RISK CONTROL AND AUDITING MECHANISM FOR HOSPITAL MATERIALS MANAGEMENT

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ABSTRACT

This study conducts a research related to risk management and audit mechanism for medical materials management in a hospital. There are four objectives in this study: (1) assessing the potential risks, causes, and consequent effects of applying medical devices in the current medical environment; (2) studying audit theories and evaluation frameworks of medical device risk management; (3) developing an audit mechanism for risk management of using medical devices; (4) verifying the practical feasibility of this mechanism.

Keyword: Medical device, risk management, auditing mechanism, COSO 2013, CMMI

EXTENDED ABSTRACTS

INTRODUCTION

Medical devices play an important role in the procedure of treatment as they can help to promptly diagnose the cause of health problems and provide adequate treatment to regain a healthy physical condition for patients [7][9]. However, it is full of different types of potential risk in the application of medical devices; for example, many medical malpractice cases were often caused by the following issues: the mismanagement of hospital inventory, the poor use and maintenance of medical instruments, the electromagnetic interference in the medical environment, and the practitioners' lacking of professional knowledge [1][12]. All of these above-mentioned problems are the non-ignorable vital causes of medical risk, and required to be controlled by an efficient risk management mechanism so as to reduce the rate of risk and prevent the occurrence of irrecoverable faults [8][13].

This study conducts a research related to risk management and audit mechanism for medical materials management in a hospital. There are four objectives in this study: (1) assessing the potential risks, causes, and consequent effects of applying medical devices in the current medical environment; (2) studying audit theories and evaluation frameworks of medical device risk management; (3) developing an audit mechanism for risk management of using medical devices; (4) verifying the practical feasibility of this mechanism. Under the guidance of Gowin's Vee knowledge map, this study was firstly conducting a systematic literature review to determine nine categories of factor on medical risks and medical device risks; secondly, applying the Delphi questionnaire technique [2][3][11] to compare and amend the factors influencing medical device risk and the items regarding internal control audit; thirdly, adopting

a COSO 2013 framework [10] and CMMI capability maturity model [4] [6] to develop an audit mechanism for medical device risk management; finally, conducting a case study to verify the feasibility of the medical device risk management audit mechanism created in this study.

Two important research outcomes are established in this study: a checklist of medical device risk assessment and an audit mechanism for risk management. The results of this research, can promote the medical institutions to risk management reference. In advance to prevent the prevention of control, in order to achieve the principle of maintaining patient safety. For the compliance of the regulations, the adjustment of management policies and the implementation of the supervision mechanism, there is a certain degree of assistance. In addition, in the academic, but also provide follow-up researchers rigorous and complete research methods, from which to explore a deeper understanding.

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