



**Submission to the
Review of the Personally Controlled Electronic Health Record**

November 2013

Submission to the Review of the Personally Controlled Electronic Health Record

November 2013

Introduction

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide a submission to the Review of the Personally Controlled Electronic Health Record (*the Review*).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF welcomes the review into the Personally Controlled Electronic Health Records (PCEHR) System. CHF has undertaken extensive work on eHealth, particularly in relation to the PCEHR. Our submission draws on consultations with our membership, which includes organisations advocating for disease specific groups and networks, state and territory peak consumer organisations and individual consumers. CHF's submission also draws on consultations undertaken through our *Facilitating Consumer Input on the PCEHR Project*, as well as previous submissions to consultations relating to the PCEHR. CHF also conducted an eHealth consultation in Feb 2012 as part of the Community Quality Use of Medicines and Medical Tests (CQUM/T) Project.

CHF's response focuses on the following areas for the purpose of the Review:

- CHF's consultations with key stakeholders during the development phase of the PCEHR;
- Barriers to increasing usage in clinical settings;
- Standards for terminology, language and technology;
- Key patient usability issues; and
- Improvements to accelerate adoption of the platform.

The PCEHR and other eHealth initiatives can provide important mechanisms to improve the safety, efficiency and effectiveness of healthcare, as well as providing a way for healthcare consumers to manage their own health. The 'personally controlled' aspect of the eHealth record is what makes it such a powerful consumer resource. It engenders consumer confidence and this is reflected in the strong consumer interest and registration for the record, which stands at more than 900,000 as on September 2013.¹

The design and implementation of the PCEHR system is only the first step in delivering comprehensive eHealth services for consumers that will empower them to manage their own health. While these systems will also enable the transfer of information between practitioners in a more efficient and effective way, from a consumer perspective an important mechanism that they provide is for consumers to convey information regarding their healthcare to health professionals.

¹ 908,134 consumers registered as on 22nd September 2013. Source: NeHTA Annual Report 2013

eHealth creates opportunities for more accurate and instantly available patient data. This is a development which has the potential to empower patients and improve individual health outcomes. There is an increasing body of evidence which shows that patients who feel well-informed and able to participate in treatment decision-making are more likely to experience favourable outcomes.

CHF research supports the position that improved communication between clinicians and consumers overall contributes to both increased adherence to treatment regimes,² improved long-term health outcomes,³ increased patient satisfaction, faster recovery, reduced emotional distress, a lower level of pain relief used and in some cases a reduced length of stay in hospital.⁴ The PCEHR is a vital tool in enabling this essential clinician consumer communication, and ensuring overall better health outcomes.

Consumers value the PCEHR and are supportive of its ongoing development. However, keeping in mind the current challenges around implementation, there are areas that will need a stronger emphasis and focus to ensure ongoing consumer confidence and trust in the eHealth system. It is vital that the PCEHR is a functional system that meets the needs of consumers.

Key concerns for CHF include consumer control, oversight and the importance of functionality in the rollout of the PCEHR system. CHF's submission also calls for greater accountability and independence in the long-term governance arrangements, reconsideration of the implementation model and above all consumer control.

Consumers have told CHF that they support the PCEHR system and have highlighted the importance of access, privacy, security and governance, including:

- **The importance of consumer participation in the governance of the PCEHR system;**
- **The importance of transparency and accountability in the operation of the PCEHR system;**
- **The need to engender robust consumer access controls; and**
- **The importance of consumer ownership of the PCEHR system.**

2 Bull, S.A., Hu, X.H. and Hunkeler, E.M. (2002) 'Discontinuation of Use and Switching of Antidepressants: Influence of Patient-Physician Communication.' *Journal of the American Medical Association*. 288: 1403-1409.

3 Stewart, M.A. (1995) 'Effective Physician-Patient Communication and Health Outcomes: A Review.' *Canadian Medical Association Journal*. 15: 1423-1433.

4 Egbert, L.D., Battit, G.E., Welch, C.E. and Bartlett, M.K. (1964) 'Reduction of Postoperative Pain by Encouragement and Instruction of Patients: A Study of Doctor-Patient Rapport.' *New England Journal of Medicine*. 270: 825-827; Hall, J.A. and Dornan, M.C. (1988) 'What Patients Like About Their Medical Care and How Often They Are Asked: A Meta-Analysis of the Satisfaction Literature.' *Social Science in Medicine*. 27(9): 935-939; Roter, D.L. and Hall, J.A. (2006) *Doctors Talking to Patients/Patients Talking to Doctors: Improving Communication in Medical Visits*. 2nd Edition. Westport: Praeger Publishing.

Recommendations

- 1. Adoption of an ‘opt-out’ model in light of the overwhelming evidence and in the interests of genuine consumer control of their health information. Consumer access and control would remain fundamental to the acceptance of any ‘opt-out’ model.**
- 2. Move to an independent governance arrangement that includes consumers. Specifically:**
 - a. the governance arrangements to be reviewed with a view to appointing an independent PCEHR System Operator; and**
 - b. the governance arrangements include an Independent Advisory Committee that includes strong consumer representation.**
- 3. CHF recommends the immediate resolution of current barriers that prevent the adoption of additional functionality in particular the incorporation of pathology results and diagnostic imaging results onto the PCEHR.**
- 4. The ‘Personally Controlled’ aspect of the eHealth record to remain central to any development and implementation of the PCEHR.**
- 5. CHF recommends the strengthening of access controls for consumers to moderate access to their PCEHR. CHF considers this measure essential to consumer confidence and participation in the PCEHR system and recommends further consultation on this issue.**
- 6. Continuation of provisions that allow access controls to be overridden in situations where the individual requires emergency care. However, this should only occur in situations where the individual is not capable of providing or communicating consent.**
- 7. A revision of the PCEHR Change and Adoption Strategy to include improved functionality of the PCEHR system and initiatives aimed at engaging consumers and clinicians in its uptake and effective use.**

Consultation with Consumers

CHF and its members have a keen interest in the successful implementation of a personally controlled electronic health record. We have provided submissions and comment to numerous consultation processes since the announcement of the PCEHR, including submissions on the PCEHR system legislation.

CHF's submissions draw on broader consultations with our membership, as well as targeted PCEHR consultations undertaken through *our Facilitating Consumer Input on the PCEHR Project*, consumer input on CHF's response to the *Concept of Operations*, and a dedicated consumer forum on legislative issues relating to the PCEHR in 2011.

CHF has also participated in consultation processes with the National eHealth Transition Authority (NEHTA) and the Department of Health (DOH), and has consulted informally with our networks to inform numerous submissions on the PCEHR system. We would be happy to provide details and copies of our submissions on request.

CHF's earlier submissions detail a number of specific concerns about the proposed arrangements for the system, including the removal of the 'no access' feature and the decision that the system will be opt-in, rather than opt-out, as well as issues like personal control of the record, the content of the record and informed consent related to the use of the PCEHR.

Overall, consumers agree that the PCEHR can be a powerful vehicle for empowering consumers to manage their own health. PCEHR that meet the needs of consumers can build consumer confidence and trust in the health system and can empower consumers to be active partners in their health and make informed decisions about their healthcare.

Consumers see that there are significant benefits of the PCEHR and these include the crucial benefit that all of their medical information is available to them and conveniently accessible when and where they need it. In particular, consumers have said that they would welcome the ability to view their test results and read hospital discharge summaries.

Practical accessibility of health information is frequently raised and widely regarded by consumers as essential to successful management of health and improved health literacy. PCEHRs and other electronic identifiers have frequently been cited as enablers of person-centred healthcare. Consumers have expressed an interest to be involved in, and informed of, the development and implementation of PCEHRs.

Patients and potential patients – health consumers – must be informed and engaged as the ultimate users of the PCEHR. They need to understand how it will affect them and how to use it to improve their health outcomes. They need to have confidence that information about their health status is appropriately stored, managed and accessed. Consumers must have control about who accesses their information, when and why this is done. Their needs and experiences must be heard, captured and channelled into a consumer knowledge base that can inform the further development of the PCEHR system. Their representatives on decision-making bodies must be competent, informed, and accountable and supported to add value to these forums on their behalf.

Barriers to increasing usage in clinical settings

As the 'Personally controlled' aspect of the record is the touchstone to its functionality, CHF argues that barriers to usage beyond just clinical settings need to be considered to enable a comprehensive review. Through our extensive consultations with consumers in the development and implementation phases of the PCEHR system, we have identified the following barriers to uptake across the system.

The Opt-In Model

Throughout a range of consultations on the PCEHR, a number of submissions from diverse groups expressed concerns that if the PCEHR operated within an opt-in framework, a large portion of the general public would not have immediate access to the record. As we noted in our earlier submissions and briefings on the subject (**Attachment A**), this would result in a low level of confidence in the system and lack of critical mass to ensure its success.

Considering the current stage of the PCEHR roll-out and the lack of meaningful usage of the record, CHF reiterates its view that the PCEHR system will be more successful if it is to be opt-out, rather than opt-in. Our extensive consultation with consumers, consideration of the positions of other key stakeholder groups and review of international experience support and consolidate this position.

CHF continues to be of the view that an opt-out system, provided that strong consumer control and a robust privacy system are central to the development and use of the PCEHR, would have considerable benefits to the system currently being pursued.

CHF has previously highlighted that there are a range of benefits that are likely to result from the implementation of an opt-out system, as opposed to an opt-in system, including:

- Wider uptake of the system, increasing its value to health professionals and, consequently, their willingness to use the system;
- 'Healthy' consumers who might not have signed up to the PCEHR under an opt-in system will be more likely to have a PCEHR, allowing access to health information which could be of particular value if they experience an illness or injury that necessitates acute or ongoing treatment;
- Vulnerable and disadvantaged consumers will not have to actively opt-in to the system, allowing them to share in the benefits without facing the potential obstacle of signing up; and
- Mechanisms will still be in place to support consumer choice, as opting-out will remain an option for those who do not wish to participate, and other consumer access controls will also be in place.

It has also been CHF's strong view that the benefits of an opt-out system will be far increased if the system is also opt-out for health providers. An opt-out system for consumers will not deliver the same level of value if the system remains opt-in for health professionals. This can be observed through issues with the UK's Summary Care Record, where less than one percent of patients opted out but access of the records by general practitioners was very low.⁵

While consumers are likely to benefit from an opt-out system, rigorous governance, access and privacy protection measures are necessary and absolutely crucial to ensure ongoing consumer participation.

⁵ Greenhalgh, T. et al 2010 Op cit. need to provide the rest of this reference.

Consumers want protection and confidence, comprehensive consumer information to ensure informed participation, and straightforward and easily accessible methods for opting-out should they not wish to participate. An opt-out model is acceptable for consumers only if the personally controlled aspect of the record remains intact.

For consumers to have confidence in the system, and for participation to be informed in the context of an opt-out system, there will need to be:

- Rigorous and accountable governance structures in place to oversee the system;
- Absolute adherence to the ‘personally controlled’ aspect of the record;
- Significant collective effort to ensure that informed consent has been given, particularly once consumers have had an initial interaction with the system; and
- Detailed, easy-to-understand information about consumer control, including how to opt-out (which must be straightforward) and how to control which information is uploaded to the record and who can see that information.

CHF appreciates the challenges that would be presented by a change to an opt-out model at this stage. However, CHF considers that this change in direction does give the PCEHR system a much greater chance of success.

Recommendation

- 1. CHF suggests the adoption of an ‘opt-out’ model in light of the overwhelming evidence and in the interests of genuine consumer control of their health information. Consumer access and control would remain fundamental to the acceptance of any ‘opt-out’ model.**

Governance of the PCEHR system

Throughout CHF’s consultations on the PCEHR, consumers have emphasised the importance of appropriate and stable governance of the system. This is essential to ensuring that there is consumer confidence in the system.⁶ Appropriate governance structures and mechanisms will be essential to the successful delivery of the PCEHR.

In CHF’s consultations, the following five principles emerged as essential to guiding oversight of the PCEHR:

- Privacy is a subset of security. The system is not secure if the information cannot be kept confidential;
- If the PCEHR is a consumer-centred system, then providers must be accountable to consumers;
- Governance arrangements should have independence from Government, and ideally there should be an independent System Operator and an Independent Advisory Committee;
- The governance arrangements must be clear to consumers; and
- Consumers must be involved in the governance of the system. Here, consumers drew a distinction between involvement and consultation. In this, consumers believe that they should be active partners in decision making.

⁶ CHF (2011) *National Consumer Personally Controlled Electronic Records (PCEHR) Workshop Report*. CHF: Canberra.

Recommendation

- 2. CHF recommends a move to an independent governance arrangement that includes consumers. Specifically:**
- the governance arrangements to be reviewed with a view to appointing an independent PCEHR System Operator; and**
 - the governance arrangements should include an Independent Advisory Committee that includes strong consumer representation.**

Comments on standards for terminology, language and technology

CHF has participated in numerous consultations around the development of the system, including ongoing consultation on the development and integration of advance care, diagnostic imaging and pathology data onto the record.

Throughout these consultation processes, conducted by NEHTA and the DoH, CHF has observed that the lack of consistent terminology and language is a key issue that limits the progress towards increasing functionality of the system.

CHF recognises that there are some challenges regarding standardised language and terminology in relation to current industry practice regarding pathology and diagnostic imaging reporting. Consumers are concerned however that these issues remain unresolved after many years of discussion.

Consumers question the validity of the argument that no progress can be made until this standardisation occurs. Given the current on-ground reality in which referrers and industry appear able to communicate in a manner that enables appropriate testing to be ordered, and results to be interpreted and reported, workflows under development should be able to reflect current best practice models.

As such, consumers expect that issues around language and terminology should be able to be resolved in order to support the early introduction of new functionality into PCEHR system in relation to pathology and diagnostic imaging results.

Recommendation

- 3. CHF recommends the immediate resolution of current barriers that prevent the adoption of additional functionality in particular the incorporation of pathology and diagnostic imaging results onto the PCEHR.**

Key patient usability issues

As mentioned earlier, consumers have told CHF that they support the PCEHR system and have highlighted the importance of consumer access, privacy and functionality, which are fundamental to the PCEHR.

Personal Control

Consumers consulted by CHF overwhelmingly argued that ‘personal control’ means more than simply having access to their record.⁷ Consumers have told CHF that they want to *actively participate* in the management of their record, rather than passively enable providers to enter information.⁸ As such, personally controlled elements of the PCEHR system that are currently available, such as the ability to withdraw consent for records to be uploaded, to block access to their record and to upload consumer-entered information are fundamental to any system moving forward. Consumers understand the need to maintain the integrity of clinical information but also recognise that other contextual information can be important and relevant.

Consent is at the heart of consumer’s understanding of personal control. Consumers have expressed the importance of being able to choose who can access to their record and the particular records that will be contained in it – CHF sees that this is even more important in an opt-out model. If this model is to be considered, discussions need to be held regarding how informed consent can be gained in a way that is realistic, appropriate and places this authority in the hands of consumers.

The experience of the initial roll-out of the PCEHR demonstrates that the overwhelming majority of consumers give blanket consent at registration for the full range of information to be uploaded and for data to be accessed by all relevant health professionals. Once consumers have provided consent, they do expect information to be uploaded to their record. While there must always be opportunity to withdraw consent, CHF supports the view that once general consent has been provided, clinicians are able to operate under the understanding that clinical documents will be uploaded onto the PCEHR once clinically curated.

In CHF’s consultations, consumer-entered information was also considered to be a vital part of the PCEHR.⁹ For example, consumers who use Point of Care Testing (PoCT) to monitor chronic conditions could benefit from including these readings on their PCEHR and sharing them with health professionals. Although these features are not currently available in the PCEHR, CHF notes that international research suggests interactive technologies for consumers often result in improved uptake. If these features were adopted, clinicians would not be required to review the material and the applications would be located within the consumer portal.

CHF also notes a consumer’s PCEHR is not intended to be a substitute or replacement for good interpersonal communication between a health practitioner and their patient. Information in the PCEHR is to be used as a guide to inform and increase the effectiveness of this communication. This is consistent with the advice on effective communication that the Australian Medical Association (AMA)’s provides to its members in the Guide to Medical Practitioners on the use of the PCEHR.¹⁰

⁷ CHF, Op Cit.

⁸ Ibid.

⁹ Ibid.

¹⁰ The AMA Guide to Medical Practitioners on the use of the PCEHR can be downloaded at <https://ama.com.au/ama-guideusing-pcehr>

Recommendation

4. CHF recommends that the ‘Personally Controlled’ aspect of the eHealth record remain central to any development and implementation of the PCEHR.

Privacy

Ensuring that there is appropriate management of sensitive data is vitally important to the development of any effective system. Consumers expect that information held in a central record will be managed with a high threshold in relation to access. Consumers need to control who is able to access their information and have information about who has accessed their information. This becomes even more important in the case where information is managed by a third party, and will be paramount in any proposed ‘opt-out’ systems of implementation.

A key privacy concern for consumers is the ability to restrict access to the information on their record, including withholding certain pieces of information. Consumers have strongly supported the use of access controls to moderate access to their PCEHR by participating healthcare providers.

However, initial proposals that would have allowed consumers to mark a clinical document as ‘no access’ were abandoned prior to implementation. These measures would have enabled consumers to exercise greater control over sensitive data in their records, such as sexual health and mental health information. Considering the centrality of these access controls to consumer trust, it is disappointing that this change was made without regard to the preferences of consumers.

CHF acknowledges that limiting access is a challenging topic. Concerns have been raised by healthcare providers about the potential consequences of limiting access to clinical information. Consumers have indicated that they may withdraw participation, refuse to grant access or simply withhold information to work around the absence of this feature. They have also argued that health professionals currently do not have access to all of their health information – consumers already withhold information, and accept the associated risks.

CHF notes and supports the AMA’s advice on patient engagement which states that patients may enter information into their PCEHR that is visible only to them, and as such a medical practitioner cannot be expected to know what the patient does not permit them to know.¹¹

During the initial roll out of the PCEHR system there was extensive discussion regarding the privacy issues related to the storing and management of personal health data, but this focus seems to have diminished in the implementation phase of the PCEHR.

The review presents a timely opportunity to ensure that personal information is being held appropriately, and in a manner that is consistent with the Australian Privacy Principles. The possibility of using third party operators elevates the importance of this issue. Consumers expect that no personal information gathered via the PCEHR will be accessed by any third party operators.

Moreover, considering that an opt-out model of implementation might be the most efficient way to facilitate effective use of the record, the focus on consumer privacy will only be more critical.

¹¹ Ibid.

Recommendation:

5. CHF recommends the strengthening of access controls for consumers to moderate access to their PCEHR. CHF considers this measure essential to consumer confidence and participation in the PCEHR system and recommends further consultation on this issue.

CHF also acknowledges health practitioner concerns that patients may hide information that is vital to care in emergency situations, but consumers argue that the current system controls already provides for this eventuality. Consumers consulted by CHF accept that some access controls may be overridden in situations where the individual requires emergency care, however consumers also emphasised that this should only occur in situations where the individual is not capable of providing or communicating consent. Consumers also recognise that in cases where they choose not to share information, the accountability of an eventuality where this may impact on their care lies with them.

Recommendation:

6. CHF supports allowing access controls to be overridden in situations where the individual requires emergency care. However, this should only occur in situations where the individual is not capable of providing or communicating consent.

PCEHR Functionality

At its current stage, the PCEHR provides a limited number of benefits to participants and limited features to assist consumers, including access to clinical documents such as:

- Shared Health Summaries;
- Event Summaries;
- Discharge Summaries; and
- Limited consumer entered information (these are provided through structured documents that will be verified by nominated providers).

This limited functionality of the system has resulted in the struggle to gain the critical mass required to function effectively. The full value of the PCEHR system will only be achieved if there is widespread adoption across the population to ensure that there is sufficient data to make the system a valuable clinical tool to healthcare providers. Some of the biggest potential benefits of the PCEHR are also linked to the ability of the record to prevent duplication of testing and related delays in treatments. The lack of such important functionality continues to limit the clinical relevance and consumer usability of the PCEHR.

Research into the Summary Care Record in the United Kingdom has shown that clinicians are unlikely to look for eHealth records if there is not widespread utilisation of the system because they are unlikely to find them.¹² Experiences of eHealth record systems in the United Kingdom and Germany also suggest that is very difficult to reestablish trust in the system if it lacks initial functionality.¹³

¹² Greenhalgh, T. Stramer, K. Bratan, T. Byrne, E. Russell, J. Potts, H.W.W. (2010) 'Adoption and Non-Adoption of a Shared Electronic Summary Record in England: A Mixed-Method Case Study.' *British Medical Journal*. 340: 3111.

¹³ Tuffs, A. (2010) 'Germany Puts Universal Health eCard on Hold.' *British Medical Journal*. 340: p171

CHF supports efforts to increase the uptake of the PCEHR by both consumers and health practitioners through the development of additional functionality. We are currently actively engaged in supporting the inclusion of additional functions in PCEHRs, particularly in the areas of pathology, diagnostic imaging and advance care planning. CHF calls for a pragmatic and common sense approach to enable the inclusion of this information that has the potential to significantly enhance the health outcomes for users.

Recommendation

7. CHF recommends a revision of the PCEHR Change and Adoption Strategy to include improved functionality of the PCEHR system and initiatives aimed at engaging consumers and clinicians in its uptake and effective use.

Suggested improvements to accelerate adoption of the platform

As detailed through the issues highlighted in previous sections, CHF suggests the following improvements to accelerate the adoption of the PCEHR:

- Improved PCEHR functionality and the inclusion of richer health information, including access to test results, discharge summaries, shared health summaries, medicines lists and advance care plans and directives.
- CHF suggests the reconsideration of an ‘opt-out’ model in light of the overwhelming evidence from other jurisdictions. Consumer access and control is fundamental to the acceptance of any ‘opt-out’ model.
- The provision of information and support for consumers to understand their options for personal control in the PCEHR.
- The timely provision of clinical information, such as tests and diagnostic information,
- The development and implementation of standards, including terminologies, across diagnostic imaging and pathology which are critical to improving the functionality of the PCEHR.
- The inclusion of provisions enabling consumers to mark a clinical document as ‘no access’ in the PCEHR. CHF considers this measure essential to ongoing consumer confidence and participation in the PCEHR system.
- The inclusion of more dynamic avenues for consumer-entered information to be included in the PCEHR as the system evolves.

Conclusion

The Consumers Health Forum welcomes the review into the PCEHR and appreciates the opportunity to provide input to this critical piece of work.

Australia has the opportunity to improve the safety, efficiency and effectiveness of healthcare through the PCEHR. The design and implementation of the system is the first step in delivering comprehensive eHealth services for consumers. CHF believes the continued advocacy for the importance of maintaining the ‘personally controlled’ element of PCEHRs is required as is a strong consumer voice in the ongoing implementation of the PCEHR.

Consumers Health Forum of Australia

Consumers agree that the PCEHR could be a powerful vehicle for empowering consumers to manage their own health. PCEHRs that meet the needs of consumers can build consumer confidence and trust in the health system, and empower consumers to be active partners in their health and make informed decisions about their healthcare. However, as detailed above there remain a number of issues that require further exploration or consideration, particularly to ensure that the system is functional and meets the needs of consumers.

CHF looks forward to providing ongoing input to the Review and await the outcomes of this significant process.



The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

CHF values:

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.

ATTACHMENT A

Benefits of an opt-out PCEHR system

*Briefing prepared for Mr Chris Picton, Senior Adviser
Office of the Hon Nicola Roxon MP, Minister for Health and Ageing*

Presented by CHF in August 2011

Summary

- After extensive consultation with consumers, consideration of the positions of other key stakeholder groups and review of international experience, the Consumers Health Forum of Australia (CHF) has come to the view that the Personally Controlled Electronic Health Records (PCEHR) system will be more successful if it is to be **opt-out**, rather than **opt-in**.
- CHF has previously supported an opt-in system for the PCEHR system, not because this was our preferred model, but because this was the model presented as the only option that was acceptable to Government.
- We consider that the benefits of an opt-out system will outweigh the opposition likely to be voiced by fringe privacy groups.
- It is CHF's strong view that the benefits of an opt-out system will be far increased if the system is also opt-out for health providers.
- While consumers are likely to benefit from an opt-out system, there must be rigorous governance and privacy protection measures in place to ensure consumer protection and confidence, comprehensive consumer information to ensure informed participation, and straightforward and easily accessible methods for opting-out should they not wish to participate.

The international experience

- International experience indicates that an opt-out system is far more likely to be successful than an opt-in system, in terms of uptake by both consumers and clinicians.
- In the establishment of a central eHealth repository in New Zealand (Auckland), very few people (under 100 out of over 1 million) opted-out of the system.
- The Auckland system was designed as opt-out for reasons of equity. Those most likely to benefit from a record were those who were least likely to sign up in an opt-in system. This situation is likely to be similar in Australia, where population groups including older Australians, rural and remote Australians, Aboriginal and Torres Strait Islander people, people with disability, people experiencing significant disadvantage and people from CALD backgrounds would all

experience considerable benefit from the PCEHR system but could also face barriers to signing up.

Issues with an opt-in system

- An opt-in system will require consumers to sign up to participate in the system, which will make it very difficult for the system to attain the critical mass necessary for it to be useful and effective and achieve the benefits possible through widespread adoption.
- The full value of the PCEHR system will only be achieved if there is widespread adoption across the population, to ensure that there is sufficient data to make the system worthwhile to healthcare providers. Greenhalgh et al's (2010) research into the Summary Care Record in the UK found that clinicians were unlikely to look for eHealth records if there is not widespread utilisation of the system, because they are unlikely to find them.¹⁴
- An opt-in system will only be effective if there is population-wide recognition of the benefits, and the understanding of these benefits is sufficient to prompt people to act to opt-in.
- Research outlined in a submission in response to the Draft Concept of Operations indicated that, while consumers are supportive of the concept of the PCEHR, they are unlikely to opt-in. However, consumers who indicated that they would not opt-in were still supportive of an opt-out system, suggesting that the requirement to opt-in would create a barrier for participation even for those who want to have a PCEHR.¹⁵
- In an opt-in system, people without the capacity to sign up (for example, those with dementia or intellectual disability) who do not have carers or representatives who can act for them will not be able to benefit from the PCEHR system, even though the benefits to them would be considerable.

CHF consultation outcomes

- Recent CHF consultations have not addressed the question of opt-in versus opt-out, as the opt-in system was presented as a 'fait accompli'. However, earlier consultations have addressed this issue. For example, at an Electronic Health Records Information Session hosted by the NSW Council of Social Services on 14 April 2005, there was discussion around opt-in/out:

Participants believed people in favour of an 'opt-out' model are generally more informed about what is happening and more actively involved. With

¹⁴ Greenhalgh, T. et al 2010 'Adoption and non-adoption of a shared electronic summary record in England: a mixed-method case study', British Medical Journal 340:c3111.

¹⁵ Lehnbohm, E. 2011 'Comments on the PCEHR system Concept of Operations', online at [http://www.yourhealth.gov.au/internet/yourhealth/blog.nsf/46886EFEAB2C6081CA2578DF0005F21F/\\$FILE/Elin%20Lehnbohm%20submission.pdf](http://www.yourhealth.gov.au/internet/yourhealth/blog.nsf/46886EFEAB2C6081CA2578DF0005F21F/$FILE/Elin%20Lehnbohm%20submission.pdf), accessed 18 August 2011.

an 'opt-in' model, word of mouth would be important, as registrations would increase as people heard about the benefits of the system.¹⁶

Benefits of an opt-out system

Various benefits are likely to result from the implementation of an opt-out system, as opposed to an opt-in system:

- Wider uptake of the system is likely, increasing its value to health professionals and, consequently, their willingness to use the system.
- 'Healthy' consumers who might not have signed up to the PCEHR under an opt-in system will be more likely to have a PCEHR, allowing access to health information which could be of particular value if they experience an illness or injury that necessitates acute or ongoing treatment.
- Disadvantaged groups will not have to actively opt-in to the system, allowing them to share in the benefits without facing the potential obstacle of signing up.
- Mechanisms will still be in place to support consumer choice, as opting-out will remain an option for those who do not wish to participate, and other consumer access controls will also be in place.

Challenges of an opt-out system

- Informed consent for participation remains essential. Even if a PCEHR is established, there must be a mechanism to ensure consumers are aware of the implications of sharing health information before they, and their health professionals, begin to populate their record.
- Consumer information and education around the PCEHR system will become even more important to ensure that their participation in the system is informed. Campaigns to encourage use of the system will be essential, so that consumers recognise the benefits of participation and play an active role in maintaining the record and urging their health professionals to contribute to it.
- Consumers who do not opt-out of the system but do not provide consent for their information to be uploaded will effectively have an 'empty' record. The issues outlined above around clinicians' willingness to seek out an electronic health record could also occur in an opt-out system if there is a large volume of empty records.
- An opt-out system for consumers will not deliver the same level of value if the system remains opt-in for health professionals. Issues with the UK's Summary Care Record, where less than one percent of patients opted out but access to the

¹⁶ CHF 2005 *Electronic Health Records Information Session Hosted by the NSW Council of Social Services*, 14 April 2005, p2, online at <https://www.chf.org.au/pdfs/rep/rep-348-ehr-sydney-session.pdf>.

records by general practitioners was very low for a range of reasons, provide an example of this.¹⁷

- It is late in the implementation process to consider a shift to an opt-out model, given that AHMC has supported an opt-in model and the Concept of Operations and enabling legislation are in the late stages of drafting. (However, it is likely to be far more difficult to implement an opt-out system after the implementation of an opt-in system.)

What will be necessary to protect consumers?

For consumers to have confidence in the system, and for participation to be informed in the context of an opt-out system, there will need to be:

- Rigorous and accountable governance structures in place to oversee the system
- Detailed, easy-to-understand information about consumer control, including how to opt-out (which *must* be straightforward) and how to control which information is uploaded to the record and who can see that information.

Conclusion

- The PCEHR system has the potential to deliver significant benefits in the management of healthcare for Australian consumers.
- CHF has become increasingly concerned that the PCEHR system will not succeed if it remains opt-in. The rationale for selecting an opt-in system remains unclear to us, and appears to be largely political.
- The roll-out of the PCEHR system represents Australia's one opportunity to get this right. We do not want to see the implementation of a system that has limited uptake and consequently fails to deliver the potential benefits for Australians.
- In spite of the challenges that would be presented by a change to an opt-out model at this stage, we consider that this is not an opportunity that can be passed up. If the success of the system is contingent upon its being an opt-out model, then this is the approach that Australia must take.

¹⁷ Greenhalgh, T. et al 2010 Op cit.