Adaptation of US Department of Energy Method of Design Basis Accident Selection to a Study of the Risks to Patients in Pediatric Emergency Medical Care

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by

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Objective: leverage results of existing risk studies to produce generic risk information on existing emergency care processes for children.

- 2001 Joint Commission for Accreditation of Healthcare Organizations
  - New patient safety accreditation standards including LD 5.2 (now PI.3.20)
    - Annual proactive risk assessment on one high-risk process
    - Requires Failure Modes Effects and Criticality Analysis
- There now exists a corpus of Failure Mode and Effects Analysis (FMEA) on emergency care and other healthcare processes
- Share the generic information as it applies to children in emergency care

Organizations represented by members of the research team

- Institute for Healthcare Studies, Feinberg School of Medicine, Northwestern University (Donna Woods, EdM, PhD, Principal Investigator)
- Battelle, Pacific Northwest Division, Pacific Northwest National Laboratory (PNNL)
- University of Florida, College of Medicine
- National Association of Children's Hospitals and Related Institutions (NACHRI)

Healthcare FMEAs qualitatively address risk

- The FMEA is a single failure analysis technique to systematically analyze a process or system
- AKA: FMECA (Failure Mode and Effects & Criticality Analysis)
- The FMEA identifies:
  - process failures (e_i)
  - failure causes (in some studies)
  - failure likelihood (p_i)
  - failure consequences (outcomes) (c_i)
- The failure and consequence is used to determine the risk of each failure: Risk (e_i) = (p_i)*(c_i)

The challenges

- Many different FMEA studies
  - Different processes
  - Mostly for adult care situations/processes
  - Analysis scope and ground rules impact results
  - Institutional artifacts effect results
- Share these results with the healthcare community at large in a meaningful way
  - Represent potential situations at a wide variety of institutions
  - Identify potential significant risks to support risk management efforts

The approach

- Collect results of FMEAs on emergency care and other related healthcare processes
- Analyze these results based on applicability to pediatric emergency care and adjust as applicable
- Use the US Department of Energy (DOE) approach to the selection of design basis accidents in nuclear safety analysis (DOE-STD-3009-94) to identify representative cases
- Adapt the methodology be modifications for the healthcare domain

Summary of DOE approach

- Identify hazards
- Perform hazard evaluations
- Select candidate accidents
  - Bin hazardous conditions
  - Select representative conditions and analyze
- Identify conditions of significance as design basis accidents
- Select and design controls for significant risk contributors

Adaptation to healthcare

- Hazard evaluations complete (set of FMEAs)
- Adjust results of FMEAs to account for:
  - Child-specific risk factors
  - Performance shaping factors
- Bin high and moderate failures by healthcare process failure types and/or causes
- Select representative cases
- Generalize representative cases to remove institutional artifacts

Child specific factors include the following:

- **Physical Characteristics**: small size, weight, morphology
- **Physical Development Characteristics**: variation in size, variation in weight, variation in morphology
- **Physiological Development**: developing physiologic systems, varied signs & symptoms, impact of growth
- **Cognitive-social-emotional Development**: developing nature of understanding, communication, behavioral regulation
- **Minor Status**: management, decision-making and consent, supervision

Performance shaping factors include the following:

- **Institutional Context**: economic, regulatory context
- **Organizational & Management**: financial resources & constraints, policy standards, goals, organizational structure, safety culture, priorities, leadership support
- **Work Environments**: staffing levels, staffing skills mix, workload, shift patterns, physical design, supplies/equipment availability, supplies/equipment design, maintenance of equipment, administrative support, managerial support, staff availability
- **Team**: verbal communication, written communication, supervision, help seeking, team structure
- **Individual Staff**: knowledge, skills, motivation, physical health, mental health
- **Task**: clarity of structure, availability & use of protocols, availability of test results, accuracy of test results, task design

Rank the adjusted results, bin, and select representative cases

- The challenge here is to determine the bases for binning and selection
  - Failure types: standard vs domain specific
    - e.g., error of commission
    - e.g., wrong dose entered
  - Medical process categories:
    - diagnostics, treatment (e.g., surgery, medications), etc.
  - Failure causes/contributors: information not always available in FMEA studies
- Account for institutional artifacts

Status of work – May 2008

- Collected ~ 5 FMEAs
- Started analysis to make adjustments for FMEA results to make them child specific
- Examining results for potential “themes” to suggest basis for binning
- Preliminary results suggest multiple bins may be used