects analysis

(FMEA). FMEA examines all potential causes or modes of failure of critical processes and of methods designed to prevent failure of those processes. Each mode is studied for potential effects.

Three measures are made of each mode and effect: severity, ease of detection, and rate of occurrence. The criticality scores derived from these measures can be used to identify those modes most in need of further error proofing and, when tracked, serve as proxies of effectiveness of medication error prevention.

Medline search of the OVID database of published papers since 1966 yields five citations of failure mode analysis or failure mode/s and effect/s analysis applied to medicine.[4] Of these five articles, four concern FMEA. All four have been written since 1994 and each describes FMEA applied to medication errors. Interestingly, none of these published articles describes a full FMEA process as applied in other industries. Not one carried FMEA to the point of remeasure of criticality scores or of outcomes.

FMEA: An Application

The following data were collected by the author at a children's hospital during an analysis of causes of medication errors. The process of medicating patients had been flow-charted and key process steps identified. Figure 1 displays the actual numbers counted during the year's first quarter and represents the data available to a fictitious FMEA team.

Fig. 1 First Quarter Errors

Order overlooked/forgotten	27
Transcription error	30
Not transcribed	9
Pharmacy misread order	57
Calculation of dose in error	9
Oral communication error	15
Drug labeling error	10
Staff education issue	11
Medication not given	19
Equipment/tubing issue	14
IV infiltration	9
Other	4

For the purpose of this exercise, imagine that these errors represent all failure modes identified by the FMEA team. In reality many more would be identified. The team would now brainstorm the effects of each of these failures (failure modes).

Imagine that the following effects have been determined for "order overlooked/forgotten":

1. Non-critical illness does not improve
2. Non-critical illness worsens
3. Non-critical illness becomes critical
4. Critical illness becomes fatal

Given the data at hand, our imagined FMEA team would assign criticality ratings (Figure 2).

Fig. 2 Criticality Ratings

Failure Mode or Effect	Occurrence	Severity	Detection
Failure mode: order overlooked/forgotten	9		
Effect #1: NC illness does not improve		3	7
Effect #2: NC illness worsens		6	5
Effect #3: NC illness becomes critical		9	4
Effect #4: Critical illness becomes fatal		10	10

What do these ratings mean? See Figure 3 for occurrence, severity, and detection scales.

Criticality scores would then be calculated as follows:

Effect # 1: 9 x 3 x 7 = 189
Effect # 2: 9 x 6 x 5 = 270
Effect # 3: 9 x 9 x 4 = 324
Effect # 4: 9 x 10 x 10 = 900

The resulting criticality scores are a numeric representation of what logic could have predicted in a rational learning system: any error likely to cause a non-critical illness to become critical or a critical illness fatal must be prevented.

However, a numeric or graphical representation of logical thought, as demonstrated in the FMEA process, may be more persuasive in effecting change. Our imaginary FMEA team recommended that orders and drug dosing for all patients with worsening or critical status at any time during an admission be reviewed on each shift by a hospital pharmacist. This recommendation was adopted by imaginary top management, largely because of criticality scores.

FMEA and the Future of Healthcare Safety

FMEA is a tool proven to drastically improve the safety of non-healthcare industries. Its success in other industries may predict success when applied, formally, in medical settings.

Still, to date there has been no published study documenting the effectiveness of a formal FMEA process applied to medication or other types of medical errors. FMEA provides health-system pharmacies an opportunity to apply and study a manufacturing industry tool in the prevention of medication errors.

About the Author

Thomas T. Reiley, MD, MHS, is past chair of the Health Care Division of the American Society for Quality (ASQ) and a member of ASQ's Education and Training Board. He has served as a planner and liaison for joint ASQ-Institute for Healthcare Improvement activities. A practicing child neurologist and founder of Synapse Consultation, he provides consultation in healthcare productivity improvement. He serves on the Board of the Colorado Foundation for Medical Care and represents CFMC in its M+CQRO contract with CMS. Dr. Reiley is a physician quality surveyor for the National Committee for Quality Assurance (NCQA), with whom he has written an NCQA/ISO 9000 gap analysis. He has worked with Beirut's Saint Georges Hospital to implement ISO 9000. He served on the Writing Group for the international quality guideline standard for ISO 9001:2000 applied to healthcare, now the International Workshop Agreement (IWA).

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Fig. 3 Criticality Ratings Scales

	Occurrence	**Severity**	**Detection**
10	Very high: inevitable failure	Dangerously high: worsening or death	Absolute uncertainty
9		Extremely high: regulatory non-compliance	Very remote
8	High: repeated failures	Very high: ineffective	Remote
7		High: high patient dissatisfaction	Very low
6	Moderate: occasional failures	Moderate: potential ineffectiveness	Low
5		Low: patient complaints	Moderate
4		Very low: lowered effectiveness	Moderately high
3	Low: few failures	Minor: a nuisance to patient	High
2		Very minor: not apparent, minor effect	Very high
1	Remote: failure unlikely	None: not apparent, no effect	Almost certain

References

[1] Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson, eds., *To Err Is Human: Building a Safer Health System* (Washington, D.C.: National Academy Press, 1999), 23.

[2] Kohn, Corrigan, and Donaldson, 27-28.

[3] Sanford E. Feldman and Douglas W. Roblin, “Medical Accidents in Hospital Care: Applications of Failure Analysis to Hospital Quality Appraisal,” *Joint Commission Journal on Quality Improvement* 23 (1997): 567-580.

[4] See Feldman and Roblin, 567-580; Ellen Williams and Ray Talley, "The Use of Failure Mode Effect and Criticality Analysis in a Medication Error Subcommittee," *Hospital Pharmacy* 29 (1994): 331-332, 334-337; Karen M. McNalley, et al., "Failure-Mode and Effects Analysis in Improving a Drug Distribution System," *American Journal of Health-Systems Pharmacy* 54 (1997): 171-177; Carol E. Fletcher, "Failure Mode and Effects Analysis: An Interdisciplinary Way to Analyze and Reduce Medication Errors," *Journal of Nursing Administration* 27, no. 12 (1997): 19-26; and Michael R. Cohen, et al., "Failure Mode and Effects Analysis: A Novel Approach to Avoiding Dangerous Medication Errors and Accidents," *Hospital Pharmacy* 29 (1994): 319-330.