Safety and Quality of E-Health Systems

2006

A focus on the safety and quality of e-health systems serves to create awareness of the potential benefits and risks associated with the use of clinical software in the medical environment.

Evidence shows that use of clinical software in the medical practice and hospital setting delivers many benefits. There is, however, growing evidence indicating that a range of factors related to the use and application of information technology can jeopardise[1] quality and safety of patient outcomes.[2]

Use of the clinical software packages available on the Australian market is expanding rapidly.[3] The lack of functional specification standards[4], the absence of an appropriate governance process to set such standards, and the lack of standardised testing of clinical software functionality, may create potential for risks to quality and safety. *'The process guiding the development and testing of most medical treatments and biomedical instrumentation, including software embedded in or linked to clinical devices, is tightly regulated. In contrast, the development of stand-alone clinical software is not. In Australia, stand-alone decision-support computer programs, such as electronic prescribing systems, are not considered 'therapeutic goods' and are not subject to regulation.*[5]

While the rapid uptake of clinical software in primary care has made a valuable contribution to patient outcomes, the AMA recognises that improvements to quality and safety in e-health have been slow in some sectors due in part to the fragmented approach of jurisdictions and lack of clear ownership of the e-health agenda. The Federal and State Health Departments and various statutory bodies have been unable to facilitate national functional standards to support regulation within the clinical software industry.

While acknowledging the immense complexities of the task, the AMA supports the development of a regulatory framework to standardise and govern the use of clinical software in medical practice. It is the AMA's view that such an approach will contribute to reducing potential risks and improve quality and safety related to the use of information technology.

Implementation of a regulatory framework will create an important industry standard for clinical software and interoperability. Such a framework will enhance take-up and use of information technology and information management systems across the health industry and, importantly, serve to improve quality and safety in medical practice and in turn patient outcomes.

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[1] With strong evidence in decision support.
[2] The Safety and Quality of Decision Support Systems. E.Coiera, J.I. Westbrook, J.C. Wyatt (IMIA Yearbook of Medical Informatics 2006).
[3] General Practice in Australia: 2004. Department of Health and Ageing, Developments in information systems (pp545-584).
[4] While there is work towards technical standards that will allow software to interoperate there are no standards around how they will behave ie functional standards.
[5] Should clinical software be regulated? Enrico W Coiera and Johanna I Westbrook (MJA Vol 184 No 12 19 June 2006)

In developing a recommended regulatory framework for clinical software a number of key issues must be considered:

- the need to develop a strong consultation process with industry which is essential to the development of appropriate and acceptable specifications for clinical software;
- the option of developing a standards based functional specification as a basis for software suitability in some specific environments that would allow potential purchasers to assess software suitability;
- the option of recognising or potentially accrediting:
  - software vendors that implement standards or undertake quality assessment;
  - products that meet agreed specifications for use in specific clinical environments;[6]
  - appropriate user training (supported by auditing) in specialised clinical software use
- the potential implementation of a system of 'hazard reporting' that includes a feedback loop to industry and system users;
- the need to undertake collection and analysis of base line data (or a hazard assessment) on the current status;
- creating strong awareness of potential risks and risk reduction measures that may be implemented when using technology throughout the health sector, and;
- where standards are established they must be professionally "owned".

[6] The complexities related to accreditation of medical software are significant but if considered would also need to take into account the necessity to establish an appropriate accrediting body with responsibility for managing and promulgating standards, and governing best practice guidelines.