Chapter 25
Human-Factor-Based Risk Management in the Healthcare to Improve Patient Safety

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ABSTRACT

'Patient Safety' tries to increase 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 a consequence, the risk awareness, fault management and quality aspects become more important. One of the most well established risk assessment method 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 several shortcomings in obtaining a quality estimate of the failure ratings with FMEA, especially when human factors play an important role. Thus, a new risk assessment method called HFdFMEA (Human Factor dependent FMEA) based on the dependency of used parameters and the observation of human factors, is proposed to address the drawbacks. The opportunity to improve patient safety is discussed as result of HFdFMEA.

1. INTRODUCTION

In the healthcare sector, the patient safety has become one of the major quality targets, with aim in reducing risks. However, it has been recognized that the patient safety risks are evolving over time and for this they and analysed in depth on an ongoing basis (Institute of Medicine, 1999), (ANetPAS, 2014), (Paula, 2007). For example, it has been shown that in 1999 2.9% to 3.7% patients across US states suffered from disclosed adverse events (Institute of Medicine, 1999). A recent American observational study found that 45% of patients' experienced adverse events, like medical mismanagement, and 17% suffered from events that led to a longer hospital stay or more serious problems (Andrews, Stocking, Krizek, Gottlieb, Krizek, & Vargish, 1997). According to Paula (Paula, 2007) 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. 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*" (Vincent, Taylor-Adams, & Stanhope, 1998), suggesting that Quality and Risk Management need to be addressed together in order to improve patient safety.

Human errors are one main source for accidents in any industry, including healthcare (Institute of Medicine, 1999). According to Reason (WHO, 2005), particularly important is the identification of cognitive processes common to a wide variety of human error types (Reason J., 1990). These errors are differentiated into variable and constant (Reason J., 1990) errors and are classified as active and latent failures (Reason J., 1990), (Vincent, Taylor-Adams, & Stanhope, 1998).

Risk Management implies the systematic handling of risks with intent of identification and avoidance of risks (Ennker, Pietrowski, & Kleine, 2007). Professional Risk Management starts before failures that would have caused any damage, happen. In practice this does not mean that we have an absence of failures, but that the accuracy, dependability and speed of handling failures reduce the consequential risks and damages. As a consequence, the use of professional Risk Management approach in an organization, can improve the safety within the organization. Quality Management deals with important risks as well but it is operated independently from Risk Management. Quality Management often serves as a methodical platform for Risk Management (Streimelweger, Wac, & Seiringer, 2015). With the updated standard ISO 9001:2015, the section Risk Management was extended and became an important part in the application of Quality Management according to ISO 9001. The gap between Risk and Quality Management seems to be reduced.

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 (Institute of Medicine, 1999), (Marx & Slonim, 2003), (Ennker, Pietrowski, & Kleine, 2007). 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 (Vikramjit, Harish, Sarabjeet, & Simranpreet, 2013), (EN 60812 - FMEA, 2006), (DeRosier, Stalhandske, Bagian, & Nudell, 2002).

An important shortcoming of FMEA concerns its limitations with respect to complex systems (Marx & Slonim, 2003), (DeRosier, Stalhandske, Bagian, & Nudell, 2002), (Vikramjit, Harish, Sarabjeet, & Simranpreet, 2013), 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, like for example Fault Tree Analysis (FTA).

In a healthcare system different risks can occur simultaneously. A problem in the measurement and rating of such risks is that unrelated individual events often influence each other (Ennker, Pietrowski, & Kleine, 2007), (Marx & Slonim, 2003). Furthermore, the dependency between the internal and external

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