

## Abstract

The interoperability of medical devices and the incorporation of these medical devices onto IT networks are becoming pervasive. This coupled with the increase in cyber-attacks on Health Delivery Organisations (HDOs), increases the risks to patient safety and data and system security. IEC 80001-1 was published to help HDOs identify and address the risks associated with medical devices sharing a common IT network with other applications and systems. IEC published a technical report ISO/TR 80001-2-7 containing a process assessment model (PAM) which can be adapted and used by the HDO to identify resources and processes that are required to implement an IEC 80001-1 medical IT network

The Health Service Executive (HSE) has indicated that that the Children's Hospital Group (CHG) will be the first implementation of a National Acute electronic medical record (EMR) with one single heterogeneous IT network planned for the hospital. Therefore it is crucial that all associated risks are identified and appropriate resources and procedures are put in place. The motivation behind this study is to determine if the PAM presented in ISO/TR 80001-2-7 is accessible enough to allow a HDO with a medical IT network self-assess their conformance with IEC 80001-1.

A literature review was conducted which highlighted the difficulties faced by HDOs in understanding and applying the requirements of this standard. One of the factor highlighted which contributed to the lack of adoption, was the lack of a PAM. Adoption and awareness of the standard remained low even after the publication of the PAM in ISO/TR 80001-2-7.

The research consisted of three different stages and was targeted at the Information Technology (IT) and Clinical Engineering (CE) Managers within National HDOs and the CHG. Ethics approval from the three children's hospitals and Trinity College was received.

Stage 1 consisted of a national survey to determine a baseline for the awareness and adoption of the standard nationally and to identify possible barriers to its implementation.

Stage 2 consisted of focus groups with IT and CE manager within the CHG to evaluate the accessibility and usability of the PAM. Combining this information with findings in the literature informed the development on an excel application which was undertaken as part of this research and presented the PAM in a dashboard style.

Stage 3 involved presenting the PAM as represented in the excel application to the same IT and CE manager within the CHG and evaluating its accessibility and usability.

The results of the national survey confirmed the lack of awareness and adoption of IEC 80001-1 and identified: Knowledge of the standard, Clarity over roles and responsibilities and Governance of medical IT network as the top three restrictions to its implementation.

The results of the focus groups confirmed the difficulty that participants were having using the PAM in its current format however when presented in a dashboard style format in the excel application, participants found the PAM much easier to use.

The results highlight that the adoption and use of standards within an organisation is greatly increased when the standards are readily available and easy to read and understand. This is consistent with other findings repeated in the literature which also identifies an investment in people, processes and specialised tools as enabling factors.

A number of professional stakeholder groups were identified and a dissemination plan informing them about the standard and results of this research is outlined.