Dr Ian Holland

Committee Secretary
Senate Standing Committee on Community Affairs
PO BOX 6100
Parliament House
Canberra ACT 2600
By email
community.affairs.sen@aph.gov.au

Dear Dr Holland,

I am writing to provide additional information in response to questions asked of the MSIA on 6 February at the Committee Inquiry into the Personally Controlled Electronic Health Records Bill 2011.

Question One - From the Chair

> ***CHAIR:*** *In terms of the safety—and the term 'safety' is important to define—this is the accuracy of the records and then the implications of not having them accurate; is that right?*
> ***Dr McCauley:*** *It is not so much the accuracy of the records as the ability to access them, the audit control around who can access and the audit trail of how that access has occurred. Fundamental to the PCEHR is the ability to control access, which is based on the organisational identifier and the provider identifier, and also to audit access, which again is based on those two identifiers, to actually identify who has accessed the system from where. Without those numbers being verifiable and validated, there is no actual control over who is auditing or accessing the system. Any number could be put into the system, and there is no way of determining whether that number is correct or has been allocated to the right practitioner or organisation.*
> ***CHAIR:*** *Your submission does not spell that out in detail. Can we get exactly what you have just said in terms of your understanding with your background? As you would expect, we will be asking NEHTA and the department these questions as well. Could we get what you have just said to us as a definition of safety? I think it is a really important thing to have defined for our issue.*
> ***Dr McCauley****: I am happy to do that. We were actually concerned about what level of detail we should go into in the submission, but we are certainly happy to enlarge on areas.*
> ***CHAIR:*** *That would be useful for the committee's purposes.*

Dr McCauley and the MSIA provide the following statement on safety issues for the Senate.

Health IT supports a safety-critical system: its design, implementation and use, can either improve the quality and safety of patient care or pose serious risks. In the e-Health context, a safety hazard is any misuse, corruption or loss of information that may lead to an adverse outcome for any participant including patients, clinical providers and organisations, as well e-Health infrastructure providers. E-Health infrastructure providers include but are not limited to:

(a) Government – Medicare, DoHA, and agencies such as NeHTA
(b) e-Health vendors – software, terminology, consultants
(c) e-Health Standards developers

Assessment of safety hazards is a continuous process but should be documented at three critical phases:

1. Design and specification of the e-Health system – there should be a formal assessment – a safety report – which documents the safety assessment process, potential safety hazards and intended mitigations.
2. Implementation – This is the process of turning a design specification into an e-Health system including software and documentation. This is the role of conformance and compliance testing, to validate that an implementation performs according to the intended behaviour and design and that safety issues are addressed.
3. Roll-out, installation (and maintenance) – This is the phase where e-Health systems are installed into patient care organisations. Training and assessment that the system has been configured correctly when installed are fundamental to safety.

Patient safety in e-health systems is not just about the safety issues that may be assessed by a clinician (such as dosage and interaction of medications and conditions for example) but should include a range of other experts – on the design and layout of the screens, how the software complements the work flow, how security and access are maintained and audited etc. There is a large body of academic work on the non-clinical assessment of clinical safety in e-health[1]

Adverse clinical outcomes for patients are front and centre - “first do no harm”. However, given the immediate possibility of up to 2 years in jail, large financial penalties and severe reputational damage, in Australia this means all other participants are also at significant risk.

[Answer to question on notice #2 not currently publicly available]

[1] *Health IT and Patient Safety: Building Safer Systems for Better Care*, November, 2011 Institute Of Medicine of the National Academies. http://www.iom.edu/Reports/2011/Health-IT-and-Patient-Safety-Building-Safer-Systems-for-Better-Care.aspx