Senate Community Affairs Committee

INQUIRY INTO PCEHR BILLS

National e-Health Transition Authority (NeHTA)

Responses to Questions Taken on Notice

Topic: eHealth sites announcement

Senator Moore asked:

I have a question regarding the media statement on 24 January. On notice, can you give us any indication of whether a NEHTA media release led to the story?

We know that a couple of journalists have a particular interest in NEHTA and are following this issue very closely. I am interested to know how it was determined that the appropriate thing was to call a halt and how the public found out about. You heard my question to the people in wave 1 and their response that they were told two days before. I want to get some sense of how the communication operates from the microcosm of that significant issue and how people found out.

Answer:

Following internal reviews in January 2012, NEHTA decided that plans to deploy NEHTA-compliant GP desktop software in the lead eHealth sites in Febuary 2012 would be postponed. This was because NEHTA had identified inconsistencies in the specifications underpinning the software. NEHTA took this decision to halt implementation of the software until the issues within the specifications could be rectified.

On 19-20 January NEHTA advised the lead eHealth sites and software vendors of this decision.

On 24 January NEHTA issued a statement on its website and to a number of media outlets responding to requests for comment.

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Topic: PCEHR support

Senator McKenzie asked: I have a general question about the people in rural and regional Australia and their health outcomes and the potential of something like this to assist them. What work has been done and resources committed to assisting rural and regional communities and health providers to be ready to go on 1 July?

Could you take on notice what support services have been provided to the NT and the quantum.

Answer:

The National Change and Adoption Partner is developing communications, events and learning strategies to help consumers and healthcare providers living in rural and remote areas transition to the PCEHR.

This will happen in a number of ways including:

- Developing the PCEHR Learning Centre, to educate providers and consumers about the PCEHR;
- Supporting events and communications to healthcare providers working in rural and remote areas, such as the Rural Doctors Association of Australia conference in 2012 and materials developed and distributed by the Royal Australian College of GPs (RACGP) National Rural Faculty and working with the Pharmaceutical Society of Australia to distribute information to rural pharmacies;
- Ensuring the national helpdesk will be readily available to answer specific questions that remote and rural consumers have;
- Engaging with a broad range of representative organisations, such as the National Rural Health Alliance. Some consultations have already taken place, including:

    - Aboriginal and Torres Strait Islander PCEHR Roundtable (Townsville, 15/16 June 2011) and follow up meeting 26 August 2011
    - Rural and Remote Target Group Consultation (Alice Springs, 24/25 August 2011)
    - SA/WA Four Corner Roundtable (Perth, 27 September 2011)
    - Briefings to the Rural Doctors Association of Australia (20 October 2011)
    - Aboriginal and Torres Strait Islander Community Controlled sector consultation (Adelaide, 26 October 2011)

- NEHTA has also developed an ‘introduction to eHealth’ Active Learning Module with the RACGP based on the quality framework of general practice;

- In addition, a number of rural clinicians serve as Clinical Leads for NEHTA,

including Dr Chris Mitchell, Dr Peter Rischbieth, Dr Rob Hoskings, Dr Trevor Lord and Dr Leonie Katekar.

Regarding the Northern Territory eHealth site specifically, the Northern Territory Department of Health and Families was selected as an eHealth site by the Commonwealth Government following an open Expression of Interest phase in 2011. The project, a consortium of Government, GP networks and Aboriginal run health services from NT, SA and WA, is transitioning its existing Shared Electronic Health Record to the PCEHR including the implementation of discharge summaries, event summaries and summary health profiles. The target high priority patient cohort in this project is the Indigenous community of the Northern Territory.

In addition to the funding and program support from the Department of Health and Ageing, NEHTA project officers provide direct support for the project team in the NT.

NEHTA also supports the Northern Territory Department of Health and Families to implement national eHealth foundations through its COAG funded work program. This includes support for the NT to implement a Continuity of Care project using the Secure Message Delivery Australian Standard developed by NEHTA.

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Question (1), (2) and (3)

Senator Boyce asked:

1.

Evidence was given by the Medical Software Industry Association (MSIA) claiming that;

Most of the sites are using "a National E-Health Transition Authority sponsored initiative to inject Individual Healthcare Identifiers (IHIs) into GP desktop software. This has been done largely without the consent or cooperation of the software vendors (who provide the 'host' systems).

This is an inherently unsafe process.

Could both NEHTA and DOHA respond to this claim in detail and with precise evidence?

2.

The MSIA claims it has made "NEHTA and the Federal Health department aware of its concerns over this process at the Conformance, Compliance and Accreditation (CCA) governance group more than 10 months ago.

"However, the roll-out has continued unchecked, and NEHTA has been unable to provide any information about subsequent evaluation of potential errors that may have been introduced into live patient records."

Could both NEHTA and DOHA respond to this claim in detail and with precise evidence?

3.

In supporting its claims, the MSIA points to a peer-reviewed paper by Dr McCauley and Dr Patricia Williams of the School of Computer and Security Science at Edith Cowan University, Perth, which warns that unauthorized "bolt ons", or "parasitic software" risk introducing a variety of vulnerabilities and threats to the PCEHR as proposed.

Could both NEHTA and DOHA respond to this claim in detail and with precise evidence?

Answer to (1), (2) and (3):

NEHTA has provided a detailed response to the claims made by the MSIA regarding the HI Service in a separate response to the Committee sent on 16 February 2012.

There are a considerable number (in excess of 25) of data extraction tools available in the health software market that serves a variety of purposes including audit, data collection and transmission. There are two data extraction tools selected for use by the eHealth Sites (produced by two software developers, PEN and HIE). NEHTA has not sponsored or directed the use of any of these products. The selection of these software vendors was entirely at the discretion of the organisations involved in the Sites. The organisations delivering the eHealth Site projects have an interest in selecting software that is clinically robust and endorsed.

Legitimate safety concerns would arise and require management if these tools sought to insert data into the underlying software without authorisation. The software developers involved in the Sites have confirmed that unauthorised data insertion does not occur with their products. In other words, all data transfers in the eHealth Sites software are authorised.

If any data is required to be sent to the underlying software product from a data extraction tool, where an agreement to insert it directly into the underlying software is not in place the data is sent via some form of a secure message. This is the same method of delivering any data from external parties (eg pathology labs, discharge summaries) to the GP desktop.

The CCA Governance Group (CCAGG) was established by NEHTA in an effort to engage with all stakeholders including MSIA, AIIA, ACTIVA, Medicare, DoHA, Standards Australia, the Jurisdictions, NATA and NEHTA. The goal of the group was to ensure that representatives provide an effective body to review, and agree, the processes and practices for major eHealth deliverables for CCA. The NEHTA CCA team provide the secretariat support for this group.

At the CCAGG meeting on the 29th August 2011 a discussion took place regarding the safety of “Bolt-on” software. The MSIA representative, Dr Vince McCauley, presented a paper which described what he assumed the software was doing and the clinical safety risks he claimed occurred.

The NEHTA representative presented a description of the software currently in use for the Wave 1 eHealth sites. This software has been tested against the HI Software Conformance Requirements by a NATA accredited test laboratory and it did meet all conformance requirements.

The CCAGG reviewed and discussed the presentations and documents. It was noted that there are potential risks in the use of ‘bolt-on’ of an unknown nature.

Through a formal vote, all CCAGG members, with the exception of the MSIA, agreed that ‘bolt-on’ type software may still continue through the HI Conformance Assessment as the conformance assessment stands. All members present at the CCAGG apart from the MSIA agreed that the current test cases are sufficient at this time.

The minutes to this meeting was endorsed with amendments via circular on the 8th December 2011.

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Topic: HI Service safety

Senator Siewart asked:

The other point that was included as part of this question is the issue of how many safety reports have been done. You indicated that some of them have been released to the community. I infer from that answer that not all have been. My question is: why not and can we see them?

My concern is that we are due to report on this legislation and to consider this legislation in the Senate in the not-too-distant future in the absence of the information in that overall report. My inclination is to ask, 'How can we be guaranteed that this is clinically safe if we have not had access to that information and that information is due to be reported only after the legislation goes through parliament?'

Answer:

A fundamental tenet to the NEHTA product development philosophy is that no product is released to the market unless it has been signed off for release by our Clinical Safety team. Therefore clinical safety reviews are inculcated within all phases of the product development lifecycle, and the Clinical Safety Team approve programme and product releases.

Release 1A of the PCEHR, which is scheduled for release in late March, provides medical software vendors with an environment in which they can: test the development of their products against the national infrastructure; retrieve information from the PCEHR and store documents or references to documents in conformant or registered repositories. A Clinical Safety Case Report will be prepared for Release 1A of the PCEHR and will be released publicly.

As the initial production release of the PCEHR is still under development further clinical safety tests will be performed during the coming months and a separate document set will be prepared for the July production release of the PCEHR.

More broadly, NEHTA offers the following comments about its clinical safety processes and management.

Quality Management and Clinical Safety Assurance at NEHTA
Clinical safety at NEHTA is managed within the broader process of quality management. At NEHTA, each program is required to drive their own quality processes for the products that they develop (e.g. Healthcare Identifiers, Referral, secure messaging, etc.). While there are differences in the details of these processes based on the nature of the product being developed, there is a common underlying product development life cycle with embedded quality checkpoints.

Assurance of clinical safety

Clinical safety processes and risk mitigation applies where systems and processes are the same or similar and where the processes are intrinsically changed by the introduction of new technology.

This process looks at situations where clinical flow [how patients move through the system] are changed by the introduction of technology as well as how the introduction of technology assists the current clinical practices.

While there is some similarities to ISO based approaches to quality management, there are important differences in emphasis, approach and the application clinical expertise to help identify and mitigate clinical safety risks.

NEHTA has a well-embedded clinical safety unit, which was established in 2009 to deliver internal clinical safety assurance services for NEHTA products and services. The clinical safety unit 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 clinical safety unit works with product teams to recommend mitigating controls and the product team is responsible for deciding how best to enact the proposed controls and communicate their approach to stakeholders.

The review process goes through a number of cycles during development and where risks are identified, mitigation strategies put in place to ensure the risks are as low as possible. The risks need to be mapped and identified based on best evidence.

To help support this clinical safety assurance process, the clinical safety team have implemented a clinical safety management system 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

NEHTA introduced a Clinical Governance Review Board to oversee clinical governance processes and effectiveness within NEHTA. Members include Dr Jenny Bartlett, Dr Mukesh Haikerwal AO, Dr John Aloizos AM, Dr Nathan Pinskier and A/Prof Chris Pearce.
Good clinical governance ensures that there are that eHealth systems do not solely focus on what can be done in the technological arena and brings a discipline to prioritize innovations that are of most relevance to enhancing patient care- from a Clinical perspective.

NEHTA is committed to continuous improvement of its clinical safety processes and from time to time has commissioned an independent audit of its clinical safety management system. The outcomes of the independent audit have been used to improve NEHTA’s approach to clinical safety management.