

Submission to the Commonwealth Department of Health and Ageing.

Topic: The NEHTA developed Personally controlled electronic health record (PCEHR) Draft Concept of Operations (ConOps for Short)

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Author's Background. The author of this submission is an experienced specialist clinician who has been working in the field of e-Health for over 20 years. I have undertaken major consulting and advisory work for many private and public sector organisations including both DoHA and NEHTA.

Previous Submission

I previously provided a Submission on the PCEHR proposal to NHHRC in May, 2009 and the views expressed in that submission remain my position despite the work undertaken by DoHA and NEHTA since.

This submission is available here:

[http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/309-interim/\\$FILE/309%20-%20Submission%20-%20Dr%20David%20More.pdf](http://www.health.gov.au/internet/nhhrc/publishing.nsf/Content/309-interim/$FILE/309%20-%20Submission%20-%20Dr%20David%20More.pdf)

Executive Summary of Submission.

The ConOps proposal provided by NEHTA is challenging document which presents a highly academic view of an Electronic Health Record and Information Sharing system which has a significant degree of Patient Control. This ambitious document contains significant flaws, misconceptions, and ill-advised positions that have taken NEHTA's quite reasonable earlier Shared or Individual EHR proposals and seen the ideas contained within distorted to create a seriously unsatisfactory outcome. The present PCEHR proposal at once does not achieve the possible benefits of the earlier proposals while being essentially useless at a clinical level.

I believe that in the presently proposed form the PCEHR is unlikely to be adopted or used by either consumers or clinicians and will become a very expensive failure to add to an existing perception of eHealth non-delivery in Australia. There is a high risk of failure because adoption is not part of strategy, is unfunded, and indeed this is not really an 'adoptable' product from a clinical perspective.

A number of key strategic issues force me to the strongly negative view of the PCEHR proposal as provided in the ConOps document. In summary these are:

- **Potential High Quality Data Sources:** The working PCEHR relies on there being quality, reliable, current and trustworthy information available to be fed into the proposed PCEHR System. This data would be mediated by a health care professional at the point of care.

This is a flawed premise as it is highly unlikely a health care professional has time to “improve” and “assure” the quality of information being fed into the PCEHR, given the financially important time pressures they are under. Investments should be made in the clinician used source feeder systems to improve the quality of data within those systems - only when this precondition is demonstrably met and we are assured we have clinical information that is really ‘fit for sharing’ should this be considered for the safety of all.

- **Patient “Opt In”:** A key principle is that patients will “opt in” to the system. Without debating the unlikely realisation of tangible benefits from the EHR due to limited (or anything less than near complete) patient take up – a clearly defined privacy and security framework which is both understandable and acceptable to patient groups needs to be articulated. A great deal more consultation and thought is required in this area as there is a very difficult set of balancing judgements required to strike the right and worthwhile levels of adoption and usage versus privacy and security concerns. Current proposals (including the use of Patient “Keys” or PUK codes) to control access to patient records are poorly articulated and require serious and prolonged consultation before solution delivery commences.
- **The How versus What Problem:** There is an extensive focus on the “how” of the solution as opposed to the “what” - a ways versus means approach. A well-articulated series of functional requirements from the Commonwealth would provide vendors with a target provision to design solutions to. As currently drafted, the ConOps transfers a considerable portion of risk to the Commonwealth. In the event that the PCEHR does not perform or function as hoped for by the Commonwealth, it is unlikely that the Commonwealth could hold the vendor(s) liable as much of the solution design has been performed by the Commonwealth within the ConOps. It makes much more sense for the Commonwealth to define what it is it needs and to let the providers and developers come up with an valid and cost-effective solution.
- **Much Needs To Be Done Before PCEHR:** Both the Boston Consulting Group Review of NEHTA in 2007 and the National E-Health Strategy of 2008 make it clear that before the PCEHR should be attempted there are a range of basic applications, capabilities and services that need to be got into place. These include operational Health Identifiers and Secure Clinical Messaging covering a wide range of clinical messages (prescriptions, reports, referrals, results, specialist letters and discharge summaries among others). Only with this and clinical terminologies in place and a range of improvements in hospital and practitioner computing (including clinical decision support) will there be a basis on which the PCEHR can be sensibly attempted. There is conservatively 3-4 years of work here and all the available funds for that period would be consumed in reaching these basic goals. To imagine a viable PCEHR program could take less than 6-8 years is fanciful I believe.

I have provided below a discussion of a range of more detailed tactical issues below which also cause me considerable concern.

I have chosen not to discuss the consultation processes that have surrounded the PCEHR proposal as I am aware some of those who have been closely involved have developed submissions in this area. Suffice to say that the secrecy that has pervaded nearly every aspect of the development of the ConOps has resulted in a document which is unlikely to succeed and places the future of eHealth within Australia at considerable risk.

A total re-consideration of virtually all aspects of this current ConOps offers the best chance to claim success from an otherwise doomed set of proposals.

Note: I have provided a set of links to postings on my blog which amplify and provide the background to most of the material provided here. See References at end of document.

Background to the PCEHR Proposal.

As a result of a series of recommendations in the Final Report to Government of National Health and Hospitals Reform Commission (NHHRC) in 2009 the subsequent Commonwealth Budget allocated almost half a billion dollars over two years to make a PCEHR available to all citizens who wanted one by July 2012.

As the PCEHR concept has evolved it has morphed into a conceptual Health Summary and then a series of Event Summaries. The Health Summary contents are intended to be the basic individual demographic details and the information that is normally held - either electronically or on paper - in the General Practitioners Summary Record. This would include allergies, regular medications, key elements of history and current diagnoses. The Event Summaries are envisaged to be such things as a set of pathology results, referral letters and so on.

The idea is that the patient will be in control of this information and will, if they agree and consent, make the information held in this record available to clinicians caring for the patient.

The patient PCEHR record is to be held by a PCEHR system - presumably run by the Commonwealth Government - which will be accessible via a web portal for a clinician, with permission, to review. At a later date the patient will also be able to contribute their personal information and comments should they choose. The system is apparently intended to be a lifelong record which will be accumulated over time.

At present the system is intended to be available for patients who choose to have a PCEHR to register for access by July 2012 - now just 14 months away. The system is presently planned to operate in an 'opt-in' fashion where an individual takes a positive decision to register for and establish a PCEHR.

Key Tactical Topics Addressed in This Submission.

1. Proposed System Architecture

The PCEHR is a system which will operate in parallel to the systems used by professional care providers and will contain a partial sub-set of the information held in those local systems.

As currently envisaged it is unclear what the clinical purpose of the PCEHR is. It is not a highly refined abstract of that clinical information (needed for emergency care) nor a complete longitudinal record to replace what is currently used by those providers who have local electronic records.

By falling in this inconclusive middle ground the planned record has no clear user audience and does not seem to have any real function and purpose. The proposal brings with it some almost insurmountable issues around the currency, reliability, and quality of the information held within the PCEHR system and this situation will mean it will be poorly used. Clinico-legal liability and related issues around the possible erroneous interpretation of data held within the system will also mean a lack of trust and adoption of the system by many clinicians.

There is published comment from Prof. Enrico Coiera on this area available. See here:

<http://aushealthit.blogspot.com/2010/11/it-seems-some-serious-thinkers-are.html>

2. Sustainability of Proposal

It was never likely that a two year half billion dollar national e-Health program initiated from what was essentially a 'standing start' would be able to demonstrate a useful outcome in the time allocated - as has been demanded by Minister Roxon. Globally we can see that every other national program has taken at least 3 times that period (i.e. six years) to even begin to show results of the scale identified by the Commonwealth.

The application of such politically driven deadlines, with no commitment to continued investment and funding adds substantially to the risks of the program as it distorts quite unreasonably what is

being attempted and what would be planned - and have a higher chance of success - in more realistic circumstances.

It is notable that the funding for the PCEHR still has not been confirmed in any amount beyond June, 30, 2012 - when even the just released Budget papers make it clear very little will be available for clinicians and other healthcare professional users.

3. The Politics of Names and Actual Reality.

The issue here is that Shared EHRs (as described on Page 108 and 109 of the ConOps) are not analogous to the PCEHR in any way. Each of these initiatives are, in fact, Shared EHR systems intended to be used by clinicians and not by patients. There is NO experience anywhere in the world with the model proposed in the ConOps. Indeed, I have often been told by people internal to NEHTA that there is a deliberate desire within NEHTA to construct something “different” to the rest of the world, and that people are chastised if their work bears too many similarities to work from elsewhere.

The statements made at the top of page 108 are deliberately distorting of the reality that the NEHTA proposed IEHR and the earlier HealthConnect Shared EHR are very different from what is proposed with the PCEHR:

“The Strategy identified a national Individual Electronic Health Record (IEHR) System as a high priority. The Strategy envisaged the IEHR as:

A secure, private electronic record of an individual’s key health history and care information. The record would provide a consolidated and summarised record of an individual’s health information for consumers to access and for use as a mechanism for improving care coordination between care provider teams. [AHMC2008]

Since the Strategy was originally developed, the term ‘PCEHR’ is now preferred as it better aligns with the perceived recommendations from the National Health and Hospitals Reform Commission which recommended that a national approach to electronic health records should be driven by ‘the principle of striving to achieve a person-centred health system.’ [NHRR2009]. In reality, “patient controlled” and “person centred” are not the same thing. The “patient controlled” moniker appears to be a knee jerk reaction to anticipated patient concerns – which have not materialised, and could be resolved by a considered approach to privacy and security. Indeed, evidence from around the world is that patients are not overly concerned and that a relatively small number express desires to “opt out” of such systems. This evidence has not been picked up on by NEHTA or the Commonwealth.”

In 2010, the Government budgeted to invest 466.7 million in the first release of a PCEHR System over two years. To suggest the earlier SEHR and IEHR are the same or even quite similar is just dishonest. Equally it is dishonest to claim the IEHR was a high priority in the National Strategy - it simply was not.

It is also quite surprising to see NEHTA claim consultations on HealthConnect which were conducted 5+ years ago and many of the other consultation processes cited on Page 103 bear any relevance to the PCEHR proposal. They do not.

4. Lack of Evidence Regarding Benefits.

Again this is an area where both NEHTA and the Department of Health have been less than frank with the public.

All the modelling undertaken by NEHTA and DoHA has indicated that it is providing clinicians with reliable information at the point of care (for medication management and so on) and providing clinical decision support is where the major benefits from e-Health can be obtained. However what we see in the ConOps, buried on page 18, is:

“2.8.1 Clinical decision support

The PCEHR System will not provide clinical decision support services. It is intended that the PCEHR System will provide information to help drive clinical decision support algorithms and the industry and healthcare professions will take the lead on delivering clinical decision support services.”

The point needs to be made that Clinical Decision Support (CDS) can only be as good as the clinical information it is basing its decision making on, the quality of the actual CDS implementation and the quality of the knowledge base which is driving its capability. The issue raised above regarding clinical data quality is also relevant here.

No business case exists to justify the PCEHR. (NEHTA did develop one a year or so back for the IEHR, but that is not really in any way comparable as it is quite different in architecture and intent.) This alone should cause some alarm. At best we have very sloppy thinking, at worse we have downright deception.

Coupled to this is the insistence of following a model of “opt in”, where the potential benefits of the PCEHR (especially with regard to epidemiology and public health) will not be realised before there is a critical mass that is representative of the entire Australian population.

5. The Proposed Consent Model.

At present it is proposed that consumers will have the option of signing up at a PCEHR for the proposed electronic record as of July 1, 2012. Signing up will be totally voluntary i.e. the system is conceived as an ‘opt-in’ system. Additionally, at any point the consumer will be able to inactivate their PCEHR as well as decide which parts of the PCEHR will be accessible to whom. As an example a spouse might have complete access to the other’s record but the same consumer may choose to make some sections of the record inaccessible to their GP. Equally the consumer can make quite the reverse decision. These decision can be changed at any point.

The problem with this ‘opt-in’ approach is that it is only successful if there is sufficient utility and value provided by the PHR to stimulate adoption. The functionality that has been found to be most valued by consumers include being able to arrange appointments, request prescription repeats and access a secure e-mail messaging system to seek information and explanations related to their care. Consumers also find it useful to have access to test results and other information sources.

Sadly the first mentioned three functions are not planned in any proposed release of the PCEHR and provision of results information is likely to take significant time being dependent on HI Service implementation, NASH implementation and system modification on the part of diagnostic system providers. The net result of this approach would seem to suggest a very low adoption and use of the PCEHR system is highly likely.

Additionally there seem to be a very limited number of circumstances when a practitioner would want to access an individual’s PCEHR given that most of the information held in the PCEHR, other than the consumer contributed material, will already be held in the provider’s clinical system.

The convoluted plans for the consent model and the potential incompleteness of what may be there when access is granted will greatly limit clinician’s interest in obtaining access to the consumer PCEHR.

If the system is not substantially utilised by clinicians the benefits for patient safety and adverse event reduction simply will not occur.

Overall, at best, significant usage of the PCEHR will take many years to evolve and the potentially transformative benefits of other architecture and consent models will come very late if at all.

6. The Lack of Appropriate National Governance and Leadership in Australian E-Health.

In order for any National E-Health Program - such as the PCEHR - to be successful there are a number of critical success factors that appear to need to be in place based on international experience. These include top level political commitment at Cabinet level, stability of long term and adequate funding, expert national leadership, appropriate consultative and governance frameworks and an agreed national vision and consensus on the way forward.

I would contend that Australia is presently lacking most of these critical success factors with but 2 years funding agreed, division of responsibility for the PCEHR between NEHTA and the Commonwealth Department of Health, no single point of accountability for PCEHR delivery and a forward plan which essentially ignores the agreed National E-Health Strategy which was approved in 2008.

A related issue around governance which has not been addressed - and which will probably need legislation to totally clarify - is how legal liability for the creation and use of information contained in the PCEHR is to be handled. Clearly, unless there are appropriate protections in place, no responsible practitioner will want to be exposed to any additional personal risk due the use or reliance on PCEHR information.

A key lesson learned from EHR experiences around the world is that **lack of clinical leadership causes national EHR programs to fail**. With clinical leadership in place (and not academic technocrats) a clear functional requirement and need for the PCEHR can be defined. As of right now, the PCEHR ConOps defines an aspirational technology approach which a) has no obvious clinical benefits and b) has not been achieved on any scale anywhere in the world.

7. The Lack of A Trained Workforce and Plans To Develop Such Capability.

Informatics Workforce. This report said we did not have enough staff capability in the domain and that there was no apparent plan in place to correct the deficiency. As far as is presently known there has really been no significant progress in the two years since the report was produced, and the skills and capability gap remains and is probably worsening if the number of job vacancies advertised by NEHTA is any guide.

As for supporting a major national implementation of the scale of the PCEHR this is simply not possible.

8. Information Sources and Lack of Clinician Incentives

The ConOps document seems throughout to have as an underpinning assumption the belief that clinicians (and diagnostic service providers) will be so excited by the prospect of what is to be offered by the planned PCEHR that they will spend their own resources to provide the technology and work effort involved to populate the PCEHR with their in-house information on individual patients at their (the providers) expense.

With the ongoing financial pressure on diagnostic service providers and clinicians currently being applied by the Commonwealth Government such altruism in the context of such unproven and potentially time consuming technology is simply not going to happen without substantial financial carrots being provided.

It needs to be clearly appreciated that without enthusiastic co-operation of the clinical community the PCEHR will be simply a useless empty vessel which will be of no use to either consumer or clinician

Amazingly even the Government's top clinical e-Health advisor is saying the same thing - but no mention of appropriate funds in the Budget is found.

In a recently published blog I have suggested the cost for just minor amounts of 'care and tending' of PCEHR records to the GP Community could be over \$500Million. See here:

<http://aushealthit.blogspot.com/2011/05/funny-how-even-nehtas-experts-know.html>

“COAG warned of need for e-health incentives

By [Beverley Head](#)

Thursday, 12 May 2011 16:15

The Federal Government and States have been warned that doctors and other health professionals will require financial incentives to encourage them to fully participate in the Government's e-health plans and prepare for the introduction of the Personally Controlled Electronic Health Record (PCEHR) according to the e-health transition authority Nehta.

According to Dr Mukesh Haikerwal, a general practitioner and national clinical lead for Nehta; "The need for incentivisation is a given and was in the business case for COAG". While this week's Federal Budget did not allocate additional funds to pay doctors to update their IT systems, it didn't strip money away from the e-health programme either, which has already been funded to the tune of \$467 million.

Asked where the financial incentives could come from Dr Haikerwal told iTWire; "Some can come from the \$467 million or from other appropriations." Nehta will have to move quick smart to get an incentive programme up, as the \$467 million allocated thus far is supposed to be used by June 2012.

Speaking at an Australian Information Industry Association healthcare briefing in Sydney today, Dr Haikerwal was part of a panel discussion examining the PCEHR, and the preparedness both of the health sector and ICT industry to implement and use the records."

More here:

<http://www.itwire.com/it-policy-news/government-tech-policy/47128-coag-warned-of-need-for-e-health-incentives>

Additionally the current ConOps proposes requesting clinician review of result information followed by release of the result information to the PCEHR repository. Another step is required here, and that is processes around informing the consumer about the outcome of their investigation before release to the PCEHR. The workflow implications of these various steps - and hence additional practitioner cost - are unknown at present.

9. Privacy and Security Concerns

It is unnecessary for this document to rehearse the potential privacy and security issues that surround the creation of a national EHR system.

It is enough to say that a range of technical and privacy experts have expressed significant concerns that have yet to be properly addressed and that until such experts are reasonably satisfied appropriate controls are in place there is likely to be major resistance to the PCEHR proposal from such sections of the community.

An example of the sort of issue that has been rather 'swept under the carpet' in the ConOps are the arrangements to ensure that, with the PCEHR accessible over the Internet, that it is possible to definitively identify the consumer who is accessing their PCEHR, and that access is not being achieved by another, possibly malevolent citizen here or overseas via identity theft or the like.

Many of the vendor community have been working around the world on developing these models. I have identified and provided links to some of the public Points of View published by those organisations. These represent the "best thinking" in the industry around Privacy and Security - and none of these appear to have been taken on board by NEHTA in the construction of the ConOps. Indeed, NEHTA seems to have thought up innovative solutions to problems which have not been articulated. This is nugatory and disruptive and will lead to both non-delivery by the chosen vendors, and failure of adoption by patients and clinicians.

NEHTA simply admits they have not worked out how this is to be managed and so have no idea of the potential cost and effort involved - which may be very substantial indeed.

10. Clear Medico Political Rejection of The Present PCEHR Plans.

The following recent article from Computerworld - and many other similar remarks from both the key GP representative organisations make it clear they are not at all satisfied with the present approaches and plans. If these key stakeholders are anything less than very enthusiastic the likelihood of success with the PCEHR program is essentially zero.

“Budget 2011: E-health communication trumps spending

Peak health groups have called for greater focus on standards, rather than spending, for effective e-health implementationg

- [Chloe Herrick](#) (Computerworld)
- 10 May, 2011 11:54

Australia’s peak health industry bodies have warned of the Federal Government’s e-health solutions becoming “siloed” without greater attention to standards surrounding implementation of technology for doctors and practitioners.

Both the Australian Medical Association (AMA) and the Royal Australian College of General Practitioners (RACGP) expect there to be little in the way of further funding for e-health initiatives in Tuesday’s federal budget, following the government’s \$467 million pour in to personally controlled electronic health records (PCEHR) last year. The government has also committed [nearly \\$400 million to subsidising telehealth services](#) from 1 July next year.

Any health funding announced by federal treasurer, Wayne Swan, is expected to be put toward mental health schemes.

However, AMA federal vice president, Dr. Steve Hambleton, told *Computerworld Australia* that even without additional funding, the industry required a greater, whole-of-sector approach to the looming initiatives.

“E-health has grown up in isolation, we’ve got to start talking about protocols we can communicate to each other nationally,” he said. “NEHTA [National E-Health Transition Authority] is trying to do that, but hospitals have different software in each state and only recently have we started getting a single unique healthcare identifier.

“GP [general practitioner] software, which we’re all going to rely on ultimately to communicate, is all different and the way GPs use the same software is different so standards are really important otherwise we can’t get up and running.”

E-consultations with GPs were particularly important, as they require standardised software and hardware at both ends.

Royal College of General Practitioners (RACGP) e-health spokesperson, Dr. Nathan Pinskier, said standards were also required for implementation, change and adoption of the technology required. He warned a lack of protocols could ultimately silo e-health outcomes.

“Medicare Australia for example struggled to roll out its initiatives for a number of years until it adopted a more broad focus on a whole sector approach,” he said.

For the PCEHR program to have utility it must be embedded into existing software programs, Pinskier said, even once technical requirements have been locked down.

“If it requires practitioners to log out of one system and into another and then copy and paste information or transcribe information it’s not going to fly, if it’s embedded into existing technology

so it's one push at the end of a consultation subject to the patient consent we're much more likely to have uptake."

The full article is here:

http://www.computerworld.com.au/article/385928/budget_2011_e-health_communication_trumps_spending/

Concluding Remarks

I had planned to address the specific areas that NEHTA's ConOps document which needed further review but after working through the ten points above there did not seem to be a great deal left to say.

The PCEHR proposal needs an insightful and pragmatic review and major revision to address the issues raised above. If this is not done the outcome is likely to be very bad indeed in my view and project failure has the possibility to set back implementation of evidenced based and useful e-Health by many years.

I urge that the Commonwealth takes on-board one of the lessons learned from around the world and publish a meaningful Functional Specification for what it wants the PCEHR to do – not how it wants it to do it. This can then be taken by vendors and Solution Architectures developed. As currently drafted the ConOps places delivery risk with the Commonwealth, is virtually undeliverable (especially in the hoped for time-frame), and quantifying delivery achievement is unlikely to be possible.

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