Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Additional Estimates 2011-2012, 15 February 2012

Question: E12-038

OUTCOME 10: Health System Capacity and Quality

Topic: EHEALTH

Written Question on Notice

Senator Boyce asked:

a) Are NEHTA and DOHA aware of the US Institute of Medicine Report entitled "Health IT and Patient Safety: Building Safer Systems for Better Care"?

b) If so, how are NEHTA and DOHA ensured that the issues and specifically the risks of harm to patient care and safety have been fully addressed in the completed architecture of the PCEHR?

Answer:

a) and b)
The Department of Health and Ageing has taken international evidence into consideration in the development of the Personally Controlled Electronic Health Records (PCEHR) system. The Department is aware that the paper:"Health IT and Patient Safety Building Safer Systems for Better Care" is currently marked as a "Prepublication Copy: Uncorrected Proof"**,** which may be subject to change. When this paper is finalised and publicly available it will be considered along with other international research.

Each stage of the development process for the PCEHR technical specifications require clinical governance and safety processes to be followed. The National E-Health Transition Authority's (NEHTA) Clinical Safety Unit (CSU) is fully embedded into all areas of NEHTA's product development and oversees clinical governance at NEHTA. The CSU is supplemented through NEHTA's Clinical Leads. NEHTA's CSU:

- identify any circumstances related to eHealth that may have the potential to put patients at risk of harm;
- is actively involved in reviews (from a safety perspective) of all specifications/products released using the Clinical Safety Management System defined processes;
- document the evidence, where possible, in a case relating to clinical safety; and
- monitor cases relating to clinical safety issues for the operational life of the product/system.

The CSU addresses safety by working across the work programs in NEHTA to provide certainty to medical software developers, end-users and policy makers. The CSU activities involve clinicians, with health IT knowledge and experience, system safety engineering and risk management as well as a:

- Biomedical engineer;

- Biomedical scientist;
- System Safety engineer;
- Test Engineer;
- Program Coordinator and Projects Coordinator/Manager; and
- Program support officer.

The outcomes of clinical safety reviews inform specifications and standards as well as any related guidance material.