Australian Federation of AIDS Organisations (AFAO)

Submission to the NEHTA re Draft Concept of Operations - Relating to the introduction of the personally controlled electronic health record (PCEHR) system

31 May 2011

About AFAO

The Australian Federation of AIDS Organisations (AFAO) is the national federation for the HIV community response. AFAO's members are the AIDS Councils in each state and territory; the National Association of People Living with HIV/AIDS (NAPWA); the Australian Injecting and Illicit Drug Users League (AIVL); the Anwernekenhe Aboriginal and Torres Strait Islander HIV/AIDS Alliance (ANA); and Scarlet Alliance, Australian Sex Workers Association. AFAO advocates for its member organisations, promotes medical and social research into HIV and its effects, develops and formulates policy on HIV issues, and provides HIV policy advice to Commonwealth, state and territory governments.

Our perspective on this Inquiry

AFAO is pleased to provide comments on NEHTA's "Draft Concept of Operations: Relating to the introduction of the personally controlled electronic health record (PCEHR) system" (Draft Concept of Operations). The advent of a comprehensive e-health system promises great benefits for individuals and communities affected by HIV, given that people living with HIV (PLHIV) who have complex health conditions are frequent users of the health system, often managing a range of medical conditions.

The Draft Concept of Operations provides important detail about how individuals will control access to their PCEHR. It raises further issues regarding access, however, including how operational and organisational structures may unintentionally limit individuals' control of their own health records. This is described below under 'Individual control'. Another key issue raised is the need for the development of clear information resources which outline how the PCEHR will work, accompanied by adequate funding for community-based organisations to help provide this information to their communities.

Individual control

AFAO welcomes the various access controls that have been proposed for the PCEHR system. It is crucial for the PCEHR system to allow individuals to choose who sees what information. However, we have concerns about the extent to which individuals will actually be able to control which healthcare professionals can access their PCEHR, due to decisions taken by government and healthcare providers about the structure of the Healthcare Provider Organisation network.

As we understand it, different approaches are being taken around Australia regarding the size of the entity to be designated as a Healthcare Provider Organisation. In South Australia, for example, we understand that the entire state health department may be deemed the Healthcare Provider Organisation, while elsewhere it may be a specialist unit of a local hospital.

The designation of a whole state/territory health department as the Healthcare Provider Organisation may mean that healthcare professionals across that department have access to an individual's PCEHR despite the fact that they may not have a clinical relationship with that individual. This may not conform with consumers' expectations, thus potentially undermining consumers' trust in the PCEHR.

Consideration should be given to designing the access control so that individuals are able to select whether they would like only their treating HIV specialist, for example, to see the their PCEHR, as opposed to a variety of workers across the state health department.

In the absence of the individual being able to specify a particular healthcare professional within a Healthcare Provider Organisation, individuals need to be educated about varying structures of Healthcare Provider Organisations around the country. Specifically, they should be encouraged to ask questions of their healthcare professional about who will be able to access their PCEHR if they agree to upload any documents from a consultation to their PCEHR. AFAO believes that consumer education and empowerment is essential to the successful functioning of the PCEHR and further comments are provided below under 'Adequate resourcing to facilitate consumer confidence and use of PCEHR'.

According to the Draft Concept of Operations, all documents posted to an individual's PCEHR by the Healthcare Provider Organisation will have the level of access control that that organisation has been designated by the individual. Therefore, if a trusted specialist has been designated general access as the individual is keen for them to have a full-understanding of their health, then any information they post will, by default, be designated general access. Under the current framework, if the individual wants that information to be available only to other trusted healthcare providers, they must post-hoc/retrospectively use the internet, or contact the phone-service, to designate the information 'limited access'. This places the onus on the consumer to ensure potentially sensitive health information is not inappropriately shared. A straight-forward way around this, balancing the need for individuals to exercise control over their own information while at the same time not overburdening them, would be to create a mechanism where any document generated by a trusted healthcare professional would be designated 'limited access' as a default, after initial set-up with the individual's consent. Providing such a design-feature would help consumers considerably in managing the complexities of the new PCEHR system.

Governance

Governance arrangements for the PCEHR must ensure the creation of a national, independent, well-resourced regulator. Robust governance arrangements are essential to ensure consumer confidence in the system, and thus uptake of the PCEHR.

1) Governance arrangements must be established prior to commencement of PCEHR

AFAO is very concerned that NEHTA and DOHA have not yet proposed any comprehensive governance model 12 months from the start of operation of the PCEHR. We note that the Draft Concept of Operation states[1]:

> The program will transition to a longer-term operational governance model once the PCEHR System has been designed and as it becomes operational.

[1] NEHTA (2011). *Draft Concept of Operations: Relating to the introduction of the personally controlled electronic health record (PCEHR) system*. Australian Government, Canberra, 85

This is simply inadequate; a governance framework must be addressed as matter of urgency. There must be adequate time for community discussion and input into any governance proposals, with a view to a governance framework being determined months in advance of the PCEHR becoming operational.

The absence of any comprehensive governance framework, including complaints processes, will likely deter some individuals with privacy concerns from signing up to the PCEHR. The existence of a governance framework will be to building community confidence in the e-health system.

2) Governance arrangements must be adequately resourced

Not only must the governance framework be clearly established prior to the commencement of PCEHR, it must be adequately funded. We are aware that when the Federal Privacy Commissioner was given jurisdiction over private sector organisations in 2001, there was no proportionate increase in funding. This led to unacceptably long delays, of over a year in many instances, in complaints investigation. The volume of complaints related to the PCEHR could be large, especially as many of those to first register and use a PCEHR are likely to be individuals who have complex health conditions, such as people living with HIV and co-morbidities who are frequent users of the health system. As well, teething-problems that are usually associated with any new enterprise are likely to generate complaints. The proposed regulator must have sufficient resourcing to ensure timely investigation and resolution of complaints.

3) Key aspects of Governance arrangements

The governance framework must include:

- establishment of an independent regulator who is charged with handling complaints about the operation of the PCEHR. The regulator should not be the PCEHR System Operator.
- clear time-frames, within which
    - consumers will receive a response to an enquiry from the PECHR System Operator; and
    - consumers will receive a response to their complaint, both from the body to whom they are complaining initially/the respondent, and if that is unsatisfactory, from the regulating authority who is then responsible for investigation of their complaint.

  30 days should be the maximum time for response to a consumer inquiry/complaint.
- an informal complaints model, under which the Regulator can quickly compel the respondent to take any corrective action and/or apply penalties.
- a range of penalties. It is important that the Regulator have a range of penalties available, in order to be able to address breaches of PCEHR regulations and rules. An appropriate penalty from that range would depend on whether the respondent's breach was the result of a

minor oversight affecting a single individual, or a result of gross negligence affecting a whole class of people.

Audit

It appears that provisions for audit, as outlined in point 5.6, are quite comprehensive. [2] However we have concerns regarding constraints on provision of information regarding who has accessed their PCEHR. We note that:

> If the individual or healthcare provider wishes to know the detail of what was accessed and by whom, they will need to formally request this information from the PCEHR System operator.

In the Draft Concept of Operations there is no explanation of why an individual may not know the details of what was accessed unless a formal request is made. In the absence of a rationale, AFAO believes that the audit system should operate so that individuals have more, rather than less, information about how their own PCEHR is being used. Further, the Draft Concept of Operation does not explain on what basis the PCEHR System operator would make a decision about whether to provide information. Without any indication of how such a decision would be made, the presumption should be in favour of providing individuals with access to their own information.

Without knowledge of what information has been accessed, it will be difficult, for example, for an individual to determine whether they believe there has been inappropriate access to their PCEHR, and thus whether it is appropriate for them to make a complaint. This example illustrates the crucial nexus between the proposed audit framework, and the yet to be identified governance framework. It is thus difficult to provide adequate feedback regarding the audit proposal on the basis of the information provided to date.

Adequate resourcing to facilitate consumer confidence and use of PCEHR

Obtaining informed consent from patients to participate in the PCEHR system is both an ethical imperative and a practical necessity, crucial to establishing trust among consumers of the PCEHR system. As the PCEHR will be a new interface for consumers, it is essential that adequate funding is provided so that the system can be properly explained to individuals, and so that ongoing support and advice to can be provided to consumers. This is essential in order that ongoing informed consent for engagement with PCEHR can be obtained by health care providers.

Key measures to help consumers understand the PCEHR include:

1) E-health guidance and tools

AFAO supports the general approach foreshadowed for the communication and engagement

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[2] NEHTA (2011). *Draft Concept of Operations: Relating to the introduction of the personally controlled electronic health record (PCEHR) system*. Australian Government, Canberra, 60

strategy to target different audiences. We note the following reference to the proposed PCEHR communication and engagement strategy:[3]:

> The communication and engagement approach will be tailored to different groups of stakeholders, including:
> - Individuals and their representatives (e.g. parents/guardians and
> - carers)
> - Healthcare providers
> - ICT industry
> - Government
> - Media

While individuals and their representatives are listed as key stakeholders, we believe that an array of community based-organisations, including AFAO and its members, should also be targeted as key stakeholders. Engaging with and providing information to community-based organisations, so they can in turn explain the PCEHR to their constituents, is essential to ensuring uptake of the PCEHR.

To help explain the working of the e-health system including the PCEHR, relevant government bodies must provide educational materials that clearly and precisely explain the workings of the e-health system. A variety of media should be considered, including brochures, short video explanations, an enquiry phone-line and public outreach through community meetings and discussions. It is crucial to create targeted materials and tools for individuals/consumers with low English and electronic-literacy, people with cognitive disability, people on low-incomes and people from culturally and linguistically diverse backgrounds.

2) Community organisations educating their own communities

AFAO agrees that "an effective communication and engagement strategy will be critical to ensure take-up of the PCEHR System"[4] , yet the Draft Concept of Operations does not outline what such a strategy should include. We believe that the communication and engagement strategy must identify consumer and community-based organisations as crucial agents for facilitating community engagement, who must therefore be adequately resourced to communicate with their constituencies about the operation of the new PCEHR system. Community-based organisations are in a strategic position, as credible and thus trusted organisations, to provide education to their own communities including guidance about the PCEHR system, addressing any community concerns about e-health, including privacy and government control of their personal information.

As stated above, we understand that different places are taking varying approaches as to what will constitute a Healthcare Provider Organisation. These complex circumstances require clear explanation so that consumers can understand and confidently manage their PCEHR. Community

[3] NEHTA (2011). *Draft Concept of Operations: Relating to the introduction of the personally controlled electronic health record (PCEHR) system*. Australian Government, Canberra, 92

[4] NEHTA (2011). *Draft Concept of Operations: Relating to the introduction of the personally controlled electronic health record (PCEHR) system*. Australian Government, Canberra, 92

based organisations, such as AFAO member organisations, may be well placed to explain these more convoluted aspects of the PCEHR system.

3) Supporting healthcare providers to explain the e-health system

It is reasonable to assume that healthcare providers will be expected to try to persuade their patients to opt-in to the new e-health system. As part of this, they will need to address any privacy concerns regarding the e-health system, including explaining the role of the PCEHR. Healthcare providers will have a particular responsibility to explain the initiative very carefully to patients who are shocked by a diagnosis, people who are mentally ill, people with dementia, and people with an acquired brain injury or any condition affecting cognition or intellectual capacity, in order to obtain informed consent to opt in to the system.

The healthcare provider must have time and resources to assist in explaining e-health in clear language; doing so will pose challenges in a hurried healthcare context where, for example, a GP may be giving an HIV diagnosis, advising of treatment options and support services and explaining HIV surveillance privacy protections.

Research

We understand that use of individuals' health information from the PCEHR system for any secondary purpose, including research, was initially ruled out. However, we believe that some clinical and consumer groups are now advocating for use of the PCEHR information for research purposes. We believe that in order for this to occur, individuals must provide informed consent. Consenting to use of health information for research should be completely separate from consent that an individual provides to participate in the PCEHR system.

Medicare and PBS information

Under the current framework, Medicare and PBS data will be included in individuals' PCEHR – an opt-out system. Due to the potentially sensitive nature of some data, such as the prescribing of HIV anti-retroviral medications, we believe that the Medicare and PBS should only be included in an individuals' PCEHR if they provide informed consent for this – an opt-in system.

Conclusion

AFAO welcomes the advances that have been made with the PCEHR proposals as we believe that the system will provide benefits for people living with HIV, especially those managing multiple comorbidities. We believe that the varying access controls are an important element in consumer empowerment. Given this variety and inherent complexity we are concerned to ensure that individuals can engage with it confidently, and so call for substantial funding to provide for outreach and education, in particular to community based organisations. We also believe that then long-term governance arrangements must be attended to immediately so that individuals can have confidence in the system from day one, and therefore can be confident to sign up to it.