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Human reliability assessment for medical devices based on failure mode and effects analysis and fuzzy linguistic theory

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ABSTRACT

Medical device systems have become increasingly complex, interconnected, and interoperating. A major challenge is how to ensure and improve the safety, security, and reliability of medical devices. An efficient human reliability analysis and assessment for medical devices is essential for improving the quality of medical treatment and preventing an iatric accident. This paper explores qualitative and quantitative methods to analyze human reliability for medical devices. First, the SHELL (named after the initial letters of its components' names, Software, Hardware, Environment, Live-ware and Central Live-ware) model is developed to make a qualitative analysis for human reliability of medical devices. The SHELL model is to consider human as an integrated and inseparable component of the productive system. After that, failure modes and effects analysis (FMEA) is proposed to evaluate the potential failures in human reliability of medical devices. Failure mode and effects analysis (FMEA) is a method to assess a system, design, process or service for possible ways, in which failures (problems, errors, risks and concerns) can occur. The most important issue of FMEA is the determination of risk factors like the occurrence, severity, and detection using the opinions of different experts. This paper applies fuzzy linguistic theory to convert the subjective cognition of experts into an information entity to obtain the numerical values of risk factors. The aim of this study is to analyze and build an assessment model for human reliability of medical devices to improve the safety of medical devices.

1. Introduction

Medical devices are special products that are directly related to patients' health and lives. They are associated with adverse events which result in death or serious injury, or have malfunctions which could lead to death/serious injury (Cheng et al., 2011). The design of medical devices has become more intricate. The designers are more concerned about the efficacy, safety, and reliability. The users and patients both want the device to operate as specified, perform in a safe manner, and continue to perform over a long period of time without failure (Fries, 2012).

In recent years, the reliability of software and hardware equipment has greatly improved, because of the advances in security measures. But, along with the increasing complexity of equipment and the increase in the workload of operators, the number of accidents caused by the unreliability of the operators' behavior has risen. So the risk of use-error is becoming the main factor in the equipment risk. According to the report "To Err Is Human" which was published by the National Institute of Medicine (IOM), as many as 98,000 inpatients in the United States die each year because of avoidable medical errors (Kohn et al., 1999). In 1999, the U.S. Food and Drug Administration (FDA) investigated the reasons for approximately 130,000 medical incidents from 1984 to 1991 and concluded that human error accounts for 60% of all medical device-related deaths or injuries (Hoelscher et al., 2006).

In order to study the real causes of medical incidents, the researchers stressed controlling various factors which cause risk from the design, production and use of medical devices. The standards for medical devices risk management ISO 14971, 2000, which was issued by the International Standards Association, provides the process and methods of use risk analysis and evaluation for medical devices (ISO 14971, 2000). In Europe, IEC 60601-1-6 stipulates that the usability engineering must be implemented in the development process of the medical devices, and the design principles of human–machine interface must be followed to ensure reasonable and reliable design (IEC 60601-1-6, 2004).

Human factor problems are frequently encountered in medical devices and design-induced errors, in that the use of such devices can result in patient injuries and deaths (Dhillon, 2003). Cooper

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et al. (2006) proposed a human reliability-centered approach to the development of job aid for reviewers of medical devices, and concluded that an improved understanding of human error, its causes and contexts, and human reliability analysis is important in the risk assessment of medical devices.

Human reliability assessment (HRA) is the common name for an assessment of methods and models that are used to predict the occurrence of "human errors" (Hollnagel, 2005). HRA has been used in high-risk industries (nuclear, aerospace, etc.) to prevent accidents, the consequences of which would be catastrophic (Cuschieri, 2000). Moraru et al. (2010) developed and applied HRA model for mine dispatchers and analyzed the importance of HRA in system safety. They concluded that human reliability assessment resulted, primary, from the necessity to reduce the risk of high-technology production systems.

Failure modes and effects analysis is a risk assessment tool that mitigates potential failure in system, design, process or service. It is widely used to define, identify and eliminate known and potential failures, problems, and errors (Liu et al., 2011). FMEA has been used as a powerful tool for safety and reliability analysis of products and processes in a wide range of aerospace, nuclear and automotive industries (Sankar and Prabhu, 2001; Wang et al., 2009). In recent years, there has been more research about FMEA application in the healthcare system (Nichols et al., 2004; Capunzo et al., 2004). Liu et al. (2012) proposed a fuzzy FMEA based on fuzzy set theory and VIKOR to assess the risk of the general anesthesia process. Reichert (2004) used FMEA in healthcare, and described the FMEA project process. Wetterneck et al. (2004) described the method and challenges of performing a process and design FMEA to prepare for the implementation of a new intravenous infusion pump, and they made recommendations for the performance of a process and design FMEA for new technology implementation in healthcare organizations. Reiling et al. (2003) used FMEA to create a replacement facility aimed at reducing errors and promoting patient safety and satisfaction. FMEA is a valuable tool in designing a healthcare facility that focuses on patient safety, and it will also result in increased architect, owner and contractor awareness.

The research is based on FMEA and fuzzy linguistic to propose human reliability assessment for medical devices to improve the quality and safety. This paper is organized as follows: the human reliability analysis tool, the SHELL model, is introduced in Section 2. The human reliability assessment model based on FMEA and fuzzy linguistic is presented in Section 3. A case study is introduced in Section 4, followed by the conclusion and discussion.

2. Human reliability analysis

Human reliability analysis identifies the errors and weaknesses in the system by examining the systems of work, including those who work in the system (Lyons et al., 2004). It has been defined as the application of relevant information about human characteristics and behavior to the design of objects, facilities, and environments that people use (Grandjean, 1980). There is a large number of methods to analyze human reliability. Here we introduce the SHELL model.

The SHELL model, introduced by Edwards (1972) and then developed by Hawkins (1987), describes the behavior of an interactive system with special regard to human factors issues. SHELL considers humans as an integrated and inseparable component of the productive system. It emphasizes the interfaces between a person (Center Live-ware) and the other four components, rather than the components themselves (Reinhart, 1996).

The elements of the SHELL model (Fig. 1) are introduced as follows (Hawkins, 1987):

- Hardware represents any physical and non-human component of the system, such as equipment, vehicles, tools, manuals, signs.
- Software represents all non-physical resources, for organic operation, like organizational policies/rules, procedures, manuals and placards.
- Environment represents not only the factors which influence the location where people are working, such as climate, temperature, vibration and noise, but also social–political and economic factors.
- Live-ware represents factors like teamwork, communication, leadership and norms.
- Central Live-ware is regarded as the core of the SHELL model and other components match with the Live-ware as the central figure.

The interaction between the Central Live-ware and Hardware (L–H System) is usually named as a man–machine system. Hawkins (1987) argued that the design of controls and displays, which is subject to the L–H interaction, should be matched with human characteristics in order to minimize the possibility of L–H error occurrences. The second interface is represented as the interaction between the Central Live-ware and Software. As the Software indicates intangible objects rather than those of the Hardware, it is

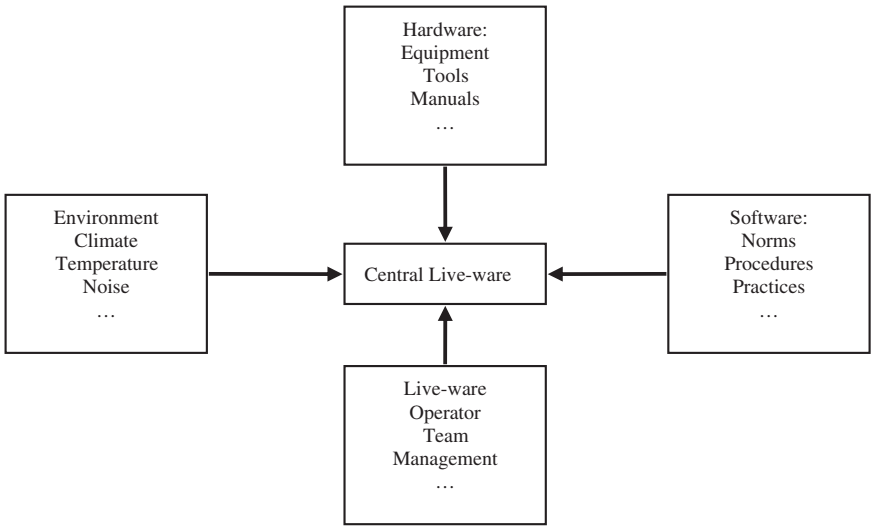

Fig. 1. The SHELL model.