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On the need for revising healthcare failure mode and effect analysis for assessing potential for patient harm in healthcare processes

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ABSTRACT

Healthcare Failure Mode and Effect Analysis is a proactive, systematic method adapted from safety-critical industries increasingly used to assess the potential for patient harm in high-risk healthcare processes. In this paper we review and discuss this method. We point to some weaknesses and finally argue for two adjustments. One adjustment is regarding the way in which risk is evaluated, and the other is to adopt a broader evaluation of barrier performance. Examples are given from prehospital critical care and from the operating room environment within hospitals to illustrate these ideas.

1. Introduction

Healthcare Failure Mode and Effect Analysis (HFMEA) is one of several proactive Human Failure Ergonomics (HFE) risk analyzing methods commonly used to evaluate error-prone work processes, before patient harm occurs [11,16,23,30]. This method is a modified version of the traditional Failure Mode and Effect Analysis (FMEA) methodology adjusted to the healthcare setting. It was developed by the National Center for Patient Safety of the US Department of Veterans Affairs in 2002 [23,39] and has been widely used ever since within various medical disciplines [20,35,42,43]. Specifically, studies have identified the importance of applying the HFMEA method to detect previously unrecognised system errors or hazards in the operating theatre [4,35] or to evaluate, prioritize and analyse failure modes in drug management and transfusion processes [21,33]. Studies also suggest that approximately 50% of all adverse events in hospitals occur in the operating room [19,34,40]. These figures point to the operating room as a "domain in which improved safety is an urgent and significant challenge" [41, p. 2]), suited to benefit from the HFMEA method. The helicopter emergency medical service (HEMS) is another example of a complex, high-risk, sociotechnical work system particularly vulnerable to adverse events and with inherent performance obstacles in which HFMEA can be applied. As far we know HFMEA has not been used in any published studies involving HEMS. Possible applications of HFMEA in the HEMS environment could be to proactively assess the risks of care transitions and to identify and assess potential vulnerabilities that could be introduced with the acquisition and implementation of new technology.

A HFMEA analysis does not exist in isolation and should be combined with other methods, such as incident learning and Structured What If Technique (SWIFT), in order to provide a comprehensive view of risk in a system [37,47]. This alleviates the concerns raised by Nada Atef Shebl and colleagues related to the reliability of the FMEA method [27,38].

Like most methods, the HFMEA method has a number of strengths and weaknesses [36]. In this method we review and discuss the HFMEA methodology and argue for two adjustments. We ask to what extent it is sufficient to rank different failure modes with respect only to probabilities and consequences (severity), and to what extent it is appropriate to take no further action if an effective control measure already exists.

We believe that there is a need to rethink these issues. Firstly, the basis for categorising the different failure modes should not only be made with respect to probabilities and consequences. The knowledge or lack of knowledge (uncertainties) is then not properly reflected. A broader perspective on risk is needed to take this aspect into consideration. One way to do this is by applying the risk perspective

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presented in [9], which defines risk as a combination of consequences and associated uncertainties. See also [5,7,12,15,24]. Secondly, from the traditional HFMEA viewpoint, there is no need for improvements in healthcare processes if an effective control measure (barrier) already exists. Generally, we consider this practice inappropriate. Several barriers might be necessary, as existing barriers may fail. The traditional HFMEA needs to be adjusted such that the cautionary principle [13] has a stronger role to play.

An adjusted version of an HFMEA taking the above aspects into consideration is presented in this article. Other methods exist to consider uncertainty, such as Safety Cases [22,28], but the focus of this paper is specifically on the development of HFMEA to account for uncertainty.

The article consists of five sections. In Section 2 we give a short review of the HFMEA. In Section 3 we discuss the appropriateness of using the HFMEA for assessing the potential for patient harm in healthcare processes. Then, in Section 4, an adjusted version of the HFMEA is presented. Finally, in Section 5, we draw some conclusions.

2. Review of the healthcare failure mode and effect analysis

The overall aim of the HFMEA is to reveal potential failure modes in healthcare processes, such that the process can be redesigned in order to reduce healthcare errors. The HFMEA is a five step methodology. A short review of these steps is presented below [23,39].

1. Define the HFMEA topic
   The topic should be a clearly defined high risk or high vulnerability area or healthcare process to be proactively evaluated. Boundaries and limitations of complex processes should be described.

2. Assemble the team
   The team should be multidisciplinary. In addition to one or more subject matter experts. This team consist of a team leader and a consultant assisting the team leader.

3. Graphically describe the process
   The healthcare process identified in Step 1 should be graphically described in a process flow diagram of consecutive steps. Each process step should be further decomposed into subprocesses.

4. Conduct a hazard analysis.
   For each of the subprocesses identified in Step 3 all possible/potential failure modes should be listed. The multidisciplinary team (see Step 2) determines the severity and the probability of each failure mode.
   Four categories are used for both the severity (minor, moderate, major, catastrophic) and the probability (remote, uncommon, occasional, frequent). Each failure mode is given a hazard score, as shown in the HFMEA Hazard Scoring Matrix in Fig. 1.
   A clear description of what is meant by the different categories of severity and probability has been provided by [23]. Severity, probability and hazard score for each failure mode are recorded in the HFMEA worksheet (Appendix: Fig. A1).
   To determine whether each of the failure modes warrant further action the HFMEA Decision Tree is used (Fig. 2).
   From the decision tree, we see that further action (continuing to Step 5) depends on the:
   i) *criticality (single point weakness)*
      Single point weakness: The step in the process so critical that its failure will result in system failure, for example, a surgeon who performs wrong-site surgery (WSS) on a patient.
   ii) *effectiveness of control measures*
      An effective control measure that serves to eliminate or significantly reduce the likelihood of the failure or adverse event occurring. For example, the use of surgical checklists prevents wrong-site surgery (WSS) on the patient.
   iii) *detectability*
      The hazard must be so visible and obvious that it will be discovered before it interferes with completion of the particular task and activity.
      The main idea is that one needs to proceed to Step 5 only in situations where the healthcare process is not considered robust. Information regarding points *(i-iii)* needs to be documented in the HFMEA worksheet. The rationale for all stop decisions should also be documented on the worksheet.

5. Actions and outcome measures
   All potential causes for failure modes with a 'proceed decision' from Step 4 should be listed in the HFMEA worksheet. Thereafter, one needs to determine whether to control, accept or eliminate the failure mode causes. For those causes that will be eliminated or controlled, there is also a need for a description of action. In addition to this, potential improvement measures (in the literature referred to as outcome measures), person responsible for implementation of the outcome measures and management concurrence need to be identified.

3. Discussion of the healthcare failure mode and effect analysis

The HFMEA is intuitively appealing, as the analysis identifies and assesses potential risks, and proposes actions on the critical parts of healthcare processes. There are, however, some weaknesses in the HFMEA that have not yet been covered in the literature. These are:

(a) Evaluation of risk is made with respect only to probabilities and consequences/severity. The knowledge and lack of knowledge (uncertainties) are then not properly taken into consideration.
(b) Attention is given to effective control measures without focusing on their reliability

Probability	Severity of Effect			
	Catastrophic	Major	Moderate	Minor
Frequent	16	12	8	4
Occasional	12	9	6	3
Uncommon	8	6	4	2
Remote	4	3	2	1

Fig. 1. HFMEA hazard scoring matrix [23].