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Expanding healthcare failure mode and effect analysis: A composite proactive risk analysis approach

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ABSTRACT

Healthcare Failure Mode and Effect Analysis (HFMEA) is a systematic risk assessment method derived from high risk industries to prospectively examine complex healthcare processes. Like most methods, HFMEA has strengths and weaknesses. In this paper we provide a review of HFMEA's limitations and we introduce an expanded version of traditional HFMEA, with the addition of two safety management techniques: Systematic Human Error Reduction and Prediction Analysis (SHERPA) and Systems-Theoretic Accident Model and Processes – Systems-Theoretic Process Analysis (STAMP-STPA). The combination of the three methodologies addresses significant HFMEA limitations. To test the viability of the proposed hybrid technique, we applied it to assess the potential failures in the process of administration of medication in the home setting. Our findings suggest that it is both a viable and effective tool to supplement the analysis of failures and their causes. We also found that the hybrid technique was effective in identifying corrective actions to address human errors and detecting failures of the constraints necessary to maintain safety.

1. Introduction

In the field of safety-critical engineering, a number of risk analysis techniques have been developed and applied. A standard practice in high-risk industries are prospective hazard analysis techniques, like Failure Modes and Effects Analysis (FMEA), Hazard and Operability (HAZOP), Systematic Human Error Reduction and Prediction Approach (SHERPA), Human Error Analysis and Barrier Analysis, just to name a few [36]. These techniques have been designed with the aim to anticipate and prevent harm in error-prone processes, rather than relying on corrective actions after the incidents have occurred [36].

Over the past two decades, similar safety approaches have been adopted in healthcare, in order to analyse high risk processes [20]. One of the most popular methods is Healthcare Failure Mode and Effect Analysis (HFMEA). HFMEA is a five-step multidisciplinary procedure developed by the United States Department of Veterans Affairs' National Center for Patient Safety in 2002. Recent studies have recognised the importance of applying HFMEA to identify potential failures, causes and consequences. It has been largely applied to the processes of administration and ordering of drugs [59,18,55], sterilization and use of surgical instruments [30], as well as prevention of errors in radiotherapy [54] and chemotherapy [12].

Despite these numerous applications, experts have debated possible amendments to the HFMEA approach in order to address its limitations [19,20]. Specifically, it has been suggested that HFMEA could be improved by combining the traditional approach with different risk analysis techniques [1,46–48,53].

The aim of this paper is to present an overview of HFMEA's criticisms and introduce an extended, hybrid version of HFMEA obtained with the addition of two supplementary risk assessment tools that can address specific HFMEA limitations – namely Systematic Human Error Reduction and Prediction Approach (SHERPA) and Systems-Theoretic Accident Model and Processes – Systems-Theoretic Process Analysis

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(STAMP-STPA). We further present prospective data to test the viability of the new technique in the context of medication administration in homecare settings. The detailed results of the application of the composite approach with the subsequent clinical implications are reported in [35].

Our work rests on the following rationale: the hybrid approach completes the healthcare focused approach (HFMEA) with human factor-focused (HTA and SHERPA) and system-focused (STAMP) approaches. SHERPA steps have analogies with HFMEA steps. For example, both methodologies require depiction of the process with diagrams, with the aim to identify failures. SHERPA focuses on human error and in this sense the combination of HFMEA failure identification with SHERPA human error identification leads to the advantages of a socio-technical risk assessment approach. Further, SHERPA consequence analysis is useful to review the severity ratings because it encourages the team members to examine in details the rates in correspondence to the consequences of each failure. STAMP-STPA formalises the HFMEA cause analysis with a system approach that helps identify the controls and constraints necessary to prevent undesirable interactions between system components.

The following section provides an overview of the HFMEA method and its critique.

1.1. Healthcare failure mode and effect analysis (HFMEA) and its limitations

HFMEA is a multidisciplinary method that combines the concepts, the components and the definitions of industrial FMEA, Hazard Analysis Critical Control Point and Root Cause Analysis

HFMEA is a proactive risk analysis method that involves a multidisciplinary team to map out a high-risk healthcare process and identify the potential failures that can occur within the process activities [14]. It comprises five main steps [14]. The *first step* consists in the choice of the topic, which usually is a highly vulnerable or/and high risk process of care. The *second step* is establishing a multidisciplinary team. The *third step* is creation of a graphical representation of the process and identification of potential failure modes. This is generally done by means of a box and arrow diagram. For major and complex processes, it is suggested to focus on a single highly vulnerable activity (known as the 'scope' of the analysis). The process diagram aims to guide the team in identification of potential failures for each activity. The *fourth step* is the hazard analysis. During this step, the failures identified in the third step are scored with severity and probability ratings (each using four point scales accompanied by written descriptions) that are multiplied to calculate a hazard score. Severity is related to the seriousness of the effects of failures; probability of occurrence is the likelihood that failures will occur. The hazard score is intended to guide the team's efforts by highlighting the failures with the highest score (called critical failures) that need attention. The critical failures that warrant further action are then selected using a decision tree, answering questions about the criticality, detectability and presence of control measures. For the critical failures, the potential causes and the potential effects are listed and further examined. Finally, in the *fifth step*, the team formulates recommendations to prevent or mitigate the critical failures with suggested outcome measures to evaluate the effect of the implemented solutions. A worksheet is used to record the failures, their causes, the team's assessment, the proposed actions, and the outcome measures.

HFMEA has been evaluated and critiqued by several authors. Table 1 summarises some of the most common HFMEA limitations and proposed solutions at each step of the process.

2. Methods

2.1. HFMEA combined with SHERPA and STAMP-STPA

We chose to combine HFMEA with two proactive risk analysis methodologies: SHERPA and STAMP-STPA. SHERPA supports the study of human-based processes [31] and STAMP-STPA improves the causal analysis with a new classification of causes in terms of unsafe, inadequate or absent controls (hence it adds the perspective of cause as control problems) [7].

2.2. Systematic human error reduction and prediction analysis (SHERPA)

SHERPA is a human error identification and analysis technique developed by Embrey [17] to predict human errors in a structured manner in the nuclear industry. It uses Hierarchical Task Analysis (HTA: [44]) together with a taxonomy of human errors to identify errors associated with the sequence of activities that compose the process. SHERPA has undergone extensive validation trials [48–51]. It comprises several steps: [46,47]:

1. The process is broken down into a hierarchy of tasks (i.e., activities executed to achieve the goals) and plans (i.e., the sequence in which the activities are executed). Each task is classified into actions (e.g., pressing a button, pulling a switch, opening a door), retrieval (e.g., getting information from a screen, manual, expert), checking (e.g., conducting a procedural check), selection (e.g., choosing one alternative over another) and information communication (e.g., talking to another party).
2. The activities are evaluated for potential errors using the human error taxonomy. The types of error that may occur fall into one of the aforementioned five categories: action, checking, retrieval, communication and selection. Each error is judged according to its consequences and probability of occurrence. Consequences deemed to be critical (i.e., it causes unacceptable losses, it results in system/process failure or in an adverse event) are noted and assessed for whether the error could be corrected at some point during the process. This is useful to determine the points of weakness (i.e., if the activity fails, the entire process would fail) and identify whether or not there are effective control measures.
3. The final stage is a proposal of error mitigation and reduction strategies. Typically, these strategies can be categorized as equipment, training, procedures or organizational, which can be evaluated by their feasibility and effectiveness.

Research comparing SHERPA with other human error identification methodologies suggests that it performs better than other similar methods in a wide range of scenarios [25,48]. SHERPA has been applied in a wide range of domains, from purchases at vending machines [5,49], through the prediction of pilots' errors [21,48] to the assessment of military command and control systems [40]. In healthcare, SHERPA has been applied to analyse the nature and the incidence of errors during laparoscopic surgery [23] and to detect errors in the process of drug administration in hospital [26].

2.3. Systems theoretic accident model and processes & system theoretic process analysis (STAMP-STPA)

STAMP is a modelling approach proposed by Leveson to capture the dynamics of a complex socio-technical system [7,27,29]. It is based on the theory that systems are interrelated components linked by feedback loops and the accidents result from inadequate control or inadequate enforcement of safety-related constraints of the system [27]. STPA is the associated hazard identification technique, that is used to predict the causes of an accident in terms of the lack or controls and constraints [38,46]. The analysis can be conducted in several steps [28]:

1. Create a complete list of control actions starting from a translation of high-level system hazards into safety constraints/requirements.
2. Represent the safety requirements thorough an architectural description that is a hierarchical control structure of a general socio-technical system (also called functional control structure). This is composed by a basic structure that includes details about the