How accessible is IEC 80001 within Irish Healthcare Delivery Organisations?

The interoperability of medical devices and the incorporation of these medical devices onto IT networks are becoming ubiquitous [1]. This coupled with the increase in cyber-attacks on Health Delivery Organisations (HDOs), increases the risks to patient safety and data and system security [2].

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 [3].

The literature highlighted that the adoption and awareness of the standard remained low even after the publication of the PAM in ISO/TR 80001-2-7 [4].

The research consisted of three different stages and was targeted at the Information Technology (IT) and Clinical Engineering (CE) Managers within National HDOs.

Stage 1 consisted of a national survey to determine a baseline for the awareness and adoption of the standard.

Stage 2 consisted of focus groups to evaluate the accessibility and usability of the PAM.

Stage 3 involved presenting the PAM as represented in a dashboard format 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, 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.

1. Delvecchio, K., *Step-by-step risk management for medical IT networks.* Biomed Instrum Technol, 2011. **Suppl**: p. 37-43.
2. IEC, *IEC 80001-1:2010 - Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities*. 2010, 2010.
3. ISO/IEC, *PD IEC/TR 80001-2-7:2015 - Application of risk management for IT-networks incorporating medical devices -- Application guidance -- Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess their conformance with IEC 80001-1*. 2015, 2015.
4. Eckhardt, K., et al., *Application of the IEC80001 standard towards integration of a real time alarm communication and management system.* TQM Journal, 2015. **27**(4): p. 397.