Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

National e-Health Transition Authority (NeHTA)

Budget Estimates 2011-12, Supplementary Estimates

**Question: 15**

OUTCOME 10.2: e-Health

Topic: PCEHR

Senator Boyce asked:

**Time and again my office and I have asked NEHTA if they really have assessed the risks associated with the PCEHR proposal. Time and again we receive assurances that a thorough assessment has been undertaken but we are never provided fact or evidence to support such a claim. Please provide all evidence, of all trials conducted by NEHTA in regard to the PCEHR connected to patient's safety, security and privacy? Please provide the detail of those trials, their outcomes and findings?**

Answer:

NEHTA has a well-established Clinical Safety Unit (CSU), embedded within the Clinical Leadership and Engagement Unit of NEHTA. The role of the Unit is to deliver internal clinical safety assurance services for NEHTA products and services. The CSU is responsible for identifying clinical hazards introduced through the design and development of NEHTA products and assessing how these may contribute to clinical harm. The CSU works with product teams during the development phases to recommend mitigating controls and the product team is responsible for deciding how best to implement the proposed controls and communicate their approach to stakeholders.

The review process goes through a number of cycles during product development and where risks are identified, mitigation strategies are put in place to ensure the risks are as low as possible. A key part of the review process is the Clinical Safety Working Group, which comprises managers from across all NEHTA products, services and related functions.

The clinical safety team have implemented a clinical safety management system (SENTRY) that supports:

- Clinical hazard identification using system safety engineering tools and techniques adapted for health
- Analysis and validation of clinical hazards
- Documentation of risk mitigation controls and recommendations
- Verification of mitigating controls in operation
- Processes for test assurance, issues management in development and incident management of products in production

The goal of SENTRY is to ensure that the residual clinical risk associated with NEHTA products and systems is as low as reasonably practicable. In addition to providing a Safety Case approach to Clinical Safety Management, Sentry promotes an effective safety culture within NEHTA.

NEHTA has a Clinical Governance Review Board to oversee clinical governance processes including clinical safety and effectiveness within NEHTA products and services.

Good clinical governance ensures that eHealth systems focus beyond what can be done in the technological arena; and brings clinical perspective to the prioritisation of innovations that are of most relevance to enhancing patient care.

NEHTA is committed to clinical quality processes and their continuous improvement NEHTA has an explicit, proactive approach to clinical safety management, with an established, active Clinical Safety function, advised by a Clinical Executive.

The Clinical Safety Case Report Release 1a is currently being prepared. The elements of PCEHR Release 1a focus on healthcare provider functionality only. It is important to note that this report is currently incomplete as it does not contain the results of testing, as this is still in progress.

A Privacy Impact Assessment (PIA) of the PCEHR has been undertaken. The Department of Health and Ageing engaged Minter Ellison Lawyers, in conjunction with Salinger Privacy, to conduct a privacy impact assessment (PIA) of the current design of the PCEHR system and legislation.

The PIA identifies a wide range of privacy positives and risks for the PCEHR system, and puts forward 112 recommendations for managing the identified risks. Further information on the PIA is available from DoHA.

Security risk assessments on the PCEHR system have been conducted in an iterative manner over the past twelve months. The results of these assessments have provided a set of requirements for the PCEHR security architecture and hence the build of the PCEHR system security.

A full end-to-end risk assessment of the PCEHR ecosystem (from user to system and back) is currently being conducted.

Work is underway as part of the Change and Adoption process to keep healthcare consumers informed of the security measures being provided to protect their healthcare information.