National Health Reform

Draft Concept of Operations: Relating to the introduction of a personally controlled electronic health record (PCEHR) system

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An introduction from the Minister for Health and Ageing

Electronic health records will help transform the patient and clinical experience.

I am pleased to present the Australian community with the *Draft Concept of Operations – Relating to the introduction of a PCEHR system*.

The Australian Government is investing almost $467 million over two years to develop the critical national infrastructure for e-health records as a key element of the national health reform agenda. This will give all Australians, from July 2012, the option to sign up for a personally controlled e-health record.

This will enable better access to important health information currently held in dispersed records around the country. It will mean that patients will no longer need to unnecessarily repeat their medical history every time they see a doctor or other health professional.

For the first time, all Australians who choose to participate will be able to see their important health information—when and where they need it. They will be able to share this information with trusted healthcare providers.

The system is being built on the foundations laid by infrastructure such as the National Healthcare Identifier Service that launched in July 2010.

Together with investments in telehealth and the National Broadband Network, e-health records will improve accessibility to health services and patient information which, over time, will significantly enhance health outcomes.

This Concept of Operations is the result of extensive detailed work on the design and operationalelements of the PCEHR system. This document provides a summary of how the PCEHR program will be delivered, including the development of key national infrastructure and connections to systems, such as the 12 lead implementation sites that are being deployed around Australia.

This document has been developed in consultation with consumers, healthcare providers, the ICT industry and government organisations. This Concept of Operations document now allows for input from the broader community to guide the system's design and planning.

I welcome your direct feedback on the PCEHR program so the system we design will best meet the needs of all Australians.

Hon Nicola Roxon MP
Minister for Health and Ageing

Document information

Purpose

The purpose of this draft document is to provide an overview of what the Personally Controlled Electronic Health Record (PCEHR) System is and how it is proposed to work. This document is intended to elicit discussion on the proposed design and to highlight areas of uncertainty where further work is required.

The information in this version of the Concept of Operations has been based on a framework for a national electronic health record system agreed by the Australian Health Ministers Conference in April 2010. It has been further informed by a range of ongoing consultations with stakeholders (see Appendix A) and lessons learned from local and international efforts (see Appendix B).

The Concept of Operations is a living document that will be periodically updated as the design of the PCEHR System progresses. Version 1.0 of the Concept of Operations will set the basis for the construction of the PCEHR System by the national infrastructure partner(s). Version 1.0 will be informed by a public consultation process and further discussion with key stakeholder groups, including individuals, healthcare providers, the information and communication technology (ICT) industry and government. Later versions of the Concept of Operations will also be informed by lessons learned from implementation within lead eHealth sites.

The information in this document will be used to inform ongoing work around governance and policy setting, change and adoption, lead eHealth sites and benefits evaluation. The Department of Health and Ageing (DoHA) will release additional documents covering these topics as the work program progresses.

This version of the Concept of Operations contains a moderate level of detail about the PCEHR System. This is intentional as it provides the reader with a single document that describes the many elements of the PCEHR System in sufficient detail to elicit informed feedback. As the design progresses some of the detail within this document will be moved to other documents.

Intended audience

This document is primarily aimed at readers wishing to understand the PCEHR System in a moderate level of detail. General knowledge about the current Australian eHealth agenda is assumed and the document should be accessible to a wide range of readers including individuals, healthcare providers, ICT industry and other interested parties.

Many parts of this document should be accessible to audiences new to the area of eHealth. Readers interested in more general material should refer to the following websites:

- eHealth and national health reform: www.yourhealth.gov.au

- General information about eHealth and work progress: www.ehealthinfo.gov.au

- Videos explaining the PCEHR System: http://www.youtube.com/watch?v=3IOoUMwSGMI

Additional material can be found at:

- Australian Government Department of Health and Ageing: www.health.gov.au

- NEHTA: www.nehta.gov.au

How to read this document

In order to describe something as significant as the PCEHR System the Concept of Operations is by necessity a large document. Readers may prefer to focus on different sections of the document:

- Readers wishing to get a summary of the PCEHR System should read the overview (Section 1).

- Readers interested in scope and core functionality around participation, information management, privacy and security should read Sections 2, 3, 4 and 5.

- More technical readers should read the section describing each of the PCEHR System components (Section 6).

- Readers interested in operations, implementation and outcomes evaluation should read Sections 7, 8 and 9.

To assist readers with key terms, a glossary is provided in Appendix D.

Throughout the document there are a number of breakout boxes designed to bring certain items to the reader's attention including:

Issue: Green issue boxes are intended to highlight areas that are under development.

Design Note: Blue design note boxes are intended to highlight significant design choices had to be made.

Scope Note: Yellow scope note boxes are used to clarify an area of functionality and indicate if it is likely to be restricted in the first release of the PCEHR System or if the functionality is an option requiring further consultation.

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eHealth Site Note: Lavender scope note boxes are used to highlight items which will be developed in one or more lead eHealth sites. These sites will be early implementers of the capabilities being developed to support the PCEHR System, and will provide practical experience that can guide the broader implementation into the future. The full set of lead eHealth sites are discussed in Section 8.5.

Feedback

Individuals and organisations are encouraged to provide feedback that:

- identifies additional information they would like provided regarding the PCEHR System.

- highlights questions they consider important to the PCEHR planning discussions.

- provides comments, opinions and perspectives on current thinking around the design and planning for the PCEHR System.

- provides comments, opinions and perspectives on the implementation opportunities and challenges.

- identifies other areas that the PCEHR implementation planning should consider.

Direct comment will not be provided on individual or organisation feedback. Rather feedback from multiple engagement activities over coming months will be incorporated into relevant future documents.

How to provide your feedback

An Internet site is available for the community and other key stakeholders to provide their views and feedback. This website will also provide updated PCEHR Program information throughout the community consultation process.

Electronic feedback should be provided at: www.yourhealth.gov.au

Written feedback should be addressed to:

PCEHR Feedback, MDP1005

GPO Box 9848

Canberra, ACT 2606

All feedback should include contact details of the individual and/or organisation providing the comments.

Feedback on the Concept of Operations will be accepted until 31 May 2011.

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1   Overview

eHealth is important to the future of health care in Australia. For individuals and healthcare providers alike, it will enhance the way healthcare is delivered.

eHealth is an integral part of the Australian Government's agenda for Health Reform, an agenda that aims to create a continuously improved healthcare system for the 21st century. A system that is accountable, affordable and sustainable, with safety and quality at its centre.

The Personally Controlled Electronic Health Record (PCEHR) System is the next step in using eHealth to enhance the healthcare system. The PCEHR System enables the secure sharing of health information between an individual's healthcare providers, whilst enabling the individual to control who can access their PCEHR.

The Government has invested $466.7 million in the first release of the PCEHR System. The first release delivers the core functionality required to establish a PCEHR System that can grow over time. The first release will ensure that all individuals seeking care in the Australian healthcare system, who choose to do so, will be able to register online for a PCEHR from July 2012.

The PCEHR System will build on the foundation laid by the introduction of the National Healthcare Identifiers for individuals, healthcare providers and healthcare organisations as well as the National Authentication Service for Health, standard clinical terminologies and methods for communicating health information between healthcare providers such as Discharge Summaries and electronic Referrals.

1.1   The need for a PCEHR System

The implementation of a national PCEHR System addresses a current challenge faced by the Australian health system — the fragmentation of information spread across a vast number of different locations and systems. In many healthcare situations, quick access to key health information about an individual is not always possible. Limited access to health information at the point of care results in:

- A greater risk to patient safety.

- Increased costs of care and time wasted in collecting or finding information.

- Unnecessary or duplicated treatment activities.

- Additional pressure on the health workforce.

- Reduced participation by individuals in their own healthcare information management.

The purpose of the PCEHR System is to address information fragmentation by allowing a person to more easily access their own health information and make their health information securely accessible to different healthcare providers involved in their care. This will result in:

- Improved continuity of care for individuals accessing multiple healthcare providers by enabling key health information to be available where and when it is needed to ensure safe ongoing care.

- Access to consolidated information about an individual's medicines, leading to safer and more effective medication management and reductions in avoidable medication-related adverse events.

- Enabling individuals to participate more actively in their healthcare by improved access to their health information.

- Improved diagnostic and treatment capabilities through enhanced access to health information.

- Improved care coordination for individuals with chronic or complex conditions by enabling the individual's healthcare team to make better-informed decisions at the point of care.

1.2   The PCEHR System

The national PCEHR System aims to place the individual at the centre of their own healthcare by enabling access to important health information when and where it is needed by individuals and their healthcare providers.

Individuals will be able to choose whether or not to have a PCEHR, and if they choose to participate, they will be able to set their own access controls. With the individual's permission, key pieces of health information may be viewed by participating healthcare providers across different locations and healthcare settings[1].

Figure 1: PCEHR System concept

In order to deliver this vision, the PCEHR System will provide the necessary national infrastructure, standards and specifications to enable secure access to an individual's health information drawn from multiple sources. Suppliers of eHealth systems will be able to enhance their products and services to become conformant with the relevant standards and specifications and support healthcare organisations in accessing the PCEHR System.

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[1] An animation outlining the PCEHR System can be found at
http://www.youtube.com/watch?v=3IOoUMwSGMI

Clinical documents[2], such as Shared Health Summaries, Discharge Summaries, Event Summaries, Pathology Result Reports, Imaging Reports and Specialist Letters will be collected from a range of participating organisations, and stored within a number of secure repositories in the PCEHR System. The PCEHR System may also share key health information entered by the individual (such as over-the-counter medications and allergies), and access information from Medicare Australia — such as an individual's organ donor status, dispensed medications funded under the Pharmaceutical Benefits Scheme (PBS), information about healthcare events from an individual's Medicare claiming history and a child's immunisation history. The PCEHR System will also collect information about the location of an individual's advance directives (if they have one).
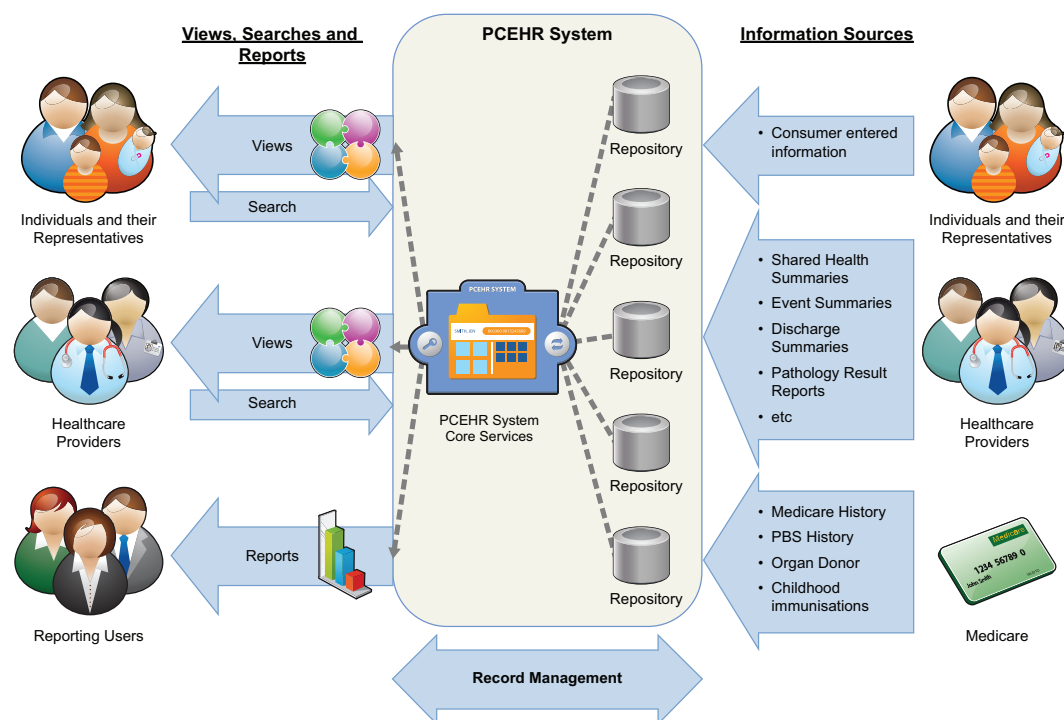
Figure 2: The PCEHR System

The PCEHR System will provide a number of core services that will allow authorised users to search for clinical documents, view clinical documents and access reports.

A key feature of the PCEHR System is its ability to provide a series of views over different clinical documents in an individual's PCEHR. These views will allow users of the system to easily see a consolidated overview of an individual's allergies/adverse reactions, medicines, medical history, immunisations, directives and recent healthcare events from different information sources. Figure 3 provides an example of a Consolidated View.

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[2]   The details of what information will be available through the national PCEHR System will be subject to further consultation with the community. The content available in an individual's PCEHR from July 2012 will also depend on the readiness of other healthcare provider information systems to participate in the national PCEHR program.

Consolidated View: Mr John D. Smith   [_] [□] [x]

Details *Sex: Male   DOB: 5 Jun 1965 (47 yrs)*
IHI:8003601234567890   ATSI: No
Contact Details: 12 Notastreet Cr, Sunnybank , QLD 4012.
ph: (07) 5555 9876
Contact Person: Mrs. Jane Smith (Wife) ph: (07) 5555 9876

Nominated Provider: Dr Simon Chu (GP)
Sunnybank Hills Clinic   ph: (07) 5555 1234
Shared Health Summary last reviewed:: **13 Jul 2012**

Allergies / Adverse Reactions
From Shared Health Summary:
12 Jul 2012   *Substance: Prochlorperazine (Stemetil)*   [View]
                 Reaction: Torticollis
Additional items from other clinical documents:
                 No information
Information from Individual
 7 Aug 2012   Rash from Elastoplasts   [View]

Medical History
From Shared Health Summary:
12 Jul   2012   Inguinal Hernia Repair (left side)   [View]
29 May 2012   Inguinal Hernia (left side)
18 Jun   2001   Essential Hypertension
Additional items from other clinical documents:
14 Sep 2012   Lower Back Muscle Strain (Physiotherapist)   [View]

Medicines
From Shared Health Summary:
18 Aug 2010   Quinapril (Accupril 20 mg)   [View]

Additional items from other clinical documents:
14 Sep 2012   Diclofenac (Voltaren Gel) (Pharmacy)   [View]

Recent Scripts:
22 Sep 2012   Quinapril (Accupril 20 mg)
                 Prescribed ☑ Dispensed ☒   [View]
                 Script runs out: 22/01/13

Information from Individual
7 Aug 2012   St Johns Wort Tablets   [View]

Immunisations
From Shared Health Summary:
 7 Jan 2008   OPV Sabin   [View]

Additional items from other clinical documents:
 22 Sep 2012   Fluvax   [View]

Additional items from ACIR:
    No information

Directives
Organ Donor   Registered with Medicare   [View]
Advance Care Directive Location:
    No Information

Notice:
An individual's PCEHR may not represent a complete set of health information.

Find Clinical Document
Keywords: [_____]   [Search]
                          [Advanced]

History Filter
Show Documents From: Last 18 Months [▼]

Clinical Documents
22 Sep 2012   Event Summary (GP)   [View]
16 Sep 2012   Pathology Report (★)   [View]
14 Sep 2012   Event Summary (Pharmacy)   [View]
14 Sep 2012   Event Summary (Physiotherapist)   [View]
 7 Aug 2012   Key Information from Individual   [View]
22 Jul 2012   Prescription   [View]
12 Jul 2012   Discharge Summary (★)   [View]
★ *warning: unstructured document*
    data may not be in view   [View Index]

Change History
16 Sep 2012   Pathology Report   [View Change]
13 Jul 2012   Shared Health Summary   [View Change]
                          [View Change History]

Medicare History
22 Sep 2012   Immunisation Provided   [View]
22 Sep 2012   Surgery Consultation - Level B   [View]
16 Sep 2012   Full Blood Count   [View]
22 Jun 2012   Surgery Consultation - Level B   [View]
 8 Jun 2012   Surgery Consultation - Level B   [View]

PBS History
22 Sep 2012   Fluvax   [View]
22 Jun 2012   Rulide 300 mg Box of 5   [View]
8 Jun 2012   Apo-pril 20 mg Box of 30   [View]
8 Jun 2012   Amoxil 500 mg Box of 20   [View]
1 May 2012   Apo-pril 20 mg Box of 30   [View]
7 Apr 2012   Accupril 20 mg Box of 30   [View]

[Print]   [Download]   [Close]

Figure 3: Example Consolidated View[3]

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[3] Note that this is a conceptual mock up of what the consolidated view could look like and is not an actual system.

1.3   Participation

1.3.1   Individuals

Individuals who would like to participate will be able to register from July 2012. Individuals who choose to participate will have the opportunity to experience the following benefits:

- *Access their health information:* The PCEHR System will provide secure, quick and easy access to an individual's key pieces of health information by both the individual and their healthcare providers.

- *Receive improved healthcare:* The PCEHR System provides opportunities for improved prevention, early intervention and treatment of chronic diseases as well as improved diagnosis and treatment in emergencies.

- *Be more informed about healthcare choices:* The PCEHR System will allow an individual to access their own PCEHR, view their own records and, in time, may link to health literacy information relating specifically to their needs.

Registration for those with a verified IHI will be supported online and assisted registration will also be supported by Medicare Australia offices and by some healthcare providers.

Once registered, individuals will be able to set up a number of 'access controls' (see Section 1.4), which moderate access by participating healthcare organisations to their PCEHR.

Individuals may also nominate representatives (such as family members and carers) to help manage their PCEHR. Authorised representatives (such as parents and guardians), will also be able to register individuals in their care and access their PCEHR. Additional processes will be put into place to manage access when the child becomes older and is able to manage their own PCEHR.

Individuals will also be given the option of nominating a healthcare provider to actively maintain their Shared Health Summary. The nominated provider can either be a single healthcare provider (e.g. their regular GP) or a healthcare organisation (e.g. their regular GP practice). The Shared Health Summary provides clinically moderated information about an individual's allergies/adverse reactions, medicines, medical history and immunisations. The nominated provider must agree to act in this role. An individual may change who their nominated provider is at any time.

Individuals will be able to withdraw at any time from the PCEHR System. A PCEHR is not mandatory for receiving healthcare services.

1.3.2   Healthcare providers and organisations

Healthcare organisations will be able to access the PCEHR System from July 2012. Healthcare organisations that choose to participate will have the opportunity to:

- *Access health information more efficiently:* The PCEHR System will provide secure, quick and easy access to a Consolidated View of an individual's key health information from participating healthcare organisations.

- *Ensure safer healthcare:* The PCEHR System will provide access to important information about an individual such as their allergies and adverse reactions as well as their medicines, medical history and immunisations.

- *Deliver more effective healthcare:* Easier access to information provides opportunities for improved prevention, early intervention and treatment of chronic and complex diseases as well as improved diagnosis and treatment in emergencies.

In order to participate, the healthcare organisation will need a healthcare organisation identifier (HPI-O), agree to be listed on the HI Provider Directory Service (HI PDS), use appropriate authentication mechanisms to access the PCEHR and use software that has been conformance tested to be used with the PCEHR System.

Healthcare organisations will be able to select which of their employees[4] are authorised to access the PCEHR System as part of their role in healthcare delivery. Only healthcare providers with a healthcare provider identifier (HPI-I) will be able to contribute information to the PCEHR System.

1.4   Personal control

Central to the PCEHR System is the concept of personal control. Participating individuals can exercise control over their PCEHR in the following ways:

- *Decide whether or not to have an active PCEHR:* The PCEHR System operates on an opt-in model, where individuals elect to register and create a PCEHR. At the point of registration, individuals establish their PCEHR by consenting to the terms and conditions of the PCEHR and set their access controls. Individuals may de-activate their PCEHR at any time.

- *Access information in their PCEHR:* Individuals will be able to view any health information contained in their PCEHR.

- *Set controls around healthcare provider access:* Individuals may determine and change settings around access to their PCEHR to participating healthcare organisations involved in their healthcare. Individuals may choose from a range of approaches to setting and managing these controls. Some access controls may be overridden in situations where the individual requires emergency care.

- *Authorise others to access their PCEHR:* Individuals may nominate other persons (such as carers and family members) to access health information in their PCEHR.

- *Choose which information is published to and accessible through their PCEHR:* Individuals may request healthcare providers to not send information to their PCEHR. There will be optional advanced mechanisms to more closely manage access to certain information.

- *View an activity history for their PCEHR:* The PCEHR System will provide an audit trail whereby individuals can view a history of actions on their PCEHR.

- *Make enquiries and complaints:* Individuals may make enquiries and complaints in relation to the management of personal information in their PCEHR and the PCEHR System. In the first instance, individuals should raise their concerns with the PCEHR System Operator. If they are not satisfied with the response, the complaint can be escalated to the appropriate investigative body.

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[4] As per the HI Service Act, an 'employee' is either an individual who provides services for the entity under a contract for services or an individual whose services are made available to the entity (including services made available free of charge).

1.5 Using the PCEHR System

1.5.1 Individuals

Individuals will be able to access their PCEHR online via a consumer portal and will be able to:

- Access their health information stored in their PCEHR.

- Link to online health literacy information.

- Share information with their healthcare providers, including information about their allergies and over the counter medications. They will also be able to keep notes online as an aide memoir for themselves and their carers.

- Manage their access controls and view the activity history on the PCEHR.

- Improve the quality of their health information by highlighting potential errors in their records and request the potential error be reviewed.

The PCEHR System will also provide the capability for independently operated conformant portals to connect to the PCEHR System, allowing individuals (in time) a choice of portal to access their PCEHR with. A call centre will also be provided to help support individuals in accessing their PCEHR and to answer general questions about the PCEHR System.

Additional avenues for access by individuals who do not have access to the Internet, are not able to use a computer, speak a language other than English or have specific accessibility needs will be provided.

1.5.2 Healthcare providers and organisations

Healthcare providers will be able to access the PCEHR System using a range of options including:

- *Clinical Systems:* Many healthcare organisations have already invested in a clinical system for healthcare delivery. In time, a range of new versions of many of those systems will become available with built in capability to access the PCEHR System. The PCEHR System will also support contracted service providers who operate healthcare software as a service on behalf of the contracting healthcare organisation.

- *Provider Portal:* Healthcare providers will be able to access health information stored in the PCEHR System via the provider portal. The provider portal is supplied as an alternative form of access to the PCEHR System. Access to the Provider Portal by healthcare providers needs to be authorised by the participating healthcare organisation.

Authorised users of these systems will be able to:

- Find an individual's PCEHR and obtain permission to access it.

- View and search an individual's PCEHR.

- Download and/or print clinical documents and views.

- Upload clinical documents (feature only available in clinical systems).

A call centre will be provided to help support healthcare providers in accessing the PCEHR System and to answer general questions about the PCEHR System.

1.6   Ensuring privacy and security

Health information within the PCEHR System will be protected through a combination of legislation, governance arrangements and security and technology measures. A multi-layered approach will safeguard the PCEHR System, and will incorporate both technical and non-technical controls. These include:

- Accurate authentication of users accessing the PCEHR System.

- Robust audit trails.

- Proactive monitoring of access to the PCEHR System to detect suspicious and inappropriate behaviour.

- Rigorous security testing, to be conducted both prior to and after commencement of operation of the PCEHR System.

- Education and training of users of the system.

- Requirements that healthcare providers and organisations comply with specific PCEHR System business rules and other relevant legislation.

Individuals will be able to make enquiries and lodge complaints regarding suspicious or unauthorised access to their PCEHR.

1.7   Implementation

The implementation of the PCEHR System will be based upon a combination of 'top down' national initiatives and 'bottom up' lead eHealth sites. This allows for tangible eHealth project outcomes on the ground whilst at the same time ensuring a focus on the central actions required to deliver a nationally interoperable system.

National initiatives will focus on delivering the core PCEHR System infrastructure. The Department of Health and Ageing will act as the program manager and engage a number of partners, including:

- *NEHTA* — who will be responsible for managing the requirements and high-level architecture of the PCEHR System as well as supporting the standards development process. NEHTA will act as a managing agent with the other partners on behalf of the Department of Health and Ageing.

- *National Infrastructure Partner(s)* — who will be responsible for delivering the infrastructure components of the PCEHR System.

- *Change and Adoption Partner(s)* — who will be responsible for supporting the programs of work around communications and engagement as well as providing change management support to adopters of the PCEHR System.

- *Benefits Evaluation Partner(s)* — who will develop a benefits realisation and evaluation framework and assess the ongoing progress of the PCEHR System. The outcomes of the evaluation process will be used to help inform the ongoing implementation program and future investments

An external delivery advisor will also be appointed by the Department of Health and Ageing will provide independent advice on the progress of the PCEHR program.

A key part of the bottom-up implementation program is the provision of two waves of funding for twelve lead eHealth sites spanning different geographic and functional parts of the Australian health sector. The lead eHealth sites collectively will aim to enrol up to 500,000 individuals. The purpose of these sites is to:

- Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.

- Demonstrate tangible outcomes and benefits from funded eHealth projects.

- Build stakeholder support and momentum behind the PCEHR System work program.

- Provide a meaningful foundation for further enhancement and rollout of the PCEHR System.

While all Australians will have the option of registering for a PCEHR in July 2012, adoption of the PCEHR System capabilities by healthcare providers and their eHealth system suppliers will take time. Beyond July 2012, the government will work with healthcare providers and the ICT industry to build upon the capabilities provided by the PCEHR System and look to incrementally expand the breadth and depth of adoption over time.

2   Introduction

2.1   Background

Australia's economic growth, productivity and long-term prosperity are underpinned by the health of its population. A healthy population is influenced by strong social and physical infrastructure and an accessible, safe and high quality healthcare system.

Recent health reform reports [DOHA2009a, DOHA2009b and NHHR2009] recognise that the health system is facing a significant set of challenges, including:

- The increased prevalence of chronic disease.

- Discrepancies in health outcomes between advantaged and disadvantaged Australians.

- An increasing and ageing population.

- Increasing demand for more costly and complex procedures.

- A shortage of skilled health sector workers.

Together these challenges are driving increased healthcare service demands and costs, and call into question the very sustainability of the Australian healthcare system in the medium to long term.

In April 2010 the Council of Australian Governments (COAG) met to discuss the health reform agenda. These reforms will deliver better healthcare via eight streams of work around hospitals, primary healthcare, aged care, mental health, national standards and performance, workforce, prevention and eHealth. Additional COAG discussions in February 2011 have made further refinements to the health reform approach. The health reform approach is described within a document titled "A National Health and Hospitals Network for Australia's Future: Delivering the Reforms" [DOHA2010c] and the "Heads of Agreement on National Health Reform" [COAG2011a].

As part of the eHealth stream within the health reform package, the Commonwealth has invested $466.7 million over two years into the key components for an electronic health record system, so that all Australians have access to a Personally Controlled Electronic Health Record (PCEHR) if they choose to do so.

This investment represents the next key step in the national eHealth strategy [AHMAC2008] and builds upon the foundations, standards and specifications developed by the National E-Health Transition Authority (NEHTA). These foundations include the Health Identifiers (HI) Service, National Authentication Service for Health (NASH) and Clinical Terminologies.

In order to fully realise the benefits of this investment, the states and territories will also need to continue their planned or expected investments in core health information systems. States and Territories will also need to provide the complementary investments to build their capacity in readiness for connection to the PCEHR System.

The Department of Health and Ageing and NEHTA is currently working with each of the State and Territory Health Departments to implement a range of foundations, including Healthcare Identifiers, Discharge Summaries and Secure Messaging, all of which will be required for the PCEHR System.

2.2   Business drivers

The implementation of a national PCEHR System addresses a current challenge faced by the Australian health system — the fragmentation of information spread across a vast number of different locations and systems. In many healthcare situations, quick access to key health information about an individual is not always possible.

Limited access to health information at the point of care results in:

- A greater risk to patient safety.

- Increased costs of care and time wasted in collecting or finding information.

- Unnecessary or duplicated treatment activities.

- Additional pressure on the health workforce.

- Reduced participation by individuals in their own healthcare information management.

The purpose of the PCEHR System is to address information fragmentation by allowing a person to more easily access their own health information, and to make their health information securely accessible to different healthcare providers involved in their care.

This will result in:

- Improved continuity of care for individuals accessing multiple healthcare providers by enabling key health information to be available where and when it is needed to ensure safe ongoing care.

- Access to consolidated information about an individual's medicines, leading to safer and more effective medication management and reductions in avoidable medication-related adverse events.

- Enabling individuals to participate more actively in their healthcare by improved access to their health information.

- Improved diagnostic and treatment capabilities through enhanced access to health information.

- Improved care coordination for individuals with chronic or complex conditions by enabling the individual's healthcare team to make better-informed decisions at the point of care.

2.3   Vision and concept

The national PCEHR System aims to place the individual at the centre of their own healthcare by enabling access to important pieces of health information when and where it is needed by individuals and their healthcare providers.

Individuals will be able to choose whether or not to have a PCEHR, and if they choose to participate, they will be able to set their own access controls. Using the PCEHR System, individuals will be able to access their own healthcare information and allow their healthcare providers to access and use this information to provide more coordinated and effective care for the individual.

Individuals will have greater involvement in their care through increased access to their information and other resources and will not be required to remember all the details of their previous healthcare.

Figure 4: PCEHR System concept

In order to deliver this vision, the PCEHR System will provide:

- Secure access for individuals and their healthcare providers to their eHealth records via a range of access channels.

- A national set of services that will allow streamlined access to eHealth records, drawn from multiple repositories, such as:

  - A Shared Health Summary including allergies/adverse reactions, medicines, medical history and immunisations.

  - Clinical documents such as Discharge Summaries, Event Summaries and other documents over time (e.g. Pathology Result Reports, Specialist Letters, etc).

- Governance, legislation and oversight to ensure trust and confidence in the PCEHR System.

- The national standards, planning and core national infrastructure required to use the PCEHR System.

In defining what the PCEHR System is intended to be, it is also important to define what it is not intended to be. The PCEHR System is intended to be:

- *Non-mandatory* — participation by individuals will be voluntary.

- *Not a comprehensive health record* — only key health information shared from participating source systems will be available via the PCEHR System, subject to access controls. This information will only be summaries of the episode of care (e.g. a Discharge Summary or an Event Summary) and not the full record of care (e.g. the full hospital medical record).

- *Not a replacement for local health records* — the introduction of a PCEHR System will not reduce the requirement for healthcare providers and organisations to maintain their own health records. It will complement existing local health records by providing a way of securely sharing health information.

- *Not a replacement for existing clinical communications* — existing provider-to-provider communications, such as Referrals, Discharge Summaries, pathology requests and result reports, prescriptions etc., will continue to flow using existing communication channels. The PCEHR System provides a new complementary communication channel.

- *Not a single central national database* — the information that makes up individuals PCEHR will originate from multiple sources and be stored in multiple repositories.

- *Not a way of directly accessing healthcare provider records* — participating healthcare providers will upload copies of clinical documents into the PCEHR System.

2.4 Approach

Delivery of a national outcome around PCEHR implementation will be challenging. The proposed approach endorsed by Health Ministers recognises the multi-jurisdictional responsibilities for health services delivery and the complexity of the public-private mix of healthcare organisations that provide direct healthcare services. The approach also recognised the key foundational eHealth elements already underway and the different levels of readiness for connection to the national PCEHR System across Australia's health sectors.

Consistent with the National E-Health Strategy, the strategy for delivering the PCEHR System also acknowledges the need for sustained systemic business related change across multiple healthcare provider and consumer representative groups.

The following elements will be required to deliver the PCEHR System:

- Government endorsement of, and support for, a national approach to governance to champion the PCEHR System, and provide national oversight of the implementation.

- Top-level health sector leadership, in order to create sustained, visible leadership and commitment to the PCEHR System.

- Involvement of healthcare providers, consumer representatives and the ICT industry across the entire PCEHR program, including the development of implementation strategies and approaches for targeted adoption.

- Planning and implementation of a comprehensive engagement and representation strategy.

- A national communications program that is understandable and compelling for both the Australian community and healthcare sector.

- Delivery of a number of lead eHealth sites that align with the national work program. The purpose of these lead implementation sites will be to:

  - Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.

  - Demonstrate tangible outcomes and benefits from funded eHealth projects.

  - Build stakeholder support and momentum behind the PCEHR System work program.

- – Provide a meaningful foundation for further enhancement and rollout of the PCEHR System.

- A national change management and adoption program that aligns with national health policy priorities and allows for tailoring to meet local requirements.

- An ICT industry program to aid suppliers of eHealth products and services in take up of relevant standards and specifications and subsequent conformance assessment.

- Targeting particular groups in the community likely to receive the most immediate benefit, including those suffering from chronic and complex conditions, older Australians, Aboriginal and Torres Strait Islander peoples, mothers and their newborn children.

- Research and evaluation strategies to identify and realise opportunities for collaboration, leverage knowledge regarding the issues, challenges and solutions experienced in implementing the PCEHR program.

2.5   Principles

There are ten key principles that have been used to inform the design and approach of the PCEHR System[5]:

- *Personally Controlled:* Individuals will be able to choose whether or not to have a PCEHR, and if they choose to participate, they will be able to set their own access controls.

- *Value:* Deliver a PCEHR System that offers value to both individuals and their healthcare providers.

- *National infrastructure:* Deliver core elements of PCEHR System infrastructure once, rather than duplicating development costs and efforts and increasing the likelihood of rework.

- *Stakeholder engagement:* Actively engage key healthcare stakeholders in the design and delivery of the PCEHR System.

- *Incremental approach:* Build the PCEHR System in an incremental and pragmatic manner, focusing initial investment in those areas that that deliver the greatest benefits.

- *Recognising different starting points:* Balance active support for healthcare providers with less developed capability, while not constraining the ability for more advanced participants to progress.

- *Leverage:* More effectively leverage and scale existing and planned eHealth activities and standards in the delivery of the PCEHR System.

- *Balancing alignment and independence:* Drive alignment of PCEHR System implementation activities whilst not unnecessarily limiting the ability of participants and vendors to implement locally relevant solutions.

- *Trust and confidence:* Deliver a PCEHR System that all users are able to trust that it is governed effectively; individuals trust that their privacy has been handled appropriately; and moreover, users are confident in the quality and safety of the health information provided by the PCEHR System.

- *Relevant skills:* Ensure sufficient numbers of skilled practitioners are available to support delivery of the PCEHR System.

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[5]   These principles have been adapted from the seven principles outlined in the National E-Health Strategy [AHMC2008]. 'The 'personally controlled', 'value' and 'trust and confidence' principles have been added as additional principles.

2.6 Timeframe

The PCEHR System must be available so that, commencing in July 2012, individuals will be able to register for a PCEHR online.

Key milestone dates can be found within plan for health reform [DOHA2010c].

2.7 Scope

The Commonwealth's investment of $466.7 million will fund the national elements of the PCEHR System. The focus of this investment will be to deliver the core functionality required to establish a PCEHR System for Australia that can be built on over time.

The scope of the PCEHR System for delivery from July 2012 will be heavily informed by consultation with key stakeholders, the community and testing of system concepts in lead eHealth sites.

By July 2012, individuals will be able to register online for a PCEHR. As the PCEHR System is taken up by healthcare providers, registered individuals will be able to progressively reap the benefits of having a PCEHR.

Beyond July 2012, the policy directions for eHealth are clear. The Government's complementary investment in tele-health coupled with the roll-out of the National Broadband Network align with the National E-Health Strategy trajectory endorsed by the Australian Health Ministers' Conference in 2008. Additionally the current 2 year investment in the PCEHR Program, including in the lead eHealth sites, will inject significant momentum for PCEHR use in designated regions and consumer cohorts building towards a tipping point for broader adoption as the national infrastructure elements come on line. The work of the PCEHR Benefits Evaluation Partner will also be critical to demonstrating tangible benefits and improvements against baseline activity.

It is recognized that the PCEHR System will grow over time and government investments, user expectations and market forces will simulate this growth. Government funding for the PCEHR System beyond July 2012 will be subject to consideration in the 2012-13 Budget context. Further consultation, including collaboration with the States and Territories, will be required to consider a sustainable model for ongoing operations of the PCEHR System (see Section 7), ongoing change and adoption (see Section 8) and further enhancements to the PCEHR System (see Section 2.8).

The scope and focus of the PCEHR System funded by the Commonwealth includes the implementation of:

- The core national infrastructure to support the operation of the PCEHR System, including key components such as:
    - Access channels, such as a Consumer Portal, Provider Portal, Report portal, B2B Gateway and Call Centre.
    - Core PCEHR Services to support major functional areas around Participation and Authorisation, Indexing, Views, Audit and Reporting.
    - A National Repositories Service to hold a minimum critical set of healthcare information about participating individuals within multiple nationally operated repositories.
    - The capability to connect to conformant repositories and conformant portals as they become available.
    - Support for a range of systems accessing the B2B Gateway, such as clinical systems and contracted service providers.
    - A new foundation service for supporting templates.

Each of these elements are described further in Section 6.

- Functional capability within the national infrastructure to support:
    - Registration and managing the ongoing participation of individuals and healthcare providers (see Section 3).
    - Access controls managed by the individual.

      The access controls will include a number of base features around access control. Options around more advanced features may also be included. Access controls are discussed further in Section 5.
    - The collection of health information from a range of points of care, including: Shared Health Summaries, Event Summaries, Discharge Summaries and Consumer entered information.

      This information, subject to the individual's access controls, will provide the base information required to support sharing of important information around allergies/adverse reactions, medicines, medical history and immunisations. This information will facilitate improved continuity of care, medication management and consumer participation.

      In addition to this, a range of optional information sources will be considered in the first release. The options include: Specialist Letters, Pathology Result Reports, Diagnostic Imaging Reports, Medicare Information (e.g. Medicare claims history, PBS data, ACIR and Organ Donor), Referrals, Prescriptions/Dispense Notifications and the location of the individual's advance care directives (if they have one).

      These options will build upon the base capability and further improve the breadth and depth of information available in the PCEHR System, thereby further enhancing continuity of care, medication management, diagnostic test selection and the consumer participation capabilities of the system.

      The details of what information will be available through the national PCEHR System will be subject to further consultation with the community. The content available in an individual's PCEHR from July 2012 will also depend on the readiness of further healthcare provider information systems to participate in the national PCEHR program.
    - The consolidation and analysis of information collected in the PCEHR System via:
        - Views to enable easy access to consolidated information about an individual's allergies/adverse reactions, medicines, immunisations and medical history.
        - Reports to support the evaluation and operational requirements of the PCEHR System.

  Managing PCEHR information is described further in Section 4.
- Establishment of an operational capability to support the ongoing operations of the PCEHR System (see Section 7).
- Standards and technical specifications used by the PCEHR System to enable the accurate and reliable collection and exchange of PCEHR-related information.

  Standards and technical services are discussed further in Section 6.1.2.
- Establishment of a national approach assessing the conformance of systems against the agreed standards and technical specifications.

  Conformance assessment is discussed further in Section 7.4.

- Establishment of lead eHealth sites to test and deploy national eHealth infrastructure and standards in real world healthcare settings and build stakeholder momentum.

  Lead eHealth sites are discussed further in Section 8.5.

- Development of a stakeholder change management strategy which accounts for the required work practice and business process changes.

  Engagement is discussed further in Section 8.4.2.

- Design and delivery of stakeholder communication strategies to drive adoption of the PCEHR System by individuals and healthcare providers.

  Change management is discussed further in Section 8.4.1.

- Governance and oversight of the national PCEHR System's implementation and operation to address required delivery accountabilities and ensure appropriate clinical safety and quality outcomes.

  Governance is discussed further in Section 7.2.

2.8 Potential enhancements

The National E-Health Strategy proposed that the PCEHR System rollout be undertaken via an incremental approach, with the capabilities of the system being expanded over a four-year implementation period.

While subject to further work, potential enhancements could focus on delivering quality improvements and enhancements based on stakeholder demand and lessons learned from earlier implementations. Candidates for later potential enhancements could include, but are not limited to:

- Enhancements to the registration processes.
- Support for collection of a broader range of health information from healthcare providers, such as:
  - Delivery of any optional elements delayed from the first release of the PCEHR System.
  - Pathology and diagnostic imaging requests.
  - Diagnostic images.
  - Health information from registries.
  - Care plans.
  - Assessments tools.
  - Reports from practice-based diagnostic tools (e.g. electrocardiograms).
- The addition of consumer-oriented features, such as:
  - Integration with consumer-oriented personal health records enabling an alternative form of consumer input and interaction with their PCEHR.
  - Collection of information from consumer devices such as blood pressure monitors, blood glucose monitors, etc.
- Addition of new views to the PCEHR System to support the needs of specific groups, such as:
  - Views to support management of chronic diseases.
  - Views to support individuals and their representatives.
  - Views to support specific healthcare providers, such as nurses and allied health providers.

- Enhancements to the template service to support more dynamic and flexible approaches to templating.

- Enhancements to the reporting service to support a wider range of approved uses.

- Enhancements to the PCEHR System access controls.

It is acknowledged that from initial consultation with a cross-section of stakeholders that some of these features are important to pursue early. However it is also recognised that in finalising the priorities for the PCEHR System capability for July 2012, the progress on the above will be dependent on work that needs to be delivered outside the PCEHR Program.

2.8.1   Clinical decision support

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

3 Participation

3.1 Introduction

This section outlines the approach to participation by individuals and healthcare providers.

3.2 Individuals

The PCEHR System is a voluntary opt-in system. Individuals who choose to participate will have the opportunity to experience the following benefits:

- *Access their health information:* The PCEHR System will provide secure, quick and easy access to an individual's key pieces of health information by both the individual and their healthcare providers.

- *Receive improved healthcare:* The PCEHR System provides opportunities for improved prevention, early intervention and treatment of chronic diseases as well as improved diagnosis and treatment in emergencies.

- *Be more informed about healthcare choices:* The PCEHR System will allow an individual to access their own PCEHR, view their own records and, in time, may link to health literacy information relating specifically to their needs.

Once registered, individuals will be able to manage their access controls and notification details, view their PCEHR and nominate a healthcare provider to help manage their Shared Health Summary. Individuals will be able to nominate representatives and withdraw from participating at any time.
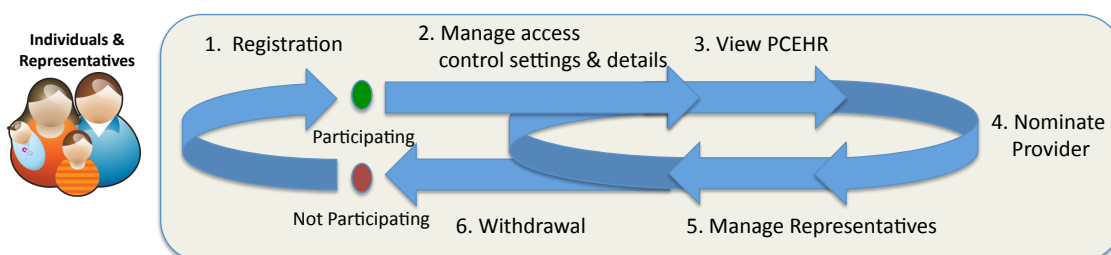
Figure 5: Simplified view of key participation processes

Individuals who decide not to have a PCEHR will not be disadvantaged in terms of their access to healthcare services.

3.2.1 Personal control

Central to the PCEHR System is the concept of personal control. Participating individuals can exercise control over their PCEHR in the following ways:

- *Decide whether or not to have an active PCEHR:* The PCEHR System operates on an opt-in model, where individuals elect to register and create a PCEHR. At the point of registration, individuals establish their PCEHR by consenting to the terms and conditions of the PCEHR and set their access controls. Individuals may de-activate their PCEHR at any time. Registration and deactivation is discussed further in Section 3.2.

- *Access information in their PCEHR:* Individuals will be able to view all health information contained in their PCEHR. Content of the PCEHR is discussed further in Section 4.

- *Set controls around healthcare provider access:* Individuals may determine and change settings around access to their PCEHR to participating healthcare organisations involved in their healthcare. Individuals may choose from a range of approaches to setting and managing these controls. Some access controls may be overridden in situations where the individual requires emergency care. Access control settings are discussed further in Section 5.5.

- *Authorise others to access their PCEHR:* Individuals may nominate other persons (such as carers and family members) to access health information in their PCEHR. Representatives are discussed further in Section 3.2.7.

- *Choose which information is published to and accessible through their PCEHR:* Individuals may request healthcare providers to not send information to their PCEHR. There will be optional advanced mechanisms to more closely manage access to certain information. Access controls are discussed further in Section 5.5.

- *View an activity history for their PCEHR:* The PCEHR System will provide an audit trail whereby individuals can view a history of their actions and the actions of their healthcare providers and representatives on their PCEHR. Audit is discussed further in Section 5.6.

- *Make enquiries and complaints:* Individuals may make enquiries and complaints in relation to the management of personal information in their PCEHR and the PCEHR System. In the first instance, individuals should raise their concerns with the PCEHR System Operator. If they are not satisfied with the response, the complaint can be escalated to the appropriate investigative body. Enquiries and complaints are discussed further in section 3.2.10.

It is acknowledged that appropriate information and support must be available to individuals to exercise proper decision-making and consent with regard to the controls described here. Further, establishment and maintenance of these controls will be available via a range of channels.

3.2.2   Registration

Individuals will be able to register for a PCEHR in a number of ways. Individuals will be able to register using an online process and assisted face-to-face registrations will be supported by Medicare Australia and some healthcare organisations. An option to register for a PCEHR by post will also be provided for those individuals who can't access online or assisted registration services.

The registration processes for the PCEHR System are expected to leverage existing registration and verification of identity mechanisms to ensure that the right record is created for the right person. Individuals who wish to register for a PCEHR will need to have a verified Individual Healthcare Identifier (IHI) assigned by the Healthcare Identifier Service (HI Service) operated by Medicare Australia. Newborns and infants under 12 months may not always have a verified IHI and an alternative process will be put in place for these circumstances.

Individuals that are enrolled with Medicare or hold a Department of Veterans Affairs (DVA) treatment card have been automatically allocated an IHI by the HI Service. An IHI can be obtained from the HI Service by providing a combination of demographic details such as a person's full name, Medicare number or DVA number, date of birth and sex.

Online registration

From July 2012, online registrations will be supported by the national consumer portal. Online registration is expected to include the following steps:

1. The individual creates or logs onto an existing consumer portal account (consumer portal account credentials are discussed further in Section 5.4.2).

2. The individual selects the option to 'Register for a PCEHR'.

3. The individual reads and agrees to the terms and conditions.

4. The individual provides sufficient identifying information to ensure that a single PCEHR is created for the individual the following information will need to be provided:

   a. Full name

   b. IHI, Medicare number or DVA file number

   c. Date of birth

   d. Sex

   e. Address (as registered with a trusted data source such as Medicare Australia)

5. The PCEHR System will verify the information provided against a trusted data source (for example, this could be against information an individual has already provided to Medicare Australia or is held by the Healthcare Identifiers Service).

6. The PCEHR System will send an information pack and activation code to the individual's address currently registered in the HI Service.

7. The individual receives and enters the activation code to activate their PCEHR.

Once the individual's PCEHR is active the individual will be able to establish a range of access controls (see Section 5.5.2).

eHealth Site Notes: eHealth Site Notes: Wave 1 lead eHealth sites will inform the development and implementation of registration processes including assisted registration and kiosk based online registration. A number of wave 2 lead eHealth sites will inform the process of registration of infants. These sites include the Mater Misericordiae eHealth site and the Greater Western Sydney eHealth site.

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

3.2.3   Driving adoption by individuals

The national roll out of the PCEHR System will actively seek to register individuals that are likely to receive immediate benefit from having a PCEHR. This includes those individuals who have complex and chronic conditions, older Australians, Aboriginal and Torres Strait Islander peoples, mothers and their newborn children.

Registration of these individuals will involve a mix of information campaigns and assisted registration processes (where appropriate) to help support uptake.

3.2.4   Ensuring access in a range of different situations

Non-computer based access

While the use of computers and broadband is becoming increasingly pervasive across Australian society, the PCEHR System will still need to support a number of avenues for individuals who either don't have access to the Internet or may not be able to use a computer. Individuals in this situation will be able to:

- Register (and withdraw) using an assisted registration process or a mail based process.

- Access a 24 hour call centre to help them manage their PCEHR and answer general questions about the PCEHR System.

- Identify representatives to help them access and manage their PCEHR (see Section 3.2.7).

Some healthcare providers may offer to assist some individuals with accessing their PCEHR information, by, for example, providing printed copies of relevant information to take home.

Support for languages other than English

Individuals accessing the PCEHR System will be able to make use of the Australian Government Translating and Interpreting Service (TIS).

The PCEHR System Operator will provide information packs in a range of languages other than English.

Accessibility

The consumer portal will support W3C Accessibility Guidelines [W3C2008a]. The primary goal of these guidelines is to ensure that Web content is accessible to people with disabilities.

3.2.5   Nominated providers

One of the key features of the PCEHR System is the "consolidated view" (see Section 4.3.3). The consolidated view presents a snap shot of an individual's health status drawn from multiple sources and it automatically assembles an individual's allergies and adverse reaction, medications, medical history and immunisations from a range of clinical documents in a single view. However, as this information is automatically assembled by the PCEHR System, it will be limited to information that can be extracted from clinical documents and it may not highlight items that are important to the individual's ongoing care. To help address this issue, the PCEHR System supports the concept of a "shared health summary" (see Section 4.2.2), which is prepared by a healthcare provider (or healthcare organisation) nominated by the individual.

The Shared Health Summary ensures that other healthcare providers accessing the individual's PCEHR have access to a clinically-moderated summary of the individual's allergies/adverse reactions, medicines, medical history and immunisations.

Only the nominated provider may update an individual's Shared Health Summary. Other providers wishing to provide similar information should use an Event Summary (see Section 4.2.3). For further information about the Shared Health Summary please see Section 4.2.2 and the related section on the Consolidated View (see Section 4.3.1).

The nominated provider can either be an individual healthcare provider or a healthcare organisation. If the nominated provider is a healthcare organisation, any healthcare provider authorised by that organisation may, if they are providing health services to the individual, update the individual's Shared Health Summary.

The establishment of a nominated provider can only occur in a consultation between the provider and the individual involved and requires agreement of both parties.

The nominated provider could be the individual's regular GP or General Practice that they regularly visit, but may also be another healthcare provider or organisation. The criteria for nominated providers include the following capacities:

- To deliver continuing, coordinated and comprehensive care to the individual.

- To assess and describe all aspects of the Shared Health Summary and to take reasonable steps to verify the accuracy of information provided.

- To commit to reviewing the Shared Health Summary with the individual on a regular basis.

A nominated provider will be optional and the individual does not need to select one.   If an individual does not have a nominated provider, other providers will be able to provide similar information about an individual's health status using an Event Summary, however, no single provider will have the responsibility for maintaining information about an individual's health status.

The individual can change their nominated provider at any time or nominate a healthcare provider or organisation at a later time if they do not already have one. An individual can only have a single nominated provider at any one time. If an individual changes their nominated provider, the previous nominated provider will be notified.

3.2.6   Withdrawal

Participating individuals (or their authorised representatives) may choose to withdraw at any time. If an individual withdraws, their PCEHR will be marked as 'de-activated'.

In a 'de-activated' PCEHR, any information that has been collected up to the point of being de-activated will continue to be stored, but the PCEHR will not be accessible via the PCEHR System to any healthcare providers, the individual, or their representatives. Records will only be accessible via the PCEHR System operator for maintenance, audit and other approved purposes.

Any information that a healthcare organisation has obtained from an individual's PCEHR and added to their local records before the PCEHR has been de-activated will continue to be available to those healthcare providers through their local record.

If an individual chooses to re-activate their PCEHR at a later time, their record will be restored and continue to operate as normal. However, there will be a 'gap' in their record for the period of time they chose not to participate. If the individual chooses to re-activate their PCEHR, any users accessing the PCEHR will clearly be able to see where any gaps exist.

Archival of de-activated records is covered in Section 4.6.3.

3.2.7   Representatives

For the purposes of managing an individual's PCEHR, an individual may also be represented by an authorised or nominated representative. These relationships will be recorded in an individual's PCEHR.

There are a range of existing laws and arrangements in place to support individuals who are deemed not to have the capacity to act on their own behalf or the capability to communicate their wishes. Authorised representatives will be able to represent individuals without capacity to act for themselves in their interactions with the PCEHR System. The authorised person will be given the same access and controls as the individual. There may be more than one authorised person for an individual.

An individual may also nominate a representative. A nominated representative is typically a carer or other person who helps manage their care. A nominated representative may view the individual's PCEHR, but they do not have the ability to provide consent on behalf of the individual.

3.2.8   Children

Except where special circumstances exist[6], parents (or other authorised representatives) will have control of their children's PCEHR from 0 to 14 years, including the decision as to whether the child participates or withdraws, as well as managing their access controls.

After a child turns 14 years old the PCEHR System will enable the child to choose to manage their own PCEHR, including the capacity to participate, withdraw, manage their access controls or disassociate representatives.

At the age of 18 years, the PCEHR System will no longer allow a parent/guardian to access the individual's PCEHR unless that parent/guardian is an authorised or nominated representative.

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.

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[6]   Special circumstances might include situations where family or personal circumstances lead to a child being assessed by a relevant authority under relevant jurisdictional legislation, to be, for example, a 'mature minor' or 'independent minor'. Under Medicare Australia guidelines a General Practitioner may assess a child less than 14 years to have the capacity to manage their own healthcare.

3.2.9   Deceased individuals

After an individual has died, the individual's PCEHR will be de-activated and all access will be suspended. The deceased individual's PCEHR will be handled in accordance with archival guidelines (see Section 4.6.3). The only way in which the deceased individual's PCEHR can be accessed is when it is required by law or required for an approved use (see Section 4.5).

The PCEHR System will rely on the fact of death data sourced from Medicare Australia to determine the status of an individual.

> **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.

3.2.10   Enquiries and complaints

Individuals may make enquiries and complaints in relation to the management of personal information in their PCEHR and the PCEHR System.

In the first instance, individuals would raise concerns with the PCEHR System Operator. If they are not satisfied with the response from the PCEHR System Operator, the complaint can be escalated to an appropriate investigative body.

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

3.3   Healthcare providers and organisations

Participation by healthcare organisations and their associated healthcare providers will be strongly encouraged and supported. Healthcare organisations that choose to participate will have the opportunity to:

- *Access health information more efficiently:* The PCEHR System will provide secure, quick and easy access to a Consolidated View of an individual's key health information from participating healthcare organisations.

- *Ensure safer healthcare:* The PCEHR System will provide access to important information about an individual such as their allergies and adverse reactions as well as their medicines, medical history and immunisations.

- *Deliver more effective healthcare:* Easier access to information provides opportunities for improved prevention, early intervention and treatment of chronic and complex diseases as well as improved diagnosis and treatment in emergencies.

Access to the PCEHR System requires participation by the healthcare organisation. If an organisation chooses to participate and they meet the participation criteria, they will be able to select which of their healthcare providers and other local users require access to the PCEHR System. At that point authorised users will be able to obtain permission to access an individual's PCEHR (based on the individual's access controls), view and search a PCEHR and load new records into an individual's PCEHR. Organisations that no longer meet the participation criteria will not be able to access the PCEHR System.
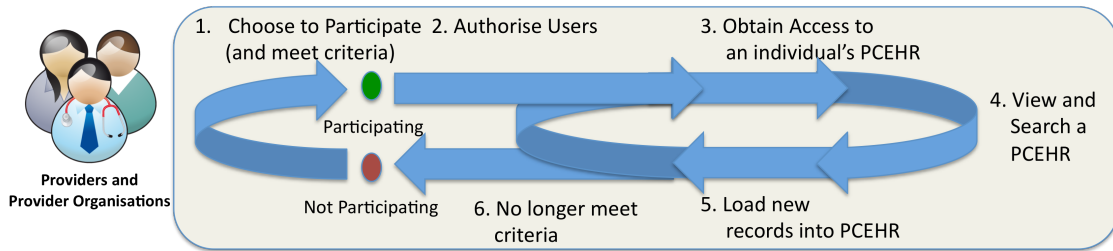
Figure 6: Simplified view of key participation processes

3.3.1   Registration

If a healthcare organisation chooses to participate, registration to access the PCEHR System involves the following steps:

- Obtaining information from the PCEHR System operator about how to participate and the healthcare organisation's rights and responsibilities with respect to the PCEHR System.

- Registering with the HI Service Operator to obtain a HPI-O (if the healthcare organisation doesn't already have one).

- Agreeing to have the organisation's details published in the HI Service's Provider Directory Service (HI PDS).

Once a healthcare organisation has completed the above steps, the healthcare organisation will need to set up one or more options for accessing PCEHR System. Options include:

- *Clinical Systems:* Participating organisations that prefer to use local clinical systems access the PCEHR System, must have:

  - A NASH conformant Digital Credential which asserts their HPI-O.

  - Software and services which have passed the conformance assessment process (see Section 6.1.2).

- *Contracted Service Provider:* Participating organisations that prefer to use a Contracted Service Provider (CSP) (see Section 3.4.1) to access the PCEHR System must:

  - Establish an agreement for supply of conformant services with their CSP.

  - Notify the HI Service Operator of the CSP's authorisation to operate on their behalf.

- *Provider Portal:* Participating organisations that prefer to access the PCEHR System via a Provider Portal (see Section 6.3.2), must ensure that local healthcare providers who need access to the Provider Portal have a HPI-I/HPI-O link recorded in the HI PDS.

Once a healthcare organisation has met the above criteria they are considered to be a 'participating organisation'.

Healthcare organisations that no longer meet the participation criteria (for example, they retire their HPI-O) will no longer be considered to be participating.

Healthcare organisations that are no longer participating will not be able to access the PCEHR System. They are permitted to retain any information they may have printed or downloaded for ongoing healthcare service delivery and medico-legal purposes.

3.3.2   Authorised users

The PCEHR System entrusts a participating organisation to grant access to healthcare providers and other local users who need to access the PCEHR System. These users are referred to as 'authorised users'. An authorised user may be any employee[7] who has a legitimate need to access the PCEHR System as part of their role in healthcare delivery. When authorised users access the PCEHR System, they are only permitted to access the PCEHR of individuals they are involved in delivering healthcare services to. All access to the PCEHR System is audited.

Only authorised users with a HPI-I and valid digital credentials may load information into the PCEHR System. Authorised users who do not have a HPI-I may not load information into the PCEHR System.

The PCEHR System entrusts the participating organisation to verify the identity of authorised users prior to letting them access the PCEHR System. The participating organisation may undertake a separate check or leverage existing verification of identity procedures (such as processes used by the organisation's Human Resources department).

Guidelines for authentication of users within clinical systems, the provider portal and contracted service providers are discussed further in Section 5.4.1.

3.4   User systems

The PCEHR System provides a consumer portal and a provider portal, which allows individuals and their healthcare providers to access the PCEHR System. In addition to this, the PCEHR System infrastructure puts in place the necessary technical services to allow both healthcare provider systems and consumer oriented systems to leverage the data within the PCEHR System. Thereby, over time, offering users a range of choice in system by which they access the PCEHR System.

It is also expected that these third party systems will be able to value add on the base features of the PCEHR System. For example, healthcare provider systems can leverage information from the PCEHR System to enhance clinical decision support algorithms or a consumer-oriented portal might access the information from the PCEHR System to help diabetics self manage their care.

The criteria for how different kinds of systems will be permitted to access the PCEHR System is outlined below.

3.4.1   Clinical Systems

In time the PCEHR System will be accessible from a range of clinical systems including GP systems, pharmacy systems, hospital systems, aged care systems, specialist systems, etc.

In order to connect to the PCEHR System, a clinical system must fulfil the following requirements:

- Implementation of the functionality, relevant standards and specifications and other requirements for clinical systems outlined in Section 6.2.2.

- Successful completion of the conformance assessment process and obtaining a Notice of Connection (NOC) from the PCEHR System Operator (see Section 6.1.2).

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[7] As per the HI Service Act, an 'employee' is either an individual who provides services for the entity under a contract for services or an individual whose services are made available to the entity (including services made available free of charge).

eHealth Site Notes: A number of wave 1 and wave 2 eHealth sites will be working with suppliers of existing clinical systems to enhance their products to put in place the necessary building blocks to enable future conformance with the PCEHR System.

3.4.2   Contracted Service Providers

Some healthcare organisations may choose to use a third party service provider to deliver health software as a service (SaaS) and facilitate access the PCEHR System on their behalf. These service providers are referred to as Contracted Service Providers (CSP). An example of a CSP might include a vendor that offers web based general practice or aged care software via a SaaS model.

In order to connect to the PCEHR System, CSP must fulfil the following requirements:

- Implementation of the functionality, relevant standards and specifications and other requirements for contracted service providers outlined in Section 6.2.3.

- Register with the HI Service Operator to:

    – Obtain a CSP Identifier.

    – Register the CSP's Responsible Officer (RO) and Organisation Maintenance Officer (OMO).

    – Request the NASH service operator to issue a NASH conformant Digital Credential which asserts their CSP Identifier.

    – Record of the CSP's authority to act on behalf of a healthcare organisation.

- Successful completion of the conformance assessment process and obtaining a Notice of Connection (NOC) from the PCEHR System Operator (see Section 6.1.2).

- CSPs which access the PCEHR System will be required to operate in Australia and be subject to Australian law.

Information stored within a CSP is treated as a separate record from the PCEHR System, and the CSP will access and load information into the PCEHR System as per other systems. If a CSP wishes to host information on behalf of the PCEHR System, rather than simply access and load information, then it will be required to support the additional requirements of a conformant repository provider (see Section 3.4.4).

3.4.3   Conformant Portal Providers

The PCEHR System supports the capability for independent consumer-oriented portal services to access the PCEHR System[8]. These portals will be used to offer value added features on top of the PCEHR System, such as self-managed care features, access to health literacy information, consumer oriented decision support, etc.

In order to connect to the PCEHR System, Conformant Portal Providers (CPP) must fulfil the following requirements:

- Implementation of the functionality, relevant standards and specifications and other requirements for conformant portal providers outlined in Section 6.2.1.

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[8]   Services which offer provider-oriented portals are treated as a CSP (see Section 3.4.1).

- Register with the PCEHR System Operator and obtain a CPP Identifier. Registration implies registration of the CPP's Responsible Office (RO) and Organisation Maintenance Officer (OMO) and agreement to the terms, conditions and service levels of a CPP.

- A NASH Conformant Digital Credential, which asserts their CPP Identifier.

- Conformant portal providers which access the PCEHR System will be required to be operating in Australia and be subject to Australian law.

- Successful completion of the conformance assessment process and obtaining a Notice of Connection (NOC) from the PCEHR System Operator (see Section 6.1.2).

Information stored within a CPP is treated as a separate record from the PCEHR System, and the CPP will access and load information into the PCEHR System as per other systems. For example, if the portal is used to help individuals self manage their diabetes, then any information will just be held within the CPP and not shared with the PCEHR system, unless loaded into it.

If a CPP wishes to host information on behalf of the PCEHR System, rather than simply access and load information, then it will be required to support the additional requirements of a conformant repository provider (see Section 3.4.4).

eHealth Site Notes: eHealth Site Notes: The Medibank Private eHealth site and the Mater Misericordiae eHealth site will inform the development and implementation of consumer oriented portals.

The Medibank Private Portal will allow individuals enrolled in the MediBank Private chronic disease management program to collect and share information with their healthcare providers. Medibank Private will not be using any of this information for the management of claims or eligibility for healthcare insurance benefits.

This work will also be required to collaborate with healthdirect Australia to ensure equity of access synergies are explored for the broader Australian community.

3.4.4   Conformant Repository Providers

The PCEHR System supports the capability to connect to additional conformant repositories. In order to connect to the PCEHR System, Conformant Repository Providers (CRP) must fulfil the following requirements:

- Implementation of the functionality, relevant standards and specifications and other requirements for conformant repository providers outlined in section 6.6.2.

- Register with the PCEHR Service Operator and obtain a CRP Identifier. Registration implies registration of the CRP's Responsible Office (RO) and Organisation Maintenance Office (OMO) and agreement to the terms, conditions and service levels of a CRP. Service levels are discussed further in Section 1.1.

- Conformant repositories will be required to be operated in Australia and be subject to Australian law.

- A NASH Conformant Digital Credential, which asserts their CRP Identifier.

- Successful completion of the conformance assessment process and obtaining a Notice of Connection (NOC) from the PCEHR System Operator (see Section 6.1.2).

eHealth Site Notes: A number of wave 1 and wave 2 sites are looking to establish conformant repositories.

4   Managing PCEHR information

4.1   Introduction

The PCEHR System will collect information from a wide range of sources within a number of conformant repositories and be able to present that information in a range of ways to meet the needs of individuals, healthcare providers and other parties.

This section discusses the various information sources; ways of accessing that information via views, searching and reports; and other aspects around how the information will be managed, including managing changes, data quality and archival.
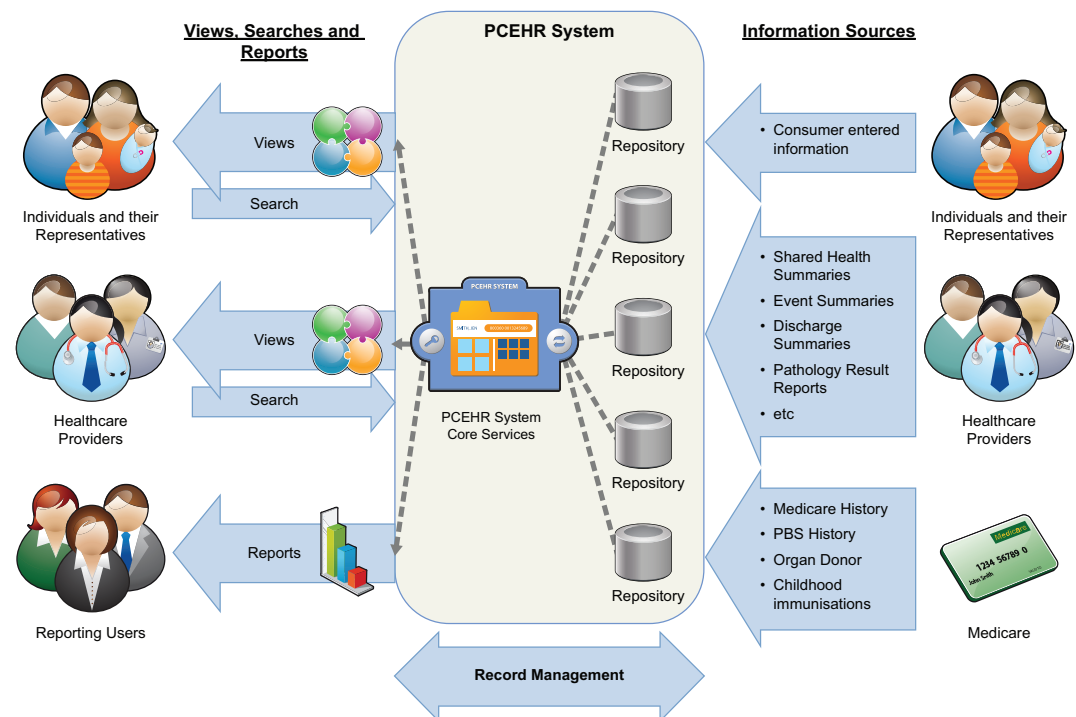
Figure 7: Managing PCEHR information

4.2   Information sources

4.2.1   Clinical Documents

The PCEHR System enables the collection of information from participating organisations, individuals and Medicare Australia within a series of conformant repositories. Information will be collected in the form of a clinical document.

For the purposes of the PCEHR System, a clinical document is an electronic document that contains personal health information about an individual. Examples include a Shared Health Summary, Event Summary, Discharge Summary, Pathology Result Report, etc.

The PCEHR System supports two forms of clinical document:

- A structured clinical document, which contains structured data describing the details of the event in an atomised form (e.g. medicines, allergies, etc).

- An unstructured clinical document, which has all the relevant fields to support indexing of the document and tracing the provenance of the document (see below) and also contains information in the form of an attached PDF.

> **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.

Types of Clinical Documents Supported

The PCEHR System shall support the collection of a range of clinical documents, including:

- Shared Health Summaries (see Section 4.2.2).
- Event Summaries (see Section 4.2.3).
- Discharge Summaries (see Section 4.2.4).
- Consumer entered information (see Section 4.2.11).

In addition to these clinical document types supported, a number of options are also be considered, including:

- Specialist Letters (see Section 4.2.5).
- Referrals (see Section 4.2.6).
- Prescribing and Dispensing information (see Section 4.2.7).
- Pathology Result Reports (see Section 4.2.8).
- Diagnostic Imaging Reports (see Section 4.2.9).
- Medicare Australia records (including Medicare claims history, PBS data, Organ Donor and the Australian Childhood Immunisation Register) (see Section 4.2.10).
- Advance Care Directives (see Section 4.2.12).

These options are subject to further consultation and will depend upon the readiness of healthcare provider organisations to participate in the national PCEHR Program.

> **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.

Common fields in all clinical documents and minimum core data sets

In order to support indexing of clinical documents and to provide sufficient information about the subject of care and the clinical document's provenance, all clinical documents (including unstructured clinical documents) must include fields about the document, such as:

- Document control information, including: unique document identifier, version number, unique identifier of any previous version, document type information (e.g. Discharge Summary, Event Summary, etc), document template (see Section 6.5.1), structured/unstructured clinical document flag, and date/time the document was attested.
- The individual's details, including: name, IHI, date of birth, sex, address, communication details and indigenous status.

- The document source, including: name of the author, HPI-I, healthcare role, organisation details, HPI-O, organisation role (e.g. general practice, hospital, etc), organisation address and communication details.

In addition to these fields, structured clinical documents will use a common library of detailed clinical models (DCM) to ensure consistency of information structures and clinical terminologies between different clinical document types [NEHT2010a]. This consistency is the basis for supporting a number of views and reports that extract data from different clinical documents.

All structured clinical documents will have a minimum core data set defining the fields that must be supplied. Any field marked as 'required' within a clinical document must be filled in for the clinical document to be valid. If the author does not have information to put into a mandatory field, then they will be required to supply a reason. For example, 'No Known Allergies' can be used for an allergies/adverse reactions field.

Managing changes to clinical documents

Consistent with healthcare record management practices, clinical documents within a PCEHR can never be deleted. Any changes will require a new version of the clinical document to be issued.

The PCEHR System treats the originating source system as the 'source of truth' and holder of the primary copy of the information. Any information held within a conformant repository is treated as a copy of information extracted from the source system. If a clinical document needs to be updated or amended, the source system must first be updated and a new version of the clinical document must be loaded into the relevant conformant repository.

The conformant repositories will be required to retain a history of previous versions of clinical documents. Users will be able to see the previous versions, if they wish through their respective systems or portals.

Downloading and printing clinical documents and views

The PCEHR System permits users to download and/or print any clinical documents and views they are authorised to access. Downloaded information can be supplied either in PDF format or a standards conformant electronic format for loading into the organisation's local electronic health record.

Users should only download and/or print information required to support the delivery of the individual's care or to ensure that medico-legal integrity requirements are addressed. Once information has been downloaded and/or printed it becomes subject to the organisation's local health information management policies.

All downloaded and printed clinical documents and views need to be clearly marked with the date and time of download/printing.

If a user has downloaded a document, they will be able to periodically check if a new version is available by using the Change History View (see Section 4.3.2).

4.2.2   Shared Health Summaries

One of the key records shared via the PCEHR System is an individual's Shared Health Summary.

A Shared Health Summary is a clinical document sourced from the individual's nominated provider, which contains key pieces of information about an individual's health status and is useful to a wide range of healthcare providers for delivery of care.

Shared Health Summaries are a key piece of information for populating an individual's 'Consolidated View', which is assembled from multiple sources (see Section 4.3.1).

The Shared Health Summary must be supplied as a structured clinical document (unstructured Shared Health Summaries are not permitted). To enable easy extraction of Shared Health Summaries from GP systems, the fields within a Shared Health Summary will be congruent with the Royal Australian College of General Practitioners (RACGP) standards for health summaries [RACGP2010].

In addition to the common fields, a Shared Health Summary includes:

- Allergies and adverse reactions (required)

- Medicines (required)

- Medical history (required)

- Immunisations (required)

The initial version and any subsequent versions of a Shared Health Summary can only be uploaded by an individual's nominated provider or organisation (see Section 3.2.4). If other healthcare providers wish to provide similar information about the individual, they should use an Event Summary.

The nominated provider should upload a new version of the Shared Health Summary when something significant changes about the individual that is important to their ongoing care. Depending on the nature of the event, a nominated provider may choose to use an Event Summary, a Shared Health Summary or both.

eHealth Site Notes: All wave 1 sites and a number of wave 2 sites will be informing the creation and management of shared health summaries.

Design Note: For notes about the design rationale behind the Shared Health Summary and its relationship to the Consolidated View please see Section 4.3.3.

4.2.3   Event Summaries

An Event Summary is used to capture key health information about significant healthcare events that are relevant to the ongoing care of an individual.

Event Summaries can be submitted to the PCEHR System by any participating organisation. For example, it could be used by an after hours GP clinic, an emergency department, an outpatient clinic, a community pharmacy or an allied health clinic.

An Event Summary may either be provided as a structured clinical document or as an unstructured clinical document.

In addition to the common fields, a structured Event Summary contains additional fields including:

- Event details (including date of event (required) and a reason for visit (optional))

- Allergies and alerts (optional)

- Medicines (optional)

- Diagnosis (optional)

- Interventions (optional)

- Diagnostic investigations (optional)

- Observations (optional)

Healthcare providers are not required to provide an Event Summary at every consultation with the individual. Event summaries should be provided when something significant happens that is important to the individual's ongoing care.

4.2.4   Discharge Summaries

The PCEHR System will support collection of Discharge Summaries. When a healthcare provider creates a Discharge Summary, it will be sent directly to the intended recipient, as per current practices, and a copy of the Discharge Summary may also be sent to the PCEHR System.

A Discharge Summary may be provided either as a structured clinical document or as an unstructured clinical document.

Structured Discharge Summaries must conform to the forthcoming Standards Australia specifications based on the NEHTA specifications [NEHTA2010e].

In addition to the common fields, a Discharge Summary may contain:

- Nominated primary healthcare providers (required)
- Document recipients (required)
- Encounter details (optional)
- Problems/diagnoses (including principal, complications and co-morbidities) (optional)
- Clinical synopsis (required)
- Diagnostic investigations (optional)
- Clinical interventions (optional)
- Current medications on discharge (optional)
- Ceased medications (optional)
- Allergies/adverse reactions (optional)
- Alerts (optional)
- Arranged services (optional)
- Recommendations (optional)
- Information provided to patient and/or relevant parties (optional)
- Attachments (optional)

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.

eHealth Site Notes: All wave 1 sites and a number of wave 2 sites will be informing the creation and management of discharge summaries.

4.2.5   Specialist Letters

The PCEHR System will support the collection of Specialist Letters. When a specialist creates a Specialist Letter, it will be sent directly to the intended recipient, as per current practices, and a copy of the Specialist Letter may also be sent to the PCEHR System.

The PCEHR System will accept a Specialist Letter as either an unstructured clinical document or a structured clinical document.

Structured Specialist Letters will be conformant with the forthcoming NEHTA specifications and Australian standards.

In addition to the common fields, a structured Specialist Letter may contain:

- Specialist (required)
- Referring GP (required)
- Usual GP (required)
- Document recipients (required)
- Response details (required)
- Recommendations (required)
- Medicines list (optional)
- Diagnostic investigations (optional)
- Attachments (optional)

> **eHealth Site Notes:** All wave 1 sites and a number of wave 2 sites will be informing the creation and management of specialist letters.

4.2.6   Referrals

The PCEHR System will support collection of Referrals. When a healthcare provider creates a Referral, it will be sent directly to the intended recipient, as per current practices, and a copy of the Referral may also be sent to the PCEHR System.

The PCEHR System will accept Referrals as either an unstructured clinical document or as a structured clinical document.

Structured Referrals will be conformant with the forthcoming Australian Standards, which are based on the NEHTA Referral specifications [NEHTA2010f].

In addition to the common fields, a Referral may contain:

- Benefits card details (optional)
- Patient's nominated contact (optional)
- Referrer (required)
- Usual GP (required)
- Referee (required)
- Referral details (required)
- Current and past medical history (required)
- Current medications (required)
- Allergies/adverse reactions (required)
- Diagnostic investigations (optional)
- Attachments (optional)

> **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.

> **eHealth Site Notes:** All wave 1 sites and a number of wave 2 sites will be informing the creation and management of referrals.

4.2.7   Prescribing and Dispensing information

The PCEHR System will enable the collection of Prescribing and Dispensing information.

Participating prescribers and dispensers who have access to the PCEHR System will be able to upload a copy of Prescription and Dispensing information to the PCEHR System. This information is a copy of information that is also sent to the Prescription Exchange Service (PES). It will primarily be used to update the Consolidated View and present information about recent prescriptions and dispenses (see Section 4.3.3).

Prescriptions and dispense records will be provided as structured clinical documents conformant with the NEHTA Electronic Transmission of Prescription Specifications [NEHTA2010f] and forthcoming Australian standards.

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.

4.2.8   Pathology Result Reports

The PCEHR System will support collection of Pathology Result Reports.

An essential requirement of the PCEHR System is to ensure that appropriate Pathology Result Reports are released to the PCEHR System after the requestor has reviewed them. To support this requirement, pathology providers may use their own conformant repository or another conformant repository.

In both instances, Pathology Result Reports will still be sent to the requestor directly who will review and then send a message to the pathology provider indicating the result is to be made available to the PCEHR System. At this point the pathology provider's system will either:

  • inform the PCEHR System that a new Pathology Result Report is available on the pathology provider's conformant repository and should be indexed; or

  • send a copy of the Pathology Result Report to another conformant repository.

The PCEHR System will accept Pathology Result Reports either as unstructured or structured clinical documents.

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.

4.2.9   Diagnostic Imaging Reports

The PCEHR System will support collection of Diagnostic Imaging Reports.

An essential requirement of the PCEHR System is to ensure that appropriate Diagnostic Imaging Reports are released to the PCEHR System after the requestor has reviewed them. To support this requirement, diagnostic imaging providers may use their own conformant repository or another conformant repository.

In both instances, Diagnostic Imaging Reports will still be sent to the requestor directly who will review and then send a message to the diagnostic

imaging provider indicating the report is to be made available to the PCEHR System. At this point the diagnostic imaging provider's system will either:

- inform the PCEHR System that a new Diagnostic Imaging Report is available on the diagnostic imaging provider's conformant repository and should be indexed; or

- send a copy of the Diagnostic Imaging Report to another conformant repository.

The PCEHR System will accept Diagnostic Imaging Reports as unstructured clinical documents.

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.

eHealth Site Notes: The Greater Western Sydney eHealth site will be informing the creation and management of diagnostic imaging result reports.

4.2.10   Medicare Australia records

Medicare Australia offers a significant opportunity to leverage the information it collects. Whilst this information lacks the clinical richness of other information sources, such as discharge summaries, Medicare Australia is able to provide a longitudinal source of information amount about an individual's healthcare events, including:

- information about healthcare events funded under the Medicare Benefits Schedule (MBS).

- information about packets of medications dispensed under the Pharmaceutical Benefits Scheme (PBS).

- childhood immunisation records for children under the age of 7 via the Australian Childhood Immunisation Register (ACIR).

- organ donor information via the Australian Organ Donor Register (AODR).

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.

4.2.11   Consumer entered information

The PCEHR System will provide three avenues for individuals to enter information into the PCEHR via the consumer portal. These avenues are:

- A way of providing 'key information' about any allergies and adverse reactions or medications (including over the counter medications), the individual would like their healthcare providers to be aware of.

- A way of providing information about the location and custodian of their advance care directive (if they have one).

- A notes area with their PCEHR, which the individual and their representatives can use as an aide memoire to record information about their healthcare.

The key information will be loaded as a structured document and included in the Consolidated View (see Section 4.3.3), thereby allowing the individual's healthcare providers to quickly access it.

The notes area is intended for private use only and will only be accessible to the individual and their representatives.

The consumer entered information described above is the first step towards a strengthening involvement of individuals in their healthcare.   The PCEHR System also allows for independently operated conformant portals to connect to the PCEHR System (see Section 3.4.3). It is envisaged that these portals will offer value added features around self-managed care. For example, this may include collecting information such as blood glucose levels and a food diary to help an individual work with their diabetes educator to manage their diabetes.

> **eHealth Site Notes:** The Medibank Private eHealth site will be informing the development and implementation of consumer entered information within a consumer oriented portal. The Medibank Private Portal will allow individuals enrolled in the MediBank Private chronic disease management program to collect and share information with their healthcare providers. Medibank Private will not be using any of this information for the management of claims or eligibility for healthcare insurance benefits.

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.

4.2.12   Advance Care Directives

Advance care directives give individuals the opportunity to make choices about future medical treatment in the event they are cognitively impaired or otherwise unable to make their preferences known.

The PCEHR System will provide an opportunity to collect information about the location of an individual's advance care directives (if they have one). Custodians are often an individual's GP, solicitor (the directive may be held with the will) or a family member.

Information about an individual's advance care directive will be loaded as a structured clinical document and will contain all common fields, plus:

- Information about the custodian of the advance care directive, including name and contact details (required)[9].

Like wills, advance care directives often change over time. Discussions about the directive form a routine part of care between individuals and their GP. They are revisited regularly to explore any changes an individual may have in his or her wishes, especially if the individual's clinical situation has changed. The custodian also assesses the person's state of mind and capacity when updating their directive.

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[9] The directive itself will not be uploaded on the basis that if uploaded it would raise issues of currency or contain legal implications extraneous to PCEHR System matters.

The consequences of acting on an individual's preferences as set out in an advance care directive can be significant, sometimes final. When considering the contents of an advance care directive, healthcare providers undertake rigorous due diligence such as confirming the directive they have is the most current version and discussing with the custodian the individual's state of mind at the time they made the directive. Healthcare Providers have advised NEHTA that they are unlikely to consider an advance care directive available in a PCEHR without first communicating with the custodian.

> **eHealth Site Notes:** The Cradle Coast and North Western Area Health Service eHealth site will be informing the development and implementation of availability of advance care directives. The eHealth site will also consider the policy implications of electronically stored advance care directives.

4.3   Views

In addition to providing access to individual clinical documents, the PCEHR System will provide a range of 'views', which assemble information from multiple clinical documents and present it in a more accessible way.

The PCEHR System will support the following views:

-   Index View

-   Change History View

-   Consolidated View

These views will form the base of commonly accessible views and will be accessible to all users.

In time, a range of additional views will be added to support the specific needs of individuals and healthcare providers (see Section 2.8).

Some clinical systems accessing the PCEHR System may also provide their own custom views for presenting data accessed on the PCEHR System.

4.3.1   Index View

The Index View presents a list of information available via the Index in an individual's PCEHR.

For each clinical document with an individual's PCEHR, the Index View includes:

-   The date of the record.

-   The type of record (e.g. Event Summary, Discharge Summary).

-   The clinical setting where it was recorded (e.g. General Practice, Hospital, Community Pharmacy, etc).

-   The author name and role (e.g. Dr John Smith, Endocrinologist).

-   A link to the original document.

By default, the Index View will be sorted in reverse chronological order, with the most recent clinical documents first. The user will be able to sort the view by some of the fields (e.g. date, type, clinical setting, role of the author, name of the author, etc).

The user will be able to filter the view by some of the fields (e.g. by date range, clinical setting, role of the author, etc). By default, the Index View will have no filters set.

If the participating individual in the past has chosen to withdraw and later decides to have their PCEHR re-activated, the Index View will indicate if there are any time period based gaps in a record.

4.3.2   Change History View

The Change History View allows the user to locate clinical documents that may have recently had a new version uploaded to the PCEHR System.

For each clinical document with an individual's PCEHR, the Change History View includes:

- The date when the new version was issued.

- The type of record (e.g. Event Summary, Discharge Summary).

- The author name and role (e.g. Dr John Smith, Endocrinologist).

- A link to the most recent version of the clinical document and an ability to link to previous versions of the clinical document (if required).

By default the view will be sorted in reverse chronological order, with the most recently updated clinical documents first. The user will be able to sort the view by some of the fields (e.g. date, type, role of the author, name of the author, etc).

The user will be able to filter the view by some of the fields (e.g. by date range). By default the Index View should have no filters set.

4.3.3   Consolidated View

The Consolidated View is intended to provide a snapshot of an individual's health status and allow easy access to information relevant to the care of the individual.

The Consolidated View assembles information from a range of clinical documents including the Shared Health Summary, Event Summaries, Discharge Summaries and other sources and then presents it in a consolidated form.

The Consolidated View will allow the user to more easily access:

- The individual's details, including name, date of birth, sex, IHI, contact details, contact person and Aboriginal and Torres Strait Islander status.

- The individual's nominated provider's details (if the have one).

- Consolidated lists for:

    - Allergies/adverse reactions (from the shared health summary, other clinical documents and key information from the individual).

    - Medical history (from the Shared Health Summary and other clinical documents).

    - Medicines (from the Shared Health Summary, other clinical document, prescription/dispensing history and key information from the individual).

    - Immunisations (from the Shared Health Summary, other clinical documents and ACIR data if available).

- A list of recent clinical documents (similar to the index view).

- A list of recently changed clinical documents (similar to the Change History View).

- Directives including organ donor status (from Medicare) and location of the individual's advance care directive.

- A list of recent healthcare events and dispensed medications indicated by an individual's claiming history from Medicare Australia.

- An ability to search and filter clinical documents (see Section 4.4).

As illustrated in Figure 8, users of the Consolidated View will be able to select a piece of information, identify where it came from and follow a link to the full clinical document where it was originally sourced.

To assure that there is quality information in the Consolidated View, it is recommended that an individual nominate a healthcare provider to maintain their Shared Health Summary. Information drawn from the Shared Health Summary will then be highlighted in the view.

As there is a risk that the Shared Health Summary may become out of date, the Consolidated View will still show additional information from other sources (such as Event Summaries). The source of the information will be clearly marked and distinguished from the information from the Shared Health Summary.

A nominated provider is optional and if not selected, the Consolidated View will not emphasise information from the Shared Health Summary and will simply present the information from the other sources.

A key piece of information in the Consolidated View will show a reconciled list of recent dispenses and prescriptions. The Consolidated View will just show the prescription if no dispense has occurred, and the dispenses where no prescription exists. It will also show the expected date when the prescription will expire.

As there is a risk that the Consolidated View may be incomplete when information is not extractable from an unstructured clinical document, the view will include a standard notice indicating that the view may not represent a complete set of health information, and any unstructured clinical documents will need to be flagged.

If the participating individual in the past has chosen to withdraw and later decides to have their PCEHR restored, the Consolidated View will indicate if there are any time period based gaps in a record.

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.

Consolidated View: Mr John D. Smith   `_` `☐` `x`

Details *Sex: Male   DOB: 5 Jun 1965 (47 yrs)*
          IHI:8003601234567890   ATSI: No
Contact Details: 12 Notastreet Cr, Sunnybank , QLD 4012.
          ph: (07) 5555 9876
Contact Person: Mrs. Jane Smith (Wife) ph: (07) 5555 9876

Nominated Provider: Dr Simon Chu (GP)
Sunnybank Hills Clinic   ph: (07) 5555 1234
Shared Health Summary last reviewed:: **13 Jul 2012**

Allergies / Adverse Reactions
From Shared Health Summary:
12 Jul 2012   Substance: Prochlorperazine (Stemetil)   **View**
                Reaction: Torticollis
Additional items from other clinical documents:
         No information
Information from Individual
 7 Aug 2012   Rash from Elastoplasts   **View**

Medical History
From Shared Health Summary:
12 Jul   2012   Inguinal Hernia Repair (left side)   **View**
29 May 2012   Inguinal Hernia (left side)
18 Jun   2001   Essential Hypertension
Additional items from other clinical documents:
14 Sep 2012   Lower Back Muscle Strain (Physiotherapist)   **View**

Medicines
From Shared Health Summary:
18 Aug 2010   Quinapril (Accupril 20 mg)   **View**
Additional items from other clinical documents:
14 Sep 2012   Diclofenac (Voltaren Gel) (Pharmacy)   **View**
Recent Scripts:
22 Sep 2012   Quinapril (Accupril 20 mg)
                Prescribed ☑ Dispensed ☒   **View**
                Script runs out: 22/01/13
Information from Individual
7 Aug 2012   St Johns Wort Tablets   **View**

Immunisations
From Shared Health Summary:
 7 Jan 2008   OPV Sabin   **View**
Additional items from other clinical documents:
 22 Sep 2012   Fluvax   **View**
Additional items from ACIR:
         No information

Directives
Organ Donor   Registered with Medicare   **View**
Advance Care Directive Location:
         No Information

Notice:
An individual's PCEHR may not represent a complete set of health information.

Find Clinical Document
Keywords: [   ]   **Search**
                          Advanced

History Filter
Show Documents From: Last 18 Months ▼

Clinical Documents
22 Sep 2012   Event Summary (GP)   **View**
16 Sep 2012   Pathology Report (★)   **View**
14 Sep 2012   Event Summary (Pharmacy)   **View**
14 Sep 2012   Event Summary   **View**
                (Physiotherapist)
 7 Aug 2012   Key Information from Individual   **View**
22 Jul 2012   Prescription   **View**
12 Jul 2012   Discharge Summary (★)   **View**
★ *warning: unstructured document*
        data may not be in view   **View Index**

Change History
16 Sep 2012   Pathology Report   **View Change**
13 Jul 2012   Shared Health Summary   **View Change**
                          View Change History

Medicare History
22 Sep 2012   Immunisation Provided   **View**
22 Sep 2012   Surgery Consultation - Level B   **View**
16 Sep 2012   Full Blood Count   **View**
22 Jun 2012   Surgery Consultation - Level B   **View**
 8 Jun 2012   Surgery Consultation - Level B   **View**

PBS History
22 Sep 2012   Fluvax   **View**
22 Jun 2012   Rulide 300 mg Box of 5   **View**
 8 Jun 2012   Apo-pril 20 mg Box of 30   **View**
 8 Jun 2012   Amoxil 500 mg Box of 20   **View**
1 May 2012   Apo-pril 20 mg Box of 30   **View**
7 Apr 2012   Accupril 20 mg Box of 30   **View**

Print   **Download**   **Close**

Figure 8: Example Consolidated View[10]

4.4   Search

In time, as the PCEHR System accumulates more clinical documents, the ability to find specific clinical documents via chronological views such as the Index View will become more challenging. In order to help users find clinical documents within a PCEHR more readily, the PCEHR System provides two search functions: basic search and advanced search.

4.4.1   Basic search

The basic search function allows users to find clinical documents within an individual's PCEHR based on matching keywords. Users will, for example, be able to find all clinical documents that contain the term 'kidney'.

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[10] Note that this is a conceptual mock up of what the consolidated view could look like and is not an actual system.

The basic search is limited and will only support simple matching methods. In time, as the number of clinical documents within each PCEHR increases and demand for this function increases, more sophisticated matching techniques will be investigated.

4.4.2 Advanced search

The advanced search function allows the user to search an individual's PCEHR for clinical documents via a number of parameters, including:

- Keywords
- Date Range
- Type(s) of Clinical Document

The advanced search function is limited in its search capabilities. In time, as the number of clinical documents within each PCEHR increases and demand for this function increases, more search parameters will become available.

4.5 Reports

Actively monitoring the PCEHR System is essential to being able to effectively manage the PCEHR System from both an operational and a benefits realisation perspective.

To help meet this need, the PCEHR System includes a reporting service, which will be used to analyse information from multiple PCEHRs and additional information in the audit trails and operational logs of the system.

The purpose of this service is to support operational reporting, to help evaluate take-up rates and to track progress around key performance indicators. In time the reporting service may be extended to support additional approved uses. The report service will be able to provide a range of reports, including:

- Operational reporting, such as, but not limited to:
    - Reporting against metrics in PCEHR System infrastructure Service Level Agreements and conformant repository Service Level Agreements (e.g. uptime, incident reports, incident resolution times, call centre reporting, etc).
    - Audit reports.
    - Data quality 'dashboard' (see Section 4.6.1).
- PCEHR System uptake and usage reporting, including access to pre-defined reports showing:
    - Numbers of individuals registering, using the PCEHR System and withdrawing.
    - Numbers of authorised users and healthcare organisations using the PCEHR System.
    - Viewing of clinical documents, views and reports.
    - Uploading new clinical documents.

    This data will be able to be broken down by:
    - Demographics (Age, Location, Gender).
    - Time (Time of Day, Day of Week, Month).
    - Healthcare provider role (e.g. GP, specialist, ED doctor).
    - Kind of information accessed or uploaded (view name or clinical document types).

- Reports related to outcomes realisation related key performance indicators (see Section 9.3.1).

Most reports will contain de-identified data. In some cases where reports may contain potentially identifiable data (e.g. audit reporting), only appropriately authorised users will be permitted to create and view the reports.

The types of reports available are expected to evolve over time as operational reporting requirements and key performance indicators mature.

4.6 Related topics

4.6.1 Correcting errors

From time to time clinical documents may contain errors, which may in turn have quality and safety implications around the ongoing care of an individual. To minimise this risk, the PCEHR System will use an active approach to managing data quality and validation (see Section 4.6.2) and complements this with support processes around correcting errors within clinical documents and managing clinical documents loaded into the wrong PCEHR.

Correcting errors within Clinical Documents

In the event that a clinical document contains incorrect information, the PCEHR System will support a number of processes to ensure that the information is corrected.

As mentioned above, if the information is incorrect, then the correction should be initiated within the source system and a new version of the clinical document should be issued to the PCEHR System.

The correction process is typically initiated by the healthcare organisation that supplied the document. Individuals or providers who wish to have a clinical document corrected should contact the healthcare organisation concerned to have the information corrected.

The PCEHR System Operator will provide a process to help individuals with this process if they prefer not to approach the healthcare organisation directly.

Managing Clinical Documents loaded into the wrong PCEHR

In the event that a clinical document has been loaded into the wrong PCEHR, the PCEHR System will support a process around the effective removal of incorrectly-posted clinical documents. Such events may occur if the healthcare organisation has inadvertently misidentified the individual in the clinical document.

This process may be initiated by the individual or the healthcare organisation supplying the clinical document. The PCEHR System Operator will work with the healthcare organisation and the individual(s) concerned to ensure that the clinical documents are loaded into the correct PCEHR.

4.6.2 Ensuring data quality

Ensuring a high standard of data quality is an essential requirement for the PCEHR System. High levels of data quality are required to assist healthcare providers and individuals in making safe healthcare decisions.

Achieving a high standard of data quality will be challenging as it will require continuous measurement and targeted improvements in culture, policies, processes and technology. To help support this change over time, the PCEHR System will implement a quality management framework and system that address the fundamentals of data quality, including:

- Stakeholder-driven identification of key metrics and their associated collection protocols on quality dimensions such as accuracy, completeness, consistency, currency, timeliness, fitness for use, provenance and compliance.

- The identification of minimum levels to be achieved within a specified timeframe.

- Preventative and corrective actions to be taken to improve data quality (including technical solutions such as enhancing data entry screens or fixing back-end system issues and non-technical solutions such as training).

- The creation of a series of data quality reports (e.g. via a 'data quality dashboard') to help profile and track different metrics in relation to their targets.

- The introduction of an issue tracking system to track known issues and progress on corrective actions.

The quality management system will be embedded within a broader clinical governance model (see Section 7.2) and will also be embedded within a Service Level Agreement and subject to performance management.

Achieving high standards of data quality is a not a single step process. It will be a process that runs over the entire life of the PCEHR System and will require continuous improvement.

Validation

One tactic employed by the PCEHR System to ensure data quality is around the validation of clinical documents loaded into the system. Validation includes:

- Ensuring that the IHI, name, sex and date of birth highlighted in the clinical document has an exact match to the details of the PCEHR it is being loaded into.

- Ensuring that the structure and content of clinical document matches against the template describing its content structure and data types (see Section 6.5.1 for the template service).

- Ensuring the integrity of any included identifier for individuals, healthcare providers or organisation.

Clinical documents that fail validation will be rejected by the PCEHR System and the feeding system will need to supply a corrected version. To mitigate the risks around a system supplying invalid content, any systems that connect to the PCEHR System will be required to undergo conformance assessment (see Section 7.4).

4.6.3   Archival

Archival of PCEHR records will be based on health sector best practices and will meet all relevant legislative requirements.

The minimum period of time before records can be archived into offline storage or disposed of will be determined through a consultative process and a legislative review. Suggested retention periods are as follows:

- While a PCEHR is active, any records within a PCEHR (and related records such as audit trails) will continue to be retained.

- If a PCEHR has been de-activated, because the individual has withdrawn or the individual is deceased, then records within a PCEHR (and related records such as audit trails) *may* be archived or destroyed after a period of time according to legislation and PCEHR System policies.

PCEHRs without any activity (e.g. access or the addition of new records) for long periods of time will be subject to the same rules as any other PCEHR.

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

5   Privacy and security

5.1   Introduction

Privacy protection and appropriate security are critical aspects of the PCEHR System. Successful delivery of both will increase an individual's access to, and control over, their health information, limit any opportunity for inappropriate access and ensure trust and confidence in the system.

The protection of privacy and security is being considered from the outset of the PCEHR system design. It should be recognised that there is no single solution to address privacy and security issues. The PCEHR System has significant potential to address the problems created by fragmented information in the current healthcare system and to provide individuals and their healthcare providers with better access to their healthcare information. A combination of technical, policy, governance and legislative safeguards will need to be in place to facilitate access by the right people and prevent inappropriate access and use of healthcare information.

Individuals will have significant control over their PCEHR and how it is used. Individuals can choose to have (or not have) a PCEHR, can access all information in their PCEHR, set access controls around healthcare provider access, apply greater controls to sensitive information, and choose which information is not available through their PCEHR. These and other controls provide numerous options for individuals. Many individuals who choose to have a PCEHR will probably not exercise all these options. However, when building a national system we must allow for those people with specific sensitivities to participate in a way that is respectful and responsive to their concerns.

In addition to this, the PCEHR system will record details of every person who views an individual's PCEHR. Individuals will be able to view this information through an online audit trail and make enquires and complaints about inappropriate access.

Furthermore, additional safeguards will underpin the PCEHR System, including: technical security measures, training, effective and transparent governance arrangements, legal protections and penalties, and regulatory oversight.

This Concept of Operations focuses primarily on the technical control and business process layers required for a PCEHR System. The PCEHR System's governance arrangements, regulatory framework, including complaints management and sanctions are being developed by government and will be informed by the Concept of Operations consultation process and will be the subject of later consultation processes.

5.2   Privacy

The privacy concepts to be supported by the PCEHR System align with the National Privacy Principles (NPPs) found in the Commonwealth Privacy Act 1988.

Currently, depending on where the PCEHR System is operated and used, different privacy laws could apply. The Department of Health and Ageing is currently working with jurisdictions to develop a consistent privacy regime that would apply to the PCEHR System irrespective of the location of the individual or healthcare provider.

The core privacy concepts to be supported by the PCEHR System are outlined below:

Table 1: How core privacy concepts are supported

Privacy Concept	Summary of how the concept is supported
Collection	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. The kinds of information proposed to be collected by the PCEHR System are defined in Section 4.
Use and Disclosure	The personal health information within an Individual's PCEHR is intended for use and disclosure by the individual, their representatives and their healthcare providers for the purposes of the Individual's healthcare. Information contained within the PCEHR System will also be reported against for operational and management purposes, e.g. to ensure that the system is running effectively or to monitor audit trails. How information is used and disclosed (including reporting) by the PCEHR System is described in Section 4.
Data Quality	The PCEHR System will use new and existing conformance, compliance and accreditation processes to ensure that the information it collects, uses or discloses is of sufficient quality to support safe and effective care. The approach to data quality is defined in Section 4.6.2.
Data Security	The PCEHR System will protect the personal information it holds through strong authentication of individuals and users, provision of access controls, auditing, security testing and education and training of users. Security is discussed further in Section 5.3.
Openness	The PCEHR System Operator will implement policies on its management of personal information. Once developed, these policies will be publicly available.
Access and Correction	All personal health information held within an Individual's PCEHR will be accessible to the individual concerned via a consumer portal. If an individual believes that information within the system is incorrect they will be able to instigate corrective action. The consumer portal is discussed further in Section 6.3.1. Correction is discussed further in Section 4.6.1.
Identifiers	The PCEHR System will adopt the identifiers supplied by the HI Service operated by Medicare Australia for individuals, healthcare providers and healthcare organisations. The HI Service provides reliable identifiers and is backed by strong legislation and oversight by government.

Privacy Concept	Summary of how the concept is supported
Anonymity	Individuals have the option of applying for a pseudonym with the HI Service in the event that they wish to use a pseudonymous identity for the purposes of healthcare.
Transborder Data Flows	All elements of the PCEHR System infrastructure and any connected conformant repositories, conformant portals and contracted service providers must operate according to the NPPs and be subject to Australian law. Any transborder flows of information to offshore sites should only be to locations with equivalent privacy protections, in line with existing privacy law.
Sensitive Information	Individuals will be able to request that certain information is not made available on the PCEHR System. Individuals will also be able to control access and limit disclosure to that information once it has been uploaded. Limiting disclosure of information is discussed further in Section 5.5.

Development of privacy protections will be informed by the ongoing utilisation of privacy impact assessments (PIAs), increasing in detail and depth as the PCEHR System design develops. Initial consultation suggests that the community will have an interest in the following topics:

- Clearly defining the purpose(s) of the PCEHR System as well as any intended future purposes and purposes that are specifically out of scope.
- Identifying authorised and permitted information flows and any prohibited flows, and identifying an appropriate consent model based on the PCEHR system design.
- Identifying an entity with clear responsibility for the management of the PCEHR System.
- Setting out the rights and responsibilities of the PCEHR System Operator and system users.
- Providing consistent and transparent arrangements for complaints handling and the application of any penalties.

5.3   Security

As the start of this section suggested, trust is one of the many critical success factors for the PCEHR System. Therefore it is essential to ensure that:

- People seeking access to information are who they claim to be.
- Information received from a claimed person is from that person.
- Information transmitted across networks is appropriately encrypted and has arrived at its destination point without being tampered with.
- Access to information is appropriately authorised.

A multi-layered approach will safeguard the PCEHR System, and accordingly the system's Security and Access Framework will need to incorporate both technical and non-technical controls. These include:

- Accurate authentication of users accessing the PCEHR System.
- Robust audit trails.

- Proactive monitoring of access to the PCEHR System to detect suspicious and inappropriate behaviour.

- Rigorous security testing, to be conducted both prior to and after commencement of operation of the PCEHR System.

- Education and training of users of the system.

- Requirements that healthcare providers and organisations comply with relevant system rules, standards and legal requirements.

The Security and Access Framework for the PCEHR System will ensure that the confidentiality, integrity and availability of information within the PCEHR System are not compromised.

Security has been designed to be 'fit for purpose', and to address health and information policy objectives. The objective of the PCEHR System Security and Access Framework is to:

- Minimise the risk of unauthorised access to the PCEHR System and the information it contains.

- Enable detection of unauthorised information access or modification, and any other breach of information security (including privacy).

- Facilitate appropriate response to, and investigation of, any such breaches.

- Assure the continued availability of the PCEHR System.

- Provide a means to continually improve security protections (including protection of privacy, confidentiality, integrity and availability).

The completion of a security and access framework is contingent on the assessment of a full range of personal, logical/systems and physical security threats and risks to be assessed and a layered set of solutions be implemented to address these threats and risks. The following frameworks will be used as inputs into that assessment process:

- Attorney-General, Protective Security Policy Framework (PSPF) [AG2010];

- Attorney-General, National Identity Security Strategy [AG2010];

- Department of Finance and Deregulation, National E-Authentication Framework (NEAF) [DOFD2009];

- NEHTA Security and Access Framework [NEHT2010b]; and

- International best practice information security management standards, including general risk management guidelines [ISO/IEC 27001] and security management in health [ISO27799].

5.4   Authentication

Ensuring that people seeking access to information are who they claim to be will be an essential issue to be addressed in the PCEHR System.

5.4.1 Authorised users

Access from Clinical Systems

Once an organisation has authorised a user to access the PCEHR System, local organisational authentication mechanisms will be used to authenticate the user accessing the PCEHR System. When accessing the PCEHR System, the local system will authenticate itself to the PCEHR System using the organisation's digital credentials and pass on user details, including name, role, HPI-I (if they have one) and), HPI-O of the point of access for the purposes of audit. Generic/shared user credentials for authorised users are not permissible.

Access via a Contracted Service Provider

Once an organisation has authorised a user to access the PCEHR System via a contracted service provider, the CSP's system will authenticate itself to the PCEHR System using the CSP's digital credentials. The CSP will pass on user details, including name, role, HPI-I (if they have one), HPI-O of the point of access for the purposes of audit. Generic/shared user credentials for authorised users are not permissible.

Access from the Provider Portal

Healthcare providers wishing to use the provider portal to access the PCEHR System will need to be linked to the healthcare organisation within the HI Provider directory Service (HI-PDS) and will need to use a NASH token (e.g. smart card or USB token) asserting their identity to log in.

If the healthcare provider is linked to multiple healthcare organisations, they will be required as part of the login process to select which organisation they are accessing the PCEHR System on behalf of.

The Organisation Maintenance Officer (OMO) will be responsible to maintaining the links between the organisation and the healthcare provider and for removing the links when the healthcare provider leaves the organisation.

5.4.2 Individuals and representatives

Authentication to the Consumer Portal and Conformant Portals

All authentication to the consumer portal and other conformant portals shall be in accordance with the safeguards indentified in the NEAF [DOFD2009].

The Consumer Portal and conformant portals will implement a range of safe guards to reduce the likelihood of threatening events occurring, enable their early detection or reduce the harm arising from them. These safeguards include:

- Informed use consent, including acknowledgement of the importance of protecting e-Authentication credentials.

- Continual reinforcement of the importance of protecting e-authentication credentials through user education, warnings or notices displayed or each online session.

- Implementing challenge-response questions or important transactions.

- Informing users of:

    - The number of recent accesses and the date of last access

    - Access attempts using invalid passwords

    - Important categories of transactions that require verification by means of "out of band" channels such as Post or SMS

The NEAF makes specific reference to safeguards in relation to health and safety including:

- Limiting transactions which can be conducted through particular channels

- Requiring stronger e-Authentication for particularly sensitive data (for example, challenge-response using knowledge-based approach or using one-time password)

It is envisaged that conformant portal providers may select from a number of mechanisms for delivering e-Authentication, which would be compliant with NEAF and PCEHR System requirements. These may include the use of smartcard technology or username/password combined with challenge-response using shared knowledge questions.

Individuals may choose a Portal provider which supports e-Authentication methods and/or supplementary, value adding services according to their preference.

> **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.

Authentication via Call Centre

When contacting the call centre, individuals and their representatives will be required to authenticate themselves by providing sufficient identifying information to help the operator locate the individual's PCEHR, and by answering a series of questions they have set at registration.

5.5   Authorisation and access control

Access to information within the PCEHR System will be moderated by a series of access controls managed by the individual. For each individual's PCEHR, the PCEHR System will maintain:

- An 'include' list and 'exclude' list.

- A series of access control settings.

- A list of suppressed documents.

Each of these items are discussed below. In addition to this, controlling information at the time of addition to the PCEHR System, Referral access keys and managing the release of diagnostic test results are also discussed. Some access controls may also be overridden in situations where the individual requires emergency care. This is discussed further in Section 5.5.4.

5.5.1   The Include and Exclude List

The individual will be able to control which participating organisations are able to access their PCEHR via an 'include list' (healthcare organisations that can access a PCEHR) and an 'exclude list' (healthcare organisations that are not permitted to access a PCEHR).

The include list and exclude list can be updated by the individual at any time.

The 'include list' and 'exclude list' contain the 'participating organisation' HPI-O and by inference includes all network HPI-Os beneath the participating organisation HPI-O. A participating organisation cannot be on both 'include list' and 'exclude list' at the same time.

5.5.2   Access control settings

Individuals will be able to exercise control over how access is managed by answering a series of questions.

The answers to these questions can be updated at any time.

The questions include:

- Do you wish participating healthcare providers to see if you have a PCEHR?

  If the individual answers 'yes', then when an individual arrives at a healthcare organisation, the organisation will be able to use the individual's IHI (and other details such as name, sex and date of birth) to search the PCEHR System.

  If the individual answers 'no', a search of the PCEHR System will return that no PCEHR could be found (refer to Section 5.5.4 for information on emergency access).

  A PCEHR can still be found with emergency access if the individual answers 'no' to this question.

- Do you allow any healthcare provider engaged in your care to access your PCEHR, or, only allow healthcare providers with your 'Provider Access Code (PAC)' to access our PCEHR?

  If the first option is chosen then any participating organisation delivering care to the individual can request to be added to the include list without requiring additional measures. If the organisation is on the individual's exclude list they will not be able to access the individual's PCEHR. If the individual wishes the organisation to have access to their PCEHR, the individuals will need to move the organisation off the exclude list via the Consumer Portal or via the Call Centre.

  If the second option is chosen then the individual will be requested to set up their PAC (effectively a PIN or passphrase).

  When the individual visits a participating organisation for the first time, the organisation will be requested to enter the PAC in order to be added to the 'include list'. If the individual provides their PAC to an organisation on the 'exclude list', the organisation will be moved from the 'exclude list' to the 'include list'.

  If the individual opts to set up a PAC, then they will also be requested to answer the following question:

  - *If you forget your PAC, do you wish participating organisations to be able to access your PCEHR?*

  If this setting is set to 'no', then access will not be granted to the organisation without the valid PAC.

  If this setting is set to 'yes', then participating organisations will be able to access the individual's PCEHR without the valid PAC when the individual forgets their PAC. The reason for accessing their PCEHR without a PAC will be recorded in the audit trail.

  If this setting is set to 'yes', the individual will also be asked:

  - *Do you want to be notified if your PCEHR is accessed without your PAC?*

  If the individual opts to be notified, they will be notified via their preferred method whenever access without their PAC occurs.

- *Do you wish to be notified when a healthcare organisation is added to your include list for the first time?*

   If the individual answers 'yes', they will be required to enter details about how they would like to be notified. From this point on, if a new organisation is added to the include list, the individual will be notified.

   If the individual answers 'no', they will not be notified when a new organisation is added to the include list.

5.5.3   Options around controlling access to clinical documents

The PCEHR System treats all clinical documents as potentially sensitive health information and provides the individual with a number of options around how each clinical document should be handled. This includes control at the time of load into their PCEHR and control after a clinical document has been loaded on their PCEHR.

Control at the time of load to the PCEHR System

The individual has the right to ask for clinical documents to not be loaded to their PCEHR.

If the individual does not want the clinical document added to their PCEHR, the healthcare provider will not send it.

The onus is on the individual to inform their healthcare provider that they do not want the clinical document loaded, although the healthcare provider should inform the individual if a clinical document may not be appropriate to load into their PCEHR.

Access controls on clinical documents in the PCEHR System

Once a clinical document has been loaded on to an individual's PCEHR, the individual will be provided with a number of additional options around how access to each clinical document should be controlled. These options can be changed at any time using the consumer portal and include:

Table 2: Access control options

Option	Description	Possible consequences
'general access'	The clinical document will be accessible by any healthcare organisation that has access to the individual's PCEHR. This is the default option for any new clinical documents loaded on to a PCEHR.	The clinical document will be available when needed for an individual's care by any healthcare organisation that currently has permission to access the individual's PCEHR.
'limited access'	The clinical document will be accessible via the individual's PCEHR to a more limited group of healthcare organisations selected by the individual (see below). The clinical document is still accessible to the healthcare organisation that supplied it and in an emergency situation (see Section 5.5.4). Shared Health Summaries cannot have 'limited access' option applied to them.	The individual has opted for more control over the healthcare organisations that can access these clinical documents, allowing them to decide the level of access based on the kind of care they are seeking. The individual will take the responsibility that this information may be important to ensuring that individual receives the right care. Where the healthcare provider does not know this information, it may mean that the individual is given inadequate or inappropriate care.
'no access'	Except the organisation which originally supplied the clinical document, the clinical document will no longer be accessible to any of the healthcare organisations, including in an emergency situation. Shared Health Summaries cannot have 'no access' option applied to them.	Provides the individual with the option of ensuring that the clinical document is not available to any healthcare organisations, except the organisation which originally supplied the clinical document. The individual take the responsibility that this information may be important to ensuring that individual receives the right care. Where the healthcare provider does not know this information, it may mean that the individual is given inadequate or inappropriate care.

Granting access to 'Limited Access' Clinical Documents

Only healthcare organisations on the 'limited access list' will be able to view 'limited access' clinical documents. The limited access list is a subset of the include list.

In order to authorise a healthcare organisations to join the limited access list, the individual will be able to create a special provider access key (PACX), which will allow the healthcare organisation access these clinical documents.

If the individual forgets their PACX, the individual will be required to call the call centre or use the consumer portal to reset it.

Creation of a PACX is only available to individuals who have opted to set up a PAC.

Viewing 'Limited Access' clinical documents

Within views such as the Consolidated View, Index View and Change History View, healthcare organisations with general access will not be able to see that 'Limited Access' clinical documents exist. For healthcare organisations with access to 'limited access' clinical documents, these views will show the presence of these clinical documents as well as any extracted information in the case of the Consolidated View.

Authorised users with access to 'limited access' clinical documents will be required to exercise increased caution regarding sharing of this information, if not clinically relevant. They may also prompt a conversation with the individual regarding any clinical risks associated with the status of the document.

Healthcare organisations that have uploaded clinical documents which have subsequently been changed to 'no access' will have a similar set of restrictions applied to views.

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.

5.5.4   Emergency access

The PCEHR System provides the option of emergency access for use in situations where the individual is in need of emergency care and is not capable of giving or communicating consent.

Emergency access will add the healthcare organisation to the individual's 'include list' and 'limited access list' and will permit access to 'general access' and 'limited access' clinical documents.   Emergency access does not provide access to 'no access' clinical documents.

Before emergency access can be used the authorised user will be provided with a warning message highlighting that they are about to use emergency access and the emergency access will be logged. The authorised user will be required to indicate that they wish to proceed.

Exclude lists do not prevent emergency access and a PCEHR which is hidden from search can still be found. If a healthcare organisation is on the individual's exclude list, then the warning message will also highlight that the individual prefers the organisation not access their PCEHR.

All use of emergency access will be logged (see Section 5.6).

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.

5.5.5   Forward consent

In the context of referring individuals who have a PAC, it may be necessary for the recipient of a Referral to have access to the individual's PCEHR ahead of the individual presenting to a healthcare organisation.

In order to provide this access, the referring healthcare provider can generate a cryptographic key known as a Transferrable Access Key (TAK) and electronically attach it to the Referral. When the recipient receives the Referral, they can use the TAK to be added to the include list.

A TAK can be used by an organisation on the 'exclude list' and will move it from the 'exclude list' to the 'include list'. A TAK cannot be used to provide forward consent to access 'limited access' and 'no access' clinical documents.

5.6   Ensuring data provenance

In order to ensure trust in the information available via PCEHR System, users will require information about the source of a clinical document.

As mentioned in Section 4.2, all clinical documents will be accompanied by document source information stating where the document was created, when it was created and who created it. The healthcare provider uploading the document will be required to have a HPI-I, and the healthcare organisation submitting the clinical document will be required to have a HPI-O.

Clinical documents will be digitally signed by the supplying healthcare organisation using the healthcare organisation's NASH digital credential and will be used to ensure that the clinical document has not been modified since it was submitted to the PCEHR System.

5.7   Audit

One of the measures to ensure accountability is an audit trail. In previous consultations, it was widely agreed that an audit function is essential to ensure confidence by both individuals and healthcare providers.

The PCEHR System will provide an audit service to record all activity on the national eHealth infrastructure services and PCEHR-conformant repositories.

The audit service will identify who has accessed the services, what they accessed, when they accessed it and what authorisation they obtained in order to access it.

The audit log will record the following information:

- The PCEHR which was accessed (including IHI, name, sex and date of birth).
- The Date and Time that access was obtained (UTC Time).
- The Name and Identifier of the Participating Organisation (in small organisations this will typically be the seed HPI-O and for larger organisations this may be some other nominated network HPI-O). This field is not required for representatives.
- The Name and Identifier of the Accessing Organisation (used when the Accessing Organisation has a network HPI-O below that of the Participating Organisation). This field is not required for representatives.
- The Name and Identifier of the CSP or CPP (this field is only required if the system is accessed via a CPP or CSP).
- Information identifying the user who obtained access.
- The role of the user who obtained access.
- Whether the PCEHR was accessed using the Individual's Provider Access Code (PAC), a Transferrable Access Key (TAK), by override (emergency or forgotten PAC) obtained by the healthcare provider, representative using the consumer portal, etc.
- Details of what was accessed.

The audit trails will be accessible by both individuals and providers. Based on who is accessing the audit trail, the view will differ as follows:

- Individuals (and their representatives) will only be able to see the audit trail relating to their PCEHR and individuals they represent.
- Healthcare providers will only be able to see their own activity in the audit trail via the provider portal.
- The OMO will be able to see any activity relating to their organisation via the B2B Gateway.

- The CSP and CPP will be able to see any activity relating to their service via the B2B Gateway.

When accessing the audit trail, users will only be able to see a summary of the audit trail. This summary includes:

- The PCEHR which was accessed (including IHI, name, sex and date of birth).

- The Date and Time access was obtained (UTC Time).

- The Name and Identifier of the Participating Organisation (in small organisations this will typically be the seed HPI-O and for larger organisations this may be some other nominated network HPI-O). This field is not required for representatives.

- The Name and Identifier of the Accessing Organisation (used when the Accessing Organisation has a network HPI-O below that of the Participating Organisation). This field is not required for representatives.

- The Name and Identifier of the CSP or CPP (this field is only required if the PCEHR System is accessed via a CPP or CSP).

- The role of the authorised user who obtained access or the name of the representative.

- Whether the PCEHR was accessed using the Individual's Provider Access Code (PAC), a Transferrable Access Key (TAK), by override (emergency or forgotten PAC) obtained by the healthcare provider, consumer portal (for representatives).

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.

The information in the audit trail will be utilised in two ways:

- Real time audit rules, based on regularly updated common patterns of misuse, will constantly monitor index usage and notify appropriate parties of a potential breach.

- Any user who is authorised to access an individual's records, including individuals, representatives and healthcare providers, will be able to request a summary of the audit trail to ensure that access was appropriate.

If it is suspected that the information has been used inappropriately, it will be escalated to the appropriate body for investigation.

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

6   PCEHR System components

6.1   Introduction

The PCEHR System is a 'system of systems', consisting of a number of core services and conformant repositories. As illustrated in Figure 9, the proposed approach will leverage existing foundations, such as the Healthcare Identifiers (HI) Service, NASH and Clinical Terminologies. The core national services include:

- A *Participation and Authorisation Service*, which stores individuals' participation preferences and manages access controls to an individual's PCEHR.

- An *Index Service*, which records the location(s) of a participating individual's records in a range of PCEHR-conformant repositories.

- An *Audit Service*, which audits all activity across the PCEHR System.

- A *View Service* and a *Report Service,* which are capable of extracting information from PCEHR-conformant repositories in order to support a range of different ways of viewing and reporting on information.

These services will be complemented by two new foundation services that operate alongside the other foundation services, such as the HI Service and NASH. These new foundation services include:

- A *Template Service*, which provides definitions about the types of healthcare information that can be shared via the PCEHR System (and other systems).

- A *National Healthcare Provider Service Directory* to provide a 'Yellow Pages' style search of healthcare providers and organisations and location of end point services for delivering electronic messages.

These infrastructure services will be used to facilitate access via a service coordination layer to a range of PCEHR-conformant repositories. This includes a national repositories service and the capability to link to other independent conformant repositories, such as repositories offered by Medicare Australia, Diagnostic Service Providers, regional operators, State/Territory public health system(s) and other parties.

The PCEHR core services and repositories will be accessible via a range of channels and user systems, including:

- Nationally provided Consumer and Provider-oriented portals, as well as independently provided consumer-oriented conformant portals.

- A call centre for individuals and healthcare provider support.

- A Business-to-Business (B2B) Gateway, to allow a range of systems to access the PCEHR System, such as: clinical systems, systems integrated via a gateway and contracted service providers acting on behalf of healthcare organisations.

- A Report Portal to support operational and evaluation based reporting.

Access to the PCEHR System will be based on Australian and International standards for ensuring interoperability of eHealth systems as well as other relevant specifications.
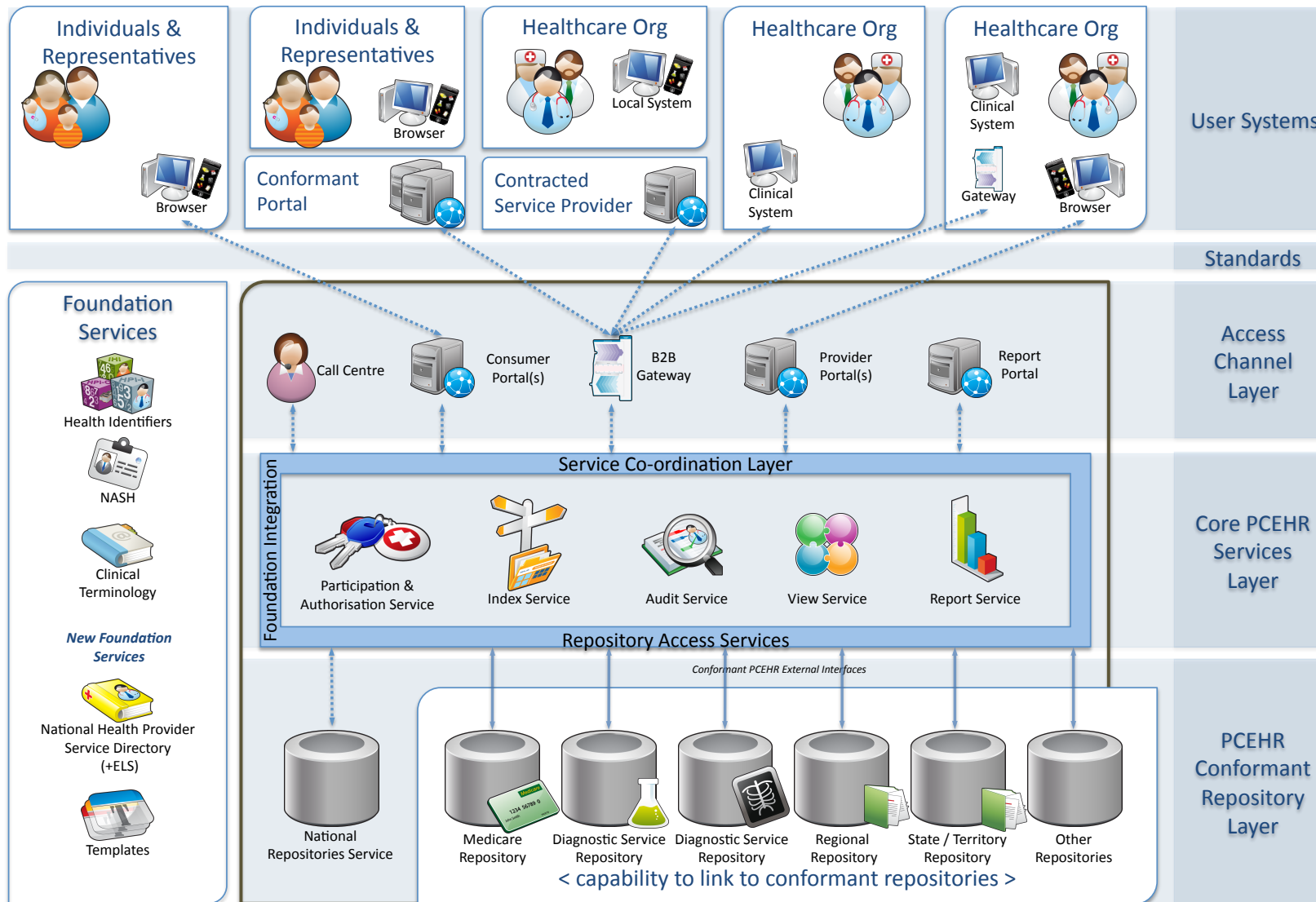
Figure 9: PCEHR System components

6.1.1   End-to-End system attributes

Even though the PCEHR System is a 'system of systems', the system as a whole will be required to ensure common levels of service around the following attributes.

Table 3: System attributes

Connectivity	The PCEHR System needs to accommodate a range of users with different levels of connectivity. This includes users with current broadband connectivity and emerging NBN connectivity, as well as users with lower levels of connectivity, such as users accessing the system via satellite connections or with intermittent connectivity.
Performance	The PCEHR System needs to achieve a high standard of performance and ensure that its performance does not hamper its ease of use.
Scalability	The PCEHR System needs to be scalable, with the capability to add extra capacity as the demand for access to the PCEHR System increases.
Availability	The PCEHR System portals, core services and repositories need to be available 24/7 with inbuilt redundancy measures. The call centre will also be available 24/7.
Business continuity	The PCEHR System will be required to meet clear expectations on how it will recover and restore interrupted critical functions within a predetermined time after a disaster or extended disruption. A succession plan also needs to be included in the event of the inability of the supplier to continue providing the service.
Serviceability	The PCEHR System will be required to be built from components that can be operated, configured, maintained, enhanced and replaced by a 3rd party.
Security	The PCEHR System must meet or exceed the security requirements set out in Section 5.3.
Data Quality	The PCEHR System must meet or exceed the data quality requirements discussed in Section 4.6.1.
Clinical Safety	The PCEHR System must meet or exceed clinical safety requirements discussed in Section 7.4.2.
Usability	The PCEHR System needs to be intuitive and easy to use. Users with basic Internet skills and no or limited training should be able to use the basic features of the system. It is anticipated that some more advanced features may require additional training.

Standards Conformance	The PCEHR System will use a standards-based approach and will leverage existing Australian and International Standards and technical specifications. This is discussed further in Section 6.1.2.

These attributes will be built into specifications and/or Service Level Agreements for the different components of the PCEHR System. A number of these attributes will also be built into standards and specifications to be implemented by conformant systems that connect to the PCEHR System.

6.1.2 Common standards and other technical specifications

The PCEHR System will use a standards-based approach and will leverage existing Australian and International Standards and technical specifications.

The final list of standards has yet to be agreed upon and this list of standards and related specifications will be developed through a consultative process. Once agreement has been reached, NEHTA will work with Standards Australia and the standards community to use, profile or develop the relevant Australian Standards.

All components of the PCEHR System infrastructure and feeder systems will leverage a set of the foundation standards and specifications listed below (where appropriate).

It should also be noted that some of the proposed standards and specifications require profiling and/or extension to align with the foundations, the PCEHR System requirements and the needs of the Australian community.

The standards to be profiled/extended for Australian use and published as an Australian Standard (or technical specification) will need to be prioritised.

The standards and related specifications identified in this section are not exhaustive. New standards and specifications may be identified during the consultation process.

Standards supported by the PCEHR System will be complemented by a conformance assessment program (see Section 7.4).

The foundation standards and related specifications are outlined below.

Additional proposed candidates are highlighted in the relevant section for each system component described in the next sections.

Foundations Standards and Related Specifications

Area	Candidate Standards and/or Specifications
Clinical Terminology	• SCT-AU (SNOMED CT®[11] Australian release) (including relevant reference sets and related cross mappings).
Medicines Terminology	• Australian Medicines Terminology (AMT).
Detailed Clinical Model	• Clinical information models for common elements, such as allergies/adverse reactions, problem lists, medication lists, etc will be based on NEHTA detailed clinical model specifications [NEHT2010a].
Individual and Healthcare Provider Identifiers	• The IHI, HPI-I and HPI-O number consists of a unique 16-digit number that complies with International standards for the assignment of healthcare identifiers [ISO7812]. • The IHI Records are compliant with Australian and International Standards [AS5017, ISO/PDTS 22220] and contain no clinical information. • The HPI-I record are compliant with the healthcare provider description portion of the Australian Standard Provider Identification [AS4846]. • The healthcare organisation service type is based on the HI Service specifications for organization classification [NEHT2010d]. • All HI Service system interface specifications are available from Medicare Australia (www.medicare.gov.au).
Authentication	• X509v3 (format of Public Key Certificates). • RSA as per PKCS#1 (type of public keys to be used). • LDAP as per RFC 4523 (for credential lookup/validation). • HTTP as per RFC 2585 (for credential lookup/validation). • RFC 5280 (for rules about certification path validation). • PKCS#12 (for transporting private keys and certificates to a certificate holder). • Microsoft CAPI, PKCS#11, CDSA/CSSM (to be supported as standard APIs for accessing and using NASH credentials/tokens.

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[11]   SNOMED CT® is a registered trademark of the International Health Terminology Standards Development Organisation.

Area	Candidate Standards and/or Specifications
Secure Messaging	• Standards Australia Technical Specification for E-health Web Services Profiles [AS WS-1] (for the purposes of point to point messaging). • Standards Australia Technical Specification for E-health XML Secured Payload Profiles [AS WS-2] (for the purposes of point-to-point messaging).

6.2 User systems

6.2.1 Conformant Portals

Purpose

The purpose of the conformant portal is to allow independently operated consumer-oriented portals to access the PCEHR System, thereby giving individuals a choice in how they access their PCEHR.

Functionality

From within a conformant portal, the individual (or their representative) will be able to:

- Access general information about the PCEHR System in a consumer-oriented form.
- Manage their portal account:
    - Register to have a portal account created.
    - Login/logout of their portal account.
    - Retrieve lost login credentials and update passwords.
    - Manage contact details.
- Manage participation, including:
    - Register to have a PCEHR created.
    - Request to de-activate a PCEHR.
    - Request to re-activate a de-activated PCEHR.
    - Associate/disassociate themselves with other individuals as their representative. (Note that this may require additional proof to be provided to the PCEHR System operator.)
    - Link their PCEHR to their conformant portal account to a PCEHR (if they already have one).
- Access a PCEHR, including:
    - Access PCEHR views (see Section 4.2.12).
    - Search a PCEHR (see Section 4.4).
    - Download and/or print clinical documents.
- Manage privacy, including:
    - Manage access controls, provider access keys, include lists and exclude lists, emergency access, notifications, etc (see Section 5.5).
    - View the audit trail (see Section 5.6).

- Access support services:
  - Access online help.
  - Contact the conformant portal operator and request support.
  - Request an erroneous record be corrected.

This list is not exhaustive and consultation will be required to refine it.

Conformant portals may provide a range of value adding services or innovative features that may not be available in the nationally operated consumer portal.

Relevant standards and specifications

- NEHTA Security and Access Framework [NEHT2010b].
- Additional standards and specifications listed in the B2B gateway section.

6.2.2   Clinical systems

Purpose

The PCEHR System will be accessible from a range of clinical systems, including GP systems, pharmacy systems, hospital systems, aged care systems, specialist systems, etc.

How the clinical system is integrated with the PCEHR System will vary from system to system. Some systems may have inbuilt features to access the PCEHR System and other may rely on a combination of backend gateways and provider portal integration to access the PCEHR System.

This section outlines the functionality required of a clinical system in order to access the PCEHR System.

Functionality

These systems will be able to:

- Utilise NEHTA foundations, including:
  - HI Service
  - NASH
  - Secure Messaging
  - Clinical Terminology
- Access a PCEHR, including:
  - Find a PCEHR.
  - Add the organisation to the include list (PAC may be required).
  - Obtain emergency access.
  - Access PCEHR views (see Section 4.2.12).
  - Search a PCEHR (see Section 4.4).
  - Download and/or print clinical documents and views.
- Upload clinical documents into the PCEHR System.
- Access support services:
  - Access online help about the PCEHR System.
  - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

Relevant standards and specifications

Relevant standards and specifications include:

- NEHTA Security and Access Framework [NEHT2010b].

- HL7 EHR-S Functional Profile [HL72007] (to be confirmed by consultation and may potentially need extension/profiling).

- Additional standards and specifications listed in the B2B gateway section.

6.2.3   Contracted Service Providers

Purpose

The PCEHR System will be accessible from a range of third party contracted service providers who offer health software as a service (SaaS) and support access to the PCEHR System on behalf of a healthcare organisation. Examples could include companies who supply primary care and aged care software as a service.

This section outlines the kind of functionality required of a contracted service provider in order to access the PCEHR System.

Functionality

These systems will be able to:

- Utilise NEHTA foundations, including:
    - HI Service
    - NASH
    - Secure Messaging
    - Clinical Terminology

- Manage user access to the system, including the ability for the OMO to authorise users to access the PCEHR System.

- Access a PCEHR, including:
    - Find a PCEHR.
    - Add the organisation to the include list (PAC may be required).
    - Obtain emergency access.
    - Access PCEHR views (see Section 4.2.12).
    - Search a PCEHR (see Section 4.4).
    - Download and/or Print Clinical Documents and Views.

- Upload clinical documents into the PCEHR System.

- Access support services:
    - Access online help about the PCEHR System.
    - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

Relevant standards and specifications

Relevant standards and specifications include:

- NEHTA Security and Access Framework [NEHT2010b].

- HL7 EHR-S Functional Profile [HL72007] (to be confirmed by consultation — may potentially need extension/profiling).

- Additional standards and specifications listed in the B2B gateway section.

6.3   Access channels

6.3.1   Consumer Portal

Purpose

The purpose of the consumer portal is to provide a nationally operated portal allow individuals to access their own PCEHR.

Functionality

From within the Consumer Portal, the individual (or their representative) will be able to:

- Access to general information about the PCEHR System in a consumer-oriented form.
- Manage their consumer portal account:
    - Register to have a consumer portal account created.
    - Support login via user credentials issued by the Australian Government Online Service Point (AGOSP).
    - Manage notification details.
- Manage participation, including:
    - Register to have a PCEHR created.
    - Request to de-activate a PCEHR.
    - Request to re-activate a de-activated PCEHR.
    - Associate/disassociate themselves with other individuals as their representative (note that this may require additional proof to be provided to the PCEHR System operator).
    - Link their PCEHR to their conformant portal account to a PCEHR (if they already have one).
- Access a PCEHR, including:
    - Access PCEHR views (see Section 4.2.12).
    - Search a PCEHR (see Section 4.4).
    - Download and/or print clinical documents.
- Manage privacy, including:
    - Manage access controls, provider access keys, include lists and exclude lists, emergency access, notifications, etc (see Section 5.5).
    - View the audit trail (see Section 5.6).
- Access support services:
    - Access online help.
    - Contact the PCEHR System operator and request support.
    - Request an erroneous record be corrected.

This list is not exhaustive and consultation will be required to refine it.

Additional requirements

The consumer portal shall support:

- Popular desktop web browsers, including, but not limited to Internet Explorer, Firefox and Safari.
- Browsers within popular tablet devices, including, but not limited to iOS and Android based devices.

- Links to the Australian Government funded healthdirect Australia consumer portal.

- Context sensitive links to health literacy information from HealthInsite on www.healthdirect.org.au. For example, the individual should be able to follow a link from their medical history and find related articles on HealthInsite.

- Space within portal pages for information about current public health campaigns.

- Links to online government campaigns around staying safe online (e.g. www.staysmartonline.gov.au).

- The Web Content Accessibility Guidelines version 2.0 [W3C2008a]. By following these guidelines, the portal will make content accessible to individuals with disabilities.

- Information kits in a range of different languages to support those individuals who are unable to read English.

Relevant standards and specifications

- HTML (e.g. xHTML 1.1 or HTML 4.01), CSS (e.g. CSS2) and HTTP 1.1.

- Australian Government Better Practice Checklist for Websites [DOFD2010].

- Web Services for Remote Portlet (WSRP) [OASIS2008] and/or JSR286 Portlet Specification 2.0 [JCP2010] (to be confirmed by consultation).

- W3C Accessibility Guidelines [W3C2008a] (to be confirmed by consultation).

- W3C Mobile Guidelines [W3C2008b] (to be confirmed by consultation).

6.3.2 Provider Portal

Purpose

The purpose of the Provider Portal is to complement existing local health record systems by providing an alternative form of access to the PCEHR.

Functionality

From within the Provider Portal, healthcare providers will be able to:

- Access general information about the PCEHR System in a healthcare provider-oriented form.

- Login to the Provider Portal using their healthcare provider NASH token containing their digital credentials.

- Select which organisation they are accessing on behalf of (if the healthcare is linked to multiple healthcare organisations in the HI PDS).

- Access a PCEHR, including:
  - Find a PCEHR.
  - Add the healthcare organisation to the include list (PAC may be required).
  - Access PCEHR views (see Section 4.2.12).
  - Search a PCEHR (see Section 4.4).
  - Download and/or print clinical documents.

- Access support services:
  - Access online help.
  - Contact the PCEHR System operator and request support.

This list is not exhaustive and consultation will be required to refine it.

Additional requirements

The Provider Portal shall support:

- All popular web browsers, including, but not limited to Internet Explorer, Firefox and Safari.

- Browsers within popular tablet devices, including, but not limited to iOS and Android based devices.

- Older browsers used within some healthcare organisational standard operating environments.

- Ability to support NASH based tokens for healthcare providers.

- The Web Content Accessibility Guidelines version 2.0 [W3C2008a]. By following these guidelines, the portal will make content accessible to individuals with disabilities.

Relevant standards and specifications

- HTML (e.g. xHTML 1.1 or HTML 4.01), CSS (e.g. CSS 2) and HTTP 1.1.

- Australian Government Better Practice Checklist for Websites [DOFD2010].

- Web Services for Remote Portlet (WSRP) [OASIS2008] and/or JSR286 Portlet Specification 2.0 [JCP2010] (to be confirmed by consultation).

- W3C Accessibility Guidelines [W3C2008a] (to be confirmed by consultation).

- W3C Mobile Guidelines [W3C2008b] (to be confirmed by consultation).

> **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.

6.3.3   Report Portal

Purpose

The PCEHR System will provide a Report Portal to support access to information within the report service (see Section 6.4.5). This portal will be accessible to users evaluating the PCEHR System and users who have permission to use data within the PCEHR System for approved uses.

Functionality

The Report Portal will allow users to:

- Access general information about the PCEHR System reporting functions.

- Manage their Report Portal account:
    - Register to have a Report Portal account created.
    - Login/logout of their Report Portal account.
    - Retrieve lost login credentials and update passwords.
    - The PCEHR System operator will be able approve requests for a Report Portal accounts and authorise the types of reports they are able to access.

- Access a series PCEHR reports, including reports outlined in Section 4.5.

- Access support services:
    - Access online help.
    - Contact the PCEHR System operator and request support.

Additional requirements

- Production of reports in a graphical form (bar charts, pie charts, etc).

- Production of report data as a downloadable comma separated value file, suitable for import into other analysis tools.

Relevant standards and specifications

- xHTML 1.1, CSS 2 and HTTP 1.1.

- Australian Government Better Practice Checklist for Websites [DOFD2010].

- Web Services for Remote Portlet (WSRP) [OASIS2008] and/or JSR286 Portlet Specification 2.0 [JCP2010] (to be confirmed by consultation).

6.3.4   B2B Gateway and Service Coordination layer

Purpose

The B2B Gateway and the service coordination layer are two highly related services.

The purpose of the B2B gateway is to provide outward facing system interfaces for 3rd party systems to access the PCEHR System.

The service coordination layer provides a broader range of system interfaces for all access channels that need to access the national core PCEHR services.

The service coordination layer also supports orchestration of the underlying core PCEHR services.

Functionality

- Provision of outward facing system interfaces for clinical systems to access the PCEHR System.

- Provision of system interfaces and orchestration services for all access channels needing to access the core PCEHR services, national repositories service and conformant repositories.

Additional Requirements

- Provision of documentation, sample code, a sandpit test environment and/or client side software libraries to help support access by conformant system suppliers. .Net and Java are preferred for sample code and/or libraries.

Related standards and specifications

- Standards and related specifications for Participation and Authorisation Service (see Section 6.4.1).

- Standards and related specifications for Index Service (see Section 6.4.2).

- Standards and related specifications for View Service (see Section 6.4.4).

- Standards and related specifications for Audit Service (see Section 6.4.3).

- Standards and related specifications for Report Service (see Section 6.4.5).

- Standards and related specifications for National Repositories Service and other conformant repositories (see Section 6.6).

6.3.5   Call Centre

Purpose

The PCEHR System operator will provide a Call Centre to allow individuals to obtain general information about the PCEHR System, register/withdraw from the PCEHR System and manage their access controls.

The Call Centre will also provide support to healthcare organisations.

Functionality

The Call Centre is available to both individuals and providers and will be able to support:

- General enquires about the PCEHR System.

- Assistance around the registration process.

- Assistance in managing access controls.

- Assistance in resolving issues around the PCEHR System.

- Resolution of complaints.

- Feedback around the PCEHR System.

Further functions may be added in time.

Additional requirements

- The Call Centre will be responsive and be built to meet agreed metrics around targets such as abandonment rates, average speed to answer, time service factors, first call resolutions, etc.

- The Australian Government provides a Translating and Interpreting Service (TIS) for people who do not speak English. A non-English speaker will be able to use this service when contacting the PCEHR Call Centre.

Relevant standards and specifications

To be determined.

6.4   Core PCEHR Services

6.4.1   Participation and Authorisation Service

Purpose

The Participation and Authorisation Service has three major functions:

1. Managing the participation process for registration of individuals and their representatives.

2. Capturing administrative information, settings and preferences about individuals and their representatives.

3. Controlling access to an individual's PCEHR based on their access control settings.

The participation process and authorisation process are discussed in more detail in Sections 3 and 5 respectively.

Functionality

The Participation and Authorisation Service supports the following functions for an individual:

- Manage participation, including:
    - Register to have a PCEHR created.
    - Request to de-activate a PCEHR.

- – Request to re-activate a de-activated PCEHR.
- – Associate/disassociate representatives with an individual (note that this may require additional proof to be provided to the PCEHR System operator).
- – Update notification individual details.
- – Update nominated provider.
- Manage access controls (see Section 5.5), including:
  - – Update access control settings.
  - – Set/Reset PAC and PACX.
  - – Manage include lists and exclude lists.
  - – TAK generation.

In order to support these functions the Participation and Authorisation Service will need to record the following information:

- Details (name, date of birth, gender and IHI).
- PCEHR status (active, de-activated).
- Contact details (phone number, mailing address, email address).
- Authentication details (e.g. user name, password).
- Date(s) of sign up and exit.
- Contact person details (name and contact details).
- Details about representatives.
- A nominated provider (name, contact details and HPI-I / HPI-O).
- Access control settings, including:
  - – Can the PCEHR be found via an IHI Search (Y/N)?
  - – Is a PAC required to be added to the include list (Y/N)?
  - – The PAC (PIN/passphrase)
  - – Can access without a PAC be undertaken if individual forgets PAC (Y/N)?
  - – Is notification required when access without PAC undertaken (Y/N)?
  - – Is notification required when new organisations are added to the include list (Y/N)?
  - – Notification details (email address or other form)
  - – The include list (list of organisations)
  - – The exclude list (list of organisations)
  - – A list of organisations granted access to 'limited access' clinical documents (a subset of include list)
  - – The PACX (optional)

Related standards and specifications

Interfacing specifications candidates include either:

- IHE Basic Patient Privacy Consents (BPPC) Integration Profile [IHE2010a] and IHE Cross Enterprise User Assertion (XUA) [IHE2010a] (may require profiling/extension); or
- HL7 Privacy, Access and Security Services (PASS) [HL72010a] (may require profiling/extension).

This list is not final and other specifications and/or standards may be added/removed via a consultative process.

6.4.2   Index Service

Purpose

If the individual chooses to participate, the index will associate an individual with a range of his/her clinical documents already stored within the PCEHR-conformant repositories.

The index stores metadata (i.e. data that serves to provide contextual information about other data) about each clinical document; the actual content of the records are stored within the PCEHR-conformant repository.

Functionality

Key functions of this service include the ability to:

- Clinical document registry functions:
    - Register a new clinical document.
    - Update an existing clinical document index entry.
    - Deregister a clinical document.
    - Search the index.
    - Execute quality functions to assess the integrity of the data.
- Repository management:
    - Register new conformant repository.
    - List available conformant repositories.
    - Update conformant repository details.
    - Deregister conformant repository.

In order to support this functionality, for each registered clinical document, the index service stores:

- The individual's IHI, Name, Sex and Date of Birth.
- The clinical document ID (a unique identifier for the information).
- The template ID (see Section 6.5.1).
- The type of clinical document (e.g. Discharge Summary, Event Summary).
- A keyword list for search function.
- The location where the clinical document can be retrieved.
- The date and time at which when the clinical document was created.
- The name, role and HPI-I of the healthcare provider that created the Clinical document.
- The name and HPI-O of the healthcare organisation where the clinical document was created.
- The name and HPI-O of the participating healthcare organisation that created the record.
- Versioning information about the clinical document.
- Management information about the integrity of the link (e.g. last time the link was checked, flag to indicate potential duplicate, etc).
- A label indicating if the information is 'general access', 'limited access' or 'no access'.

- A flag indicating the clinical document had to be 'effectively removed' because it was posted into the wrong PCEHR.

The index service will also maintain information about available conformant repositories and manage the registration process.

Related standards and specifications

Interfacing specification candidates include either:

- IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] (to be confirmed via consultation — also may require profiling/extension); or

- HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (to be confirmed via consultation — also may require profiling/extension).

This list is not final and other specifications and/or standards may be added/removed via a consultative process.

6.4.3   Audit Service

The PCEHR System will provide an Audit Service to record all activity on the national eHealth infrastructure services and PCEHR-conformant repositories.

The Audit Service will identify who has accessed the services, what they accessed, when they accessed it and what authorisation they obtained in order to access it.

Audit is discussed in the section on privacy and control in Section 5.6.

Functionality

Key functions of the audit service include:

- Add audit entry.

- Access audit trail summary.

- Request full audit trail.

- Archive old audit trail entries.

- Perform rule-based analysis of audit trail.

Related standards and specifications

Interface specification candidates include, either:

- IHE Audit Trail and Node Authentication (ATNA) Integration Profile [IHE2010a] and IHE Consistent Time (CT) Integration Profile [IHE2010a] (may require profiling/extension); or

- HL7 Privacy, Access and Security Services (PASS) (may require profiling/extension).

This list is not final and other specifications and/or standards may be added/removed via a consultative process.

6.4.4   View Service

Purpose

The purpose of the View Service is to allow authorised users, individuals and their representatives to access a series of 'views' of an individual's PCEHR. These views are intended to allow the underlying information within a PCEHR to be reassembled in different ways for different categories of users with different needs.

Functionality

The View Service will support the following functions:

- View definition lifecycle support:
    - Load Draft View Definition.
    - Approve View Definition.
    - Update View Definition.
    - Deprecate View Definition.
- Request View (The types of views to be supported by the PCEHR System are discussed in Section 4.2.12).
- Update View Content (see below).
- Execute quality functions to assess the integrity of the data.

Related standards and specifications

Interface specifications candidates include either:

- IHE Retrieve Information for Display (RID) [IHE2010a] (may require profiling/extension); or
- HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (may require profiling/extension).
    - This list is not final and other specifications and/or standards may be added/removed via a consultative process.

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.
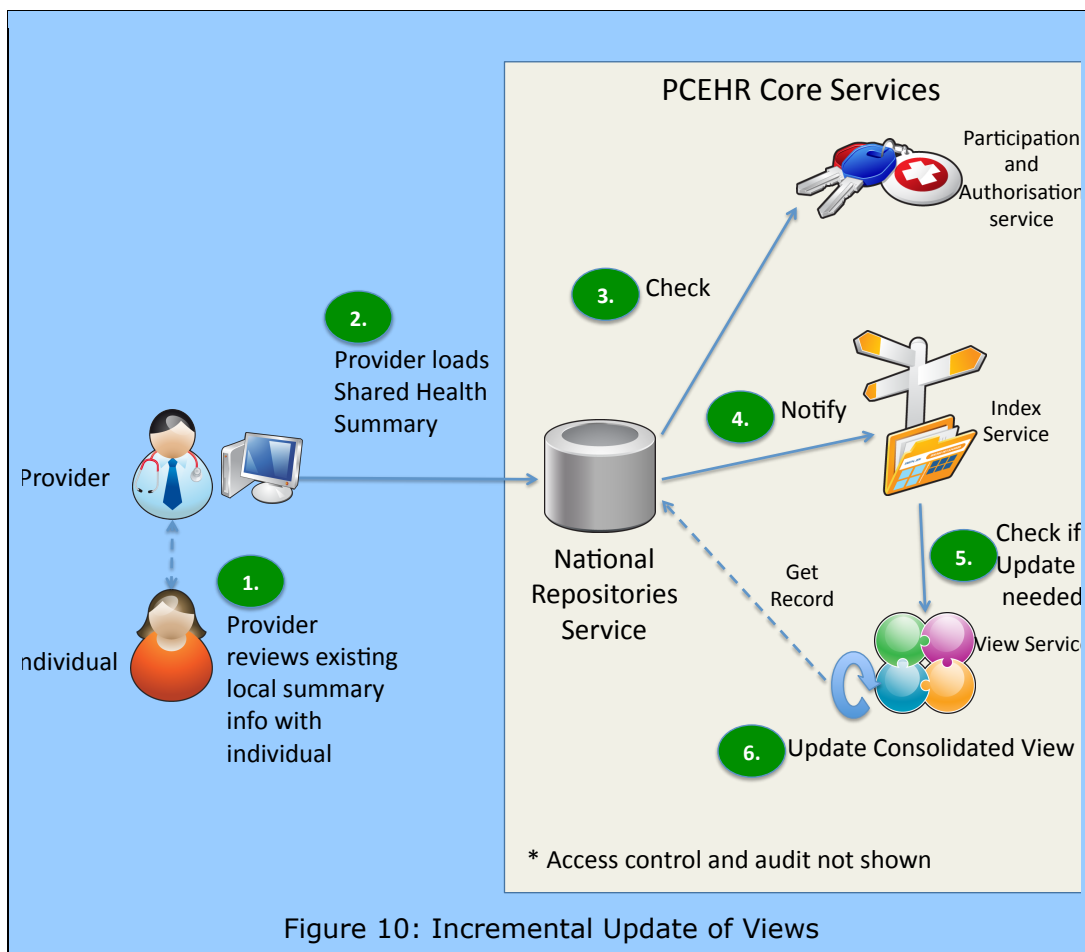
Figure 10: Incremental Update of Views

6.4.5   Report Service

Purpose

The Report Service is designed to support reporting and analysis of information across the set of personal health information managed by the PCEHR System. In the first release, the report service will only be used for operational reporting and evaluation of the PCEHR System. Reporting is discussed further in section 4.5.

Functionality

Key functions of the Report Service include:

- Data extraction, transformation and loading services to load PCEHR data into a data warehouse.

- De-identification services (including the option of making data re-identifiable if required).

- Data warehouse and related data mart services to store data and enable creation of the reports identified in Section 4.5.

Related standards and specifications

To be determined.

6.5   New national infrastructure services

6.5.1   Template Service

Purpose

The purpose of the Template Service is to provide a metadata service or data dictionary, which provides definitional information about the structure and semantics of different types of records. For example, the Template Service will publish definitional information for Shared Health Summaries, Discharge Summaries, etc.

The PCEHR service uses the Template Service to help support governance over information that can be shared via the PCEHR System.

The PCEHR System also uses the definitional information in a template to help validate clinical documents.

Other eHealth applications may use the Template Service to publish new templates.

Functionality

The Template Service supports the following functions:

- Template lifecycle management, including:
    - Load draft template definition and related information (e.g. schemas, schematron assertions, style sheets, etc).
    - Approve template.
    - Update template definitions and related information.
    - Deprecate templates.
- Find templates.
- Retrieve template and related information.

In order to support these functions, the template service contains:

- A template ID (including the version number).
- A flag indicating that the template is currently supported by the PCEHR System.
- The type of record (e.g. Discharge Summary, Event Summary, etc).
- Usage notes.
- Logical data structure information (structure, attributes names, field definitions, value domain information around data types and terminologies, etc).
- Links to conformant HL7 message definitions.
- Links to schemas and schematron assertions for validating content.
- Links to default style sheets for viewing/printing clinical documents.
- The date of publication/deprecation.

Templates will need to be able to include a mix of structured and unstructured data and cater for the possibility of attachments.

Standards and related specifications

General standards and related specifications the Template Service will support include:

- General: XSD, XSLT, XSL-FO, CSS; and
- Metadata specifications: ISO/IEC 11179.

Standards and specifications for searching and managing templates require further consultation.

Initial templates and related exchange formats to be registered within the Template Service include:

Table 4: Template Service

Template	HL7 Message Definition
Shared Health Summary	HL7 CCD or HL7 CDA (to be confirmed by consultation and will need profiling/extension).
Discharge Summary	Australian profile and extensions to HL7 CDA (as per current NEHTA Discharge Summary work).
Event Summary	HL7 CCD or HL7 CDA (to be confirmed by consultation and will need profiling/extension).
Specialist Letter	Australian profile and extensions to HL7 CDA (as per current NEHTA Specialist Letter work).
Pathology Result Report	Approach to be confirmed.
Diagnostic Imaging Report	Approach to be confirmed.
Referral	Australian profile and extensions to HL7 CDA (as per current NEHTA Referral work).
Medicare Data	Scope and approach for initial release to be confirmed.
Prescriptions and Dispense Notifications	Australian profile and extensions to HL7 CDA (as per current NEHTA ETP work).
Consumer Entered Information	Approach to be confirmed.

6.5.2   National Healthcare Provider Service Directory

Purpose

The National Healthcare Provider Service Directory (NHSPD) provides 'Yellow Pages' style directory services for healthcare organisations.

The directory is similar to a national version of the Victorian Health Services Directory (HSD), but will be integrated with the HI Service and will also provide a national end-point location service (ELS) to help clinical software systems find end point addresses where secure messages can be delivered.

Functionality

The NHSPD supports the following functions:

- Register healthcare provider.
- Update healthcare provider details.
- Remove healthcare provider.
- Find healthcare provider.
- Register end-point.
- Update end-point details.
- Remove end-point.
- Find end-point.

Standards and related specifications

Candidate interface specifications include:

- HL7 Healthcare and Community Services Provider Directory (HCSPD) (may required profiling/extension); and
- Endpoint Location Service [AS WS-3].

Scope notes: The National Healthcare Provider Service Directory is funded separately by COAG from the PCEHR Program.

6.6   Repositories

The PCEHR System will provide the necessary national infrastructure, standards and specifications to enable secure access to an individual's health information drawn from both national repositories and other conformant repositories.

6.6.1   National Repositories Service

Purpose

The National Repositories Service ensures that there is capacity to store a minimum critical set of health information about participating individuals. The National Repositories Service does not consist of a single central data repository. It will consist of a number of nationally operated repositories. The minimum critical set of health information managed by this service includes:

- Shared Health Summaries
- Event Summaries
- Discharge Summaries
- Consumer Entered Information

Functionality

The National Repositories Service supports the following functions:

- Load clinical document (loading includes validation and updating the Index Service).

- Update clinical document with a new version.

- Retrieve clinical document.

- Execute quality functions to assess the integrity of the data.

Standards and related specifications

Clinical document content specifications, as identified by the template service will be required to be supported.

Interface specification candidates include either:

- IHE Cross Enterprise Document Sharing (XDS.b) [IHE2010a] (may require profiling/extension); or

- HL7 Retrieve, Locate and Update Service (RLUS) [HL72010a] (may require profiling/extension).

This list is not final and other specifications and/or standards may be added/removed via a consultative process.

> **Issue:** While a minimum critical set of information will need to be stored nationally, consultation will be undertaken to determine the type and extent of information stored in this manner. This information could include Shared Health Summaries, Event Summaries, Discharge Summaries and Consumer Entered Information. Not all information needs to be stored nationally as the Change and Adoption Strategy will facilitate on the ground adoption of the PCEHR System and the development of additional distributed conformant repositories. However, it will take time for additional conformant repositories to be developed.

6.6.2   Conformant Repositories

Purpose

In addition to the National Repositories Service, the PCEHR System will have the capability to connect to other conformant repositories operated by a conformant repository provider.

Examples of conformant repositories may include:

- Medicare-operated repositories holding Medicare history, PBS history, organ donor information and childhood immunisation information.

- Diagnostic service repositories holding Pathology Result Reports and Diagnostic Imaging Reports.

- Regional or State/Territory operated repositories.

Functionality

Same as the National Repositories Service.

Additional requirements

- Repository operators will have an obligation to ensure that information within a repository is available via other means (e.g. by placing it in escrow) if the repository is to be shut down.

**Standards and related specifications**

Same as the National Repositories Service (see section 6.6.1).

7   Operating model

7.1   Introduction

The PCEHR System will be delivered by a single PCEHR System Operator, who will be required to manage the various channels, core services, National Repositories Service and operational aspects of the system. Participants accessing the PCEHR System will be supported by a range of implementation services around change and adoption. The system as a whole will be subject to a common form of governance and assurance.

Governance, assurance and the PCEHR System Operator are described below. Related topics around program management, change and adoption, lead eHealth sites and outcomes evaluation are discussed in Sections 8 and 9.
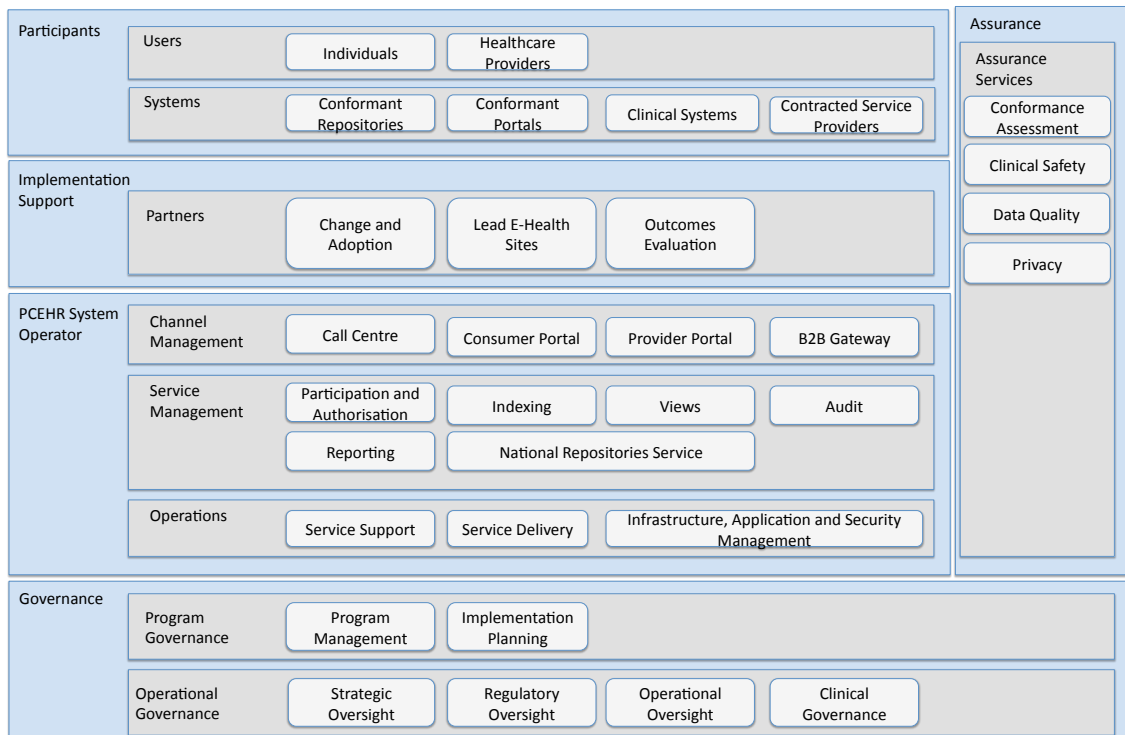
Figure 11: Operating model

Issue: The decision concerning the governance model and PCEHR System Operator is being considered as part of the consultation process with the states and territories'. The consideration of the issues and options for governance and PCEHR System Operator is being undertaken within the Council of Australian Government committees responsible for health reform and eHealth. This includes the National eHealth Information Principal Committee and its subcommittees

7.2   Governance

One of the keys to successful delivery of the national PCEHR System will be the establishment of the appropriate governance structures and mechanisms to provide management and oversight of the national PCEHR program and its operation. This will require a governance model that provides a focus on delivering capabilities that meet the needs of the Australian health sector while at the same time ensuring fiscally responsible expenditure of the government investment.

The governance model for the PCEHR System will be established with the following key governance principles in mind:

Table 5: Governance principles

Governance Principle	Description
Accountability	Clear roles, responsibilities and audit processes to ensure the obligations conferred on the PCEHR governance body are met.
Leadership	Strong strategic leadership is provided to ensure health policy requirements are embedded and enacted throughout the PCEHR program.
Engagement	Key stakeholders are engaged to ensure broad ownership and a balanced approach to the delivery of the PCEHR program.
Clinical viability	The governance model is structured to ensure it is health outcome focussed and delivers benefits for both the health workforce and the consumer.
Effectiveness	Designed to be fit for purpose, balancing national with local requirements without introducing unintended consequences.
Efficiency	Streamlined to ensure that it fits within the business practices of healthy services delivery and leverages existing and related investments.
Integrity	Encompassing honesty, objectivity, high standards of propriety and probity in the stewardship of public funds and resources and in the management of the organisation.
Transparency and Openness	Ensuring stakeholders have visibility of status and can have confidence in the decision-making processes and actions of the governing body(s).
Sustainability	Flexibility to respond dynamically to changing requirements over the PCEHR System lifecycle.

During the PCEHR planning phase to June 2012, the primary accountability for the PCEHR system rests with the Minister for Health and Ageing. Planning responsibility for the PCEHR system's implementation into the broader health sector, and its strategic fit with multi-jurisdictional health policy, rests with the Australian Health Ministers' Conference.

The program will transition to a longer-term operational governance model once the PCEHR System has been designed and as it becomes operational. The approach to program management and sourcing model is discussed further in Section 8.3.

The eHealth governance structure, recommended as part of the *National E-Health Strategy* [AHMC2008] and endorsed by Health Ministers in December 2008, requires three key governance functions: strategic oversight, operational oversight and regulatory oversight. Clinical governance was added to the governance functions as a part of the framework agreed by Australian Health Ministers in April 2010.

7.3 PCEHR System Operator

The PCEHR System will be operated by a single system operator who will take on the responsibility for operating the national infrastructure. The operator will be subject to the future operational governance model of the PCEHR System and be required to meet a common set of service levels (see system attributes described in Section 6.1.1).

The PCEHR System Operator will be responsible for supplying operational capabilities around:

- Channel Management of the consumer and provider portal, the B2B gateway and the call centre.

- Management of core services, such as the participation and authorisation service, index and view service, report service and audit service.

- Management of the National Repositories Service.

- Supply of operational capabilities around service support, service delivery, infrastructure management, security management, application management, asset management and corporate services (such as HR and finance).

The core elements of the PCEHR infrastructure (including portals, core services and the National Repositories Service) will be operated within dual data centres. The data centres will be required to meet all appropriate government standards for operating a national system.

7.4 Assurance functions

The PCEHR System will include a range of assurance functions, covering critical aspects of assurance around conformance assessment, clinical safety and data quality.

7.4.1 Conformance assessment

Suppliers of clinical systems, conformant portals and conformant repositories that interface with the PCEHR System will require a Notice of Connection (NOC) from the PCEHR System Operator.

The NOC verifies that suppliers' software products have been correctly interfaced with the PCEHR System's online channels. Suppliers must book in for and complete this verification process prior to gaining access to the PCEHR System production environment.

As a precursor to undertaking the verification process, the supplier will be required to provide evidence of passing a suite of independently conducted conformance assessments against the relevant Australian standards and other relevant specifications (see Section 6.1.2).

Using conformance assessment as a key element of the PCEHR System operating model will:

- Ensure an agreed level of interoperability, which in turn supports improved patient safety and quality of care.

- Reduce the risks in eHealth system procurement.

- Facilitate access to international eHealth markets (if products are assessed against international standards).

The Medical Software Industry Association (MSIA), Australian Information Industry Association (AIIA), National Association of Testing Authorities (NATA), Joint Accreditation System of Australia & New Zealand (JAS-ANZ) and NEHTA, have achieved consensus on the basis of an approach that will be leveraged for the PCEHR System [NEHT2009c].

7.4.2   Clinical safety

The governing body (or bodies) responsible for the PCEHR System will be responsible for ensuring that any identified clinical safety risks associated with the appropriate use of the PCEHR System have been mitigated. To help support this requirement the PCEHR System Operator will need to implement a clinical safety management system that:

- Considers clinical safety risks from a range of perspectives, including patient and healthcare provider perspectives.

- Follows best practice principles adopted in the safety critical software industry and is compliant with international standards relating to the management of clinical risk, such as ISO/IEC 80001 [IEC80001].

- Provides policy, procedures and document templates for managing patient safety for a software release and documenting the clinical safety case.

- Involves the participation of representatives of relevant colleges and other organisations in the process of assessment and recommendations for mitigation.

- Has a process for continuous improvement that will over time refine the approach to clinical safety.

The clinical safety management system is a logical extension to the operator's and governing bodies' risk management system(s) and its application will highlight:

- Potential clinical safety risks in the development lifecycle processes.

- Product quality and design flaws around clinical safety

It will be possible to:

- Identify the scale and scope of the risks and issues faced.

- Manage clinical safety risks.

- Identify and prioritise recommendations for improvement.

From time to time, the governing body (or bodies) will request an independent audit of the clinical safety aspects of the PCEHR System.

7.4.3   Data quality

The governing body (or bodies) and the PCEHR System Operator will be required to take reasonable steps to ensure the quality of the data in the system. The governing body (or bodies) may request an independent audit of the data in the PCEHR System. Data quality was discussed earlier in Section 4.6.2.

7.4.4   Privacy

The governing body (or bodies) and PCEHR System Operator will be required to take reasonable steps to ensure the protection of privacy of PCEHR System participants. The governing body (or bodies) may request a privacy audit. Privacy was discussed earlier in Section 5.2.

8 Implementation

8.1 Introduction

The establishment of a national PCEHR System is a complex undertaking, given the number of systems to be integrated and the magnitude of stakeholders who will require support to adopt the system.

This section outlines an implementation approach, including strategy, the PCEHR Program, change and adoption approach and lead eHealth sites. Outcomes evaluation is covered in Section 9.

8.2 Implementation strategy

Given the fragmentation of Australia's health sector and the breadth of autonomous and independent stakeholder systems that will need to be integrated, implementation of a national PCEHR System will need to be driven at both the national and the regional/local level. Focusing on one area but not the other will simply lead to the creation of regional and local information silos or the building of national infrastructure with no ability for local systems to integrate with it.

The proposed approach to building a national PCEHR System is based upon a combination of 'top down' national initiatives and 'bottom up' lead implementation projects. This will allow the delivery of tangible eHealth project outcomes on the ground, which is critical for building healthcare provider, individual and political support for the national PCEHR agenda, while at the same time ensuring a focus on the national frameworks and actions required to deliver a nationally interoperable PCEHR System.

For the proposed approach to be successful it must be supported by a number of core streams of activity:

- Governance (see Section 7.2).
- Legislation (see Section 5.2)
- Policy integration, including integration with the national hospital and health reform agenda.
- Change and adoption, including engagement and communications as well as change management support.
- Lead eHealth sites.
- Outcomes and benefits evaluation (see Section 9).

Stakeholders have also identified that additional funding and/or incentives are likely to be required to drive adoption.

8.3 The PCEHR Program

The Department of Health and Ageing is responsible for the management of the PCEHR Program, and the program will transition to a longer-term operational governance model once the PCEHR System has been designed and becomes operational.

The Program needs to satisfy all the Australian Government review processes, recommended by the Department of Finance and Deregulation (Australian Government Information Management Office and Gateway Unit).

The Department's role in the delivery of the PCEHR Program includes:

- Overall accountability for delivery of the PCEHR Program.
- Management of relationships with the Minister's Office and Australian Government initiatives and programs.
- Setting policy.
- Being responsible for communications and, if agreed they are required, any further national business case development.
- Determining overarching strategies for the implementation of the PCEHR Program.
- Leading the establishment of governance mechanisms, assessment of privacy requirements and the development of relevant legislation.
- Leading nationally focused stakeholder engagement.

The Department will source a number of partners, including a national infrastructure partner, a benefits evaluation partner and a national change and adoption partner to help deliver the PCEHR System. In addition to these partners, ancillary contracts will be undertaken with a program management service provider, a strategic advisory and an external delivery assurance advisor. The external delivery advisor will provide independent advice on the progress of the PCEHR program.

NEHTA under contract to the Department will:

- Develop specifications and manage all processes necessary to support the creation of PCEHR Program standards through Standards Australia.
- Develop solution architecture and high-level design for the PCEHR Program.
- Undertake acceptance and conformance testing of PCEHR Program infrastructure and solutions interfacing with infrastructure.
- Leverage existing forums and networks for stakeholder engagement and communications activities.
- Oversee and manage lead eHealth site activity.
- Plan and manage cross program activities.

The National Infrastructure Partner will provide system integration services across the lifecycle for development of national infrastructure, including:

- Delivery of product and solutions across a range of product bundles built as part of the PCEHR System.
- Provide supporting services necessary to oversee the effective and efficient delivery of the National Infrastructure.

The National Change and Adoption Partner will:

- Leverage health sector and ICT industry knowledge and capability to inform the rollout of the PCEHR Program.
- Develop a national change and adoption strategy for the rollout of the PCEHR Program that will encourage adoption and uptake of the PCEHR System.
- Coordinate and conduct policy-related stakeholder engagement forums, including report writing.
- Cooperate with NEHTA in order to utilise and leverage its existing stakeholder engagement forums and networks.
- Interact with the National Infrastructure Partner to exchange knowledge of change and adoption frameworks for large ICT infrastructure projects to inform the rollout of the PCEHR Program.

- Lead the delivery of the PCEHR Program marketing and communications campaign in line with the marketing and communications strategy provided by DoHA and NEHTA.

- Provide event management and logistical support to DoHA for its stakeholder engagement activities.

- Design, develop and deliver products and services to support healthcare organisations, workforces and individuals to transition into the PCEHR System. This will be undertaken in line with policy, strategy and direction provided by DoHA and NEHTA.

- Leverage the lessons learnt from international change and adoption activities for the implementation of electronic health record systems.

- Participate in and provide governance support to DoHA and NEHTA.

The Benefits and Evaluation Partner will:

- Develop and deliver a PCEHR Program Benefits Realisation Framework.

- Design and deliver a PCEHR Program monitoring and measurement capability.

- Provide a deep and thorough PCEHR Program analytical and evaluation capability.

- Provide a complementary research capability to support and assist policy development for the PCEHR Program.

- Provide a capability to support, advise and report to the Department on applying all aspects of the above services to the successful delivery of the PCEHR Program by other major partners.

The lead eHealth sites will:

- Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.

- Demonstrate tangible outcomes and benefits from eHealth projects.

- Build stakeholder support and momentum behind the PCEHR Program.

- Provide lessons learnt that will inform the future implementation of PCEHR System infrastructure and standards in other sites.
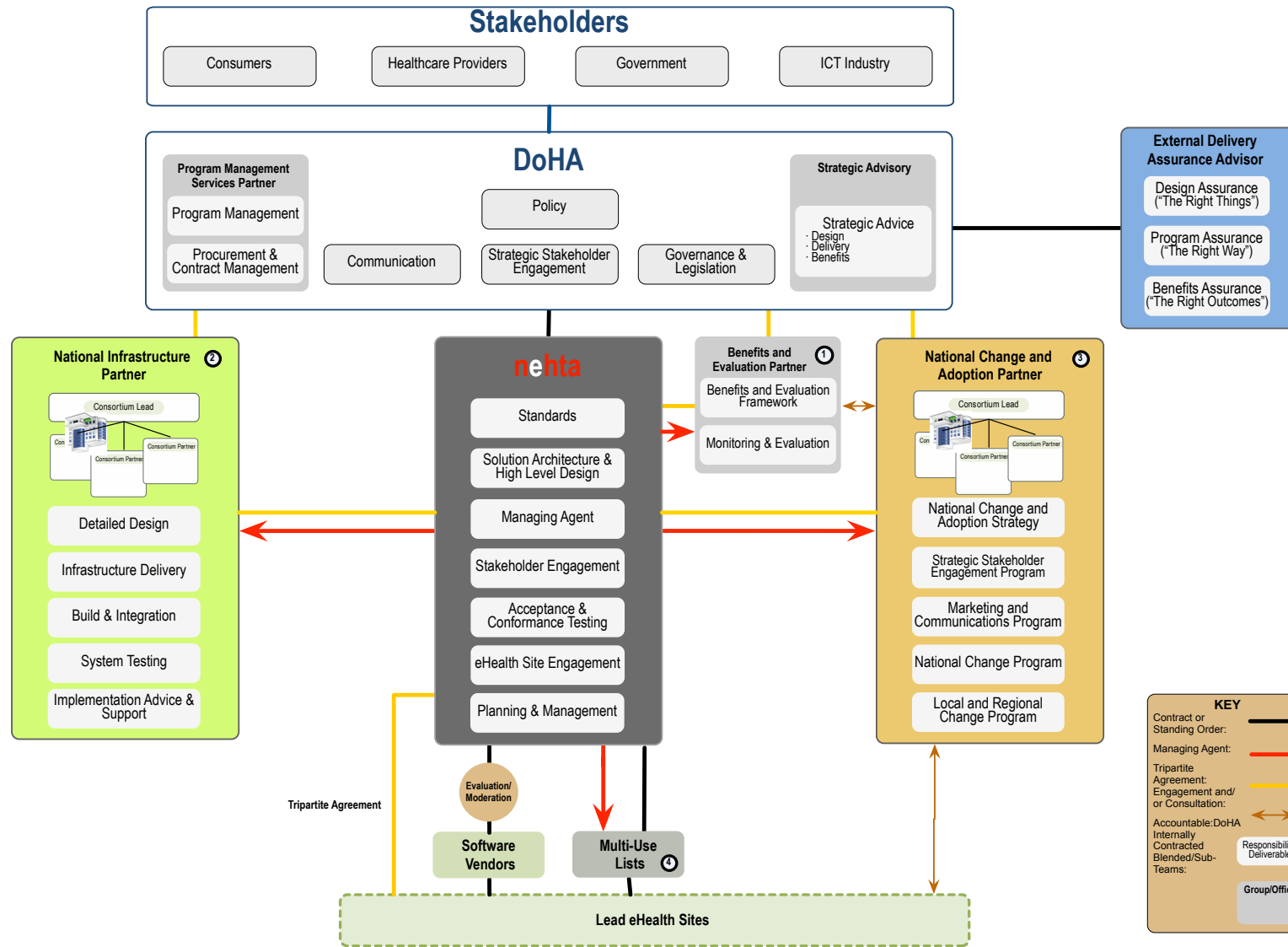
Figure 12: Sourcing Model

8.4   Change and adoption

The successful implementation of a national PCEHR System will require individuals and healthcare providers to be motivated and appropriately supported to use the system. This is a two-way relationship, as the quality of the underlying PCEHR System and the information contained in it will also play a critical role in driving stakeholder take-up and support of the PCEHR System.

Given the requirement for a voluntary participation model, meaningful adoption will not be achieved without a deliberate strategy of engagement with the health sector to drive awareness of the PCEHR capabilities and support the change required to embed their use into clinical practice. While national coordination of change and adoption efforts will be required to ensure consistency and alignment, engagement must also occur at the grass-roots level within the health sector to effect the change and business integration that will be required to ensure adoption.

While many of the change and adoption activities will be undertaken and managed at local and regional levels across the Australian healthcare system, these will be conducted within a nationally agreed framework. There is a need for central coordination of those devolved change and adoption activities to ensure consistency and alignment between national, regional and local change and adoption activities. These include national awareness and education campaigns, the establishment of national PCEHR stakeholder reference groups and the creation of stakeholder adoption support regimes.

The national change and adoption activities will focus on communication and engagement, as well as support for change management.

A change and adoption partner will be procured to support this activity.

8.4.1   Communication and engagement

An effective communication and engagement strategy will be critical to ensure take-up of the PCEHR System. A phased approach to communication and engagement will be undertaken and the style used will reflect the current stage of development of the PCEHR System.

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

The communication and engagement approach will recognise that the introduction of the PCEHR System is not taking place within a 'Greenfield' environment. Much has already been done at national, state and local levels. Therefore the communication and engagement approach will integrate existing work and utilise, leverage and, as required, reorient existing channels of communication to ensure stakeholder requirements are addressed across the implementation of the PCEHR System.

Throughout the program three key messages need to be acknowledged in all PCEHR communication and engagement activities. These messages are:

- Trust is critical for the success of the rollout and uptake of the PCEHR System.

- Communication with stakeholders needs to be customised to ensure a gradual *transition* and *acceptance* of the PCEHR System.

- Stakeholders need to be *informed, educated and supported* about the approach and benefits of the PCEHR System.

Marketing and communications

A range of targeted communications programs will be put into place, including social marketing programs for individuals, healthcare providers, government agencies and other stakeholders to specifically raise understanding and awareness of the national PCEHR program.

The public will be made aware of the benefits of having a PCEHR, what services they can access, how to use those services, and how these services will give them better control over their healthcare and information.

To ensure the messages being delivered are consistent, there will be one broad, cohesive national marketing plan developed by the Department of Health and Ageing.

The marketing and communications activities will be multi-faceted with a coordinated approach developed for the overall program. Specific marketing will then be segmented to address the different needs of well individuals and those 'actively receiving healthcare' (e.g. aged care, antenatal care, chronic disease management, etc.) and different healthcare provider groups.

Engagement

In the area of engagement, the PCEHR development team will actively work to increase awareness of key stakeholders through a consistent approach to stakeholder engagement. The team will do this by:

- Engaging in public consultation on key issues.

- Assigning relationship/account managers to priority stakeholder organisations to ensure accountability for coordinated engagement.

- Utilising reference groups associated with each work program area to ensure that a representative group of key stakeholders, including consumers, are actively involved in the work program.

- Operating a clinical leaders program that embeds practicing healthcare providers into the work program on a part time basis to ensure the outcomes are clinically relevant.

8.4.2   Change management and adoption support

To help create an understanding of what is required to support change management, the Change and Adoption Partner will develop a change management plan.

The change management plan will include activities for analysis of work practices and training and awareness activities. Ongoing evaluation of the success of take up strategies and learning lessons from lead implementations will be the key focus of the work.

Lessons learned from the lead eHealth sites around the full life cycle of implementation and adoption of the PCEHR System will be used to inform tools, techniques and guidelines for:

- *Pre-transition:* activities done in the lead up to change over. This may include planning the transition, assessing readiness for change, communicating the change, benchmarking of existing work practices to support later benefits measurement, completion of any final testing, etc.

- *Transition:* activities done during the introduction of a new system. This may include initiating the transition, data migration, running the old and the new system in parallel, training, temporary surges in onsite support teams, etc.

- *Post-transition:* activities done after a new system is operating and has successfully passed the transition phase. This may include ongoing support, decommissioning old systems, measuring and monitoring benefits, responding to changes, project closure, etc.

The lessons learned will be built into a knowledge base that can be used as part of broader adoption support mechanisms provided by the PCEHR System Operator and the Change and Adoption Partner. This support includes:

- Call Centre support by the PCEHR System operator for implementers of the PCEHR System.

- Web-based information resources for implementers of the PCEHR System.

- Creation of training courses for implementers of the PCEHR System, which can be offered by the PCEHR System operator.

- Training and support for implementers, local change agents and clinical champions.

- Working with professional bodies to identify opportunities for including PCEHR System related training in ongoing professional education.

By far the most critical element above is training and support for local change agents and clinical champions, as evaluation of international implementations have demonstrated that implementation success or failure is highly sensitive to the skills of these critical individuals.

8.5   Lead eHealth sites

While all Australians will have the option of registering for a PCEHR, adoption of the PCEHR System capabilities by healthcare providers is likely to be initially focussing on a range of lead eHealth sites.

The lead eHealth sites will be used to:

- Deploy elements of eHealth infrastructure and standards in controlled, real world healthcare settings to inform future national rollout.

- Demonstrate tangible outcomes and benefits from funded eHealth projects.

- Build stakeholder support and momentum behind the national PCEHR System work program.

- Provide a meaningful foundation for further enhancement and rollout of the national PCEHR System.

The implementation profile for each of these lead eHealth sites will represent a natural grouping of stakeholders (healthcare providers and individuals) sharing the same PCEHR change journey.

These eHealth sites will demonstrate the capacity to address:

- Breadth of coverage (i.e. to a large population).

- Depth of coverage (thorough coverage of healthcare participants e.g. acute, primary, aged care, allied health).

- Ability to demonstrate early benefits.

- Ability to implement innovative solutions.

There are two waves of lead eHealth sites, which have been funded.

The first wave of lead eHealth sites includes three divisions of General Practice: GPpartners in Queensland, GP Access in New South Wales and Melbourne East GP Network (MEGPN) in Victoria. Each site will support a community of services for individuals using a range of community and health service providers with appropriate linkages to clinical support. The wave 1 projects aim to support up to 243 participating practices and 90,000 individuals. Pharmacies, after hours services and public outpatient services will also be engaged.

The second wave of lead eHealth sites includes nine additional sites:

- *Medibank Private Limited Project* will implement a consumer-oriented portal, which integrates consumer entered information into a 'Health Book'. The 'Health Book' will be initially made available to all Medibank Private customers and their healthcare providers enrolled in Medibank's Health Management and Chronic Disease Management programs. Medibank Private will not be using any of this information for the management of claims or eligibility for health care insurance benefits.

- *Brisbane South Division Limited Project* will deliver a substantial eHealth site in one of Australia's major capital cities. The project will aim at enrolling up to 25,000 individuals in the Brisbane and Ipswich region. A key focus will be on individuals with disabilities and their carers, war veterans and war widows, and children commencing school. The project will bring two Division's of General Practice onboard, Brisbane South and Ipswich and West Moreton, and public and private hospitals, allied health and GP's. The project will leverage wave 1 infrastructure.

- *Mater Misericordiae Health Project* will deliver an eHealth site to enhance healthcare for mothers and newborns. The population reach of the project is 9000 mothers and involves three GP Divisions (South East Alliance, Brisbane South and the South East Primary HealthCare network), local specialist obstetricians and a software vendor InterSystems. The project will leverage wave 1 infrastructure.

- *Northern Territory Department of Health and Families Project* will deliver a lead eHealth site for Indigenous Australians living in the Northern Territory, South Australia and Western Australia. The project will leverage the existing NT shared electronic health record and extend the existing service to all Northern Territory residents and Indigenous individuals in Western Australia and South Australia.

- *Greater Western Sydney eHealth Consortium (NSW Department of Health) Project* will implement key building blocks for state-wide eHealth infrastructure that will allow NSW Health to connect to the PCEHR System when it becomes available. The initial focus will be on priority consumer groups in the Greater Western Sydney region. The project includes four GP Divisions (WentWest, Nepean, Blue Mountains and Hawkesbury-Hills) and will leverage previous technology investments. With a population reach of 1,750,000, the project will be able to expand the entire solution quickly to encompass a significant geographic area and ultimately the whole of NSW.

- *Cradle Coast, North-West Area Health Service Project* will provide end of life policy lessons for the PCEHR System. The project targets aged and palliative care patients and their families, palliative care medical specialists and clinical nurse consultants. The project will use off-the-shelf care planning software to share the advance care directives until the national PCEHR infrastructure is in place.

- *St Vincent's and Mater Health Sydney Project* will establish a lead eHealth site based around St Vincent's and Mater Health Sydney, in conjunction with partnering Divisions of General Practice, participating specialists and software vendors including Smart Health, Precedence, HCN and Best Practice. The project has a population reach of 1 million individuals attending the St Vincent's campus and aims to improve clinical communication across the project's footprint through the delivery of key PCEHR components.

- *FRED IT Group MedView Project* will demonstrate the ability for up to 2 million individuals and their healthcare providers to access their prescribing and dispensing history via a medicines repository using national electronic prescription and other standards. The project will deploy MedView to all pharmacies and GPs in the Geelong region and to a further 10% of this target market nationally. The project will bring together a grouping of private sector eHealth vendors including FRED, eRx, Best Practice, Zedmed, iCare, Microsoft and SIMPL.

- *Calvary Healthcare Project* will support a cross-border population of approximately 800,000 individuals in the ACT and regional NSW by bringing together a major grouping of private sector eHealth vendors. The vendors involved include iSoft, HCN, HealthLink, Smart Health Solutions and Precedence HealthCare.

As described in the lavendar boxes throughout this document, each site will specifically target elements of the proposed system design in controlled settings to inform the future national rollout.

The operational management of the eHealth site program is being managed by NEHTA under contract to the Department. Additionally the 12 sites selected as part of waves 1 and 2, will be required to work collectively with the Department to ensure strategic health policy alignment, leverage of complementary national infrastructure and toolsets, adherence with national equity and access principles and communication program synergies.

Once the design of the national system has been completed, an assessment of the 12 lead eHealth sites will be undertaken and a transition plan developed, for incorporation of the lead sites into the National Change and Adoption Program. This will allow early adoption of the PCEHR System for individuals participating in the eHealth lead sites from July 2012, including the capability to target approximately 500,000 individuals enrolled in those sites.

9 Outcomes evaluation

9.1 Introduction

The advice from organisations that have implemented large-scale eHealth technologies is that outcomes and benefits are not automatically delivered through the deployment of new eHealth systems, but rather the value has to be actively managed [FISH2004]. This reinforces the importance of measuring outcomes and benefits for the purpose of informing course correcting activities and driving change. In order to sustain the case for investment in a PCEHR System, it is critical to show how the outcomes and benefits will be demonstrated as the system is developed and deployed.

The outcomes and benefits are likely to start modestly due to the need to implement the foundations and commence implementation of the solutions necessary to support the free flow of information. However, it will be critical to show meaningful progress linked to the desired PCEHR System outcomes and benefits.

In order to realise the value of the PCEHR System, an outcomes management framework will be required. This framework will be required to:

- Identify candidate outcomes and benefits, source evidence for their achievability and achieve consensus on the final set of outcomes to be sought.

- Map the relationship between outcomes/benefits and understand how these outcomes/benefits relate to stakeholders (e.g. individuals and healthcare providers), health system performance indicators (e.g. effectiveness, safety and responsiveness), health reform outcomes (e.g. hospitals, primary care and workforce) and existing eHealth infrastructure and standards (see Figure 13 for a draft map).

- Specify the roles and responsibilities required for outcomes realisation and clarify the ownership and commitments by different parties to realise the outcomes.

- Define the level of specificity, measurement techniques, frequency of outcomes reviews and how double counting will be avoided.
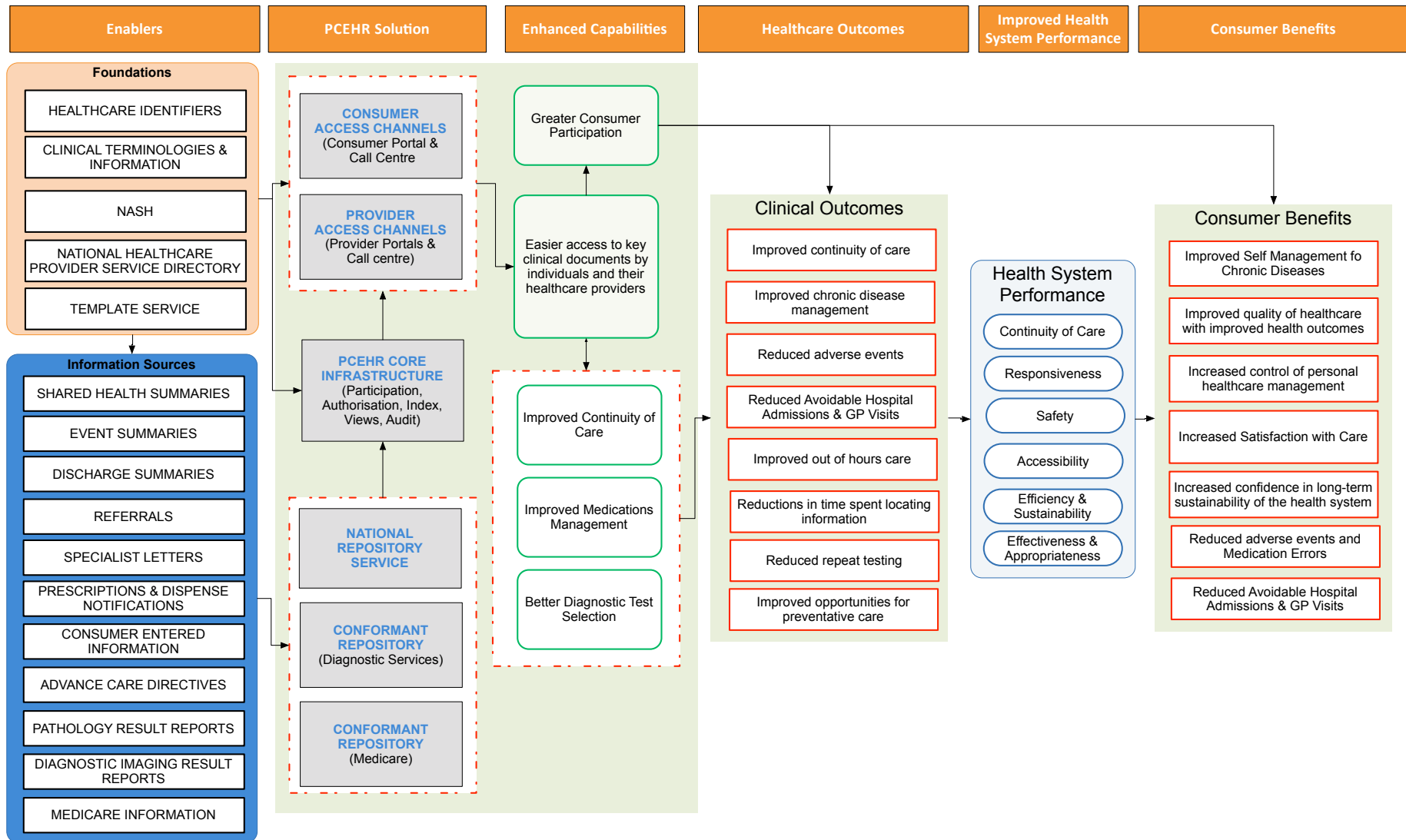
Figure 13: Realisation of Outcomes

9.2 Outcomes and benefits

The implementation of a PCEHR System will enable more person-centred healthcare and will support a range of benefits and outcomes, including the following:

Area of Outcome[12]	Type of Outcome and/or Benefit
Continuity of Care — supporting the provision of uninterrupted coordinated care across different healthcare providers over time.	The PCEHR System shall enable easier access to Event Summaries, Discharge Summaries and other related clinical documents by both healthcare providers and the individual, and will contribute to improvements in: • Continuity of care. • Chronic disease management by healthcare providers. • Self-management of chronic diseases.
Responsiveness — the ability of the health system to meet the population's legitimate expectations regarding their interaction with the health system.	Timely access to an individual's key health information by both the individual and their healthcare providers may contribute to improvements in: • Participation by individuals in their healthcare delivery. • Patient satisfaction with their healthcare delivery.
Safety — avoid or minimise situations which can harm or have the potential to harm patients during the course of care delivery.	Access to better quality, more timely patient health information will contribute to: • Improvements in medication safety (e.g. a reduction in medication adverse events and near miss events). • A reduction in avoidable/unplanned hospital admissions, emergency department attendances and GP visits.
Accessibility — the ability of individuals to obtain healthcare at the right place and right time irrespective of socio-economic status, physical location and/or cultural background.	The PCEHR System has the opportunity to contribute to improvements in: • Out of hours care.

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[12] Based on the National Health Performance Framework [AIHW2009].

Area of Outcome[12]	Type of Outcome and/or Benefit
Efficiency and Sustainability — achieving the desired results with the most cost efficient use of resources (i.e. avoiding wasted equipment, supplies, personnel and energy).	Access to better quality, more timely health information will have the opportunity to contribute to: • Allowing clinical staff to spend more time delivering health services instead of locating information. • A reduction in duplicate testing. • A reduction in avoidable/unplanned hospital admissions, emergency department attendances and GP visits.
Appropriateness and Effectiveness — the application of evidence-based best practice at the right place and the right time.	The PCEHR System will enable healthcare providers timely access to better quality health information across the health system, which in turn will contribute to: • Improved clinical decision-making. • Enhanced quality of recommendations provided by decision support systems. • More opportunities to provide preventative care.

9.3   Measurement and outcomes evaluation

An evaluation framework will be established early in the PCEHR System implementation lifecycle to ensure that the PCEHR System is strategically aligned with government policy, strategy, objectives and health reform decisions and there is robust take-up across the community.

The evaluation framework will include use of research and evaluation monitoring principles, methodologies and toolsets to ensure consistent application across the PCEHR System program's lifecycle. The expected benefits will be mapped and actual benefits captured and measured across all stages and levels of implementation.

All benefits will be linked to outcomes such as improved overall health of the population, improving the effectiveness of healthcare delivery, and improving the efficiency of healthcare delivery. The following represent some of the key categories of evaluation measures:

•   *Capability enablement* — as capabilities within the PCEHR System are delivered (such as enabling infrastructure), progress will be measured by outcomes such as on-time delivery, and the use and operation of the capability. Examples could include numbers of registered users and endorsement/support of clinical peak bodies.

•   *Lead implementations* — as these commence, the local outcomes will be captured and measured. This information will be captured and used as the basis to confirm that further rollout and use can be justified based upon take-up and use within each implementation.

•   *Sector penetration* — as this occurs, it will be possible to capture and measure activities that are strong indicators of sector penetration.

•   *Health system outcomes* — ultimately full health system impacts will start to be understood. In the long term, it may be possible to measure benefits nationally.

- *Stakeholder outcomes* – the outcomes for each stakeholder group, including consumers, healthcare providers, government and the ICT industry needs to be assessed and regularly monitored*.*

The evaluation framework will allow the PCEHR System to be implemented in a way that ensures the needs of the community, healthcare sector and governments are able to be achieved. A formal evaluation framework will be designed in consultation with key stakeholders. Figure 14 below summarises how the proposed framework would support evaluation of the outcomes supported by the PCEHR System.
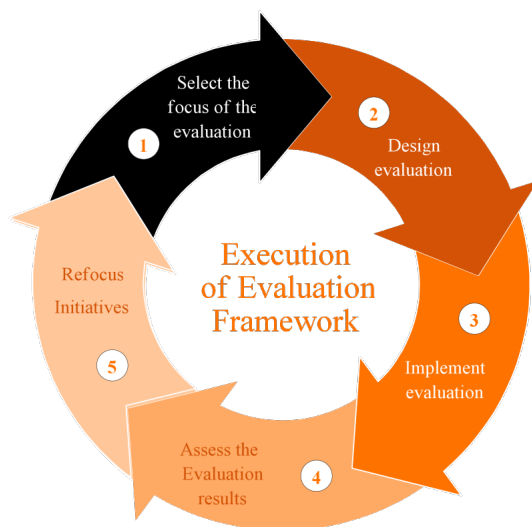
As evaluations are executed:

- Evaluation principles and objectives are defined.
- Evaluation questions and approach are designed. (What data? From whom? How?)
- Data is gathered and analysed.
- Comparing evaluation results to strategic objectives.
- Redesign PCEHR initiatives based on evaluation results to better meet objectives. (What decisions? e.g. funding, risk, outcomes? Disseminate, share and use information i.e. Who? How? When?)

Figure 14: Evaluation framework

The final step in the evaluation framework is most significant — using the evaluation lessons to enhance the PCEHR System value over time. Consistent with the National E-Health Strategy's principle of evidence-based implementation, the lessons learned will form an essential pillar of the ongoing governance and management of PCEHR System investment, and will inform decisions such as:

- Further investment to ramp-up and accelerate promising results achieved in early phases.
- Redirection or re-phasing of investment where experience shows that planned outcomes cannot be achieved or require alternative approaches.
- Escalation and consideration of health system impacts and options that can take advantage of the outcomes being achieved.

9.3.1 Draft key performance indicators (KPIs)

The table below shows a summary of the stages of implementation alongside key performance indicators (KPIs) that might be used in evaluating the success of the PCEHR System. Overall, the performance measures should not only show an effectively functioning program but should also show realisation of benefits around better healthcare, improved satisfaction of individuals receiving healthcare and progress towards meeting the objectives of health reform.

Lessons from other work on KPIs and minimum datasets indicate that embedding their capture into the PCEHR System's design, reporting tools, and evaluation program and change management strategies will ensure greater compliance than if developed as a separated function. The next steps will include a piece of work associated with the evaluation framework to develop a confirmed set of KPIs for the PCEHR program, including taking into account the costs of their measurement. The table below presents a high level consideration of KPIs for the PCEHR System.

Table 6: Key performance indicators

Category	Description	Example metrics
Capability Enablement	Metrics and indicators against key enablers and infrastructure for the PCEHR	Work Program Metrics Deliverables endorsed by relevant bodies Number of Standards endorsed
Lead eHealth Sites	Metrics and indicators collected by lead eHealth sites	Numbers of lead eHealth sites implementing PCEHR solutions (e.g. number of hospitals, number of divisions of general practice) Numbers of vendor products conformance tested within the lead eHealth sites Numbers of PCEHRs created Number of records added to repositories Viewing rates on PCEHRs
Sector penetration (beyond the lead eHealth sites)	Metrics and indicators collected nationally	Numbers of additional local sites implementing PCEHR solutions (e.g. number of hospitals, number of divisions of general practice) outside the lead eHealth site program Numbers of vendor products conformance tested outside lead eHealth sites Numbers of PCEHRs created outside lead eHealth sites Number of records added to repositories outside lead eHealth sites Viewing rates on PCEHRs outside lead eHealth sites
Health system outcomes	Metrics linked to the National Health Performance Framework	Reduction in avoidable readmissions Reduction in duplicate testing Reductions in reported adverse events
Stakeholder outcomes	Metrics collected nationally across all participants	Consumer surveys Healthcare provider surveys Government stakeholder surveys ICT Industry surveys

Appendix A: Consultation

A.1　Health*Connect* Consultations, 2004 – 2005

Many of the outcomes from the previous public consultation on Health*Connect* were considered in this report.

A.2　IEHR Consultations, June 2008

NEHTA conducted two Clinician and Consumer Roundtable sessions in June 2008 as part of the consultation for the then Individual Electronic Health Record (IEHR) service proposal. One in Brisbane (5 & 6 June) with an urban focus and one in Alice Springs (11 & 12 June) discussed issues relating to a rural and remote context. A Peak Body Summit was also held in Canberra (18 June). The aim of the Summit was to present and validate the key recommendations from the Roundtables in Brisbane and Alice Springs. In total, over 150 people attended the sessions.

A.3　Privacy Blueprint, July 2008

NEHTA's *Privacy Blueprint for the Individual Electronic Health Record* (IEHR) was released for public comment on 3 July 2008 [PRIVROF08]. It was distributed to a range of key stakeholders and also published on NEHTA's website.

In total 37 submissions were received. Of these, six were submitted in confidence. Copies of the non-confidential submissions have been published on NEHTA's website.

This report provides a summary and analysis of the key themes that emerged from the submissions. It also outlines the next steps NEHTA will be taking to further the work on privacy and eHealth initiatives [NEHTA2008a].

A.4　IEHR Consultations, September 2009

A workshop was held on 18 September 2009 in Sydney to demonstrate the use of IEHR scenarios for future consultation. This workshop was attended by Clinical and Consumer representatives. The event was positioned as a working discussion rather than a consultation session. Previous consultation on the IEHR has centred on 'round table' discussion of policy and privacy issues.

The workshop provided the opportunity to:

- discuss how the IEHR solution could be demonstrated;
- test ideas and concepts with representatives prior to the commencement of consultation;
- understand and capture key issues and concerns so that NEHTA can consider these prior to commencement of consultation; and
- improve understanding, share ideas and gather feedback on the IEHR.

A.5　NEHTA Quantitative Survey Report, August 2008

This quantitative survey was undertaken throughout the month of July 2008. In total 2,700 people were asked their opinion on a number of issues relating to the implementation of an IEHR Service for all Australians [NEHT2008b]. The number of respondents from each state and territory was as follows:

- NSW – 500
- Victoria – 500

- Queensland – 400

- South Australia – 400

- Western Australia – 400

- Tasmania – 300

- Northern Territory – 200

A.6   eHealth Conference, November 2010

On the 30th of November 2010 and 1st December 2010, the Department of Health and Ageing conducted an eHealth conference. The conference had a specific focus on two topics: telehealth and PCEHR; and included both local and international speakers. Over 400 delegates were invited to attend.

The Conference included a number of specific sessions aimed at engaging the community on the topic of PCEHR.

In the lead up to the conference NEHTA conducted a series of 'roundtable' sessions with specific groups, including: consumers, medical providers, nurses, allied health and the ICT industry.

The findings of the eHealth conference and lead up roundtables have been summarised in the Report of the National e-Health Conference [DOHA2011a].

A.7   NEHTA Reference Group Meetings, July 2010 – Present

In July 2010, the Department of Health and Ageing requested NEHTA to undertake a consultation and engagement activity using its clinical leads and reference group members.

Since July 2010, NEHTA has arranged a number of reference group meetings and leveraged the experience and skills in each of its existing groups.

Each group has a mix of participants and includes clinical representatives, consumer representatives, state and territory representatives and representatives with other backgrounds.

NEHTA also periodically runs a series of roundtable sessions with specific groups, such as consumers, medical providers, nurses, allied health and ICT industry in order to review stakeholder specific issues.

NEHTA will continue to run reference group meetings and roundtable sessions throughout the length of the PCEHR Program.

A.8   Future consultations

The Department of Health and Ageing will undertake additional rounds of consultation with consumers, healthcare providers and the ICT industry as the PCEHR Program progresses.

Appendix B: Current state

This appendix outlines the general trends around eHealth in Australia as well as lessons learned both locally and internationally in shared electronic health records.

B.1   General eHealth trends within Australia

Australia is one of the more information and communication technology enabled societies in the world. At the end of June 2009 there were 8.4 million active Internet subscribers in Australia, with 57% of subscribers having a download speed of 1.5Mbps or greater [ABS2009]. The existing Internet capability in Australia is able to support most current eHealth applications. Once implemented, the National Broadband Network will extend broadband support and facilitate new opportunities in eHealth.

The current healthcare system operates in a mixed mode of using paper-based and electronic-based systems for collecting and sharing health information. A number of different eHealth applications are in wide use in a number of different areas in the health sector including patient administration systems (PAS), clinical information systems (CIS), diagnostic imaging systems, pathology systems, practice management systems, etc.

The National E-Health Strategy noted during the consultation process that there is strong support for eHealth within Australia, and stakeholders recognise the potential efficiency, quality and many safety benefits it can deliver. Coupled with this widespread support, there was also a high degree of frustration with the pace of progress. In 2004, progress was too piecemeal and fragmented[13], and lacked sufficient levels of investment and national coordination. This desire for a more nationally coordinated approach led to the creation of the National E-Health Strategy.

In terms of specific groupings, the following common themes are emerging across the community:

- **States and Territories:** All State and Territory governments are in the process of either defining or implementing some form of jurisdiction-wide eHealth strategy. These strategies typically involve substantial government investment on the upgrade of core IT infrastructure or the implementation of clinical information systems across the acute sector.

  Common classes of systems in use in the States and Territories include simple PASs used in smaller regional facilities to fully developed CISs capable of interfacing with emergency department, theatre booking, hospital pathology, radiology and hospital pharmacy systems. Most States and Territories are somewhere in between and may have different mixes of capabilities from health service to health service.

  It should be noted that all States and Territories are at different stages on their eHealth journeys. While they all use common classes of systems, they need to take specific approaches to solving their local challenges. However, these eHealth programs should result in the establishment of State and Territory eHealth platforms that provide the basis for integration with national infrastructure.

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[13]   This view was also reflected in a report by the Boston Consulting Group (BCG) in 2004 [BCG2004]. The BCG undertook a system wide review of eHealth related activities across all jurisdictions in Australia. The review identified over 360 current or planned eHealth initiatives. The large majority (more than 70%) of these initiatives were small localised initiatives with a budget of less than $500,000.

- **General Practice:** According to the Australian Medical Association (AMA), over 95% of GPs have computerised practice management systems. The majority of GPs with a computer at work used it for printing prescriptions, recording consultation notes, printing test requests and Referral letters and receiving results for pathology tests electronically. Roughly one third of GPs keep 100% of patient information in an electronic format and the remainder of general practices use a combination of paper and electronic records.

- **Community Pharmacy:** Anecdotal evidence indicates the uptake of systems within community pharmacies is quite high as it is a business necessity for pharmacists to manage their stock or print labels for dispensed medicines.

- **Allied Health:** Whilst there are some software packages available for managing allied health practices (e.g. around billing and bookings), anecdotal evidence indicates limited uptake of electronic health records in private allied health practices. Some public sector operated community health centres offer electronic health records for their allied health providers, but this is uncommon.

- **Specialists:** A Royal Australian College of Physicians survey of 1,266 Specialists found that 97.5% of respondents had access to computers at work [IMJ2009]. Most specialists are currently using practice management systems at their front desk for billing and booking; take-up of clinical systems within consulting rooms varies as much as 10% to 40% (depending on the speciality). A number of specialist systems are modified GP systems with additional modules added to support the needs of the specialist.

- **Private Hospitals:** There are a number of different products used across Private Hospitals, employed under different software implementations and underlying supported platforms. Their level of sophistication and function varies from simple PAS systems used to provide billing and booking in smaller day surgeries to fully developed CISs used in some of the not-for-profit groups. Outside of the not-for-profit hospitals, it is not uncommon for electronic health record systems be operated mainly by specialists and the hospital mainly focuses on patient administration and theatre booking.

- **Diagnostic Services:** Private pathology and radiology providers have taken up ICT in order to be able to support their increasingly automated businesses and advanced diagnostic equipment. Pathology is one of the more advanced users of ICT and has a range of different vendors who supply systems into this space as well as supporting the delivery of electronic Pathology Result Reports. Similar levels of advanced usage are also seen in diagnostic imaging with a range of different vendors who supply both picture archive systems and radiology information systems into this space.

B.2   The National E-Health Strategy

Australian governments have recognised, consistent with the experience of many other countries, that moving from a paper-based system to an electronic one requires a long-term plan with multiple staged goals that are linked to the experiences of patients as they journey through the health system.

The key lesson from analysis of comparable developed countries is that the success of an eHealth implementation depends on focused strategic plans [ECIS2007, DHC2004, MHSA2006]. These plans have been implemented with strong leadership by government and supported by appropriate investment over long lead times.

Australia has acknowledged this need for leadership through its collaborative approach between governments to address eHealth and through the development and public release by all Health Ministers of a National E-Health Strategy in 2008 [AHMC2008]. The Strategy provides a guide for the further implementation of eHealth in Australia.

The National E-Health Strategy proposes an incremental and staged approach to developing eHealth capabilities and supports the existing collaboration of Commonwealth, State and Territory governments. The Strategy also provides sufficient flexibility for individual jurisdictions and health sector participants to determine how they implement eHealth solutions within a common framework and set of priorities. It recognises the current eHealth work program to be delivered through NEHTA and the need for other investments over a ten-year timeframe to deliver a full national eHealth capability. It also recognises the significant role of the market in delivering eHealth solutions that will respond to a dynamic health sector.

The key principles that underpin the Strategy's approach to deliver Australia's national approach to eHealth are around creating the necessary national infrastructure; using an approach heavily informed by stakeholder engagement; an incremental approach to implementation; recognising that different stakeholders will have different starting points; leveraging existing systems where appropriate; striking a balance in national alignment and local independence; and fostering relevant skills in the community.

In order to deliver the vision for eHealth, the Strategy recommends work be conducted in four major work streams: Governance; Foundations; eHealth Solutions; and Change and Adoption.

The Strategy focuses on the development of eHealth solutions in priority health areas that will provide the greatest tangible benefit to all Australians and their healthcare providers. The three categories of solutions identified as high priority by the Strategy are:

- Electronic information sharing
- Service delivery tools
- Health information resources

Much of the Strategy's foundation work for information exchange is funded and delivery is underway. The NEHTA work program funded to June 2012 is focused on achieving the foundations for information exchange to support eHealth solutions.

The foundations for a national eHealth system include:

- A system for uniquely identifying individuals, healthcare providers and the organisations in which they work.

- Authentication services to ensure that transactions are private, traceable and only conducted by known identities.

- Healthcare providers using computer software that meets common standards for communicating information such as Prescriptions, Referrals, Discharge Summaries, Pathology Result Reports and Diagnostic Imaging Result Reports.

- A robust privacy framework for the handling of personal health information.

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

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

Since the Strategy was originally developed, the term 'PCEHR' is now preferred as it better aligns with the recommendations from the National Health and Hospitals Reform Commission which recommended that a national approach to electronic health records should be driven by 'the principle of striving to achieve a person-centred health system.' [NHRR2009].

In 2010, the Government has invested 466.7 million in the first release of a PCEHR System.

B.3   Experiences with PCEHR Systems in Australia

Prior to 2010, a number of shared electronic health record systems have been developed.   Consideration of shared electronic health records in Australia started with the National Electronic Health Records Taskforce (NEHRT) in 2000, which was commissioned by the Australian Government to consider the potential for a network of electronic health records. The recommendations of the NEHRT led to the creation of the Health*Connect* program and work on a range of trials on PCEHR progressed initially through Health*Connect* and Medi*Connect* programs in Tasmania, Queensland, New South Wales, South Australia, Western Australia and the Northern Territory. In 2005 it was recognised that for eHealth to progress further in Australia, key infrastructure and standards were required, and NEHTA was established.

Since the Health*Connect* days, a number of regional Shared Electronic Health Record (SEHR) Systems have continued, including:

- **GP Partners in Brisbane Health eXchange** — GP Partners, one of the divisions of general practice in Australia offers a variety of services to GPs within its remit. One of these services is a health information exchange, offering connectivity between 166 of the 800 GPs in the area, six local hospitals, allied care providers and residential care facilities. The GP Partners Health eXchange offers automatic notification to GPs when a health record is checked or updated with results from an investigation by another care team member, and is integrated into GPs' Clinical Systems to minimise the disruption to GP workflows [GPP2008].

- **eHealth NT Shared Electronic Health Record** — The Northern Territory Department of Health and Families has been progressively implementing a SEHR across the NT. In rural and remote communities implementation activities are being coordinated with the accelerated rollout of the Primary Care Information System (PCIS). In urban communities, activities are being focused on aboriginal medical services and clusters of urban private general practices. Feasibility is being assessed for expanding the SEHR into regions of Western Australia and South Australia. A major new initiative is the implementation of a current health profile, updated automatically when the individual attends their principal primary care GP or health centre. Future plans include provision to store and update Healthcare Management Plans and the capacity for an individual to access their SEHR via the Internet [NTH2008].

- **Goldfields Esperance GP Network** — The Goldfields Esperance GP Network has implemented a Regional SEHR. The SEHR is part of the GoldHealth Network and is used to support Kalgoorlie-Boulder patients and currently connects local general practices, specialist practices, aboriginal community controlled health services, a major regional hospital, a district hospital, and an aged care facility.

- **Healthelink in NSW** — Healthelink is a SEHR operated by NSW Health in Maitland (Hunter Valley) and Western Sydney. As of November 2009 it had over 90,000 individuals enrolled and allows health information to be shared between GPs, Community Providers and Hospital-Based Providers. NSW Health is currently reviewing the future of this program in light of the PCEHR System.

- **Smart Health** — Smart Health Solutions provide a SEHR alongside other chronic disease information management and secure online solutions. Smart Health has existing SEHR implementations at Royal Adelaide Hospital, The Alfred, New England (Armidale, Tamworth, Inverell and Moree Hospitals), St Vincent's and Mater Health (Sydney). Additional implementation sites are also proposed or under development.

From the earlier Health*Connect* trials, a range of independent evaluation reports have been produced. The findings documented in these reports are brought together in the overarching 'Lessons Learned Report' [DOHA2005a]. In addition to the needs for national infrastructure and standards, the major lessons learned include:

- Feasibility:
  - A SEHR System is technically feasible, but the underlying infrastructure and connectivity (including the availability of CISs particularly in hospital, access at the point of care and network and communications infrastructure) limited the success of most implementations.
  - While community pharmacists and GPs are currently better positioned technically to move towards SEHR than hospitals, specialists and other private providers, there will be change management and business process challenges for all.

- Registration:
  - While the full process of registering individuals for a SEHR is too time-consuming for most healthcare providers, the trust between healthcare providers and their regular patients means that individuals will be strongly influenced in their decision to participate by the attitude of their healthcare providers towards eHealth.
  - Succinct and audience-specific information should be provided before registration, with further information available to those seeking it.
  - A Health Summary with key clinical information should be established as early as possible and appropriately funded/resourced.

- Consent:
  - Consent models need to be simple and practically workable at the point of care.
  - Individuals preferred voluntary participation based on an 'opt-in' model for participation.
  - Individuals prefer to provide some form of 'standing' consent to nominated healthcare providers to have ongoing access to their record (rather than consent at every episode of care).

- – The most popular consent model for when a healthcare provider sends an individual's health information to a SEHR was for the healthcare provider to assume consent unless the individual says 'no'.

  – Some individuals may never be sufficiently comfortable to participate, even with the most stringent controls.

  – Most healthcare providers were concerned about the completeness of the SEHR if individuals withhold information.

- Drivers for Adoption and Change Management:

  – A critical mass of both individuals and healthcare providers is needed to deliver benefits efficiently. It is important to complete the care chain wherever possible — gaps in the electronic health record reduce the healthcare provider's perceptions of the utility of the record.

  – The key to provider healthcare participation will be demonstrable benefits and seamless interaction (such as the creation of Event Summaries) through integration with their normal business processes. Use of their clinical system is preferred over a separate web based Internet interface.

  – Where it meets an existing business need, healthcare provider engagement and change management is significantly easier.

  – Successfully engaging healthcare providers and the provision of effective change management support is a critical success factor. Clinical champions and the Divisions of General Practice are key change management facilitators.

- Governance and Stakeholder Management:

  – There is a need to effectively engage stakeholder groups at both national and local levels that will facilitate strong governance and engagement with the national approach.

  – The roles of funder and stakeholder need to be separated in the governance arrangements.

  – Early and ongoing vendor engagement is required to test, deliver and maintain functionality.

A number of lessons learned are also reported in an evaluation of the NSW Healthelink system [KPMG2008]. The report highlighted that building a SEHR is technically feasible and that there is support from both individuals and healthcare providers for such systems. However, the report also highlighted that uptake was slower than expected due to a number of reasons:

- Healthelink had not yet reached a critical mass of patients, and therefore did not yet contain sufficient information for its potential to be realised.

- The process of accessing and using Healthelink was not yet seamlessly integrated into clinicians' routine system processes. This reflects the decision of NSW Health to contain the degree of sophisticated functionality as part of its pilot risk management strategy.

- Healthelink has experienced difficulties with some independent vendor software products that were not originally designed to accommodate a SEHR. This will remain an issue until the software products used by GPs are able to accommodate the requirements to transmit information to a SEHR.

B.4   International experiences

eHealth has been viewed as an integral element of health sector reform in many countries. Prominent programs include:

- *England:* National Health Service (NHS) Connecting for Health is an agency of the UK Department of Health, which was formed in 2005 to modernise the NHS ageing IT infrastructure. As part of that program, there is a driver for the creation of a national 'spine', which includes a clinician-oriented summary care record (SCR) and a consumer-oriented 'healthspace' portal that complements locally held electronic health records.

- *Scotland:* The Scottish NHS in 2006 introduced a national 'Emergency Care Summary', which is available for all individuals and accessible by after-hour clinics and emergency departments.

- *USA:* Historically, the US has been the source of notable electronic health record (EHR) success stories, including large institutional EHRs in Kaiser Permanente, Veterans' Affairs, Intermountain Health and the Mayo Clinic. More recently, in order to realise the anticipated benefits of eHealth, the US Centres for Medicare and Medicaid Services have announced a proposed rule to implement the HI TECH provisions of the American Recovery and Reinvestment Act of 2009 that provide incentive payments for the 'meaningful use' of certified EHR technology. This funding includes funding for hospital and physician uptake of EHRs in their practices, but also is complemented by additional funding for a National Health Information Network to link regional Health Information Exchanges to enable sharing of healthcare information.

- *Canada:* In 2005 the Canadian government created Infoway, a not-for-profit organisation that collaborates with the provinces and territories, healthcare providers and technology solution providers to accelerate the use of EHRs in Canada. A key part of the Infoway approach is to drive the creation of a Health Information Access Layer (HIAL) in each province.

There are also other notable national EHR implementation programs in Denmark, Germany, Singapore and Hong Kong.

A review of European initiatives [CSC2009] highlighted a number of key lessons from these programs:

- Implementation is more likely to be successful if it is viewed as a healthcare reform initiative, supported by technology. In particular, it is essential that the healthcare value of the shared record be understood at the outset of the program, be designed into systems as early as possible and continuously be re-assessed. Furthermore, as with many IT systems, those who create the data often bear the most significant costs, whereas those who use the data gain the benefit. Therefore, funding models need to reflect this difference.

- Early communication regarding privacy options is essential.

- An effective shared record depends on an effective form of unique patient identification.

- Certification of systems against nationally agreed standards is a 'must have' element of any successful program.

- A comprehensive communication and engagement strategy is essential.

- The more the implementation is linked to policy, the more successful the adoption will be.

A consistent finding across a number of international studies suggests that a 'middle out' approach based on collaboration between government, the ICT industry, and healthcare providers to create an evolving set of standards and promote dialogue across sectors is more likely to be effective [IOSP2008, JAMI2009]. Large scale implementations based on centrally procured systems tend to receive greater levels of resistance from the community and end up being much more expensive than initially predicted due to the high levels of customisation required. In contrast, bottom-up approaches relying on organic growth, while initially being cost effective by preserving existing systems and infrastructure, can lead to limitations on the information that can be captured and shared for the benefit of broader health outcomes.

Additional findings from other reports include:

- A report on the Danish shared record scheme found that increasing the level of complexity does not bring a corresponding increase in benefits [GART2006]. The report recommended focusing on a simple, basic design and concluded getting the level of functionality right is essential.

- A report on the UK SCR reiterated that achieving critical mass is essential as clinicians will stop using a system if they fail to find shared records within it [BMJ2010a]. The same report also found that implementing a shared SCR is a major socio-technical challenge, and harvesting benefits will be highly contingent on the abilities of clinical champions and change agents. These champions and change agents need to be able to bridge different stakeholder groups, negotiate complex interdependencies and tensions between groups and mobilise implementation efforts.

Appendix C: Scenario

C.1   Introduction

The following scenario is intended to illustrate how the PCEHR System can be used, to highlight the benefits and identify key questions for consultation.

Some of the key features demonstrated by this scenario include:

- how a healthcare provider can gain access to a PCEHR (see Scene 1);
- the type of information a healthcare provider can access (see Scene 1); and
- access to records by the individual (see Scene 3).

The benefits illustrated in this scenario include:

- how access to prior information streamlines the collection of an individual's medical history (see Scene 1);
- how the PCEHR facilitates better continuity of care (see Scenes 2 and 4); and
- how the PCEHR facilitates improved consumer participation in their healthcare (see Scene 3).

Note that this is a simple scenario intended to highlight some of the basic features of the PCEHR System. Some of the more complex features around access control settings are not illustrated in this scenario.

C.2   Frank Harding

Frank is a 62-year-old retired schoolteacher, who has decided to travel around Australia. Frank and his wife Daphne have just purchased a 4WD and campervan and have headed north from their home in Croydon in Victoria. He had been diagnosed with Type II Diabetes (Non-Insulin Dependent Diabetes) and moderate depression. Both conditions require monitoring and treatment modification. His initial anti-depressant (Prozac) was ineffective and resulted in a rash and vomiting. He is now on Metformin to manage his diabetes.

Frank has consented to have a PCEHR and agreed that any healthcare provider involved in his care can have access to his PCEHR.

Scene 1: Frank visits the Emergency Department in Cairns

While on his holiday in Cairns, Frank presents to the Cairns Emergency Department (ED) complaining of chest pain and presenting with shortness of breath and cough.

In the current system, the Cairns ED would need to rely on Frank's memory for his medical history. At best, if the ED had time and Frank's GP was contactable, the ED would phone Frank's GP to find out his medical history.

With access to the range of new eHealth capabilities, the Cairns ED can use the health identifier service to quickly locate Frank's IHI by using Frank's Medicare Card and other identifying details (name and date of birth).

After locating Frank's IHI, the local clinical system also identifies that Frank has a PCEHR. As Frank's access controls permit any healthcare provider involved in his care to have access to his PCEHR, the Cairns hospital adds itself to his 'include' list.

From now on, the Cairns Hospital can use the PCEHR System to locate Frank's health information in a range of different repositories. This authorisation will remain in place until Frank revokes it.

When the doctor is able to see Frank, he/she can view a copy of Frank's Consolidated View. The Consolidated View includes the Shared Health Summary from his regular GP in Croydon and also shows any new information about Frank's allergies/adverse reactions, medicines and medical history that may have been collected in his PCEHR on his travels (e.g. Event Summaries from visits to walk in GP practices).

At the conclusion of Frank's consultation in the ED, the emergency physician diagnoses Frank with pneumonia and prescribes a course of antibiotics. Frank's Liver Function Test (LFT) performed at the hospital showed a mild out of range result. The LFT results were explained to Frank by the ED physician and Frank was advised to have a follow up LFT in 2 weeks. Frank's Discharge Summary is sent to Frank's regular GP in Croydon and a copy is uploaded to Frank's PCEHR.

Scene 2: Frank in Port Douglas

Two weeks later while in Port Douglas, Frank is feeling better and remembers that he needs to have a pathology test done. Frank attends a walk-in GP clinic in Port Douglas to have his pathology test organised.

In the current situation, Frank would need to remember the name of the pathology test and the details of his episode of care within Cairns for the Port Douglas GP to undertake the right course of action.

With access to the range of new eHealth capabilities, the Port Douglas GP can access Frank's PCEHR to locate the Discharge Summary from the Cairns ED. Then using the information from Frank's Discharge Summary, the Port Douglas GP can request a LFT for Frank electronically.

At the conclusion of this consultation, an Event Summary is sent by the GP to Frank's PCEHR.

Scene 3: Coffs Harbour

After a day in Port Douglas, Frank is not feeling up to doing the full lap of Australia, so he and Daphne head home to Croydon. While in Coffs Harbour, the GP office in Port Douglas calls Frank requesting him to come back for a follow up visit to review his results. The GP has also released the pathology results to Frank's PCEHR.

Frank is now too far away from Port Douglas to return for his follow up appointment, so the practice recommends that he should see his GP back in Croydon as soon as he returns.

Ordinarily in this case Frank would not have direct knowledge of his health records. Using the PCEHR System, Frank is able to become more involved in his own care. Frank is able to use the consumer portal to view his health information and then look up online resources such as HealthInsite and LabTestsOnline help him his condition and lab test results.

Scene 4: Croydon

On return to Croydon, Frank books an appointment with his regular GP to review his results.

Ordinarily, Frank's GP would need to request a copy of Frank's results from the pathology laboratory in North Queensland or have the pathology test repeated. In this case, by using the PCEHR System, Frank's GP is able to locate Frank's results quickly. Frank's GP can also easily see the entire medical history of his journey from the PCEHR index view, including visits to other healthcare providers.

Frank's GP recommends that Frank undertake a new course of antibiotics and gets some rest before heading west to Broome and the Kimberly.

Appendix D: Glossary

Term	Acronym	Definition
Advance Care Directive		An advance care directive is a statement by a competent person expressing the intention to refuse medical treatment in the future, at a time when he/she may no longer be competent to make a treatment decision.
Australian Childhood Immunisation Register	ACIR	The Australian Childhood Immunisation Register is a national register administered by Medicare Australia that records details of vaccinations given to children under seven years of age who live in Australia.
Australian Health Practitioner Regulation Agency	AHPRA	The organisation responsible for the registration and accreditation of a range of healthcare professions across Australia.
Australian Organ Donor Registry	AODR	The Donor Register is the only national register for organ and/or tissue donation for transplantation. The Donor Register keeps a record of the individual's donation decision and of the organ and tissue the individual agrees to donate.
Authentication		Validating that the user wishing to access the PCEHR is who they claim to be. In electronic environments this is achieved by providing a user with a credential such as a user-id + password, a smart card or a one time password device.
Authorised Representative		A person that legally represents an Individual in relation to any interaction with a healthcare service. This may include a parent, guardian or a person with power of attorney.
Authorised User		A person authorised by the healthcare organisation to access the PCEHR System on behalf of the participating organisation.
Availability		A measure of how long the system is scheduled to be accessible by users of the system.
Clinical Document		A clinical document is a document that provides personal health information about an individual. Examples include a Shared Health Summary, Event Summary, Discharge Summary, Referral, pathology result, report, etc.
Clinical Document Architecture	CDA	A HL7 standard intended to specify the encoding, structure and semantics of clinical documents for exchange.

Term	Acronym	Definition
Conformant Portal Provider	CPP	A supplier of a consumer-oriented portal that is capable of connecting to the PCEHR System.
Conformant Repository		A repository that conforms to the appropriate PCEHR standards and specifications required to ensure interoperability, privacy, integrity and long term availability of the healthcare information it holds.
Consolidated View		A view intended to provide a summary of an individual's PCEHR. It presents information from the Shared Health Summary and also indicates if other related information from other clinical documents is available.
Contracted Service Provider	CSP	A third-party organisation that supplies health software as a service to healthcare organisations.
Council of Australian Governments	COAG	An organisation consisting of the federal government, the governments of the six states and two mainland territories and the Australian Local Government Association.
Data Quality		The result of ensuring that data held in PCEHR has the necessary attributes including: accuracy, completeness, consistency, currency, timeliness, fitness for use, provenance and compliance.
De-identified Data		Data is de-identified when it is not possible to reasonably ascertain the identity of a person from that data. It is context dependent.
Detailed Clinical Model	DCM	A common underlying information model used to ensure consistency of structured information and clinical terminologies between different types of structured clinical document.
Department of Health and Ageing	DOHA	An Australian Government department. The Department of Health and Ageing has a diverse set of responsibilities, but throughout there is a common purpose, which is reflected in the Department's vision statement: Better health and active ageing for all Australians.
Electronic Health Record	EHR	A repository of personal health information in a computer processable form. Its primary purpose is the support of continuing, efficient and quality healthcare. (Definition adapted from [ISO 20514].)
Electronic Transfer of Prescription	ETP	A NEHTA specification for supporting transfer of electronic prescriptions between prescribers and dispensers.
End Point Location Service	ELS	A NEHTA specification for locating the address for where secure electronic messages should be delivered.

Term	Acronym	Definition
Event Summary		A clinical document summarising one or more healthcare events.
Exclude List		A list of participating organisations the individual does not wish to access their PCEHR.
Health Level Seven	HL7	A non-profit organisation involved in development of international healthcare informatics interoperability standards.
Healthcare Identifier Provider Directory Service	HI PDS	A voluntary provider directory service provided as part of the HI Service.
Healthcare Identifier Service	HI Service	The HI (Healthcare Identifier) Service will enable the consistent identifiers to be created for individuals and healthcare providers across the Australian health system through the introduction of unique healthcare identifiers — see IHI, HPI-I and HPI-O.
Healthcare Provider		A person who is involved in or associated with healthcare delivery. A synonym for clinician.
Healthcare Provider Identifier for Individuals	HPI-I	The Healthcare Provider Identifier for individuals (HPI-I) is a 16 digit unique number used to identify providers who deliver healthcare in the Australian healthcare setting.
Healthcare Provider Identifier for Organisations	HPI-O	The Healthcare Provider Identifier for Providers (HPI-O) is a 16 digit unique number used to identify organisations who deliver care in the Australian healthcare setting.
Healthcare organisation		Organisations that participate in providing health services to individuals.
Include List		A list of participating organisations the individual has authorised to access their PCEHR.
Index View		A view listing all clinical documents available in a PCEHR.
Individual		People who are, or could be, seeking care in Australia. Individuals are sometimes referred to as patients, clients and consumers. For the purposes of the PCEHR System, an individual must have an IHI.
Individual Healthcare Identifier	IHI	The Individual Healthcare Identifier (IHI) is a 16 digit unique number used to identify individuals who receive care in the Australian Health system.
Information and	ICT	A generic name for both information technologies and communication technologies,

Term	Acronym	Definition
Communication Technology		and their convergence.
Interoperability		The ability of two or more systems or components to exchange information and to use the information that has been exchanged [IEEE90].
National Authentication Service for Health	NASH	A national digital credential management service for healthcare providers and healthcare organisations.
Nominated Provider		A healthcare provider or healthcare organisation nominated by the individual to manage their Shared Health Summary.
Nominated Representative		A representative nominated by the individual to be able to access their PCEHR.
Notice of Connection	NOC	A notice issued by the PCEHR System operator indicating that a system is ready to connect to the PCEHR System.
Organisation Maintenance Officer	OMO	The role within an organisation responsible for maintaining information about the organisation within the HI Service.
Participating Organisation		A healthcare organisation, which chooses participate in the PCEHR System and meets the participation criteria.
PCEHR System		A system of systems used to manage a collection of PCEHRs.
Personal Health Information		Personal information about an individual's health or is collected to provide a health service.
Personal Health Record	PHR	A Personal Health Record (PHR) is a type of EHR that is initiated by and under the control of the individual. The personal health information it contains is at least partly entered by the individual. (Definition adapted from [ISO 20514].)
Personal Information		Information or an opinion recorded about an individual whose identity is apparent, or can reasonably be ascertained.
Personally Controlled Electronic Health Record	PCEHR	A type of EHR that is initiated and personally controlled by an individual. Personal controls are specifically as outlined in Section 3.2.1.
Pharmaceutical Benefits Scheme	PBS	An Australian Government scheme aimed at providing all Australians with affordable access to a wide range of prescription medicines.

Term	Acronym	Definition
Privacy		As used in the context of this report, privacy refers to the collective or rights and obligations contained in the National Privacy Principles and the related Information Privacy Principles and Health Privacy Principles. These cover inter alia matters to do with collection and use, access, security and data quality.
Provider Access Code	PAC	A code (i.e. PIN or passphrase) an individual can provide to an authorised user in order to have the participating organisation added to the include list.
Provider Access Code (extended)	PACX	A code (i.e. PIN or passphrase) an individual can provide to an authorised user in order to have the participating organisation to have access to 'limited access' clinical documents.
Registration		The processes associated with the creation by an individual of their PCEHR. Registration will include processes covering verification of identity and evidence of entitlement (i.e. meeting the criteria for participation, such as having an IHI).
Report		Data extracted from one or more clinical documents from one or more PCEHRs for reporting purposes.
Responsible Officer	RO	A person with authority to act on behalf of a healthcare organisation with respect to the HI Service.
Royal Australian College of General Practitioners	RACGP	The professional body for General Practitioners in Australia.
Shared Health Summary		A clinical document summarising an individual's health status and includes important information such as allergies/adverse reactions, medicines, medical history and immunisations. Only a nominated provider can create or update the Shared Health Summary.
Software as a Service	SaaS	Software that is either supplied as a cloud based service or deployed over the Internet to run locally. Licenses and support for SaaS systems are commonly provided on a subscription basis, but other models are also used.
Transferrable Access Key	TAK	A cryptographic key included in Referrals to authorise the Referral recipient to be added to the include list.
View		Data extracted from one or more clinical documents within an individual's PCEHR for the purposes of supporting the information needs of

Term	Acronym	Definition
		an individual or healthcare provider.

Appendix E: References

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