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Abstract

National and international efforts under the initiative 'patient safety' aim for more safety and transparency within healthcare systems for both patients and professionals. Within the healthcare sector, workflows become more and more complex, while time and money become scarce. As the consequence, the risk awareness, fault management and quality aspects in general become more important. One of the most established risk assessment methods is Failure Mode and Effect Analysis (FMEA) – a reliability analysis and risk assessment tool widely used in various industries. The traditional FMEA is using a Risk Priority Number (RPN) ranking system to evaluate and identify the risk level of failures, and to prioritize actions. However, there are shortcomings in obtaining a quality estimate of the failure ratings with FMEA, especially when human factors play a role, as it is in healthcare. Thus, a new risk assessment method named HFdFMEA (Human Factor dependent FMEA) based on dependency of used parameters and observation of human factors, is proposed to address these drawbacks. The results of this paper show that the HFdFMEA does not only increase risk level of failures based on the inclusion of human-factors but also gives the possibility to reduce the risk level of failures through means of addressing human-factors via trainings, motivation, etc. Finally, we discuss the opportunity to improve patient safety as result of the proposed HFdFMEA, used as technique for Human-Factor-based Risk Management (RiDeM).

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1. Introduction

In the healthcare domain, the patient safety has become one of the major quality targets, targeting reducing risks; risks are recognized and being analysed in depth on an ongoing basis[1, 2, 3]. For example, it has been shown that in 1999 2.9% to 3.7% patients across US states suffered from disclosed adverse events[1]. A recent American observational study found that 45% of patients' experienced medical mismanagement and 17% suffered from events that led to a longer hospital stay or more serious problems[4]. An adverse event is a damage caused by the medical treatment and not by the disease itself and therefore is as a patient safety issue[3]. Vincent et al. suggested that "the patient's safety needs to be addressed on the basis of a broad assessment of a system's health"[5]. The patient safety became one of the major quality targets within the healthcare. Both Quality and Risk Management are required to improve patient safety.

Human errors are one main source for accidents in any industry including health care[1]. According to Reason[7], particularly important is the identification of cognitive processes common to a wide variety of human error types[6]. These errors are differentiated into variable and constant[6] errors and are classified as active and latent failures[6, 5].

Risk Management implies the systematic handling of risks with intent of identification and avoidance of risks[8]. Professional Risk Management starts before failures happen that would have caused any damage. In practice this does not mean the absence of failures but the accuracy, dependability and speed of handling failures and the consequential risks and damages. As a consequence of professional Risk Management, the safety within a company or organisation can be improved. Quality Management deals with important risks as well but it is operated independently from Risk Management. Namely, the Quality Management often serves as a methodical platform for Risk Management.

One of the most established risk assessment methods in healthcare is the Failure Mode and Effect Analysis (FMEA). The FMEA is used to demonstrate how a Risk Management methodology can be used to improve patient safety[1, 9, 8]. The FMEA approach with its failure ratings based on an ordinal scale for occurrence, severity and detection of an event is simple but there are some shortcomings in obtaining an accurate estimate of the failure ratings[10, 14, 11].

Each established risk assessment method has its advantages and disadvantages and consequently limitations in practice, e.g. FMEA has limitations with respect to complex systems[9, 11, 10], in which a critical error arises from a sequence of errors. This can be evaluated by the FMEA but the causes of errors per se cannot be evaluated. Therefore other methods are needed, e.g. Fault Tree Analysis (FTA).

Different risks can occur simultaneously in a healthcare system. A problem in the measurement and rating of such risks is that unrelated individual events often influence each other[8, 9]. Furthermore the dependency between the internal and external risks and respectively risks indicators, as well as the dependency with human factors is not taken into consideration in the current approaches. A new risk assessment method based on the dependency of risks and extended by the human factors has the potential to deal with these shortcomings.

In this paper we propose the enhanced Failure Mode and Effect Analysis, i.e., HFdFMEA method. This is a human factor-dependent FMEA to model the dependency between different risk factors expressed by human factors Some other approaches that investigate human factors in risk management frameworks for healthcare focus mainly on the determination of these factors[12, 25, 5]. The HFdFMEA can assess the risk level of failures based on human factors. In general human factors can increase risk levels and the associated Risk Priority Number (RPN). A reduction of the risk levels can be done by addressing human factors in interactive sessions like trainings, motivation management, etc.

We present a Human-Factor-based Risk Management (RiDeM) system which we then evaluate (showing that it enables to increase the patient safety) with real world data acquitted from a Critical-Incident-Reporting-System (CIRS).

The paper is organized as follows. Section 2 provides overview on the related work, while Section 3 is used to present our HFdFMEA approach. In section 4 the HFdFMEA is evaluated with actual data from a healthcare system. The evaluation results are discussed in section 5 and finally we conclude our paper.

2. Background and Related Work

In this section we first focus on the understanding of Quality Management and Risk Management at large, and then specifically in healthcare. We further explain FMEA and the "human factor" approach and the different roles of human factors and their impact on risks related to investigations.

Quality Management: In general quality is defined as "*degree to which a set of inherent characteristics fulfills requirements*"[12]. In the last years different quality standards and systems as well as "best practice models" have been developed and established in the healthcare area like KTQ (Cooperation for Transparency and Quality in healthcare), EFQM (European Foundation for Quality Management), or EPA (European Doctor's Surgery Assessment).

Risk Management: Quality Management and Risk Management are independent but related terms. "*Risk Management aims to conscious dealing with opportunities and risks,*"[8]. Quality Management also deals with risks and serves as a *platform base* for the Risk Management.

FMEA: is as a systematic method for identifying failure modes of a system, item or function, and tries to evaluate and identify the effects before they occur[13]. The purpose of the FMEA is to seek for answer for questions like: "*what could go wrong with [the system or process] involved in creating [the system]; how badly might it go wrong; and what needs to be done to prevent failures?*"[10]. The traditional FMEA is based on the three factors: *severity*, *occurrence*, and *detection*, to determine the RPN[14, 10, 15]. The FMEA was recommended by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) for the annual risk assessment since 1 July 2001[9]. Unfortunately this official accreditation does not specify if and how the human factors shall be included.

Most of the methods for risk assessment and accident investigation that are still used today in safety critical industries have their origin in the 1960s. Driven by major accidents, risk assessment methods have been enhanced. Some further major changes and developments since the mid-1990s are for example the associated change in view on "human error", from the "old" look to the "new" look[17] or the change from reactive to proactive safety, as marked by resilience engineering.

"Human Factors": In most branches the conception of the error-free working employee is no longer valid. Rather the efforts are made to understand the human error as a "human factor", to plan and to control it by the use of appropriate strategies[3]. Vincent for example describes the "human factors" approach "*as a hybrid discipline that focuses on the human component within complex sociotechnical systems*"[5]. Research in the area of human factors is just beginning to be applied to healthcare since 2005[1], borrowing from industrial engineering and psychology. In the meantime, two approaches for research including human factors have been established (1) Critical Incident Analysis and (2) "naturalistic decision making"[19].

Human Factors in Clinical Practice: Errors in medicine are among the ten most common causes of death in healthcare[20, 21, 22, 8]. Risk Management in clinical practice considers errors, failures and adverse events. Leape[23] emphasized that safer practice can only come from acknowledging the potential for error and building in error reduction strategies at every stage of clinical practice. Reason[24] pointed out, that "*human factors problems are a product of a chain of causes in which the individual psychological factors (that is, momentary inattention, forgetting, etc.) are the last and least manageable links…*". This means, not all errors lead to serious harm. In fact, it usually requires a string of errors to result in harm to patients. Yet it is important to consider these human factors.

Management of Human Factors in Clinical Practice: To mitigate errors in healthcare, CIRS are used. Their goal is to gather enough data about incidents/events such that one can predict errors before they occur. Countries such as, e.g., Germany, Switzerland, Sweden, England, USA, and a number of others, have already established voluntary, national CIRS systems. In some countries, e.g., USA and Sweden, the use of such a system is compulsory, which results in more accurate and meaningful reports based on the investigated data. WHO provides a guideline of defining the content and implementation of CIRS[1]. However none of the existing CIRS systems automatically enables to leverage human factors in Risk Management.

3. Human-Factor-based Risk Management

This paper addresses the challenge of increasing the patient safety through active Risk Management by classifying human factors and by taking into consideration those human factors for risk assessments using FMEA.

Our proposed approach is based on the components: (1) CIRS, (2) human factors, their weighting and (3) derived risk factors HFdFMEA.

(1) A CIRS as described in the previous section is leveraged to derive (2) human factors and weighted them for the human-based risk determination later on. This is done once over the frequency of all reported events per a human factor category (according to the column in CIRS) and once per each reported event over all human factors (according to the rows in CIRS). In practice, the human factor evaluation of the available CIRS data and risk-scoring need to be done by an expert team; scores of different experts must be evaluated for inter-expert agreement. (3) An expert team defines for each event the risk factors in terms of its severity (S), occurrence (O), and detection (D), all three on a scale from 1..10 in traditional FMEA, from 1..5 in HFdFMEA. A scale from 1..5, allows the experts a clearer allocation of risk factors for O, S, and D. Furthermore, a Risk Priority Number (RPN) is assigned per each event in CIRS (RPN = S*O*D)[14, 10, 15].

Therefore, the inputs of HFdFMEA method are weighted human factors derived from all the CIRS-contributory factors. The outputs of HFdFMEA are human-factor based RPNs assigned by each event in the CIRS.

We evaluate our HFdFMEA approach by a multiple regression analysis where the traditional (FMEA-based) RPN will be defined as the dependent variable and the weighted human factors are defined as independent variables.

3.1. The Proposed HFdFMEA Model

To derive human factors from a CIRS, we employ the framework by Vincent[5] which is used for analysing critical incidents/events. This framework includes factors of relevance to clinical practice and outcome by combining the strengths of Reason's model of organizational accidents[6, 26] with socio-technical pyramid of Hurst and Ratcliffe[27, 28, 29, 30, 31]. In this framework, the hierarchy of factors has been derived from previous publications[23, 25, 32, 33, 34, 30] as follows: Patients (patient factors) and staff (task factors) as individuals are at the bottom, team factors and working conditions in the middle, and organizational and institutional factors at the top[31].

Given the contributory factors from CIRS, the human factors can be derived by their encodings similar to Vincent's framework. More than one contributory factor can be assigned to the same event. If a contributory factor is assigned to an event it can be yes (HF=1=present) or no (HF=0=not present). Events with non-assigned contributory factors are classified under "not assigned."

The human factor (HF) for an event (E) is expressed in terms as follows:

$$HF_j = HF_1 + HF_2 + \ldots + HF_k = \sum_{j=1}^{k} HF_j \quad (j=1, 2, \ldots k) \tag{1}$$

In which HF_j is the cumulated human factor consisting of a number of different contributory human factors.

$$HF_{j,E_i} = HF_{1,E_i} + \ldots + HF_{k,E_i} = \sum_{j=1}^{k} HF_{j,E_i} \tag{2}$$

Whereat HF_{j,E_i} is the human factor HF_j (j=1, 2, …k) of an Event i (i=1, 2, …n)

There are two possibilities to weight the contributory human factors for the human factor HF_j. There are different weighting methods available. Our method is based on the conventional reliability allocation method by Kim, which typically considers a series system consisting of independent subsystems[35].

(A) Weighting over frequency of ONE human factor over all events (weighted per column).
The weighting of the contributory factors of HF_j can be expressed in terms as follows:
Weighting factor $w_j(HF_j)$ of a human factor weighted over frequency of ONE human factor over all events

$$w_j(HF_j) = \frac{\omega_j}{\sum_{j=1}^{k} \omega_j} \quad \text{with} \quad \omega_j(HF_j) = 1 + \frac{HF_{j,E_i}}{\sum_{i=1}^{n} HF_{j,E_i}} \tag{3}$$

(B) Weighting on the frequency of ALL human factors per each event (weighted per row)
Weighting factor $w_j(HF_j)$ of a human factor weighted on the frequency of all human factors per each event

$$w_i(E_i) = \frac{\omega_i}{\sum_{i=1}^{n} \omega_i} \quad \text{with} \quad \omega_i(E_i) = 1 + \frac{HF_{j,E_i}}{\sum_{j=1}^{k} HF_{j,E_i}} \tag{4}$$

3.2. HFdFMEA Computation

As we have indicated, the objective of the FMEA is to compute the RPN per an event (equation (5)). The event having a higher RPN will have a higher priority for corrective action or preventive measure.

$$RPN = S * O * D \tag{5}$$

$$RPN_{E_i} = \sum_{i=1}^{n} (O_i * S_i * D_i) \qquad RPN_{E_i} \dots \text{RPN of an event i, i=1, 2, \dots n} \tag{6}$$

For our extended FMEA the traditional calculation of RPN is enhanced by the human factors HF_j:

$$HF_j = HF_1 + HF_2 \dots + HF_k = \sum_{j=1}^{k} HF_j \tag{7}$$

Related to an event E_i this results in:

$$HF_{E_i,j} = HF_{E_i1} + \dots + HF_{E_ik} = \sum_{i=1}^{n} \sum_{j=1}^{k} HF_{E_i,j} \qquad \text{i=1, 2, \dots n; j=1, 2, \dots k} \tag{8}$$

Therefore:

$$RPN'_{E_i,HF_j} = \sum_{i=1}^{n} RPN_{E_i} + \sum_{i=1}^{n} RPN_{E_i} * \sum_{j=1}^{k} HF_{E_i,j} \qquad \text{i=1, 2, \dots n; j=1, 2, \dots k} \tag{9}$$

$$RPN'_{E_i,HF_j} \dots \text{human-factor-based } RPN_{E_i}$$

The output of the proposed HFdFMEA model (RPN'_{E_i,HF_j}) is validated by means of regression analysis, as follows.

In this section we derive the values of RPN_{E_i} for each of the human factors (as described in equation (9)) and further validate the HFdFMEA model.

In the HFdFMEA model the setting of measures is depending on the RPN as well as on the rated factor occurrence, severity and detection itself. For example, if RPN=15 whereas occurrence=3, severity=5 and detection=1, according to RPN the put measures are strongly recommended, but due to severity=5 the put measures becomes mandatory required.

The human-factor-based RPN (RPN_{E_i,HF_j}) shows, that the increase of the non-human-factor-based RPN (RPN_{E_i}) depends on the approach of weighting of these factors: Using the approach (B) "weighting on the frequency of all HF per each event" results in a higher RPN_{E_i,HF_j} then using approach (A) "weighting over frequency of one HF over all events". On the other hand, when comparing the percentage share, the results differ only very slightly. And that implies that the used approach of weighting is relevant regarding RPN_{E_i,HF_j}.

4. Evaluation Setting and Results

To evaluate our approach we could rely on data acquired from cires-health-care.de (developed by Inworks GmbH), a public, not compulsory, representative CIRSs for Germany and Austria where currently 400 medical institutions take part and report their critical incidents and events. The database entries are anonymous. Each listed event entry is assigned to one or more of 32 expertise areas, e.g. surgery or neurology. Additional data about the professional category (doctor, nursing staff, other staff), a place (e.g., hospital, preclinical / emergency medical service, ambulance) and, e.g., a professional category, time of day, area of supply, gender of the patient, and state of an event, as well as (optionally provided) 'contributory factors' are stored. There are nine main categorised contributory factors: (1) patient, (2) organisation, (3) task, (4) person / individual, (5) communication, (6) working environment, (7) equipment /material, (8) team & social factors, (9) education. Except communication and education, which are specific to given CIRS databases employed in our research, all other are as defined in the Vincent's framework[5, 25]. These entries provide the basis for the human factor evaluation. The CIRS uses up to 9 pre-defined categories for the contributory factors. From 2013 to November 2014, 194 TOP-events out of 5000 events were used for our analyses. The TOP-events are the evaluated and risk-rated events by an expert-team, consisting of healthcare professionals. Furthermore the experts define necessary measures to help to avoid and minimize such risks in the future. The O, S and D ratings of an event range from 1…5, with $RPN_{max} = O*S*D = 5*5*5 = 125$.

4.1. Defining the Human Factors

The traditional RPN of an event is calculated according to equation (6) as a result of the three factors O, S, and D.

The above mentioned contributory factors simultaneously form the nine human factors for each event (HF_{j,E_i}). Due to the contributory factors as well as other factors e.g. professionals, places etc. are provided as text, they need to be encoded before they can be used for further analysis, in that way 1=present/true and 0=not present/false.

4.2. Weighting the Human Factors

The derived nine human factors are weighted. Given the two approaches possible (A), (B), we selected both approaches to compare the impact on the accuracy human-factor-based RPN.

Comparing the reported events with weighting over frequency of one human factors over all events (approach A) and with weighting on the frequency of all human factors per each event (approach B) shows, that in the first case the weighted human factors are significantly lower compared to approach (B). That means on the one hand, approach B emphasizes the human factors more, and on the other hand that implies that the risk depends on the number of human factors assigned to an event.

4.3. Evaluation of HFdFMEA model via Regression

To test the validity of the proposed HFdFMEA model we have used the multiple regression analysis. This was done to evaluate the statistical significance of the relation between dependent variable RPN and the human factors[36]. Three special measurements can indicate the significance of a regression 'R', 'adjusted R square' (R^2). The final output of a multiple regression is an equation derived from the computed coefficients, which can be used to predict a new value for the dependent variable only using the independent variables in our case the human factors.

We hypothesize that the human factors help to indicate the RPN level. Based on our CIRS database we run the regression analysis and verified the statistical significance. To compute the regression results we have used the nine human factors. The regression output was evaluated using the following six assumptions. (1) Independence of the observations was fulfilled due to an acceptable Durbin-Watson value of 1.589. (2) Linearity, was confirmed by graphically identifying a horizontal band on the scatter plot between the residuals (Y axis) and the predicted values (X axis). (3) Homoscedasticity was tested using a scatter plot of the studentized residuals versus the unstandardized predicted values. Homoscedasticity can be rejected, as the residuals are mainly equally spread over the unstandardized predicted values. (4) Multicollinearity was excluded as the highest variance inflation factor (VIF) was 1.522 and the smallest tolerance value was 0.657. (5) Outliers with a standardized residual higher than 3 and all leverage and influential points are not part of the final model. (6) Normality was confirmed with a histogram of the standardized residuals.

As all six assumptions are fulfilled, the statistical significance of the regression result can be interpreted. R can be between 0 and 1, and a value of 0.274 unfortunately indicates a not so good prediction level. The R^2 value of 0.025 explains only 2.5% of the variability of the dependent variable. More importantly, the adjusted R^2 value of 0.025 means that the regression model explains just 2.5% of the proportion of variance, which indicates a low effect size. The effect size, which is explained by Cohen's classification, could be better, but based on the available data, it was not possible to find a better model. In general the R, R^2 and adjusted R^2 values not always represent the real quality of a regression model. Also with a low adjusted R^2 the regression model can be a got fit for the data. Due to the fulfilled test assumptions the regression output indicates a significant relation between the RPN and the human factors. As the prediction level is low we have to check why we have a significant relation, but we have problems predicting RPN with self-selected human factors. The final regression equation is shown in equation 10.

$$RPN'_{E_i,HF_j} = 192.482 - (272.018 * HFpat) + (476.975 * HForg) + (102.189 * HFtask) +$$
$$(197.043 * HFind) + (792.104 * HFwen) + (289.222 * HFcom) + (221.302 * HFequ) -$$
$$(1297.785 * HFtsf) + (835.812 * HFedu) + (597.902 * HFnoa) \tag{10}$$

5. Discussion

5.1. To which restrictions and limitation lead the CIRS-databases?

Based on our research we conclude that it is important that all fields of a CIRS database are filled with informative, real data. Otherwise each kind of evaluation result becomes vague and inconclusive. Furthermore it is necessary to define the required information in a way, that there is no space for giving answer like "all", "other" or a blank field. A concrete assignment is absolutely necessary, since this leads to more accurate results for subsequent analysis. To be able to compare with other hospitals also over their own national borders, it is necessary to use similar contributory factors, which results in human factors. Therefore Vincent's framework or ISO standards could be used as guideline for the definition.

5.2. How generalised are the results?

The derived human factors from a CIRS database are only valid for the analysed database for a given period of data available for us. A CIRS database can only provide national data. Ideally all healthcare facilities are obligated to provide information for a CIRS database. However it makes sense to perform it within an individual hospital. In this case the hospital can profit mostly because this will help hospitals to improve their individual standards for patient safety.

5.3. What are implications for the health system, practitioners and patients?

The proposed HFdFMEA method allows improving patient safety by means of enabling better understanding and management of human-factors influencing risks and the Risk Priority Number (RPN), which in turn is of importance for the patient. Investigations in the relation between risks and human factors help healthcare professionals to identify potential problems, to improve processes, to minimize risk and respectively to avoid adverse events and incidents by putting proactive and predictive measures. An open communication regarding the reporting shall be encouraged. Anonymity should help the practitioners to ensure that they have no fear of negative consequences when reporting an event.

The HFdFMEA can be implemented by hospitals using a CIRS database through this the human-factor-based RPN (RPN_{E_i,HF_j}) can be evaluated per event and depending on the assigned human factors it would be possible to take appropriate measures to minimize risks. On the other hand it offers the possibility to handle chances, too.

6. Conclusions

The target of our research was to answer the question "Is it possible to increase patient safety through active Risk Management by classifying human factors and by taking into consideration human factors for risk assessments based on FMEA?" and the answer can be summarized as follows.

The proposed enhanced HFdFMEA embraces the human factor approach. The data recorded in the CIRS database upon an event can be used for this purpose. Therefore the event-specific contributory factors are converted into the human factors, which are used in this model, by decoding into 1=present/true and 0=not present/false. As a result those human factors are weighted. The HFdFMEA does not only increase risk level of failures based on the human factor but also gives the possibility to reduce the risk level of failures through means of human factor interacting like trainings, motivation, etc. This allows considering negative impacts, known as the 'typically risk', and positive impacts, known as 'chance'. Further the results of the regression analysis show that human factors, inter alia, may be interdependent.

In our research we didn't differentiate between the different areas of expertise whereas this information could be provided quickly and easily by the analysis carried out in each area of expertise.

Our on-going research activities are focused on a human-factor-based Risk Management (RiDeM) method, extended by the proposed HFdFMEA, which will quantify the relation between risks and human factors for an improved Risk Management method and consequently will facilitate to improve patient safety.

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