To: community.affairs.sen@aph.gov.au

Committee Secretary
Senate Standing Committees on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
Australia

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Submission to the Senate Community Affairs Committee

Inquiry on Personally Controlled Electronic Health Records Bill 2011, and the Personally Controlled Electronic Health Records Bill 2011 (Consequential Amendments) 2011

Author: Dr Ian Colclough

This submission draws on the deep well of experience gained as a registered medical practitioner with a 35+ year career in health informatics spanning medical practice, hospital administration, health software research and development, business development, sales management and marketing with global ICT vendors in Australia, South Africa and the United Kingdom.

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This enquiry is of national import. Its outcome should determine whether the very substantial sums of money being poured into the development of a national PCEHR are being applied wisely, whether the concept and design as currently proposed has validity, and whether the leadership, management and governance of the PCEHR project is effective and appropriate.

In reviewing the issues before the Committee a lot of valuable time and intellect will be wasted if the many weighty issues involved in this extraordinarily complex subject are addressed inadequately or in the wrong order. For example, it is acknowledged that privacy, security, and confidentiality are very important issues. Any shortcomings on that front will undermine and destroy the eventual development of a functional, affordable, community-wide PCEHR that is broadly acceptable to most people and to their health service providers.

However, no matter how important these issues are they pale into insignificance when put up against the many hard-nosed questions that have repeatedly been asked by a wide cross-section of health industry experts and technology developers; questions which those in-charge of the PCEHR project seem unwilling or unable to answer.

It will be inordinately difficult for Committee Members to sift the chaff from the grain and disperse the fog of confusion that constantly swirls around every facet of e-health. Even so, one hopes the Committee will be able to arrive at some conclusions which make good sense to people with broad, deep, practical experience gained from working at the coalface in the health and ICT industries. This level of commonsense support is needed in order to navigate a less contentious way forward for developing the PCEHR; a way which embraces cautious incremental evolution of key building blocks and e-health application solutions. The current 'big bang' approach is overly ambitious, swamped with problems and most unlikely to succeed.

1. **Timing**

In considering the Bills at this time it seems the Government believes that the bulk of the work required to enable the PCEHR to be deployed safely in the marketplace is close to completion, that the PCEHR will satisfy clinical software vendors, clinicians and other stakeholders, that it will be embraced readily by consumers, and that it will make the delivery of healthcare safer and more efficient. I am not alone in believing the PCEHR is far from being close to completion. If that is the case then the Bills should be deferred until further work has been undertaken starting with the rationale underpinning the design of the PCEHR and a critical examination of how the PCEHR project came into being.

2. **Safety and Security; Accreditation and Certification**

Clinical misadventures do happen. They are usually followed up, investigated for root cause and corrective systems and procedures put in place to prevent a recurrence. Dearne's recent article *"Patient safety a mystery at Health"* [1] suggests much more work needs to be done before a national rollout of an untried and unproven PCEHR system is permitted to proceed. The Committee should be acutely aware that if patient safety risk assessments do not exist then passage of the Bill(s) at this time is premature.

Available evidence seems to indicate that for the PCEHR the most basic steps have yet to be taken to reassure health practitioners and patients that patient clinical safety is paramount. Dearne reports there is an absence of *"any patient safety risk assessments in relation to the huge IT change management project".* [2] The logical consequences of this 'omission' are that liability for adverse outcomes arising from incorrect functioning of the system will fall on everyone involved in developing, deploying and using the system; including health providers, software developers, NEHTA, government agencies and Government.

NEHTA is responsible for specifying the functionality and business processes underpinning the PCEHR, and for defining safety, security, accreditation and

[1] Karen Dearne, *Patient Safety a mystery at Health*, The Australian IT, 23 December 2011

[2] ibid

certification requirements. That being so it is reasonable to expect that some of the potential liabilities inherent in the PCEHR should rest with NEHTA and be underwritten by its shareholders; the Federal, State and Territory Governments.

This should be clarified and resolved to the satisfaction of The Australian Privacy Foundation before the project progresses much further; particularly in light of the recent controversy over e-health liability [3] and Government agencies escaping e-health penalties". [4]

3. Accountability and Transparency

DOHA has indicated that *"NEHTA is responsible for ensuring patient safety"* [5] but as *"NEHTA is exempt from Freedom of Information laws"* [6], and as the Department admits to having no knowledge of what patient safety risk assessments have been undertaken the Committee has no reliable way of knowing what work NEHTA has undertaken in this vitally important area.

In a project as broad and as complex as the PCEHR, which is totally funded by the taxpayer, which impacts the entire national health service, and which relies on the support of clinicians, patients and technology developers, it is reasonable to expect to find a high level of transparency and accountability to be operating. Unless the PCEHR project and by association NEHTA become more transparent and accountable the project will spiral irretrievably into disrepute.

4. Standards, specifications and implementation

Through NEHTA the government is attempting to define and specify standards for vendors to build into their various application software solutions. It does seem that NEHTA and the Department expect that health software vendors will be prepared to re-engineer their products to comply with the mandated standards and specifications and then happily deploy them in the field.

This is a high risk strategy which many vendors, who aspire to remain viable, will be wary of. They will be reluctant to invest the tens of thousands of dollars required to modify their software to embrace the standards until they have been proven in the field. It simply does not make much sense to do so without being appropriately compensated to cover the risks and work involved.

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[3] Karen Dearne, *Australian Privacy foundation slams e-health liability law*, The Australian IT, 1 Nov 2011

[4] Karen Dearne, *Govt agencies escape e-health penalties*, The Australian IT, 6 October 2011

[5] Karen Dearne, *Patient Safety a mystery at Health*, The Australian IT, 23 December 2011

[6] ibid

Notwithstanding the foregoing the ‘adoption’ of Standards underpins the concept of information exchange and interoperability between e-health vendors’ software solutions. Vendor compliance to common standards should be the overall objective.

History has shown that the development of standards, which are intended to be universally adopted, is best achieved when they are allowed to evolve, rather than being dictated as a fait accompli from the top down. Standards Organisations cannot expect the standards they are proposing will be readily adopted until the Standards Organisation can prove that the proposed standards will work and, equally importantly, that they can be implemented successfully before being formally designated as a ‘Standard’.

This raises some very important commercial and strategic considerations for health software vendors and for NEHTA. Who should ‘carry the risk’ of proving that the intended standards being developed and then recommended can be implemented and will work?

The complex nature of the healthcare environment dictates that standards must be allowed to evolve over time and not be enforced in the form of an ultimatum for all and sundry to adopt. It should first be proven that the proposed standards work in a controlled live environment and, as such, are acceptable to the vendor community. Only then is it reasonable to consider the implications of subsequently mandating the standards and exploiting market forces to drive their uptake; perhaps through the use of certification and accreditation procedures.

Consequently, mandating standards prematurely should be avoided if at all possible. A more pragmatic and less risky approach is to create a collaborative environment which is conducive to allowing standards to evolve; an environment which is based on consensus and in which the ‘health-ICT’ vendor community is closely involved. This needs to be done in a way which sensibly supports health software vendors who work at the coal-face delivering solutions.

In one way or another many health software vendors break new ground when developing and implementing new applications which are needed to keep pace with the rapid changes in hardware and communications technology. In any industry this carries significant commercial risks; more so in the health sector, due to its inherent complexities and the fact that it lags significantly behind other market sectors in the deployment of advanced Information Communications and Management Technologies.

To offset the risks canny health software vendors adopt a philosophy of ‘progressive implementation’. In this way they can continue to break new ground along the way as they stretch their skills, intellect and resources to get closer to the ‘elusive goal’ on the distant horizon – integration of, and interoperability between, the multitude of elements which lie across the many domains that contribute to the Electronic Health Record (EHR).

It is only through the 'progressive implementation' of solutions that continue to break new ground that the developers and implementers can truly understand and fix problems as they arise. In such an intense and complex R&D environment as health, it is folly to set a deadline and say 'that a standard has been created and is now ready for implementation'. Similarly it is folly to believe that the recently introduced 'tiger teams' can deliver a set of standards in a matter of weeks or months that all and sundry can embrace.

It is high time that the 'evolutionary progressive implementation approach' is understood and embraced at the policy making level and implemented from the top down.

5. **Is Australia ready for the PCEHR?**

The key business driver underpinning the PCEHR project is the perceived need to have more complete and up-to-date health information available for sharing, so that consumers and their healthcare providers can make decisions *'in partnership'* and through *'shared access to'* the same information.

Whilst intuitively this seems like a sensible proposition it should not be accepted on its face value alone, for it does not automatically translate to support a business case for developing a national PCEHR!

We need to examine the business case in support of the proposition. We also need to review whatever evidence exists that reflects what work has been done that convincingly demonstrates the value proposition that sharing clinical information across agencies will *'result in improved capabilities and better service delivery'*.[7] Such evidence should also highlight the problems encountered, the steps taken to effectively overcome them, and the compelling business relationship models employed to motivate and sustainably engage participating software developers to work together in a collaborative environment.

The National Health and Hospitals Reform Commission's (NHHRC) Supplementary (Interim) Report - *Person-controlled Electronic Health Records 30 April 2009* [8] - recommended that by 2012:

- "every Australian should be able to have a personal electronic health record that will at all times be owned and controlled by that person"

and

[7] HealthConnect Charter v04 20061222 FINAL

[8] http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/310-interim/$FILE/310 - Submission - National Health Call Centre Network.pdf

- "the payment of public and private benefits for all health and aged care services be dependent upon the provision of data to patients, their authorised carers, and their authorised health providers, in a format that can be integrated into a personal electronic health record."

Although **this seems to have been the starting point for the current PCEHR project** it is not clear what evidence was used to underpin the recommendation. This key recommendation is alluring. Most people would agree that the efficient and effective use of ICT in healthcare is fundamental to any attempt to modernise the health service delivery model. They would also probably agree that development of some iteration of a Shared Electronic Health Record [SEHR] and/or a Personal Electronic Health Record [PEHR] and / or a Personally Controlled Electronic Health Record [PCEHR] is an essential component at the heart of health system reform.

Hence, it is easy to be seduced into believing the development of the PCEHR is readily achievable and for many advocates it is convenient to forget lessons from the past and hastily rush into this still uncharted territory.

The concept of PEHRs and SEHRs is relatively new; so too for the PCEHR. Consequently, available solutions are immature and the experience and understandings of health providers, agencies and consumers minimal. This accounts for why so few studies have been undertaken to validate their adoption.

One recent major review stated that:

- *"Patients, policymakers, providers, payers, employers, and others have increasing interest in using personal health records (PHRs) to improve healthcare costs, quality, and efficiency. While organizations now invest millions of dollars in PHRs, the best PHR architectures, value propositions, and descriptions are not universally agreed upon. Despite widespread interest and activity, little PHR research has been done to date, and targeted research investment in PHRs appears inadequate."* [9]

and

- "*additional PHR research can increase the likelihood that future PHR system deployments will beneficially impact healthcare costs, quality, and efficiency."* [10]

Furthermore, patient surveys suggest that:

- "*patients want to use PHRs and believe that they will be valuable. One survey found that about 75 percent of Americans report they would communicate electronically with their physicians if given the means to do so, while another study found that 60 percent*

[9] http://www.jamia.org/cgi/content/full/15/6/729

[10] Ibid Page 1

of patients said they would look up test results and track medication use through PHRs if these records were available." [11]

In Australia similar findings have emerged, supported by recent research commissioned by NEHTA which states that:

- *"82 per cent of consumers in Australia support the establishment of an electronic health record."* [12]

Consequently, it is now broadly accepted in America, Canada, Europe, and Australia that substantial benefits will flow from implementation of some form of Shared Electronic Health Record (SEHR) in ways which will contribute to improving the quality and safety of healthcare; particularly for patients with chronic disease and complex health needs.

It is difficult to argue with the premise that a person-controlled electronic health record would be helpful to many individuals who wish to take a more active role in managing their health and making informed health care decisions. Indeed the shared electronic health record is probably the single most important tool needed to drive home the changes required to achieve a more holistic person-centred health care system; one which is aimed at empowering the consumer to assume a more active role in the management, monitoring and recording of their essential health information.

Even so, **the PCEHR and the SEHR remain elusive;** despite plenty of benefits having been identified by enthusiastic advocates for the solution. Many reasons can be found to account for why this is so. They include the complexity and diversity of clinical information, conflicting professional cultures, poor communication and misunderstandings between health and IT professionals, and a multitude of internecine political issues. However, the fundamental reasons stem from an apparent inability of PCEHR enthusiasts to comprehend the complexity of the task, and a failure to appreciate that first and foremost, the approach which should be adopted to developing the PCEHR must be underpinned by the development of a core solution which can be implemented in manageable incremental steps, then embedded to become a routine feature of the day-to-day functions of the health system and subsequently scaled-up and built upon with confidence.

6. **National e-Health Strategy**

In December 2008 the Department published a summary of the Deloitte National eHealth Strategy[13]. Deloitte recommended that the building of long term e-health capability should be undertaken incrementally, and that critical to driving the uptake of e-health and support by consumers and care providers will be the quality of the

[11] Ibid page 1

[12] NEHTA, *'Individual Health Record Consultation Report'*, July 2008

[13] Deloitte-AHMAC, *National E-Health Strategy Summary*, 12 Dec 2008

underlying e-health solutions and a relationship between them which involves a two-way data exchange.

To achieve this Deloitte advocated focusing initial investment in those areas that deliver the greatest immediate benefits for consumers, care providers and health care managers. Deloitte recommended a **National ePrescription Exchange Service** as the highest priority e-health application solution which should be developed immediately.

It makes good sense to move away from large scale, all encompassing national e-health projects and focus on projects which are more modest in scope and geography. Subject to the architecture they can then be scaled-up and rolled out nationally. This more 'contained' approach is easier to manage, less risky and less costly to 'prove'. It also makes it very much easier to quickly counter disruptive vested interests and overcome difficult political and technical hurdles as they arise.

In that regard it is a mystery why the Deloitte Recommendation to establish a National ePrescription Exchange Service has not been embraced by NEHTA and the Department.

Since 2008, in response to Deloittes profoundly clear message that the Electronic Transfer of Prescriptions [ETP] and the electronic Medication Record [eMR] should be developed as a high priority, the private sector has successfully deployed two Prescription Exchange Services serving medical practices and community pharmacies in every State and Territory of Australia.

A National ePrescription Exchange Service should be a fundamental building block in the early development of the PCEHR.

As electronic prescriptions and the eMR are most often mentioned by clinicians as the shared **ehealth information they want immediate access to [!]** we should not waste this opportunity or dally any longer.

We should build upon that which is already working in the field. Failure to do so, more than anything else, will jeopardize NEHTA's deeply troubled PCEHR project.