

Title: Development & Validation of an assessment method for
IEC 80001-1 (IEC 2010)

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Abstract

Background

The increasing use of medical devices incorporated into the IT-network creates a medical IT-network with additional risks to patient safety. The standard IEC 80001-1 (IEC 2010) addresses risk management of medical IT networks, however implementation has been slow, due to lack of an assessment method.

Aim & Objectives

This study aimed to contribute to the development and validation of an assessment method for IEC 80001-1 (IEC 2010), to enable healthcare organisations to assess their risk management processes and conformance. Additionally, this research intended to raise awareness of the standard and improve risk management processes related to medical IT-network modification.

Methods

The assessment method (containing a question set and guidance) was developed using the IEC 80001-1 PRM & PAM and in compliance with ISO/IEC 15504. The assessment method was used in the context of a medical IT-network modification project in a healthcare organisation. The IT-network modification project involved replacing the blood gas analysers and interfacing the new ones on the network with the laboratory and clinical information systems. The assessment feedback and findings were used to refine the question set.

Findings

The findings showed that while participants used standards, none had used IEC 80001-1 (IEC 2010). No formal risk management resources were assigned to the project. Many risk management processes were undertaken informally, there was no formal risk management plan or process and documentation was mainly informal (meeting minutes). The assessment identified strengths, weaknesses, opportunities and threats in the risk management processes of the medical IT-network project. There was improved communication and collaboration among risk management stakeholders and increased knowledge and awareness of the standard among participants following the assessment. Implementation of recommendations arising from the assessment resulted in improvements in risk management of the medical IT-network leading to increased patient safety.

Conclusions

Study participants indicated they would use the assessment method in future medical IT-network modification projects increasing the likelihood of IEC 80001-1 (IEC 2010) implementations. This study has contributed to International standards development work related to risk management of medical IT-networks. The developed assessment method has been incorporated into a technical report (ISO/IEC TR 80001-2-7) for IEC 80001-1 due for publication in 2014. The study has raised awareness of the standard IEC 80001-1 among risk management stakeholders and improved risk management processes at the study site.