



Response to Request for Comment

on the Draft PCEHR Concept of Operations

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Note: as a result of the extension of the Response submission deadline from 31 May 2011 to 7 June 2011, the College undertook an additional round of document review; any material changes to the original Response V1.0 have been marked with black sidelines.

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Comment on "Draft PCEHR Concept of Operations"

Executive Summary

The Australasian College of Health Informatics (ACHI) welcomes the opportunity to comment on the Draft PCEHR Concept of Operations released by the Department of Health and Ageing in April 2011.

The College is the professional body for Health Informatics in the Asia-Pacific Region. The credentialed Fellows and Members of the College are national and international experts, thought leaders and trusted advisers in Health Informatics. ACHI sets standards for education and professional practice in Health Informatics, supports initiatives, facilitates collaboration and mentors the community. The Fellows and Members of the College are widely involved in e-Health research, standards development, system design and implementation work in Australia, the region and globally.

ACHI supports the Australian government's national health reform agenda as informed by the National Health and Hospitals Reform Commission, the Primary Health Care Reform Report and the National Preventative Health Strategy Roadmap. We welcome an agenda that aims to create an improved healthcare system that is safe, of high quality, accountable, affordable and sustainable.

The College agrees that e-Health is an important enabler to the way healthcare will be delivered in the future in Australia. An Electronic Health Record (EHR) is clearly one of the next steps in progressing e-Health. Therefore, the College welcomes the Department's release of the draft PCEHR Concept of Operations for public comment. The Fellows and Members of the College have reviewed the draft and have formulated 46 recommendations for the next revision of the Concept of Operations.

In summary, the Concept of Operations is in most parts sufficiently comprehensive and detailed to outline what the PCEHR System is and how it will work. However, there are a number of areas where substantial improvements for the next release of the Concept of Operations can be achieved:

- *Provide clarification if the PCEHR is part of a total EHR and what the specific goals of the PCEHR are*
- *Provide more detailed information on the business case for the PCEHR*
- *Include recommended implementation approaches and criteria*
- *Include "Build on and strengthen the patient-doctor relationship" in the PCEHR Principles*
- *Include more rationale how practitioners' will use electronic systems vs paper-based systems*
- *Add features to increase the trust of patients (particularly "opt out" patients) and practitioners*
- *Make the access arrangements more implementable and simpler for the majority of users*
- *Include more details on a simple and complete audit trail access by consumers*
- *Provide more details on PCEHR data retention/archival and access for secondary use of data*
- *Give priority to a small number of useful "low hanging fruit" functions to ensure fast adoption*
- *Combine the approach to Referrals and Discharge Summaries and add hospital dispensing systems*
- *Include more details on which interfaces and interface standards are to be used for which function*
- *Ensure the 12 first and second wave projects are able to seamlessly interoperate and share data*
- *Include specific design guidelines how the clinical quality of unstructured data can be assured*
- *Review the value and data quality of consumer-entered information*
- *Include a long-term implementation timeline with clearly defined major milestones*
- *Include consideration of the e-Health Workforce limitations*
- *Include a section on how the PCEHR will compete with and leverage new technologies*

The Australasian College of Health Informatics looks forward to working with DoHA and NEHTA on the next revision of the Concept of Operations to enable the creation of PCEHR e-health systems that will enable the common goal of better healthcare for all Australians.

Comment on "Draft PCEHR Concept of Operations"

Scope of Comment

The Australasian College of Health Informatics is pleased to have the opportunity to comment on the Draft for Consultation of the "Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system" prepared by the National e-Health Transition Authority (NEHTA) and published by the Department of Health and Ageing in April 2011.¹

The College in this submission document is providing constructive input and comment on relevant government or NGO proposals and drafts. The PCEHR is seen by many as a vital next step in progressing the adoption of e-Health in Australia and the College is keen to see this step be a success. The Fellows and Members of the College are widely involved in e-Health work in Australia and globally and are recognised as the key professional organisation in Australia in the discipline of "health informatics". They and the College are keen to assist DoHA in focusing its programs on initiatives that will deliver the most value to Australia.

These comments were authored and compiled by Fellows and Members of the College, with additional specific input sought from outside its membership.

Note: The College's comments have been formatted according to the structure of the Concept of Operations draft document, adopting the same headings and citing the breakout boxes as suggested in the "How to read this document" section.

The College would welcome feedback on its comments and offers to provide further input to the development and implementation of the PCEHR Concept of Operations.

General Observations

The definition of the PCEHR in the document is "the PCEHR System will only collect personal information for the purposes of providing individuals with access to their own personal health information and enabling them to make this information more readily available to their chosen healthcare providers". It is not made clear if it is a standalone concept or it is part of a total EHR.

There also appears to be some confusion as to whether the desired outcome is a collection of personal health information for consumer reference like a health diary/log, a system to empower the patient to control access to their personal health information as collected by health care providers or a system to benefit health care providers in their day-to-day work. These different objectives require different functionality and different governance approaches. Clarifying and separating these approaches will simplify things as trying to achieve multiple functions makes the PCEHR project unnecessarily more complex and therefore less likely to succeed.

Recommendation: That the next version of the PCEHR Concept of Operations provide clarification if the PCEHR is part of a total EHR and what the specific goal of the PCEHR is.

In responding to the draft Concept of Operations document, some of the College's comments are set against the following implementation criteria for a large, distributed and interoperable e-Health system:

¹ Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system 8 April 2011 NEHTA Version Number: 0.13.6

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1. Collaborative: a successful e-health system must developed openly and be built on a common infrastructure, the sharing of the "best-of-breed" modules that can occur within a shared infrastructure.
2. Scalability: the infrastructure must not only handle thousands of patients and hundreds of thousands of observations, but also be scalable to tens of thousands of patients and millions of observations.
3. Flexibility: these systems must be able to support all clinical care states and their ancillary support systems.
4. Rapid form design: data collection in clinical care is a moving target, therefore form design and deployment must allow for continual change.
5. Clinically useful: the feedback of information (in particular with Clinical Decision Support tools) to providers and caregivers is critical. So if the system is not clinically useful it will not be used.
6. Use of standards: these permit maximum flexibility and extensibility of the system.
7. Support high quality research: via non-ambiguous coded data primarily captured during the care process.
8. Web based support for intermittent connections: this allows for e-Health information management in communities where there are unreliable power supplies and interrupted internet connections. Internet based technologies also facilitate scalability.
9. Low cost: these systems to have wide availability they must be adaptable to all social scenarios and cost must not inhibit adoption.

These criteria have been defined from the knowledge and experience of successful and evolving e-Health systems on the international stage.² These criteria complement the 10 principles listed in the draft Concept of Operations document.³

Recommendation: That the next version of the PCEHR Concept of Operations include recommended implementation criteria.

The breadth of the draft Concept of Operations document is adequate, but short on detail. This may be appropriate as the authors seek to elicit informed feedback from "a wide range of readers including individuals, healthcare providers, ICT industry and other interested parties".⁴ However, considering that the PCEHR Concept of Operations outlines a project of significant expenditure, it is expected that substantially more detail will be added in the next version. Like in most large ICT projects, the document reflects the difficulties with keeping up with the requirement to detail specific objectives and deliverables while at the same time documenting the expected medium and long-term impacts and desired benefits.

Recommendation: That the next version of the PCEHR Concept of Operations include more specific detail.

² Burke W. Mamlin, M.D. †‡, Paul G. Biondich, M.D., M.S. †‡, Ben A. Wolfe†, Hamish Fraser, M.B. Ch.B., M.Sc. §, Darius Jazayeri§, Christian Allen§, Justin Miranda§, William M. Tierney, M.D. †‡ Cooking Up An Open Source EMR For Developing Countries: OpenMRS – A Recipe For Successful Collaboration. AMIA 2006 Symposium Proceedings Page - 529

³ Concept of Operations section 2.5 Principles

⁴ Concept of Operations page iv "Intended audience"

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The current draft Concept of Operations document does not appear to reference and digest past and ongoing consultation findings as well as reported experiences of the three decades of e-Health projects in Australia and globally to allow readers to understand why certain design choices were made.

Recommendation: That the next version of the PCEHR Concept of Operations include references to past and ongoing consultation findings as well as reported e-Health system implementation experiences beyond what is listed in Appendix B.

It appears that current draft Concept of Operations document does not fully consider many of the consultation findings about e-Health strategies from the health reform processes reported by the NHHRC and the Primary Care Strategy and Preventative Care Strategy taskforces. A key international lesson is that *e-Health* reforms must be seen as clinical health reform with ICT support. The current draft appears to lack of information on PCEHR system design features and operational procedures to actively promote the health care aspects, especially continuity of care within a trusted patient-doctor relationship. Continuity of care is viewed as having informational, management and relational dimensions, with the EHR (= PCEHR + Shared EHR?) being a facilitator of the information dimension directly, but also all the other dimensions indirectly. There is also little reference to the "medical home" discussed in the NHHRC report.

Recommendation: That the next version of the PCEHR Concept of Operations include more detailed responses to the NHHRC report and the subsequent NHHRC and the Primary Care Strategy and Preventative Care Strategy taskforces.

The current draft PCEHR Concept of Operations document appears to sideline, with the potential to undermine, the patient-doctor relationship. The specific examples are "hiding the PCEHR" i.e. stating that there is no health record as opposed to stating to health providers seeking information that they are denied access to the relevant health record. One encourages open and transparent discussion, while the other does not. As such, to promote trust in the system, it is suggested that the principle of building on and strengthening the patient-doctor relationship is added to the ten listed in the document.

Recommendation: That the "Principles" section of the next version of the PCEHR Concept of Operations include "Build on and strengthen the patient-doctor relationship".

Another issue is that there is no hard evidence to suggest that e-systems will replace paper ones. There is however evidence to suggest clinicians share user credentials and use paper printouts and then transcribe information into e-health systems.⁵ The issue of e-systems vs paper systems is very profound. We have conclusions such as Brent James in his QMMP project on quality: "The foundation for quality patient care is information - comprehensive, accurate, up-to-the-minute clinical information, and is not possible using current paper-based medical record systems",⁶ but we also need to understand/comprehend the major changes here will be societal and cultural especially with the physicians component of care. This was pointed out by Lucien Leape in his review "5 years after To Err is Human"⁷ in 2005, e.g. 6 years after the original report.⁸ Other clinicians, in particular nurses,

⁵ Fernando, J & Dawson, L. (2009) "The health information system security threat lifecycle: An informatics theory" *Int J Med Inform* (78)12 p.815

⁶ Brent James IHC, QMMP project. Chicago, Illinois. 1989.

⁷ Leape, L. L. and D. M. Berwick (2005). "Five years after To Err Is Human: what have we learned?" *JAMA* 293(19): 2384-90.

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pharmacists and patients have moved forwards to use e-health clinical information management tools.

Recommendation: That the next version of the PCEHR Concept of Operations include more detailed information on the business case and business practice of practitioners' use of electronic systems vs paper-based systems.

There is also a fragmentation issue linked to running parallel healthcare information systems, as practitioners will mainly depend on PC-based practice management systems and paper practice records.

If the clinician's workload is significantly increased without directly tangible benefits, the PCEHR system will go the same way as has the UK EHR.⁹ Clinicians are already time poor and if they need to adopt new practices that reduces the number of patients they can consult per day then this will negatively affect the costs of providing primary care services. It needs to be remembered that the PCEHR currently is designed to fit on top of existing systems not to replace them. Logically this translates into more work for clinicians and/or their staff and if staff are transcribing clinical notes into the PCEHR system then we are back to a paper-based approach.

In this context, it is also important that the current flows of clinical information are not changed without careful analysis and good reasoning. Practitioners in primary care and hospitals settings rely on first-hand clinical information from sources they have established trust in, eg pathology labs, diagnostic imaging departments, medication management systems, etc. In most cases, these trusted sources send their clinical information to GP practice management computer systems (PMS) or hospital clinical information systems (CIS). As a result, most clinicians see PMSs and CISs as the "source of truth" for patient data. The current PCEHR architecture does not take this approach but appears to rely on "2nd-hand" data uploaded by clinicians - if and when they have time. As a result, the information held in a patient's PCEHR will be patchy as best and minimal at worst. This reduces the incremental value of a patient's PCEHR data to supplementary information and personal comments. This makes the access of PCEHR data during consultations by time-poor practitioners unlikely.

In summary, we do not believe there has been enough consideration of human factors in the current draft PCEHR Concept of Operations.

Recommendation: That the next version of the PCEHR Concept of Operations include a detailed consideration of the issues of running parallel systems and proposals for the remediation of this situation.

The College believes that a national approach must be taken as highlighted in current draft Concept of Operations document. However, it appears that already NSW and Victorian legislative differences are making this process difficult in cross-jurisdiction locations such as Albury Wodonga.

Recommendation: That the next version of the PCEHR Concept of Operations include some guidance on how cross-jurisdiction locations could operate.

The current draft Concept of Operations document is silent on where clinicians will store "unfavourable comments" on the patient (i.e. "patient has drug seeking behaviour" or "patient is likely suffering from a first episode of schizophreniform psychosis"). Should patients be allowed to see this? If patients could see this, they would simply switch this off from view and hence many of the benefits

⁸ To Err is Human: Building a Safer Health System", Kohn L T, Corrigan J M, Donaldson M S (eds), 1999, Committee on Quality of Health Care, Institute of Medicine, National Academy Press, Washington DC

⁹ iHealthBeat, "Audit slams British EHR Program for being Largely Unsuccessful"
www.ihealthbeat.org/articles/2011/5/18/audit-slams-british-ehr-program-for-being-largely-unsuccessful.aspx

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of a PCEHR would be lost due to the record being artificially cleansed. If this occurs, will the integrity in the record be maintained or will clinicians feel that the records are not sufficiently true and accurate and therefore continue to keep and maintain their own paper-based records?

The current PCEHR design may work well for most people, however certainly not for everyone. It is therefore necessary to work out now which demographic groups the current PCEHR design will not work for and make pre-emptive corrections in the next version of the PCEHR Concept of Operations.

Recommendation: That the next version of the PCEHR Concept of Operations include the functionality to add patient-sensitive comments without losing the trust of patients and practitioners.

The current draft Concept of Operations document outlines roles and responsibilities but not accountability. Transparency about accountability is essential to generate the trust that is required to make the PCEHR a success for patients, providers and carers.

Recommendation: That the next version of the PCEHR Concept of Operations include outlines the accountability required to establish trust with patients, providers and carers.

Regarding the implementation timeframe, the date of July 2012 appears to be unrealistically ambitious for any EHR system with a real benefit. However, the Department of Health and Ageing CIO Paul Madden has recently hinted at a more realistic implementation timeframe.¹⁰

Recommendation: That the next version of the PCEHR Concept of Operations include a long-term implementation timeline with clearly defined major milestones.

2.3 Vision and concept

The participation in the PCEHR system will be voluntary. This is important because there are those in the community that who are anxious to protect their privacy, notwithstanding information provided showing that EHRs are good for care, will be fundamentally against sharing any of their information with anybody at any time for any reason.

This would indicate that by accepting the "opt out" option for any EHR their information should be kept off the shared e-Health systems "grid". This information includes diagnostic test results and pharmacy information that would normally be in local records as a part of the information exchanges, etc. Using these concepts there needs to be a PCEHR "opt out" process that confirms to the patient that by taking this position:

- "This could result in harm to me and even my death due to lack of critical information at critical times."
- "I will not hold my health care provider(s) liable for any damages caused by their not having the information they need to make the best decisions about my care".

The current draft Concept of Operations allows providers to "opt out" of caring for these individuals in without the PCEHR information. The patients are permitted to act in this way and without preventing the use of EHRs and other Health IT systems for others.

On the other hand, there also the concern that people who "opt out" might erroneously believe they will not be able to get Medicare or other reimbursement for their medical costs. These concerns are documented to cause negative health outcomes in Australia.¹¹ It also appears that at the recent

¹⁰ www.theaustralian.com.au/australian-it/low-cost-high-security-systems-that-hinge-on-giant-virtualised-computers-cloud-computing-catches-on/story-e6frgax-1226061374157

¹¹ "Fear of Insurance Rejection deters potentially Life Saving Genetic Tests for Bowel Cancer" <http://newsroom.melbourne.edu/news/n-130>

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"PCEHR 4 Corners Round Table" it was stated that insurers can ask and charge consumers on the basis of whether the individual has a PCEHR or not.

Recommendation: That the next version of the PCEHR Concept of Operations consider measures to ensure that "opt out" patients do not feel disadvantaged.

2.8.1 Clinical decision support

According to the current draft PCEHR Concept of Operations document, 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."¹²

Providing electronic clinical decision support through effective information management tools is seen by many e-health experts as fundamental to effective health reform and is the cornerstone of many e-Health implementations. This need for electronic clinical decision support has been known for decades and the issues relating to this domain have been well documented by experts such as Coiera,¹³ the Institute of Medicine¹⁴ and the WHO ("There is no health without management, and there is no management without information" - Gonzalo Vecina Neto, head of the Brazilian National Health Regulatory Agency).¹⁵

The College is pleased to see that the supporting clinical decision support is part of the goals of the PCEHR but believes that the draft Concept of Operations does not adequately come to terms with the implications this has.

Recommendation: That the next version of the PCEHR Concept of Operations include a section that details how the PCEHR enables decision support and documents the type of clinical decision support it will support and the type of clinical decision support that the current design will rule out.

3. Participation

3.2 Individuals

3.2.2 Registration

Issue: The processes for assisted registration and mail based registration are under development.

The registration model stated in the Concept of Operations is "opt-in", which is problematic as it will be very difficult to attain the critical mass required to make the PCEHR useful, meaningful & effective. The value of the PCEHR will only be realised with a large adoption rate, which in an "opt-in" model can only be achieved with an attractive value proposition. In the current draft Concept of

¹² Concept of Operations section 2.8.1

¹³ Coiera, E., A Guide to Health Informatics 2nd Edition., ed. O.U. Press. December 2003

¹⁴ Institute of Medicine. Crossing the Quality Chasm: A New System for the 21st Century. Washington, DC: National Academy Press, 2001

¹⁵ Leão BF. Terms of Reference for Designing the Requirements of the Health Information System of the Maputo Central Hospital and Preparation of the Tender Specifications. Geneva: World Health Organization; 2007.

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Operations document an attractive value proposition for patients and consumers is not clearly stated.

Interestingly, there is also the reverse view. The draft Concept of Operations document and briefings suggest newborn babies, for example, will be opted in by default and parents will have to opt them out if they do not consent to participation. It is not difficult to attain critical mass in a service that is useful to people (i.e. Army of Women¹⁶ in the UK) and based on our reading of the draft Concept of Operations, the Individual Health Identifier (IHI) is only of use in point-to-point data exchange at present. This does not instil the community with a sense of confidence. Moreover, the draft Concept of Operations document outlines changes that could result in government storing information about citizens beyond what is required for clinical care. Regardless of how the information (such as discharge summaries, radiology and other clinical reports) is used in the context of the PCEHR, how will secondary uses of the data, such as research be governed? The draft Concept of Operations document is silent on this.

We found it interesting that the New Zealand position is "opt out" was important because of equity - those less likely to "opt in" where those most likely to benefit. All the other arguments we have heard were about critical mass.

In work reported from Kenya with HIV/AIDS,¹⁷ (initially the Kenyans were not even measuring the disease) they provided "opt in" for HIV testing with low participation rates. Because of the importance for disease management, prevention and epidemiology, they then instituted "opt out" as the alternative and now have HIV testing rates of over 99%. Of course, the social dynamics may be significantly different in Australia; however, the same system is now used in more than 20 countries for all disease states.

Regarding the model needing to be "opt out" rather than "opt in", apart from the ICT and health-savvy health informaticians at one end of the spectrum and perhaps the civil libertarians at the other, the vast majority of health user will fall into the middle band. If users are given the choice, then we are likely to see the Victorian Myki ticket system scenario over again. The system works well, however because users were given a choice combined with unfavourable and negative media attention, the majority of people just ended up sticking with what they knew and never got around to applying to utilise the new system. Change management literature certainly points to the need to remove current / previous processes to order to be successful moving forward. In a complex health system where efficiencies and improved standards of care are going to be largely derived out of standardised processes, opt out models are going to provide for a far greater level of success.

The main point to remember is that only if the PCEHR is a compelling or useful offering, people will "opt-in". If there is no clear and attractive value proposition, patients will not "opt-in" and practitioners will not use. The crucial factor is that the value of the PCEHR results largely from widespread adoption; "if there is no useful info there, GPs will stop to look". Kaiser Permanente's experience (high voluntary adoption, useful system)¹⁸ and the UK NHS experience (low adoption and a useless, slow offering) are good examples of this.¹⁹

Recommendation: That the next version of the PCEHR Concept of Operations include considered and specific recommendations regarding an "opt out" or "opt in" approach. That the next version of the PCEHR Concept of Operations also address the secondary use of data.

¹⁶ Army of Women (2011) Webpage, "Love Avon, Going beyond a cure." www.armyofwomen.org

¹⁷ Einterz, R. M., S. Kimaiyo, et al. (2007). "Responding to the HIV pandemic: the power of an academic medical partnership." *Acad Med* 82(8): 812-8.

¹⁸ Effect of Doctor-patient Secure Messaging on Health Outcomes for Diabetic Patients. A. Compton-Phillips, C. Bredfeldt, Kaiser Permanente; D. Rourke, Arsanalytica; M. Snyder, Kaiser Permanente AMAI Proceedings 2009. Workshop.

¹⁹ HuffPost Health: www.huffingtonpost.com/stephen-soumerai/dont-repeat-the-uks-elect_b_790470.html

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3.2.8 Children

Issue: The Australian Law Reform Commission (ALRC) currently recommends 15 years of age and Medicare policies recommend 14. Currently the PCEHR System reflects the Medicare policy.

Medicare Australia also have a policy of limiting online access to claiming information about children aged from 14 to 18 for privacy reasons. Access to this information requires a paper form signed by both the parent and the child. The requested information will be sent directly to the child. Whether the PCEHR System needs to adopt a similar policy requires further consultation with consumers and other stakeholders.

Recommendation: The College's view is that existing regulations appear to be adequate.

3.2.9 Deceased Individuals

Issue: Further consideration needs to be undertaken of what access is required to the PCEHR of a deceased individual to align with current medical and legal practice.

The issue of access to the PCEHR after a patient's death is non-trivial and needs specific attention. To quote David Rind at the Centre for Clinical Computing, Harvard University: "All information is confidential. What is required is the determination of the rights of access".²⁰

Recommendation: That the next version of the PCEHR Concept of Operations include specific guidelines regarding the access to a patient's PCEHR after death.

3.2.10 Enquires and Complaints

Issue: The Commonwealth is consulting with States and Territories to determine the appropriate bodies for investigation.

Recommendation: The College's view is that roles, responsibilities and accountability need to be explicitly stated following the conclusion of the Commonwealth's consultations.

²⁰ Safran C, Rind D, Citroen M, Bakker AR, Slack WV, Bleich HL. Protection of confidentiality in the computer-based patient record. MD Comput. 1995 May-Jun;12(3):189-92

4. Managing PCEHR Information

4.2 Information Sources

4.2.1 Clinical Documents

Design Note: In order to support integration of feeder systems that are not yet ready to supply information in a structured atomised format, the PCEHR System will accept unstructured data for certain clinical document types (see below). The design trade off accepted here is that in order to increase the breadth of content available in the PCEHR System, some views and reports may not be complete in the interim. In time unstructured clinical documents may be phased out.

The Concept of Operations is not clear how the issue of clinical data quality will be addressed when unstructured data is accepted into the PCEHR. This is a major risk factor that may diminish the value and so the usage of the PCEHR by clinicians.

Recommendation: That the next version of the PCEHR Concept of Operations include specific design guidelines how the clinical quality of unstructured data be assured.

Issue: As indicated above, the scope and extent of information that can be supported by the PCEHR System is dependent on the healthcare sector readiness to participate in the PCEHR System. Each of the clinical documents will need to be considered on a case-by-case basis and further input from the consultation process on the value of each clinical document type to consumer and healthcare provider stakeholders and organisational readiness to supply the proposed information is being sought.

The document recognises that the scope and extent of information that can be supported by the PCEHR System is dependent on the healthcare sector readiness to participate in the PCEHR System. However, what is planned does not appear to address the readiness or desire of the health sector to participate in the system.

The proposed approach to manage changes in the documents is good, but we wonder how practical it is in terms of compliance. In addition, to be consistent with the 10 listed principles, the breadth / scope of the document content should be focused on a small number of useful functions to ensure that what is done is done well. This could be shared medication and investigation records in the first instance; these are "low hanging fruit" that could leverage the work already done with MediConnect.

Recommendation: That the PCEHR System implementation give priority to a small number of useful functions ("low hanging fruit") to ensure substantial participation of the health care sector and so a reasonable return on the substantial investment in resources.

4.2.4 Discharge Summaries

Scope Notes: Note that NEHTA Discharge Summaries are currently limited to the context of discharging an individual from hospital to the care of a GP.

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The Discharge Summaries should be structured; however, the compliance to this requirement may be suboptimal due to the limited amount of information provided. As an alternative, an easier to implement and support clinical information object is required.

To achieve the full benefits of electronic Discharge Summaries, the next revision of the PCEHR Concept of Operations should include a Discharge Summary road-map for other areas such as GP-to-Specialist, Specialist to GP, GP-to-Allied Health, etc.

The differences between Discharge Summaries and Referrals are increasingly blurred in real clinical practice therefore both need to be looked at holistically and a combined approach taken. Refer "4.2.6 Referrals" below.

Recommendation: That Discharge Summaries are structured so that an easy to implement and support clinical information object is utilised. That a roadmap for other Discharge Summaries be created. System design must give consideration to domain specific design formats through the use of an expandable Concept Dictionary.²¹

4.2.6 Referrals

Scope Notes: Note that current NEHTA specifications only support GP to Specialist Referrals. Other forms of Referral will be supported via unstructured clinical documents in the first release.

The differences between Discharge Summaries and Referrals are increasingly blurred in real clinical practice therefore both need to be looked at holistically and a combined approach taken. Refer 4.2.4 Discharge Summaries above.

Recommendation: That a combined approach to Referrals and Discharge Summaries be taken.

4.2.7 Prescribing and Dispensing Information

eHealth Site Notes: The FRED IT Group Medview eHealth site will be informing the development and implementation of the sharing of prescribing and dispensing information.

Given that the majority of extensive documentation and medication reconciliation from pharmacy coming from hospitals is directed back out into community pharmacies, it would be prudent to engage the two main hospital dispensing systems (iSoft "iPharmacy" and Pharmhos "Merlin") to ensure that development in this area does not take an unnecessarily limited view of this process. While both FRED and eRx are involved in the Second Wave trials, it is our view that these systems are not representative of the broader pharmacy sector within health as it covers mainly community pharmacies only.

Recommendation: That hospital dispensing systems be added to the next draft of the PCEHR Concept of Operations.

²¹ IRDResearch Concept Dictionary : www.youtube.com/watch?v=5hEYn7cXZPY

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4.2.8 Pathology Results Reports

Issue: The model described here is an initial view of the proposed model for sharing Pathology Result Reports. This model will be refined through consultation.

The electronic reporting of Pathology Results is probably the most well-established areas of e-Health in Australia, with systems in place since 1992. This is a good example of the "low hanging fruit" referred to in section 4.2.1 Clinical Documents above.

Recommendation: The next version of the PCEHR Concept of Operations include specific design details on Pathology Result reporting.

4.2.9 Diagnostic Imaging Reports

Issue: The model described here is an initial view of the proposed model for sharing Diagnostic Imaging Reports. This model will be refined through consultation.

The electronic reporting of Diagnostic Imaging is well-established, in particular since the availability of IHE implementation profiles in Australia.²² This is a good example of the "low hanging fruit" referred to in section 4.2.1 Clinical Documents above.

Recommendation: That the next version of the PCEHR Concept of Operations include specific design details on Diagnostic Imaging reporting.

4.2.10 Medicare Australia Records

Issue: The process by which Medicare Australia information is loaded and used in the PCEHR System requires further review and consultation. NEHTA and Medicare will be developing proof of concept mock-ups of how Medicare information might be loaded and used by individuals and their healthcare providers. This will help inform the review and consultation process.

The clinical information held by Medicare Australia is potentially a rich source of information. However, the data quality and legality of access needs to be explored.

Recommendation: That the next version of the PCEHR Concept of Operations include specific design details on clinical information obtained from Medicare Australia.

²² See IHE Australia www.IHE.net.au

4.2.11 Consumer Entered Information

Issue: In making a decision about what individuals should enter about themselves and with whom this should be shared, the following issues must be resolved:

- *Confirmation from consumers about the information they want to record to assist them in managing their own healthcare.* International experience suggests that to encourage uptake by individuals, the technology needs to be closely designed around the healthcare needs of the individual and their relationships with healthcare providers, family members and carers. As a result, the type of information that individuals may want to record will also vary greatly from individual to individual.
- *Expectations on healthcare providers.* Healthcare providers and their insurers have expressed concern that individuals may have an expectation that healthcare providers would review information (such as information in a personal health diary) outside a consultation. They are concerned that the PCEHR may create an obligation for them to review that material, at least in some cases, as part of their duty to take reasonable care, and that this practice would fall outside current healthcare relationships and funding models. Healthcare providers have also raised the concern of information overload, and that high value clinical information could be less accessible if large volumes of unverified information are entered into a PCEHR by individuals. The process of sifting through information could increase the workload on our healthcare workforce that is already stretched.

NEHTA is currently discussing these issues with consumer groups, healthcare providers and their medical indemnity insurers and the approach presented here has been informed by that discussion. The proposed approach is intended to start small and grow support for a broader range of consumer-entered information in time. The final design will be determined through a consultative process.

Consumer-entered information should not be an initial focus of the PCEHR. That type of information is an integral part of history taking within a patient-doctor therapeutic relationship. The medical home concept addresses this as part of information exchange within a trust relationship - the consumer-entered information is filtered through negotiation with the personal doctor or nurse. This is consistent with general practice which considers the patient demand for care (= presenting complaint) and its negotiation between patient and doctor into a manageable reason for encounter (problem formulation), which is then followed by a diagnostic and management plan. This is what is meant by supporting the patient-doctor relationship - rather than undermining it. This is also a realistic approach to health literacy and patient empowerment.

Examples of consumer-entered information are home-measured blood sugar levels, spirometry values, general worries and concerns, etc. The problem with this information is that it is not reviewed by a clinician soon after entry; rather it may be viewed when the patient next presents. As a result, the "alerting benefit" of any consumer-entered information is lost; eg "The patient might as well take the spirometer printouts to their next consult".

Recommendation: That the next version of the PCEHR Concept of Operations carefully review the value and data quality of consumer-entered information.

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4.3 Views

4.3.3 Consolidated View

Design notes: A number of models have been proposed around health summaries including models based purely on automatically created views, models based on a nominated provider and a 'wiki' style health summary that can be collaboratively edited by multiple healthcare providers.

No one model is perfect and each model has its own advantages and disadvantages in terms of its accuracy, completeness, consistency, currency, provenance and ability to deal with different individual circumstances.

A hybrid model, which relies on a nominated provider created Shared Health Summary complemented by an automated Consolidated View, is the model currently being pursued based on initial consultation feedback.

Scope notes: There are a number of optional features accessible via the Consolidated View, which may not be available in the first release. Please see the scope note in Section 4.2.

An optional nominated healthcare provider increases the choices and program complexity. This flexibility requires that a core set of information be collected in all the "summaries" so that the information is available even if some documents are not available. The hybrid model is an important design principle but will require greater consideration and understanding of the medical home concept outlined in the NHHRC recommendations in the design. Implementation will require rewards for the nominated provider. Taking a "wiki" approach is forward-looking, but needs careful design regarding access and tracking of changes.

Data quality is the elephant in the room and details are lacking in this version of the PCEHR Concept of Operations document. The provenance model is sound but the practicality is debatable. Discovering errors in the PCEHR and using this to inform and initiate corrections in the source system(s) is an example of how the PCEHR may be useful to some clinicians and improve data quality in source systems. Considering the (low) quality of routinely collected data in current clinical information systems, data quality metrics and processes should be embedded into the PCEHR from the beginning. In addition to the IHIs, other automated processes to identify/authenticate individuals should be in place. To be consistent with the principle of redundancy, a suggested approach is to use a combination of deterministic and probabilistic matching to identify individuals associated with the range of documents that make up the PCEHR. The PCEHR is starting as an imperfect system, so the data quality emphasis is critical right from the start.

Recommendation: That the next version of the PCEHR Concept of Operations include more details on the "nominated provider" approach and possibly a road-map to capabilities that support data error discovery and correction.

4.6 Related Topics

4.6.3 Archival

Issue: Archival will need further consultation and review of legal issues.

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For a longitudinal electronic health record the issue of data retention and archival is vital, as many experts see this as a main benefit of an EHR. Although some research has questioned the value of older data²³, this issue needs to be exhaustively addressed in the PCEHR Concept of Operations.

The current draft PCEHR Concept of Operations is silent on what data has persistent value and should therefore be archived. It also does not appear to address the governance and cost of data archiving and retention. Additionally, Australia does not yet have national healthcare data archiving and retention regulations which would need to be put in place before any PCEHR data archiving or purging is undertaken.

Recommendation: That the next version of the PCEHR Concept of Operations include more details on PCEHR data retention and archival.

5. Privacy and Security

5.4 Authentication

5.4.2 Individuals and Representatives

Issue: Authentication to the consumer portal and other conformant portals has yet to be determined..

One method currently under consideration is the use of the Australian Government Online Service Point (AGOSP).

A range of perspectives on this topic is currently being sought.

It is doubtful if doctors in the current environment will trust and use an EHR while the patient has control. College members can cite examples of recent visits to doctors to illustrate this.

Another issue is the "hype" about electronic systems generically needing special security provisions over existing paper systems. Electronic communications are far more secure than paper mail.²⁴ On the other hand, health information stored in a repository - which may well be located in a "cloud" - is potentially accessible by anyone with access to the internet and therefore the security risks and their mitigation are fundamentally different to a paper patient file held in a GP's filing cabinet.

By one estimate, 85 percent of all computer security problems involve employees inside the organisation.^{25 26} "The major vulnerabilities are related to inappropriate use of patient-specific information by health workers who have access to those data as part of their regular work. Such risks are greater when data are stored in paper charts".²⁷

Recommendation: That the next version of the PCEHR Concept of Operations include a more detailed evaluation of the security issues, in particular distinguishing the security risks of healthcare information transport vs health information storage.

²³ Prof. Bernd Blobel, University of Regensburg, Germany

²⁴ Refer the common practice of leaving pathology reports on surgery front desks or open letter boxes ...

²⁵ R. L. Simpson, 1996. Security threats are usually an inside job. *Nursing Management* 27(December);43

²⁶ Security of medical Information: The threat from within. J Anderson, Maria Brann. *MD Computing*. March/April 2000. 15-17

²⁷ The evolution of health-care records in the era of the Internet. EH Shortliffe. Semi-Plenary. MEDINFO Seoul, August 1998

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It is also noted that to date professional records and patient held records have had different levels of protection and security; how this will work in the PCEHR is currently unclear. This important topic will need substantial consultation to avoid unintended consequences.

Also, people seem to overlook the fact that unless the clinician is registered for the PCEHR, then the patient's own PCEHR is useless.

Recommendation: That the levels of protection and security of professional records and patient held records be defined after consultation and be included in the next version of the PCEHR Concept of Operations.

In summary, the issue of privacy comes down to risk vs benefit. Nothing is ever guaranteed as private but if this is acknowledged and weighed up with the benefits of an EHR, we believe that this will be a successful approach as it is already becoming evident that many patients are happy to take some risk for their health outcome benefit.^{28 29}

In a recent international discussion on this issue, most of the people who were worried about their data "getting out there" are worried because they have pre-existing conditions that, if they became known, might cause them to lose their health insurance, have detrimental effects on their employment, etc. Therefore, the PCEHR Concept of Operations should look seriously at the different aspects of health insurance reform, which may go a long way to alleviate the privacy concerns for the vast majority of people.

Recommendation: That the next version of the PCEHR Concept of Operations include an evaluation of the experiences of disease-burden motivated patient cohorts regarding electronic systems privacy.

²⁸ J Am Med Inform Assoc. 1998 Jan-Feb;5(1):104-11.

²⁹ www.sans.org/reading_room/whitepapers/legal/e-mail-communication-patients-wake-hipaa-final-security-rule_1057

5.5 Authorisation and Access Control

5.5.3 Options around Controlling Access to Clinical Documents

Design Notes: Limiting access to clinical documents is a challenging topic.

A number of the controls described above aim to accommodate the need for all individuals to set some basic controls around their PCEHR. It is recognised however that some individuals may wish add information to their PCEHR over which they wish to apply tighter access restrictions (and closer management). It is also recognised that concerns have been raised by healthcare providers about the utility and potential impacts of this feature. However, failure to include this feature may result in some individuals changing their behaviour (e.g. withdrawing participation, refusing to grant access, withholding information, etc) to work around the absence of this feature. Therefore in line with the central concept of a personally controlled EHR, 'limited access' has been included as an advanced feature.

The inclusion of this feature means that improving health literacy will become more essential and individuals need to be educated about the consequences of limiting access.

Implementation of the limited access feature has also been acknowledged as challenging. The proposed approach does not require the feeder system to support the feature and limits the ability to change the status of a clinical document to being accessible only via the consumer portal. The design trade off means that only individuals who are able to use the portal and have set up a PAC will be able to access this feature.

Issue: The limited access feature is requires further consultation as some stakeholders are concerned about the extra complexity it introduces.

The access arrangements in the current PCEHR Draft Concept of Operations appear unduly complex, particularly when applied in practice. Only a minority of users will actually limit access or hide information. The needs of the minority should be addressed, but should not complicate the overall technical design. There are potential effects on trust within the patient-doctor relationship as well as the trust and confidence that are essential for the success of the PCEHR. The needs of the minority can be addressed by other strategies that do not involve the technical operations of the PCEHR. The system should be designed for the majority of users i.e. the default option is general access. The focus should be on strengthening the functionality of general access, with adequate privacy and security arrangements under existing laws and regulations as a starting point. One option is that private information not to be shared should not be recorded in the PCEHR at all. With personal health information created by third parties such as reports, referral letters, etc which may be sensitive, there are existing rules and regulations which cover, or can be enhanced to cover, misdemeanours associated with these third party created personal health information. If we are clear about these types of information, then we can keep the access arrangements in the PCEHR fairly simple and therefore do-able and sustainable with incremental increase in scope over the longer term.

The default general access makes sense, but the other access-limiting functions make it more complex especially when translated into the clinical workflow. Along with the "hiding" function, these access arrangements go against the international lesson learnt that the focus should be on strengthening the simple but relevant functions of an EHR. There are usually no added benefits gained from increasing the complexity beyond a certain point. In addition, this approach will strengthen the case

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for an "opt out" consent model as regulations are in place to deal with sensitive personal and family/genetic information.

Recommendation: That the access arrangements in next version of the PCEHR Draft Concept of Operations be focussed on the majority of users, be simpler and be more implementable. That the need of a minority of users to actually limit access or hide information be satisfied with a simpler approach.

5.5.4 Emergency Access

Issue: Current privacy law permits emergency access to health information and gives protection to individuals by defining the circumstances in which this might be applied.

The proposed model allows emergency access to override certain access controls, including controls around the ability to: hide a PCEHR from search, prevent access via an exclude list, control entry to the include list via a PAC, and limit access to specific clinical documents. One access control it cannot override is clinical documents marked for 'no access'.

Getting the balance right around which access controls can be overridden and how they can be overridden using emergency access is the subject of further consultation. Some stakeholders have suggested that options should be given to the individual around how emergency access should be supported with the PCEHR. Other stakeholders are concerned about the increased complexity in making these options available.

The emergency access model requires further consultation and may change.

Many experts see emergency access to clinical data of a patient as a main benefit of an EHR. The current PCEHR Concept of Operations does not provide enough detail on this functionality.³⁰

Recommendation: That the next version of the PCEHR Concept of Operations include more details on emergency access.

5.7 Audit

Issue: The Commonwealth is consulting with States and Territories to determine the appropriate body for investigations

An audit function recording all activity on the on the national e-Health infrastructure services and PCEHR will ensure confidence in technical aspects the PCEHR System by both individuals and health-care providers.

The audit functions outlined in the PCEHR Concept of Operations are complex, but it is expected that these functions will usually be used by trained professionals. The consumer-facing part of the audit functions needs to be simple and confidence-building. The need to issue a formal request to the PCEHR System operator if detailed access information is required appears to be counter-productive.

Recommendation: That the next version of the PCEHR Concept of Operations include more details on simple and complete audit trail access by consumers.

³⁰ This is implemented and documented in the Dartmouth-Hitchcock healthcare system: www.dhmc.org

6. PCEHR System Components

6.3 Access Channels

6.3.2 Provider Portal

Scope Notes: In the first release the Provider Portal will be primarily a read-only system. Clinical documents can only be created from Clinical systems.

The fact that it is to be updated by templates-based CDA Technology (as different to CDA Principles, HL7 V3 Principles or RIM) means that the information will have severe limitations regarding searching, retrieval and identification of what is being sought as well as limited computational capabilities

The PCEHR Concept of Operations draft acknowledges that there is likely to need to be some level of flexibility in the beginning until processes are bedded down. This is probably a reasonable approach in terms of getting an appropriate level of "buy in", however it is very difficult to "sun set" and undo these customisations. Maybe this process needs a little more consideration as to how non-standardisation is going to be phased out once in place.

We would also like to see more detail on how the PCEHR will integrate with existing systems both in primary health and in the hospital sector. Who will determine and how will data be shared between these systems? Is there duplication of effort involved? We are aware that the Victorian government is starting to look at electronic medical records for the public hospital sector and hopefully this undesirable outcome will not occur in isolation from the PCEHR.

In the current PCEHR Concept of Operations draft, there are no details of the Standards to be used for its implementation. The draft lists a number of specifications recently authored by NEHTA of which only two³¹ have been approved by Standards Australia. There is no information on the maturity and number of local and international implementations of these specifications. The large number of widely implemented approved local and localised international standards³² appear to be ignored in the current PCEHR Concept of Operations draft.³³ This amounts to the omission of the majority of data interfaces deployed by the Australian jurisdictions and their associated investments of the last 20 years.

There is some concern about standards information and the fact that these will not be made public for the PCEHR. In response to a recent query whether standards would be made publicly available, it appears that NEHTA replied "No, however at a later stage the Standards Matrix will form the basis of the PCEHR Standards Catalogue." It is of deep concern that the current PCEHR Concept of Operations draft gives no information on which of the many tried and tested interoperability standards will be utilised.

The lack of clarity about what will be the format of the "clinical documents" that will be transferred to the PCEHR is seen as high risk to achieving the July 2012 implementation deadline. Additionally, this severely hampers the possibility of implementing clinical decision support in the near future!

Recommendation: That the next version of the PCEHR Concept of Operations include more details on which interfaces and interface standards are to be used for which function. That the next version

³¹ Standards Australia AT55820-2010 E-Health Web Services & AT55821-2010 E-Health XML Secured Payload Profiles

³² See www.e-healthstandards.org.au/Home/Publications.aspx

³³ The only other Australian Standards referenced in the Con Ops are AS4846-2006 Healthcare Provider Identification & AS5017-2006 Healthcare Client Identification

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of the PCEHR Concept of Operations also include more details on approaches not approved by Australian Standards and how the non-standardisation will be phased out over time.

6.4 Core PCEHR Services

Design Note: In some cases the View Service will assemble views using information from the index or other services. For some kinds of views, such as the Index View, this approach is appropriate as such information can be readily requested from the Index Service. However, for other kinds of views, such as the Consolidated View, which have greater performance demands, it may be necessary to incrementally update the views as new information is added to the PCEHR System. It is likely that the View Service will need to maintain an atomic data store specifically for this purpose.

In the case of the Consolidated View, for example, when a new Shared Health Summary or Event Summary is loaded into the national repositories, the Consolidated View for that individual will need to be updated.

How this update will be supported has yet to be defined, but one possible process relies on the repository first updating the index, which in turn notifies the View Service that new information is available. The View Service then in turn pulls a copy of the new Shared Health Summary or Event Summary from the national repositories and uses that information to update the Consolidated View.

The College believes that the updating function is fundamental to the PCEHR's technical design and that the current draft Concept of Operations document lacks details of the update services is of substantial concern.

There is a need to use pseudonyms as a strategy to improve the privacy of personal health information. The use of hashed identifiers as pseudonyms is a promising technique.

Recommendation: That the next version of the PCEHR Concept of Operations contain more details on the update services.

Other Considerations

The following are other comments and recommendations on the current draft PCEHR Concept of Operations that are either not addressed in the draft or do not readily fit into the headings above.

Implementation

There are now 12 first and second wave projects and therefore we may end up having 12 different PCEHR implementation approaches. The 12 projects are intended to trial bits of the puzzle before the PCEHR launch in July 2012. There is a good chance that we may end up with 12 silos of Australian e-health records that are suboptimal for data sharing. This is why we have different HL7 implementations in the first place - why can't we learn from the past?

There currently appears to be a lack of uniformity for the standardisation of data transfer within the Australian health community and this must be resolved for the PCEHR (and all other aspects of e-health) to work. Using existing standards has worked in overseas e-health models and they have an

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adaptability to cope with modifications of these over time as the systems demands. They have not impeded the development of effective clinical decision support tools.

Furthermore, we may be creating "Silo Australia" as the current draft PCEHR Concept of Operations does not appear to take into account the EHR approaches of our neighbouring countries and major business and trade partners.

Recommendation: That the next version of the PCEHR Concept of Operations contain consideration of the current EHR approaches in neighbouring countries and Australia's major business and trade partners. That the next version of the PCEHR Concept of Operations outline an approach to ensure that the 12 first and second wave projects are able to seamlessly interoperate and share data.

More questions regarding implementation are:

- What System Design methodology will be used?
- What system implementation strategy and therefore which tools will be used?
- How will maintenance of the software be managed?
- Who will do the maintenance?
- Who will be able to lodge change requests?
- What mechanism will be created to enable and manage change processes?

There are two models that could be used: a closed proprietary model where maintenance and change requests are kept secret or an open model where the change processes are managed on a public information board that everyone can see.

Software maintenance is an issue that would need to be dealt with at a number of levels: policy/strategy, project management (involving systems procurement) and at the operational level, where ultimately all ongoing maintenance contracts with PCEHR systems or outsourcing vendors would need to be managed.

Some College members have first hand experiences with the open model³⁴ and their evidence would suggest that this model has many positive advantages over a proprietary approach. These College members would definitely favour an open source licensing and project management approach to the PCEHR.

Some College members believe that the PCEHR implementation approach needs to be underpinned by at least the following:

1. A multi-layered governance model - this is a highly complex project which requires a well-defined governance structure that embodies a high level of transparency and accountability and which allows engagement of the critically necessary stakeholder communities. Whereas this should ultimately conform to a conventional pyramidal structure, with clear lines of authority and reporting, there is also a need to specifically address design, implementation, operational governance and quality assurance / evaluation requirements within this overall structure, which will enable specific management issues to be optimally addressed. These specific governance arms would be accountable to the strategic and overall project management at the top of the pyramid. For example, the PCEHR Design governance arm of the structure would need to preside over all technical aspects of the design process - including design methodology, technical architectures, etc, whereas the PCEHR Implementation governance would include responsibility for the implementation planning, implementation methodology, project management and delivery, systems procurement, systems integration etc. Within these governance arms would be technical / advisory groups and management groups with clear roles and responsibilities, lines of authority / reporting and collaboration both within and between governance groups. Management of change requests and risk management would need to be optimally addressed within the

³⁴ As employed by the OpenMRS system (www.OpenMRS.org/help/developers) or HL7 International (www.wiki.HL7.org)

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appropriate governance arm in the first instance with a clear escalation process to ensure change requests and risks are appropriately assessed and addressed efficiently and at the appropriate level. Similarly, a dispute resolution process needs to be fully articulated to ensure clarity of how disputes are resolved within the governance structure.

2. Implementation methodology dealing with the full specification of deliverables, deliverable entry and exit acceptance criteria, testing - unit, systems, integration and user acceptance testing (including functional, process / workflow, systems performance, parallel and load testing), implementation standards, systems conversion / production handover,
3. Project management, including detailed planning - development of a detailed project planning documentation covering the overall project, separate project stages and all sub-projects, resourcing, scheduling / timeframes, budget management, project management deliverables, project standards - covering systems / software environment management, systems security, access, data backup, retrieval, archival etc) , project reporting, risk management, project staging and management of many sub-projects, vendor contract management, etc.
4. Quality management - planning, resourcing, preparation, review and acceptance of deliverables, etc.
5. Communication and change management - including planning, communication of project status, information management, consultation, training / education, etc.
6. Process / Workflow planning, consultation and redesign, and implementation
7. Systems Integration -detailed planning, technical design (in conjunction with the Design governance group), standards compliance, testing and implementation
8. Systems Procurement - specification, tendering, evaluation, contract negotiation and selection of system vendors etc (note - this would at least address the issue regarding the development of clinical feeder systems and systems interfaces required between provider systems and the PCEHR systems)
9. Production and Support - in conjunction with the Operational Governance arm - planning, resourcing, post "go-live" support and maintenance, issue management / escalation, etc.

Recommendation: That the next version of the PCEHR Concept of Operations contain more details on guidelines for the recommended management approach for implementation, changes and updates.

Open Source

Some College members also have firsthand experience with the open source EHR software. Their evidence suggests that this approach has many advantages over proprietary software.

An open source EHR software approach could be done by the Commonwealth funding a range of corporations to make contributions to different aspects of the system. Subsequently they could then fund a group to sustain the Open Source effort. Then interested users could make additions in areas where they have most interest.

The benefits of leveraging an open source implementation model as outlined above certainly sounds like a logical move, however it will need to be checked if currently available open source systems meet the requirement of the Australian health system. It is believed that this will be the case, but needs to be verified.

Recommendation: That the next version of the PCEHR Concept of Operations contain some consideration of an open source vs a proprietary software approach.

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Architecture

Some College members would favour an architecture that was more orientated on the indexing of data in its locations than the uploading of data into a central repository. The indexing strategy can be brought on line more quickly, has lower overheads at the central storage location, has lower engineering and design demands, can be more easily brought to a demonstration state and can be expanded more readily. This is not to argue that no data should be centrally located, for example, life critical information might be stored centrally in case the real storage location is down.

Recommendation: That the next version of the PCEHR Concept of Operations contain some consideration of centralise vs decentralised EHR implementation architectures.

e-Health Workforce Limitations

The current draft Concept of Operations document does not appear to consider the shortages of all types of e-Health implementation skills in Australia, which may well be the limiting factor. The College believes that we need to recruit people into the EHR development space, as there is a great shortage of interested talent.³⁵

The current workforce limitations are a major impediment to the success of the PCEHR or any national e-health project and has been a significant factor in many of the failures.

In Australia, we have very few "clinical informaticians" and these need to be involved at the initial phase of implementation. The involvement of the College as the key accredited professional health informatics organisation in Australia is essential. There remains strong resistance to and significant lack of understanding of the benefits of health IT. Several studies have shown that specialised care delivery has a main focus on IT as securing reimbursement benefits rather than patient care. In primary care extensive use of IT has not been documented as improving care delivery within this country.^{36 37}

A number of universities are embedding e-health into their clinical degrees, but these changes will only influence doctors in training and have long lead times.

Recommendation: That the next version of the PCEHR Concept of Operations contain some consideration of the e-Health Workforce limitations. The College offers to actively contribute to these considerations.

Governance

There are probably a number of things that need to be clarified regarding the PCEHR governance:

- Who ultimately owns the data stored in the PCEHR?
- Who is responsible for maintaining and adding information to the PCEHR?
- Who will be the governing body in the longer term to ensure that the information stored and maintained in the PCEHR is of an appropriate standard?
- What auditing would be performed?

The plan seems to be to create all the layers of governance needed after the PCEHR system is designed and signed off. The framework is scheduled for development during the last quarter of 2011.

³⁵ One commentator suggested that an Open Source project has a real chance of doing this especially if it is sponsored by the Government.

³⁶ Hannan TJ. Physicians need to understand the importance of information technology in the 21st century. Intern Med J. 2009 Oct;39(10):633-5

³⁷ Hannan T., MJA 2011; 194 (4): 211-212

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This is after the legislation is introduced to parliament in October 2011. Also, it appears that the Australian, Territorial and State laws that require harmonisation will not be complete by July 2012. Organisational governance (quality, registration, etc.) is being trialled by the Wave sites. A project governance framework for the entire national system is planned to be completed in only 3 months, however we do not believe the health authorities understand the complexity of the task.

A governance framework should guide the PCEHR design, however the current governance approach looks a bit like an afterthought.

Recommendation: That the next version of the PCEHR Concept of Operations contain a clear governance approach and timetable.

Benefits and Sustainability

The benefits of the PCEHR will be greatly diminished if there is not large take up. There will not be sufficient, comprehensive data to make it worthwhile. "Opt out" rather than "opt in" will help with this process. It is likely to cause more pain in the short term, however benefits will be realised in the longer term. It is not a case as to whether we should have a PCEHR; rather how it is best built, implemented and maintained in the longer term.

We must pilot locally, get the basics rights, then upscale using an "opt in" system to ensure we reach critical mass. Once this has been achieved there will be many other issues to deal with, however to move to a PCEHR for the majority of Australians, will be a monumental achievement in itself. Politically it is also important to get some runs on the board too. The concern is that if substantial amounts of taxpayer funds are spent with little output, then future funds will go other programs rather than e-Health and it may take a long time for e-Health to get funding again. Therefore, on many levels the PCEHR must work and must be sustainable. Sustainability is often gained by leveraging off bigger systems and processes, such as open source EHRs. This is a good means by which to ensure ongoing sustainably without having to have substantial ongoing expenditure always propping up the process, which is clearly not sustainable.

The current draft Concept of Operations document has not properly considered benefits in any depth or how they may be practically achieved. It would be hoped that the Department of Health and Ageing will conduct a comprehensive and detailed cost-benefits analysis once the full scope of the PCEHR is determined. This analysis should be used in conjunction with completion and review of the detailed planning and specification, including detailed functional and technical specifications. It is noted that the recent review of the NHS EHR implementation³⁸ has highlighted the results of failing to complete the detailed planning and specification prior to implementation of an EHR. The PCEHR needs substantial and critical pieces of work yet to be completed to enable an informed decision making process by the Government on not only whether or not to proceed with the PCEHR as scoped but also whether it is prudent to contemplate or enact any alternative options / approaches if the costs, technical complexity or risks are considered to far outweigh the benefits of the PCEHR as currently scoped. It should be noted that a PCEHR cost benefits analysis should accordingly consider a range of strategic and technical options which need to be considered in terms of their strategic value, ability to satisfy the primary objectives, costs, benefits, etc. as well as an impact assessment for technical, stakeholder, implementation, adoption etc.

The benefits outlined in the current draft Concept of Operations document are mainly centred on access to the PCEHR information, improvements in care delivery and provider productivity and efficiency related benefits. However, realisation of these benefits will be problematic, given the following:

³⁸ www.nao.org.uk/publications/1012/npfit.aspx

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1. The value of the PCEHR in terms of provision of care delivery is highly dependent on the scope, quality, accuracy, comprehensiveness and integrity of the data held and the utility of the information within a broad range of clinical scenarios / patient settings.
2. The comprehensiveness of the data held in the PCEHR cannot be guaranteed (due to the "opt out" option afforded to patients) and the broad summary data intended to be drawn on to populate the PCEHR, there is questionable value to clinicians as opposed to detailed medical records that clinicians already hold and rely on for care delivery.
3. From a medico-legal perspective, the liability of providers that make clinical decisions based on data held in the PCEHR (compared with their own comprehensive medical records) and also for the providers of information that will populate the PCEHR is uncertain across a range of scenarios, eg if there was critical information missing, wrong information or inaccurate information stored in a PCEHR record that the provider was unaware of and the provider made clinical decisions on care delivery to the patient based on exactly what information was held in the PCEHR, and this resulted in a patient adverse event. The Department will need to seek legal advice on medico-legal liability for the providers and users of the information, once the final scope and detailed specification of the PCEHR has been completed.
4. There appears to be no consideration of the impact of the PCEHR on clinical providers in their provision of care in a time-constrained, fee for service patient consultation setting - in particular given the requirements of providers to populate and review PCEHR data in a patient consultation as envisaged in the draft Concept of Operations document - this is a major assumption that would need to be properly tested (investigated fully through broad consultation with all stakeholder provider groups) as there is no analysis of the willingness of providers to do this nor any mention of any financial compensation for the additional time required of providers to do this.
5. There are many references in the literature that substantiate the significant benefits of provider based EMR's in terms of patient care and safety when implemented in conjunction with electronic clinical decision support. The PCEHR, as currently scoped is a summary based record (as opposed to a comprehensive provider based EMR) and there has been no reference to the implementation of clinical decision support as part of this project. Currently, there is no reference in the literature to any EHR implementations that have delivered any quantifiable patient care delivery and safety benefits.
6. The quantification of the benefits identified in the CONCEPT OF OPERATIONS will be difficult. Achievement of the benefits is predicated on provider care delivery process changes. It would be recommended that a comprehensive benefits assessment (as part of the proposed cost-benefits analysis - see above) be conducted to identify exactly what stakeholder and provider operational changes / workflow changes need to be made to realise the productivity, efficiency and care delivery benefits proposed and to complete the necessary planning and costing of this for due consideration .
7. Timely access to clinical information across the full range of clinical settings is an important benefit for time-starved clinical providers; however, there is currently no detailed technical architecture of the PCEHR. It is not clear how PCEHR longitudinal data will be sorted, archived and accessed efficiently over by providers over time - particularly for chronically ill patients with complex conditions, multiple morbidities, numerous treatments, interventions etc and hence a large amount of data will potentially be stored " over time - fast, efficient access, navigation and presentation of the most clinically relevant and important information is critical in a patient consultation setting
8. Patient benefits do not appear to include the assurance of privacy, security and confidentiality of information held within the PCEHR over time, however these are benefits that should be properly evaluated. The PCEHR project must include systems and processes to ensure that all access to, manipulation, processing and use of information held within the PCEHR systems is appropriately authorised and fully monitored and any breach or unauthorised access, manipulation, dele-

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tion, merging, copying / replication, transmission or encryption of PCEHR information must be detectable and the source identifiable for prosecution or remedial action. Most importantly, in the event of a breach, there needs to be appropriate action taken to maintain patient confidence in the PCEHR system through formal commitment to make any reasonable operational changes to PCEHR systems promptly and effectively to mitigate or avoid any further breaches of the same type. The benefits of privacy, security and confidentiality of PCEHR information to the patient should be properly evaluated over time. This should consider a range of metrics that evaluate the effectiveness and efficiency of the detection, remedial action and notification processes, such as incidence of breaches, severity / type of breaches, number of successful prosecutions / enactment of remedial action, number of unresolved / outstanding breaches, number of notification of breaches, amount of compensation paid to patients, costed amount of actions taken to improve / rectify deficiencies in PCEHR handling of privacy, security and confidentiality of data accessed or stored in the PCEHR systems etc. Data concerning breaches should be made publicly available. In addition, all patients impacted by a specific breach should be properly notified with appropriate details concerning the nature of and action taken to remedy / rectify the breach.

9. The benefits realisation and flow will be heavily dependent on:
 - (i) the timeframe for delivery of the scoped functionality. The roll-out of the PCEHR system will take many years to be fully functional with the richness of data intended (at least 2020, according to Paul Madden, DOHA CIO - refer to Australian IT Section - 24/5/2011). Given that there is currently no detail regarding the functional specification of the PCEHR, it is currently unclear what level of functionality is required (or should) be delivered and in what (realistic) timeframe this can and should be delivered to provide an acceptable positive impact on adoption by patients and providers
 - (ii) the adoption rate of the PCEHR system by patients and providers will impact on the realisation of benefits and the quantum of benefits over time - this needs to be properly modelled as part of the cost-benefits analysis (referred to above).
 - (iii) many of the required clinical feeder systems (that are referred to in the current Concept of Operations document to be connected to the PCEHR systems) do not currently exist or will require substantial modification to enable them to be interfaced to the PCEHR systems. This will require a substantial number of sub-projects that are critical to the delivery of a fully functional PCEHR to be delivered as part of the overall project. In addition, this does not appear to be costed and will need to be incorporated into the detailed planning and finalisation of scope yet to be completed.

To inform the understanding of the PCEHR benefits and sustainability, DoHA should release any cost/benefits studies for the PCEHR that were used to develop the \$476m investment program.

It is also noted that earlier business cases developed by NEHTA had a heavy dependence (over 50% of total) for benefits on Clinical Decision Support. However, this functionality is specifically excluded in the current draft Concept of Operations document.³⁹

Recommendation: That the next version of the PCEHR Concept of Operations contain an analysis of the PCEHR business case and a detailed description of its benefits to all stakeholders.

Future Technologies

The current technology buzz includes the rapid proliferation of tablet computers amongst clinicians⁴⁰ and looking at how to move data into "the cloud" which will significantly influence e-health projects.

³⁹ Concept of Operations section 2.8.1

⁴⁰ See www.informationweek.com/news/healthcare/EMR/228800929

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Additionally, many providers in the health system will have resources that will be, in effect, cloud-based. As a hospital or GP, how you choose to get your services provided means that your information will be stored in a way that can be accessed by other providers - "the cloud" is seen by many as the solution to these requirements. The current draft Concept of Operations document is silent on the effect of new technologies and the possibility to leverage them.

Recommendation: That the next versions of the PCEHR Concept of Operations include a section on how the PCEHR will compete with and leverage new technologies.

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References

See the footnotes on each page.