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ACHI COMMENTS

on the

Information Requirements

Shared Health Summary

Version 0.5.2 - 3 June 2011

Draft for External Review

Please note our overarching comments in the Key Points document.

National E-Health Transition Authority

National E-Health Transition Authority Ltd
Level 25
56 Pitt Street
Sydney, NSW, 2000
Australia.
www.nehta.gov.au

Document Information

Change history

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v0.0.1	2010-12-14	Rob Eastwood	Initial version, adapted from the RACGP GP Health Summary Information Requirements
v0.1.1	2010-12-20	Rob Eastwood	Updated version following updates to the RACGP GP Health Summary Information Requirements. Removed 'confidentiality indicators'
v0.1.2	2010-12-21	Rob Eastwood	Minor updates, added overview and scope, reordered content.
v0.1.3	2011-01-18	Rob Eastwood	Updated version in preparation for small group Clinical Leads workshop, 21 Jan 2011. Removed Medical History 'active' status.
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v0.4.3	2011-03-11	Rob Eastwood	Updated version following further agreement with the eMM team re medication duration.
v0.4.4	2011-03-28	Rob Eastwood	Updated version following comments received from Qld Health
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Version	Date	Contributor	Comments
			component's corresponding DCMs
v0.5.0	2011-05-16	Rob Eastwood	Initial updated version following Clinical Leads meeting, 12 May 2011
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V0.5.2	2011-06-03	Rob Eastwood	Minor correction

Document authorisation

Name	Title	Signature
Stephen Johnston	Head of Solutions Development	
Sean Holmes	Program Manager, Continuity of Care	

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Preface

Document Purpose

This document presents the information requirements for a Shared Health Summary, which are recommended for use within Australia.

The Shared Health Summary Information Requirements are a logical set of data items for exchange and are therefore independent of any particular platform, technology, exchange format or presentation format.

Updates to this document will be published as additional package components are developed, with feedback from the sector.

Intended Audience

This document is intended for all interested stakeholders including:

- Clinicians, such as general practitioners
- Early adopter hospitals and health departments in the process of planning, implementing or upgrading eHealth systems
- Software vendors developing eHealth system products
- Early adopter general practitioner desktop software vendors
- Senior managers and policy makers, clinical experts, health information managers, IT operations and support teams, system integrators
- Stakeholders associated with the development and use of upcoming eHealth initiatives relating to 'continuity of care'
- Both technical and non-technical readers.

ACHI Comments:

The College notes that in the stakeholders list ('intended audience') does not explicitly include patients or patient representatives. This is a serious oversight. No healthcare professional is in a position to provide a proxy perspective for patients, even if they believe they can because they are/have been patients themselves. The stated 'owner' or 'controller' of the patient controlled EHR is after all the patient.

Recommendation SHS.1: *That the "intended audience" list of the SHS be expanded to include patients as well as patients and consumer representatives.*

Document Status

This document is a draft subject to external consultation and review; therefore the document content will evolve with iterations of the package development process.

Definitions, Acronyms and Abbreviations

For a list of abbreviations, acronyms and abbreviations, see the Definitions section at the end of the document, on page 46.

References and Related Documents

For a list of all referenced documents, see the References section at the end of the document, on page 47.

1 Introduction

1.1 Overview

This document presents the Information Requirements for Shared Health Summaries, as recommended for use in Australian eHealth systems.

The Information Requirements are the minimum set of data items that are recommended for implementation in any system that creates and transfers Shared Health Summaries, to support the delivery of quality collaborative care. The inclusion of data in this minimum set is determined by two criteria:

1. The clinical relevancy of the data
2. The potential for the data to ensure clinical safety in a collaborative care environment.

As these specifications define the Information Requirements for exchange, it is anticipated that some Shared Health Summary templates may contain additional types of data to satisfy specific local or specialty healthcare requirements.

1.2 Scope

1.2.1 Scope Inclusions

The aim of a Shared Health Summary (SHS) is to provide key pieces of information about an individual's health status facilitating care across a wide ranging healthcare domain.

The PCEHR Concept of Operations [PCO-2011] states that a SHS "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. SHS's are a key piece of information for populating an individual's 'Consolidated View', which is assembled from multiple sources. To enable easy extraction of SHS's from GP systems, the fields within a SHS will be congruent with the Royal Australian College of General Practitioners (RACGP) standards for health summaries."

A SHS can only be sourced and uploaded by an individual's nominated healthcare provider, which may be an individual or an organisation. Only the current version of the SHS is visible to PCEHR users (but access to historical records for audit and medico-legal reasons is only through the PCEHR Service Provider). If other providers wish to provide information about the individual to the PCEHR, they could use an Event Summary, specialist letter, or other clinical documents.

The nominated provider is not required to update a SHS at every consultation; it should be updated when clinically appropriate to do so at the discretion of the nominated provider.

In scope for the information requirements for the SHS, in the first release is information managed by the patient's nominated provider which is most often their usual GP.

The content of a Shared Health Summary will vary depending on the individual, and the information available. Therefore, information should only be included in a Shared Health Summary where it will and be useful to the healthcare provider for the ongoing care of the patient.

The information identified in this document will be electronically extracted from the GP clinical information system to populate the Shared Health Summary.

ACHI Comments:

In the context of this scope the question arises if the SHS is intended to be an emergency care record or a much fuller summary. This will determine issues such as emergency care access overrides, etc.

Recommendation SHS.2: *That the intended use of the SHS, in the context of the PCEHR, be clarified by the Continuity of Care Program Team and Workshop to ensure that the 'right' access provisions are made.*

1.2.2 Scope Exclusions

Out of scope is information gathering for the full patient records within the GP clinical information system, the way the data is transferred from GP desktop to PCEHR and how the information is formatted for display.

ACHI Comments:

A common theme raised by ACHI Members and Fellows alike is the question of whom the intended user of the PCEHR will be. Such clarification is deemed necessary to help determine whether the Shared Health Summary (SHS) is primarily patient-focused or doctor-focused; as the needs of patients and doctors are quite different.

The targeted primary user of the PCEHR will of course in turn govern who provides the content and how this content finds its way into the PCEHR. If the PCEHR is primarily intended for the patient, are we likely to see a high number of doctors providing clinical content into the system? Conversely, if the PCEHR is intended for clinicians, will it be populated automatically and if so, will all the content be appropriate for patient access?

Recommendation SHS.3: *That the intended user(s) of the SHS, in the context of the PCEHR, be clarified by the Continuity of Care Program Team and Workshop to ensure that the 'right' data is provided from the 'right' sources to ensure optimal useability of the SHS.*

The assumption is that this PCEHR project is aiming for a SHS generated from nominated provider(s) and is interoperable with the PCEHR. Having a consolidated view is possible if it involves a federation of records to form a PCEHR for 'eyeballing' only, however not for any other automated use. This is unlikely to encourage providers to share private and confidential information on their patients with unknown third parties unless they can see value in sharing e.g. for decision support.

An Australian research report to be presented to the American Medical Informatics Association (AMIA) conference in October 2011 will show that the data in the source systems are mostly, either not collected, or accessible for 'export'. The report will contend that one of the key reasons for these data 'gaps' is the lack of protocols as well as 'sticks and carrots', to encourage entry of structured / coded data.

The College believes that the 'out of scope' elements listed above are in fact actually key elements to the success of the SHS within the PCEHR.

Recommendation SHS.4: *That the source(s) and quality of the data for the SHS in the context of the PCEHR be clarified by the Continuity of Care Program Team and workshop to ensure optimal useability of the PCEHR SHS.*

The electronic healthcare summary (commonly referred to as the Summary Care Record "SCR") has been a contentious entity for quite a number of experts for some time.[1] The electronic healthcare summaries are essentially an unevaluated idea / concept. In the only major review of the SCR internationally, a recent analysis of 416,325 encounters in primary care, out-of-hours

[1] www.mja.com.au/public/issues/194_02_170111/coi10895_fm.html

and walk-in centres in England found that the SCR was used in only 4% of GP consultations (21% if only those patients for whom the GP had actually created an SCR were counted).[2] Similarly, a recent Texan study in the United States came to similar conclusions.

Recommendation SHS.5: *That the recent research into use and effectiveness of electronic healthcare summaries, SHS and SCR be reviewed by the Continuity of Care Program Team and workshop to ensure that the planned PCEHR SHS will attract sufficient use to justify the investment made.*

The strategic question of value for money also needs further investigation; if the SHS were to be one or many dynamic views of whatever data is available from the PCEHR sources, it would be a fairly straightforward technical task to create. In the current model however, there appear to be additional steps of data entry requiring human curation, reduction of what data is able to be stored in the summary sub-record, as well as specialised central repositories to store them. Therefore the question arises; aside from concerns about completion, accuracy, multiple provenance and timeliness; whether we should be building a specialised summary in this manner with summary views of all available data is contentious. Would a viewer which tailors the needs of the user, perhaps be far more feasible, valuable and most cost effect option?

Recommendation SHS.6: *That the method by which the SHS is created be reviewed by the Continuity of Care Program Team and Workshop to ensure that the planned PCEHR SHS will attract sufficient use to justify the investment made.*

1.3 Purpose

The purpose of the Shared Health Summary Information Requirements is to define the information requirements for a nationally-agreed exchange of information between healthcare providers in Australia, independent of exchange or presentation formats.

It is anticipated that these Information Requirements will:

- Promote a common understanding of the requirements for constructing and consumption of Shared Health Summaries
- Provide a common framework for development and use of semantically interoperable information components to be exchanged between applications, providers, jurisdictions
- Provide a common framework for defining queries using these information requirements at logical levels, which may be adopted for implementations in local, jurisdictional or national Electronic Health Record environments
- Provide a common framework upon which to define nationally-agreed, specialty-specific information requirements
- Provide a common framework for nationally-defined mappings to specific exchange formats
- Provide a framework (along with other documents and structures) suitable for the development of national terminology sets that associate specific data items with valid values. These values will be derived from nationally endorsed terminologies maintained and distributed on behalf of Australia by NEHTA's National Clinical Terminology and Information Service (NCTIS). The current terminology sources that will provide this content are LOINC for defined areas of Pathology content, SNOMED CT-AU for all other clinical content and Australian Medicines Terminol-

[2] www.mja.com.au/public/issues/194_02_170111/coi10895_fm.html#i1095946

ogy (AMT) for medicinal products. Administrative content will be derived either from SNOMED CT-AU or specifically defined external code-sets.

ACHI Comments:

The College believes that from a knowledge management and patient-centred care perspective, the SHS scenarios are good. There are however, some outstanding issues that we believe they can be overcome. It would appear that the most significant of these issues is that standardisation of data for interoperability purposes, given that the summary record should ideally pull data from Patient Management Systems in the GP environment, specialist environment, hospitals and other health services.

Recommendation SHS.7: *That the Continuity of Care Program Team outline how the SHS data will be standardised for interoperability purposes.*

Overall the discussions on the SHS have identified a number of substantial concerns regarding useability. It would appear that to date, the SHS has not undergone a focussed useability review. The topic of systems and software useability has been deeply researched and is well established.[3] In particular, the Continuity of Care Workshop and the subsequent teleconference identified issues with:

- The number of documents that need to be clicked on for a clinician, new to the patient's care, to get an overview of their health situation. This might be critical in an emergency care situation.
- The presentation of the information in a chronological tabular format; this is important for the effectiveness of the SHS for time-poor clinicians.
- The display of information in a state-of-the-art manner as expected from other popular information systems.
- The presentation of SHS data on popular handheld devices such as iPads and smart phones which are enjoying exponential market saturation and thereby alternating the means by which the average person now accesses a wide variety of information. As such, it would appear short-sighted to not consider these platforms. It is appreciated that security around such devices is a bone of contention; however this argument needs to be examined in context. The banking industry has already readily adopted the use of such devices, certainly not because it is seen as a preferred platform from a security perspective; rather they recognise and understand this to be an essential part of the saturation uptake by the broader community to have their applications available across multiple platforms. It is important that at least some consideration is given to providing end users with these platform options and then allow users themselves to make their platform decision. To 'railroad' end users down a particular path, particularly in the setting of an opt-in system, again needs to be carefully considered so that investments are being put toward supporting the right application infrastructure. The average person, even if not completely computer literate, can generally navigate their way around a smart phone or iPad; this cannot always said of many government websites, despite this being their intention.
- The trends towards more interactive PHR's (eg Dossia[4], etc.) should also be noted and accommodated.

Recommendation SHS.8: *That the Continuity of Care Program Team avail itself of systems and software useability expertise to ensure effective use and optimal uptake of the SHS.*

[3] http://en.wikipedia.org/wiki/Usability

[4] See www.Dossia.org

Recommendation SHS.9: *There is no meta-data in the SHS that is useful to allied healthcare providers or to the patient themselves. There is potentially some debate as to the usefulness of broad access by these allied healthcare professionals accessing SHS, however in a modern multidisciplinary health care environment where traditional role of health care practitioners are increasingly becoming blurred, these factors must be considered. Good meta-data for the SHS should include who last updated what and when; the "Document Control" section of this document does not appear to address this need. That the Continuity of Care Program Team outline where the metadata on creation and updating of the SHS can be found.*

It would also be useful if these information requirements do not assume that only GPs should update the SHS and be responsible for it. There is a philosophical issue with only one healthcare provider being responsible for the shared data. Even amongst doctors there are different interpretations of what's important, what certain data means and who should be using it for what purpose. While GPs are the fulcrum for the large majority of patient care, there is a significant team of providers, who are appropriate and valid providers of care in their own right and who should be able to access, use and provide input into the SHS.

Recommendation SHS.10: *That the Continuity of Care Program Team outline what type of healthcare providers it envisages will be creating, updating and taking responsibility for the SHS.*

In the documents that explain the PCEHR it appears that the PCEHR has been designed for 'the individual' who is assumed to be the person that the record is about. The document titled 'Key Points'[5] states that this individual or proxy 'is able to manage their own PCEHR.' In the examples of the SHS record they look like documents created by doctors for use by doctors. This again raises the question regarding who the SHS is intended for, as noted in section 1.2.2 above.

The SHS document and PCEHR appear to adhere to the principles of knowledge management in that the information in the document supports decisions and actions. An impression is created that the only stakeholders who could do this are doctors, for example in a scenario where the SHS has been created to meet doctors' needs. If the patient is to derive benefit from the summary, then at the very least the meta-data related in the date of prescription and renewal date should be included so patients can use the information to act too. There are also other ways in which the patient can make use of this record, for example, discuss it with their nutritionist for treatment planning purposes.

Trust is an important part of knowledge management. It is not clear how trust will be developed or supported so that the summary record will be a success. This issue was also discussed at the recent SHS/ES Workshop.

Recommendation SHS.11: *That the Continuity of Care Program Team outline its strategies to ensure that the medical practitioners will maintain sufficient trust of the SHS to ensure its effective use.*

If a busy GP is expected to update the SHS the work may be delegated to someone else in the practice and the GP will check it and sign it off. In this case, there is a substantial risk of poor quality data, especially incomplete data.

Recommendation SHS.12: *The Continuity of Care Program Team outline its strategies to ensure that the SHS data quality is maintained even if the GP does not personally update the SHS.*

[5] "NEHTA PCEHR - Key Points Concept of Operations", NEHTA, July 2011

The explanatory documents say that the GP doesn't have to update the record every time the patient visits – how can users of the SHS be assured that no data is missing that should be there? The contact details of the GP may be visible but there appears to be no way of knowing from the SHS how to contact other key providers, e.g. the diabetes specialist nurse, etc.

Recommendation SHS.13: *The Continuity of Care Program Team outline its strategies to ensure that the information in the SHS is complete.*

Recommendation SHS.14: *The Continuity of Care Program Team outline how contributors to the SHS other than GPs can be contacted for queries.*

A lot of data lies in the background of the SHS. If the summary is not linked to the background data by robust means, then the summary will have limited value. Clinician users should be able to search at the very least lab results, if they want more than what is recorded in the summary record.

Recommendation SHS.15: *That the Continuity of Care Program Team clarify if and how access to base data can be provided.*

The College notes that this document mixes fact with professional opinion. This approach is of concern because there is a real risk of the design being detrimentally affected by individual assumptions and human error. The Continuity of Care Program materials make assertions that are not supported by evidence; for example chronic or complex illnesses are reduced to a homogeneous condition when in fact we are speaking of a heterogeneous and complex range of conditions. The College prefers an evidence-based design approach and believes that the distinction between facts and professional opinions should be reflected in all PCEHR design documents.

Recommendation SHS.16: *That the Continuity of Care Program Team identify and advise the Workshop what sources, research and other evidence was leveraged to create these Shared Health Summary information requirements.*

1.4 Exchange and Presentation Formats

The information presented here is defined at the logical level, and is therefore independent of specific exchange or presentation formats (e.g. HL7 v2 or HL7 CDA).

Consequently, the Information Requirements may be mapped to multiple exchange formats. It is anticipated that such mappings will be defined and published following the endorsement of the Information Requirements.

Similarly, the requirement that a particular piece of data be exchanged in a Shared Health Summary does not imply a requirement on the user interface. Some data elements (e.g. 'Document Originating System Identifier') are intended purely for purposes of internal processes within the receiving system. Similarly, other data elements (e.g. 'Date of Birth') have a number of different presentation options available (e.g. 'Birth Day' + 'Year of Birth' etc), which are not considered here. In addition to this, the names given to data components and data items are in many cases not appropriate to be used as field labels on a user interface.

Implementations which modify the data item names in the 'Item' column of the following section to accommodate local practices (e.g. 'Person name' represented as 'Patient Name') may still conform to this specification, but only if the meaning of the variables listed in the other columns are not modified.

Please also note that the order in which the data items are listed in this document is not indicative of the order in which this data should be exchanged or presented to the user.

ACHI Comments:

This is a standard approach to data dictionaries and the College is comfortable with this methodology.

1.5 Adding Data

Note that some of the data elements included in this specification are required for ALL Shared Health Summaries whereas others need only be completed where appropriate. That is, a conformant Shared Health Summary implementation must be capable of collecting and transferring/receiving all Information Requirement elements.

However:

- Not all data elements require a value in each and every Shared Health Summary (e.g. items that are categorised with '0..1' or '0..Many'). For example, Medication "Additional Comments" (0..1): not all medications would actually require an additional comment.
- Not all data elements are required to be displayed to users, and their labels may be different from those used in the 'Item' column of the Proposed Data Model table in the following sections.

2 Core Components

2.1 Overview

The information components include:

Component
Individual
Source of Shared Health Summary
Allergies and Adverse Reactions
Medicines
Medical History
Immunisations
Document Control

Each component is firstly described in terms of what the requirements are, providing a rationale.

A small number of indicative samples for usage are included to provide additional clarity but are not intended to be a prescription for display. Note also that all content in the samples is completely fictitious.

This is followed with a representation of the proposed data model for each.

Following recent stakeholder engagement with this draft version, a number of requests were made for consideration. These items have been included into the relevant sections, as known issues. The following request for an additional component stands alone and is therefore described here.

Known Issue #1

> ***Considerable interest has been expressed to include a section on Alerts. Example alerts were suggested, such as "difficult intubation", "mechanical heart valves", "patient is a VRE carrier", "pacemaker", or other medical devices etc.***

ACHI Comments:

The College agrees that clinical ("mechanical heart valves") and administrative ("can be aggressive to female healthcare staff") alerts would be of great value to the ES. It is assumed that the information content of any such alert will include all the information that might be needed to validate the source and content of the alert.

Recommendation SHS.17: *That clinical and administrative alerts be added to the Event Summaries ensure their optimal useability.*

2.2 Guide to this document

The proposed data model for each of the components is defined below, using the following columns:

- *Component*: A high level section or group of data elements
- *Item*: An individual data element or data group. A data item may be a single unit of data (e.g. "Date of Birth"), or a set of data that has a standard structure (e.g. "Address")
- *Type*: The type of data associated with the component or data item. Note that this may be a simple data type (e.g. text, date) requiring a single field, or a predefined structure requiring a group of fields. Refer to legend in section 2.2.1 below.
- *Number of Values Allowed*: The number of times that the given component/item may be included in a Shared Health Summary. For items, this is the number of times that the given item may be included, each time the component. Refer to legend in section 2.2.2 below.

The following legends are included to assist the reader with the content of the tables that follow.

2.2.1 Data Type legend

Datatype	Notes
Boolean	A Boolean value can be either true or false, or may be empty.
Codeable Text	Codeable Text is a flexible data type to support various ways of holding text - both free text and coded text.
Coded Text	Values in this data type must come from the bound value list, with no exceptions.
DateTime	DateTime is used for specifying a single date and/or time. It can indicate a level of precision, and define estimated or partial dates.
Integer	Whole numbers.
Quantity	The Quantity data type is used for recording many real world measurements and observations. Includes the magnitude, value and the unit.
Text	Free text string.
Time Interval	Time Interval contains a Start DateTime and (optionally) an End DateTime.
Unique Identifier	An identifier that uniquely identifies a given entity.

2.2.2 "Number of Values Allowed" legend

Value	Minimum	Maximum	Notes	Example
1	1	1	Must have 1 value and only 1	Vaccine Brand Name (i.e. per each immunisation record)
0..1	0	1	Does not need a value in every ES, but when it does, it can only ever have 1	Medicine Additional Comments (i.e. additional comments are not required for all medicines)
1..Many	1	Many	Must have at least 1 value, and can contain multiples	Individual Address
0..Many	0	Many	Does not need a value in every SHS, but when it does, it can contain multiples	Individual Communication Details

ACHI Comments:

This is a standard approach to data typing and the College is comfortable with this methodology.

The approach to "Number of Values Allowed' is non-standard.

Recommendation SHS.18: *That the standard approach and notation to data item cardinality be adopted in the Shared Health Summary information requirements.*

3 Component: Individual

Description: The individual is the person about whom the healthcare event has been captured – that is, the subject of the information.

3.1 Requirements

Data item	Requirement statement	Rationale
Component	Each SHS shall always contain information about the individual and shall always contain the following mandatory items.	A SHS is only created pertaining to an individual and one cannot exist without that individual.
Person Name	The name of the individual shall be recorded in every SHS.	Clinical safety. Identification of the individual. Supports the indexing of clinical documents.
	The recording of individual name shall be consistent with Australian Standards of naming.	Allows interoperability. Eliminates ambiguity.
Person Identifier	Every SHS shall contain the individual's Individual Healthcare Identifier (IHI).	Allows interoperability. Eliminates ambiguity. Clinical safety. Supports the indexing of clinical documents.
	A SHS shall also be allowed to contain multiple identifiers for the individual.	Optionally the individual's local identifier to support transition to the use of national identifiers.
Date of Birth	Every SHS shall contain the individual's date of birth.	Clinical safety. Identification of the individual. Supports the indexing of clinical documents.
	An approximation for the date of birth is allowed (such as only the year, or the month and year) when the exact date is not known. If the exact date is known, the full date shall be provided.	The individual's exact date of birth may not be known. <Example of how the Requirement Statement might be clarified - the current wording does not work well as a conformance point.>
	When the date of birth is an approximation, an indication of such shall be included.	Eliminates ambiguity
Sex	The individual's sex shall be recorded in every SHS.	Clinical safety. Identification of the individual. Supports the indexing of clinical documents.
	The individual's sex shall be recorded using (and be restricted to) the Australian Institute of Health and Welfare Person—Sex Data Element Concept values.	Allows interoperability. Eliminates ambiguity.
Address	The individual's address shall be recorded in every SHS.	Identification of the individual.
	The recording of individual address shall be consistent with Australian Standards of address recording.	Allows interoperability. Eliminates ambiguity.

Data item	Requirement statement	Rationale
	There shall be provision for recording the individual's address as not known or that they have no fixed address.	Individuals may not always have a fixed place of abode nor may the address be known in all cases.
Communication Details	The SHS shall have the provision to record contact details for the individual.	Allows ready access to contact the individual, should the recipient not have those details at hand.
	A value for individual's communication detail shall only be included when it is deemed to relevant/appropriate to do so (i.e. optional to include a value).	A individual's contact may not be available or appropriate to include.
	A SHS shall be allowed to contain multiple individual communication details.	This allows recording of (for example) a home landline, a work mobile and an email address.
	The contact details record shall include provision for the medium (e.g. telephone, email), usage (e.g. home, work) as well as the actual details.	Allows interoperability. Eliminates ambiguity.
Indigenous Status	An indication of whether a person identifies as being of Aboriginal or Torres Strait Islander origin (or an indication of it being not stated etc) shall be recorded in every SHS.	Aborigines and Torres Strait Islanders are eligible for a range of specific services. This will contribute to improved data quality on indigenous health.

ACHI Comments:

The College notes that this may have been the wrong methodology to achieve the stated objectives. It would have been preferable to leverage the existing expertise and work done and documented by GPs and Specialists groups to define the information requirements. Examples of work done exist in Victoria (GP Division Victoria) and NSW; areas of specialist expertise[6] include asthma and falls prevention[7].

The meaning of the term "shall" is unclear. In design documents that list requirements and conformance points the term "shall" has the meaning of "mandatory". This document does not include a definition of the term "shall" nor an indication of what term is used when requirements are optional or conditional.

Recommendation SHS.19: *That the definition of the term "shall" and the terms used when requirements are optional or conditional be added to the Shared Health Summary information requirements.*

[6] Liaw ST, Deveny E, Morrison I, Lewis B. Clinical, information and business process modeling to promote development of safe and flexible software. Health Informatics Journal 2006; 12(3): 199-211

[7] Liaw ST, Sulaiman N, Pearce C, Sims J, Hill K, Ng CK, Grain H, Tse J. Falls Prevention within the Australian General Practice Data Model: methodology, information model and terminology issues. J Am Med Informatics Assoc 2003; 10: 425-3

Some fields do not appear to have sufficient granularity for best useability. E.g. the address field should be broken down to include a specific postcode field, etc.

Recommendation SHS.20: *That the granularity of the data items be reviewed for best useability and secondary use of data.*

3.2 Samples & usage

1. The individual has only provided the least amount of information - that is, one address and no contact details. They have declined to state their Indigenous status.

INDIVIDUAL		
Name	Mr William SMITH	
IHI	8003600200002222	
Date of Birth	01/01/1946 (63 years)[8]	**DOB approx?** No
Sex	Male	
Address	Residence: 20 Chapel Street, Lilydale, VIC, 3002	
Contact		
Indigenous Status	Not stated	

2. Later, the same individual provides more demographic information.

INDIVIDUAL		
Name	Mr William SMITH	
IHI	8003600200002222	
Date of Birth	01/01/1946 (63 years)	**DOB approx?** No
Sex	Male	
Address	Residence: 20 Chapel Street, Lilydale, VIC, 3002 Postal: PO Box 123, Lilydale, VIC, 3002	
Contact	Home Phone: 03 3988 7156	

[8] The age of the individual would be a calculated value rather than being a separate data item.

	Mobile: 0411 378 942 Email: mwsmith@internetprovider.com.au
Indigenous Status	Neither Aboriginal nor Torres Strait Islander origin

3. Another Individual does not recall the exact date of their birth.

INDIVIDUAL		
Name	Mr Albert HENRY	
IHI	8003600200003333	
Date of Birth	1946 (63 years)	**DOB approx?** Yes
Sex	Male	
Address	Residence: 1 General Street, Broome, WA, 6725	
Contact	Home Phone: 06 1212 1212	
Indigenous Status	Aboriginal but not Torres Strait Islander origin	

3.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
Person Name	Person Name data group	1	The individual's name, structured using a predefined type, consistent with Australian standards of naming (e.g. family name and first name etc).
Person Identifier	Unique Identifier	1..Many	The unique identifier of the individual. This must include the individual's Individual Healthcare Identifier (IHI) and optionally the individual's local identifier.
Date of Birth	DateTime	1	The individual's date of birth. Where the exact date of birth is not known, this may be an approximation, which includes only the year, or the month and year.
Date of Birth accuracy Indicator	Boolean	0..1	The level of certainty or estimation of an individual's date of birth.
Sex	Coded Text	1	The sex of the individual. Sex is the biological distinction between male and female. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.[9]
Address	Address data group	1..Many	The address of the individual, recorded in a structured format, consistent with Australian standards of address recording. Where the individual's address is not known, the address line can be populated with text entry of "Individual has no known address." This may include "No fixed address" if appropriate.
Communication Details	Electronic Communication Details data group	0..Many	The individual's preferred means of contact should be included to facilitate clinical follow-up. Each Contact Details data item includes the medium (e.g. telephone), usage (e.g. home) and details. A value is not always required because it may not be available or appropriate.
Indigenous Status	Coded Text	1???	A description of whether a person identifies as being of Aboriginal or Torres Strait Islander origin. Refer to the AIHW definition and code set.[10]

[9] Source of definition: Australian Institute of Health and Welfare; Person—sex Data Element Concept (METeOR identifier: 269716) http://meteor.aihw.gov.au/content/index.phtml/itemId/269716 (accessed 19 May 2011)

[10] Australian Institute of Health and Welfare, METeOR, Metadata Online Registry. Person—Indigenous status http://meteor.aihw.gov.au/content/index.phtml/itemId/291036 (accessed 19 May 2011)

ACHI Comments:

The "Number of Values Allowed" attribute does not follow the standard approach to indicate cardinality. This makes it very difficult for implementers to create systems that comply with these Information Requirements. It also make is impossible to undertake formal conformance checking. The ISO Standard 11179:2005 "Information technology - Specification and standardization of data elements"[11] gives very detailed and clear information on how meta data and data dictionaries are to be constructed. The College believes it would be beneficial that this Information Requirements document uses these Standard guidelines.

Recommendation SHS.21: *That the Continuity of Care Program Team apply the principles of ISO 11179 to this Information Requirements document and ensure that the conformance points in this document are clearly documented.*

The use of and reference to the METeOR meta-data item definitions (for example, "Sex", "Indigenous Status", etc.) is acknowledged and appreciated. However, it is unclear why references to all other available meta-data definitions (eg person date of birth[12], etc.) are not included in the 'Proposed Data Model' tables.

Recommendation SHS.22: *That the METeOR meta-data item definitions are included for every data item, where available.*

The description of the "Date of Birth accuracy Indicator" is inconsistent with the datatype "boolean". The description saying "level of certainty or estimation" appears to infer a confidence level between 0.00 through to 1.00, eg 0.3, 0.50, etc. The boolean datatype does not support these values.

Recommendation SHS.23: *That the description and data type of the "Date of Birth Accuracy Indicator" be made consistent.*

[11] http://en.wikipedia.org/wiki/ISO/IEC_11179

[12] http://meteor.aihw.gov.au/content/index.phtml/itemId/287007

4 Component: Source of Shared Health Summary

Description: The health provider nominated by the individual as being responsible for managing their Shared Health Summary.

4.1 Requirements

Data item	Requirement statement	Rationale
Component	Each SHS shall record details about the person who was the source of the SHS with details as described below.	Medico-legal requirement to clearly identify the person who was the source of the SHS.
Person Name	Every SHS shall record the name of the source.	Clearly identifies the source of the SHS.
	The recording of the name of the source shall be consistent with Australian Standards of naming.	Allows interoperability. Eliminates ambiguity.
	Only 1 name record shall be allowed for the source.	Avoids unnecessary complexity.
Person Identifier	The SHS shall always record the Healthcare Provider Identifier of the author (HPI-I).	Allows interoperability. Eliminates ambiguity. Clinical safety.
	A SHS shall be allowed to contain multiple personal identifiers of the author, as required.	Such as provider or prescriber numbers.
Healthcare Role	The SHS shall record the role of the source.	In many cases the source will be the patient's GP but may encompass a broader range of healthcare providers.
	The Reference set for Healthcare Role shall be derived in such a way that it can be integrated with other related codes sets, such as that required for NESAF.	Allows interoperability and system integration.
Person Communication Details	At least one person contact detail for the source shall be recorded in every SHS.	Downstream readers of the SHS may need to contact the source.
Organisation Name	The SHS shall record the name of the organisation/practice to which the source is affiliated.	Eliminates ambiguity.
Organisation Identifier	The SHS shall include the unique organisation identifier to which the source is affiliated; that is the Healthcare Provider Identifier of the organisation (HPI-O).	Whilst the source may practice at multiple organisations, an individual is generally managed at one of those organisations.
Address	The practicing address of the source shall be recorded in every SHS.	Whilst the source may practice at multiple organisations, an individual is generally managed at one of those organisations.
	The recording of the address shall be consistent with Australian Standards of address recording.	Allows interoperability. Eliminates ambiguity.

Data item	Requirement statement	Rationale
	A SHS shall be allowed to contain multiple addresses for the source.	Caters for the street address as well as the postal address.
Organisation Communication Details	At least one organisational contact detail for the source shall be recorded in every SHS.	Downstream readers of the SHS may need to contact the source.
	A SHS shall be allowed to contain multiple source communication details.	This allows relevant telephone numbers (i.e. daytime, after hours, mobile, etc.) and email addresses to be recorded for future reference.
	The contact details record shall include provision for the medium (e.g. telephone, email), usage (e.g. after hours) as well as the actual details.	Allows interoperability. Eliminates ambiguity.

ACHI Comments:

Recommendation SHS.24: *That communication contact details be added for the person.*

4.2 Samples & usage[13]

1. The Individual usually sees a particular GP, at a given practice, who authors a SHS.

SOURCE OF SHARED HEALTH SUMMARY	
Name	Dr Ethan JONES [HPI-I: 8003610200002388]
Healthcare Role	General Practitioner
Practice	Family Medical Practice [HPI-O: 8003620000000222]
Address	40 General Street, Brisbane, QLD 4001

[13] Health identifier numbers are predominantly for system to system usage and it is likely that they would not be displayed to end users. The HI numbers are only displayed here to provide additional clarity for these specifications and as such, the reader should not consider this a display requirement.

Contact	Email: admin@fmp.com.au Phone: 07 3998 7156

4.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
Person Name	Person Name data group	1	The name of the source, structured using a predefined type consistent with Australian standards of naming (e.g. family name and first name etc).
Person Identifier	Unique Identifier	1..Many	The unique individual identifier of the source which must include the Healthcare Provider Identifier of the provider (HPI-I) and optionally other identifiers (such as provider or prescriber numbers).
Healthcare Role	Codeable Text	1	The role the provider is playing in the course of being the source of the SHS. For example, 'Usual GP' or 'Locum GP'.
Organisation Name	Organisation Name data group	1	The name of the healthcare provider organisation at which the source practices. In most cases the source will be associated with an organisation, but in some circumstances they will not. For this reason, a value is not mandatory is all cases. When the source is associated with an organisation, the Organisation Name must be provided.
Organisation Identifier	Unique Identifier	1..Many	The unique organisation identifier of the practice, for which the Healthcare Provider Identifier of the organisation (HPI-O) must be provided. Optionally, local identifiers may also be included.
Address	Address data group	1..Many	The address of the source, recorded in a structured format consistent with Australian standards of address recording.
Communication Details	Electronic Communication Details data group	1..Many	The contact details for the source. The preferred means of contact should be included and should include at least one method of communication. Each Contact Details includes the medium (e.g. telephone), usage (e.g. work) and details.

5 Component: Allergies and Adverse Reactions

Scope: The categories of allergies and adverse medicines events have been combined into this component and therefore includes allergies and adverse reaction to all substances not just medications / medicines. This might include food allergies, bee sting allergies as well as prescription and non-prescription medicines. NB: An indicator of compliance with the RACGP Practice Standard 1.7 on health summaries is that a practice can demonstrate that at least 90% of their active patient records contain a current health summary that includes, where appropriate, a record of known allergies.

These requirements have been developed in collaboration with a specific MMRG Project Working Group and following discussions within Standards Australia.

5.1 Requirements

Data item	Requirement statement	Rationale
Component	Information regarding Allergies and Adverse Reactions is required for every GP e-health summary (SHS) and shall contain the following items.	Information regarding an individual's allergies and adverse reactions is vital to ensure high quality safe clinical care.
	Each SHS shall either include one (or more) Allergies and Adverse Reactions or a statement as to why none are included.	Allergies and Adverse Reactions may not be listed in a SHS for a variety of reasons – it has not been asked about, there are none, or this information is unknown. This provides assurance that an absence of Allergies and Adverse Reactions is for a specific reason, rather than having just being omitted.
Review Date	Each SHS shall contain a record of when the information in this section was entered, last reviewed or updated by the nominated provider.	It is important for the reader to know how current the information is.
	The review date shall be recorded in the format of date (and optionally time).	Allows for date calculations to be made i.e. 6 months since last update.
	The review date shall be present when there are Allergies and Adverse Reactions as well as when none are present.	Provides clarity for the reader to know unambiguously at what point information is current, in this case when information is absent (i.e. not asked etc).
Agent Description	Every allergy and adverse reaction listed in the SHS shall contain a description of the causative agent.	To ensure high quality safe clinical care.
	Values for the description of the allergy and adverse reaction agent shall be derived from a SNOMED code set with the option for free text.	Allows for electronic transmission of information and decision support.
Reaction Description	There shall be the provision for an allergy and adverse reaction record to include the description of the reaction	Unambiguous description of the reaction for clinical safety and allows better informed future management.

Data item	Requirement statement	Rationale
	that was caused by the aforementioned agent.	
	There shall be the provision for more than one reaction to be recorded for a single agent, when appropriate.	An individual may experience multiple adverse reactions to a single agent.
	Preferably, values for the description of the reaction shall be derived from a SNOMED CT (whilst allowing for the option for free text).	Allows for electronic transmission of information and decision support.
	A value for the reaction description shall only be included at the discretion of the SHS author, i.e. when it is deemed relevant / appropriate to do so (i.e. optional to include a value).	It may not always be known what the specific reaction is to a given agent. Individuals may report that they have been told that they have a reaction to a given agent but it may not be clear what the reaction was. For example, an adult reporting that they were told as a child that they reacted to a given agent but they cannot recall what happened to them.

ACHI Comments:

The lack of coding and data entry rules in clinical practice together with the fact that many GP and hospital systems do not collect allergies in structured format raise problems with the SHS concept. However, that said, the codified data using SNOMED and SNOMED CT is certainly the appropriate direction to head. To go down the line of free text information with allergies and adverse reactions would miss most, if not all of the advantages that will come with an electronic system, particularly in relation to decision support functionality.

Recommendation SHS.25: *That the collection and storage of allergy information be clarified.*

5.2 Samples & usage

1. The individual has not been asked about any allergies and adverse reactions.

   Individuals may be acutely unwell or otherwise indisposed and unable to provide the relevant health information to their health provider.. In these circumstances, it is suggested that GP software functionality be configured to default this section's exclusion statement to "Not Asked". Rather than displaying nothing in this section, it is considered clinically safer to record the true state that the individual wasn't asked. Note that a date & time stamp is still required with the exclusion statement.

ALLERGIES / ADVERSE REACTIONS	*22 Sep 2009 11:23*
Not asked	

2. The individual has been asked and they do not have any allergies and adverse reactions.

ALLERGIES / ADVERSE REACTIONS	*22 Sep 2009 11:23*
None known	

3. An individual has been asked and a number of reactions are recorded. Note that the individual has 2 reactions to penicillin, 1 reaction to Metoprolol, but it is not been ascertained what reaction they have to nuts.

ALLERGIES / ADVERSE REACTIONS	*22 Sep 2009 11:23*
Agent	**Reaction description**
Penicillin	Severe urticaria on trunk and legs; Nausea and vomiting
Nuts	Not known
Metoprolol	Acute exacerbation of Chronic Obstructive Airways Disease

5.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
Review Date	DateTime	1	The date (and optionally time) that the record of Allergies and Adverse Reactions was entered, last reviewed or updated by the GP. This is required when just an exclusion statement is recorded as well when one or more Allergies and Adverse Reactions are listed.
One (or more) reactions must be provided or a reason why no reactions are provided. That is, must have one of the following (a or b), but not both:			
a) Allergies / Adverse Reactions Exclusion Statement	Coded Text	0..1	The exclusion statement allows for explicit assertions of exclusion of all Allergies / adverse reactions, i.e. that the individual has no known Allergies / adverse reactions, the individual has not been asked about this information or that the information is unknown.
IF no exclusion statement THEN…			
b) Allergies / Adverse Reaction	Group	0..Many	The data group of the known adverse reactions for the individual containing the relevant reaction details. Multiple reactions are allowed and the following 2 data items apply for each reaction added.
Agent Description	Codeable Text	1	The agent / substance causing the allergy / adverse reaction experienced by the individual. The agent must always be recorded.
Reaction Description	Codeable Text	0..Many	The signs and/or symptoms experienced or exhibited by the individual as a result of the allergies / adverse reaction to the specific agent/substance.

ACHI Comments:

This is not the type of data models in existing systems, with many existing systems have basic and at best variable levels of functionality. Even if the data is extractable, the mapping to a reference terminology will be challenging (if this were be attempted).

6 Component: Medicines

Scope: The Medicines section should contain prescription medications, non prescription/over the counter medications, medicines self prescribed by the individual and complementary and alternative medicines. NB: An indicator of compliance with the RACGP Practice Standard 1.7 on health summaries is that a practice can demonstrate that at least 75% of their active patient records contain a current health summary that includes, where appropriate, a current medicines list.

These requirements have been developed in collaboration with a specific MMRG Project Working Group and following discussions within Standards Australia.

6.1 Requirements

Data item	Requirement statement	Rationale
Component	Information regarding medicines is required for every SHS.	Information regarding an individual's medicines is vital to ensure high quality safe clinical care.
	Each SHS shall either include one (or more) medicines or a statement as to why none are included.	Medicines may not be listed in a SHS for a variety of reasons – it has not been asked about, the individual is not on any medicines, or the information is unknown. This provides assurance that an absence of medicines is for a specific reason, rather than having just being omitted.
Review Date	Each SHS shall contain a record of when the information in this section was entered, last reviewed or updated by the GP.	It is important to know how current the information is.
	The review date shall be recorded in the format of date (and optionally time).	Allows for date calculations to be made i.e. 6 months since last update.
	The review date shall be present when there are medicines as well as when none are present.	Provides clarity to know unambiguously at what point information is current, in this case when information is absent (i.e. not asked etc).
Item Description	Every medicine listed in the SHS shall include details that fully describe it, including the name of the medication (must include the active ingredient and where available, the brand name), strength and dose form, where appropriate.	Allows interoperability, eliminates ambiguity and is vital to ensure high quality safe clinical care.
	Preferably, where the medication can be identified by an Australian Medicines Terminology (AMT) concept, this shall be the AMT ConceptID and Preferred Term.	Allows interoperability, eliminates ambiguity and is vital to ensure high quality safe clinical care.

Data item	Requirement statement	Rationale
	Where the medicine cannot be identified by an Australian Medicines Terminology (AMT) concept, the item description shall be allowed to be carried in free text.	This enables the ability to enter medicines not recognised by AMT e.g. overseas medicines such as those taken by international visitors and students.
Dose Instructions	Every medicine listed in the SHS shall include the dose instructions describing how the medicine is taken.	Vital to ensure high quality safe clinical care.
Reason for Medicine	There shall be the provision for a medicine record to include the reason why the individual is taking the medicine.	It is important for the GP and other recipients to understand the rationale for medicines, particularly given that some medicines may have multiple purposes.
	A value for Reason for Medicine for a given medication shall only be included when it is relevant / appropriate to do so (i.e. optional to include a value).	It may not be clear to the GP the reason an individual may be taking an over the counter or complementary medicine.
Additional Comments	There shall be the provision for a medicine record to include additional information that may be needed to ensure the continuity of supply, continued proper use, or appropriate medication management. This may include comments regarding medication duration.	Clinical safety.
	An Additional Comment for a given medicine shall only be included when it is deemed by the author to be relevant/appropriate to do so (i.e. optional to include a value).	Not always required.

ACHI Comments:

This is where it might work because the data is coded and easily accessible except possible OTC and complementary medicines. It is noted that the 'reason for medicine' field is optional. A similar field was added to the national inpatient medication charts as it felt to be an important data element to capture. However, given the national inpatient medication chart is a paper record there is no means of mandating the completion of this field; as a result national audits have shown that this field is very rarely, if ever, gets completed. Therefore applying this learning to an electronic system, by making this field optional, we are effectively not going to see this field used. Given that the PCEHR is all about communication between patient and health care providers, it should be considered whether this very important field is actually made mandatory (or at least an opt out field, where the user has to actively select that they do not wish to disclose the indication of a particular medicine, but otherwise complete the indication information.

Many medicines have multiple indications and having the medicine without the indication, is analogous to being told a patient has a reaction, without knowing the severity of the reaction or what the actual reaction is. A great deal of Pharmaceutical Benefit Scheme dollars could potentially be saved each year if the indication for medications was always included whenever a medication was written. Far

too many medications are just 'left as they are' even if they seem to be inappropriate, as a care providers cannot easily see or understand why some patients on a particular medication. Large advances would be made in the area of quality use of medicines if this field was adopted as a mandatory field. The National Prescribing Service is also likely to strongly endorse this view. Added to this, there is clear benefit from a patient perspective if they are actually see the reason they have been placed on various medications. Again, this would be one of the key benefits from a patient perspective of the entire record; yet this opportunity would be missed if left as an optional field.

6.2 Samples & usage

1. The individual has not been asked about any medicines.

   Individuals may be acutely unwell or otherwise indisposed and unable to provide the relevant health information to their health provider.. In these circumstances, it is suggested that GP clinical desktop system functionality be configured to default this section's exclusion statement to "Not Asked". Note that a date & time stamp is still required with the exclusion statement.

MEDICINES	**i**	*22 Sep 2009 11:23*
Not asked		

2. The individual has been asked and they are not taking any medications.

MEDICINES	*22 Sep 2009 11:23*
None known	

3. It has been determined that the individual taking a number of medications.

MEDICINES			*22 Sep 2009 11:23*
Medicine	**Dose Instructions**	**Reason for Medicine**	**Additional Comments**
Lasix (frusemide 40 mg) tablet	1 tablet once daily oral	Fluid retention	In Dose Administration Aid (DAA)
Spiriva (tiotropium bromide 18mg per inhalation) inhalant	1 inhalation per day	COPD	Review Inhaler Use
St John's Wort	As directed by packaging	Depression	Not packed in DAA

6.3 Proposed Data model

Data items			DataType	Number of Values Allowed	Notes
Review Date			DateTime	1	The date (and optionally time) that the record of Medicines was entered, last reviewed or updated by the GP. This is required when just an exclusion statement is recorded as well when one or more Medicines are listed.
One (or more) medicines must be provided or a reason why no medicines are provided. That is, must have one of the following (a or b), but not both:					
	a) Medicines Exclusion Statement		Coded Text	0..1	This exclusion statement allows for explicit assertions of exclusion of all medicines, i.e. that the individual is not known to be taking any medicines, the individual has not been asked about this information, or that the information is unknown.
	IF no exclusion statement THEN…				
	b) Medicine		Group	0..Many	The data group for the medicines that the individual is known to be taking. Multiple medicines are allowed and the following data items apply for each medicine added.
		Item Description	Codeable Text	1	The details that fully describe a medicine, including the name of the medicine (must include the active ingredient and where available, the brand name), strength, dose and form, where appropriate.
		Dose Instructions	Text	1	A description of how a particular product is to be taken. This must include the route, dose, frequency and any additional instructions required. In clinical desktop systems which support the separate collection of dosage instructions, this item only needs to be populated when the separate dosage items are not.
		Reason for Medicine	Codeable Text	0..1	The specific therapeutic effect intended for the use of the medicine.
		Additional Comments	Text	0..1	Any additional information that may be needed to ensure the continuity of supply, continued proper use, or appropriate medication management – e.g. "Patient requires an administration aid", "Dosage to be reviewed in 10 days", "Target INR for warfarin management". This may include comments regarding medication duration.

ACHI Comments:

Further to comments from 6.1, the example above shows the 'reason for medicine' fields completed. This is appropriate. However, the example is inaccurate as the specifications for this document deem this field to be 'optional'. From the learnings as described above in 6.1, if this field is optional, it will rarely, if ever for some patients, be completed. This would be certainly be seen as a terrible loss for communication between health care providers and dilute the benefit to the patient, as they are not able to easily see why they are on certain medicines. This is a very common and frequent issue when patients are brought into hospital and asked about their medications. Often patients will carry and present a paper list of their medications, however rarely do they list (or know) which medications are for which conditions. One of many commonly seen examples where this issues occurs is; proton pump inhibitors initiated in hospital in an acute setting (intended for a short period of time), however because the reason for medicine is not stated, subsequent health care providers along the line assume (falsely) that the patient must need this long term as it was initiated in hospital and therefore there must be a valid reason for using it. As a result many patients are left on these medications unnecessarily for sometimes years, adding to person cost, PBS cost and risk of longer term adverse outcomes. Such situations could be easily prevented with mandating these 'reason for medicine' fields.

7 Component: Medical History

Scope: Data structure for capturing information about an individual's current and past medical history which includes problem/diagnosis and medical or surgical procedures performed. The information can then be extracted for display to users as chronologically ordered list. NB: An indicator of compliance with the RACGP Practice Standard 1.7 on health summaries is that a practice can demonstrate that at least 75% of their active patient records contain a current health summary that includes, where appropriate, a record of current health problems and relevant past health history.

7.1 Requirements

Data item	Requirement statement	Rationale
Component	Information regarding Medical History is required for every SHS and shall always contain the following items.	Information regarding an individual's medical history is vital to ensure high quality safe clinical care.
	Each SHS shall either include one (or more) medical history items or a statement as to why none are included.	Medical history may not be listed in a SHS for a variety of reasons – it has not been asked about, there are none, or this information is unknown. This provides assurance that an absence of medical history items is for a specific reason, rather than having just being omitted.
	A SHS shall be allowed to contain multiple medical history items.	Individuals often have multiple entries in medical history and allows for future decision support capability.
Review Date	Each SHS shall contain a record of when the information in this section was entered, last reviewed or updated by the Nominated Provider.	It is important for the reader to know how current the information is.
	The review date shall be recorded in the format of date (and optionally time).	Allows for date calculations to be made i.e. 6 months since last update.
	The review date shall be present when there are medical history items as well as when none are present.	Provides clarity to know unambiguously at what point information is current, in this case when information is absent (i.e. not asked etc).
Medical History Description	Every medical history item listed in the SHS shall contain a corresponding description.	This provides the content for the medical history.
	Preferably, values for the description of the medical history items shall be derived from SNOMED CT with the option for free text.	Allows for electronic transmission of information and decision support.
	The semantically distinct concepts of diagnoses and procedures shall be combined into one data item.	A chronological list may reduce clinical risk due to the viewing of information in an expected manner.

Data item	Requirement statement	Rationale
Medical History DateTime Range	There shall be the provision for a Medical History record to include the date of onset.	Clearly identifies when a particular medical history item commenced or occurred.
	There shall be the provision for a Medical History record to include the date of resolution.	Clearly identifies when a problem has resolved, if at all.
	The date of onset and resolution shall be allowed to be expressed as an estimate, i.e. dd/mm/yyyy or yyyy.	Provides flexibility as an individual may not always be clear about events occurring in the past.
Medical History comments	There shall be the provision for a Medical History record to include an additional comment.	Provides flexibility to add context or notes etc.

ACHI Comments:

It is difficult to see how a useful SHS medical history can be generated from most of the current GP systems as the culture of electronic documentation is not very mature at this point in time.

7.2 Samples & usage

1. The individual has not been asked about their medical history.

   The *RACGP standards for general practice (4th edition)* state that practices demonstrate that at least 75% of the active individual health records contain a current health summary, including current health problems and relevant past health history. However, the individual may be acutely unwell or unable to provide this information. In these circumstances, it is suggested that GP clinical desktop system functionality be configured to default this section's exclusion statement to "Not Asked". Note that a date & time stamp is still required with the exclusion statement.

MEDICAL HISTORY	*22 Sep 2009 11:23*
Not asked	

2. The individual has been asked and there is no known medical history.

MEDICAL HISTORY	*22 Sep 2009 11:23*
None known	

3. It has been determined that the individual has a number of medical history records. It is not known when the hypercholesterolaemia commenced and it is still a current problem. The individual had a total knee replacement on the 27th February 2001. The individual was diagnosed with osteoporosis and Atrial Fibrillation in 2007 and 2009, respectfully and both continue to be problems. The individual was diagnosed with pneumonia in Aug 2010 which resolved the following month.

MEDICAL HISTORY		*22 Sep 2009 11:23*
Description	**Date Range**	**Comments**
Hypercholesterolaemia		
Left TKR	27 Feb 2001	Cementless
Osteoporosis	2007 –	But T-score greater than –3
AF (Atrial Fibrillation)	2009 –	
RLL pneumonmia	Aug 2010 – Sep 2010	

7.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
Review Date	DateTime	1	The date (and optionally time) that the record of medical history was entered, last reviewed or updated by the Nominated Provider. This is required when just an exclusion statement is recorded as well when one or more medical history items are listed.
One (or more) medical history items must be provided or a reason why no medical history is provided. That is, must have one of the following (a or b), but not both:			
a) Medical History Exclusion Statement	Coded Text	0..1	This exclusion statement allows for explicit assertions of exclusion of any medical history, i.e. that there is no known medical history, that this information has not been asked about, or that the information is unknown.
IF no exclusion statement THEN…			
b) Medical History	Group	0..Many	The data group for recording the Medical History. Multiple items of medical history are allowed and the following data items apply for each one added.
Medical History Description	Codeable Text	1	A description of the problem, diagnosis or intervention. The datatype of Codeable text allows for free text entry in the short term, with coded options in the longer term.
Medical History DateTime Range	Time Interval	0..1	The date range (start date and/or end date) during which an individual's diagnosis was active, or that the clinical intervention was performed. If necessary, this may be an estimate (such as April 2005, or 1998 - 2007).
Medical History comments	Text	0..1	Free text comments providing additional information relevant to the problem, diagnosis or intervention in question.

ACHI Comments:

Many GPs meet the RACGP standards, but the data is not sufficiently granular to be useful to share and incorporate in a SHS.

8 Component: Immunisations

Scope: Details of immunisations/vaccinations that have been administered (or reported to be administered). NB: An indicator of compliance with the RACGP Practice Standard 1.7 on health summaries is that a practice can demonstrate that at least 75% of their active patient records contain a current health summary that includes, where appropriate, a record of immunisations.

These requirements have been developed in collaboration with a specific MMRG Project Working Group and following discussions within Standards Australia.

8.1 Requirements

Data item	Requirement statement	Rationale
Component	Information regarding immunisations is required for every SHS and shall always contain the following items.	To achieve the lowest incidence of vaccine-preventable disease by attaining and maintaining the highest possible levels of effective immunisation coverage, and protect individuals at high risk of vaccine-preventable disease
	Each SHS shall either include one (or more) immunisations or a statement as to why none are included.	Information regarding immunisations may not be listed in a SHS for a variety of reasons – it has not been asked about, there are none, or this information is unknown. This provides assurance that an absence of immunisations is for a specific reason, rather than having just being omitted.
	A SHS shall be allowed to contain multiple immunisations.	An individual may have multiple immunisations.
Review Date	Each SHS shall contain a record of when the information in this section was entered, last reviewed or updated.	It is important to know how current the information is.
	The review date shall be recorded in the format of date (and optionally time).	Allows for date calculations to be made i.e. 6 months since last update.
	The review date shall be present when there are medical history items as well as when none are present.	Provides clarity to know unambiguously at what point information is current, in this case when information is absent (i.e. not asked etc).
Vaccine Name	Every immunisation included in the SHS shall include its generic and brand name.	Ensures unambiguous identification of the particular immunisation.
	Preferably, where the immunisation can be identified by an Australian Medicines Terminology (AMT) concept, this shall be the AMT ConceptID and Preferred Term. The name shall include both the generic and brand names.	Allows interoperability, eliminates ambiguity and is vital to ensure high quality safe clinical care.

Data item	Requirement statement	Rationale
	Where the immunisation cannot be identified by an Australian Medicines Terminology (AMT) concept, the item description shall be allowed to be carried in free text.	This enables the ability to enter vaccinations not recognised by AMT e.g. vaccinations administered overseas.
DateTime Administration	Every immunisation included in the SHS shall include the date or date and time that a dose of vaccine is administered.	Determines when further doses of immunisations may be required.
	The date shall be recorded in the format of date (and optionally time).	Allows for date calculations to be made for decision support i.e. that a Individual is overdue for the completion of an immunisation dose.

8.2 Samples & usage

4. The individual has not been asked about immunisations.

   Individuals may be acutely unwell or otherwise indisposed and unable to provide the relevant health information to their health provider.. In these circumstances, it is suggested that GP clinical desktop system functionality be configured to default this section's exclusion statement to "Not Asked". Note that a date & time stamp is still required with the exclusion statement.

IMMUNISATIONS	*22 Sep 2009 11:23*
Not asked	

5. Where the individual does not have any known immunisations, the section will be empty apart from the date/time reviewed (that is, that the Nominated Provider saved the complete Shared Health Summary). Alternatively, the software may be configured to convert an absence of immunisations to the text "none recorded" (or similar).

IMMUNISATIONS	*22 Sep 2009 11:23*
None recorded	

6. The individual has a number of immunisations over a period of time.

IMMUNISATIONS	*22 Sep 2009 11:23*
Vaccine Name	**DateTime Administration**
Engeryx b (Hepatitis B)	9 Oct 2010 2.24pm
Meningitec (Meningacoccal)	10 Sep 2010 11.56am
Fluvax (Influenza)	3 Oct 2009

8.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
Review Date	DateTime	1	The date (and optionally time) that the immunisation record was entered, last reviewed or updated by the Nominated Provider. This is required when just an exclusion statement is recorded as well when one or more immunisations are listed.
One (or more) immunisations must be provided, or a reason why none are provided. That is, must have one of the following (a or b), but not both. Individual immunisations listed may have been actually administered or refused by the individual to be administered (see Conscientious Objection below).			
a) Immunisations Exclusion Statement	Coded Text	0..1	This exclusion statement allows for explicit assertions of exclusion of any immunisations, i.e. that there are no known immunisations, or that this information has not been asked about, or that the information is unknown.
IF no exclusion statement THEN…			
b) Immunisation	Group	0..Many	The data group for recording the immunisation details, which can include details of immunisations that have been administered as well as those that have been refused by the individual/caregiver. Multiple immunisations are allowed and the following data items apply for each one added.
Vaccine Name	Codeable Text	1	The vaccine generic and brand name.
DateTime Administration	DateTime	1	The date or date and time that a dose of vaccine is administered.

Known Issue # 2

As immunisations are given by a wide range of healthcare providers, an immunisation may not be recorded in the PCEHR. As such, Clinical Leads queried whether the nominated provider would always know what a given immunisation's sequence was up to, if this information was not included in the SHS. Therefore, should the immunisation sequence number also be recorded?

9 Component: Document Control

Description: A section that describes information about the health summary document. Much of the information contained in Document Control is technical in nature and as such is not described here, but is included in Appendix A. Described below are those elements which have clinical relevance.

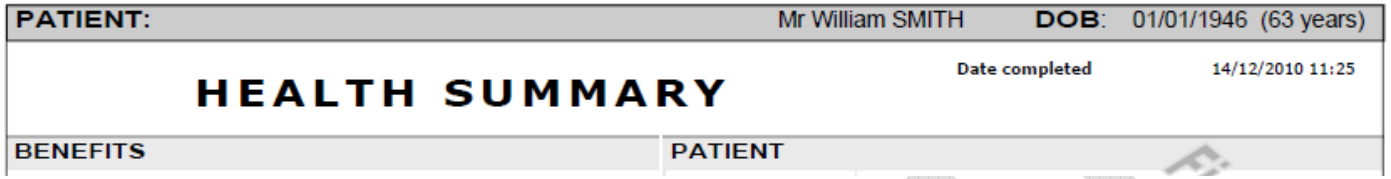
9.1 Requirements

Data item	Requirement statement	Rationale
Component	Each Health Summary document shall include metadata about the document.	Document management requirements.
	Document control information is predominantly technical and as such does not require display for end users.	
DateTime Attested	The date/time when the HS document was attested (or finalised, or signed off) by the document author.	Clinical safety requirement to ensure that the reader knows exactly when the document was written.

9.2 Samples & usage

1. Document Header

A health summary may display various elements of the document control near the top of the summary.



9.3 Proposed Data model

Data items	DataType	Number of Values Allowed	Notes
DateTime Attested	DateTime	1	The date/time when the ES document was attested (or finalised, or signed off) by the document author.

10 Technical Document Control Requirements

The following data items are included for completeness as they represent technical requirements to ensure correct identification of each document etc.

Data items	DataType	Number of Values Allowed	Notes
Document Instance Identifier	Unique Identifier	1	The universally unique identifier of this instance of the Shared Health Summary document.
Document Set Identifier	Unique Identifier	1	The universally unique identifier of the set of documents related to the same healthcare encounter, of which the Shared Health Summary document is a versioned instance.
Version Number	Integer	1	The version number of the Shared Health Summary document instance.
Document Originating System Identifier	Unique Identifier	1	A universally unique identifier of the system used to create the Shared Health Summary document.
Business Document Type	Coded Text	1	The name of the Shared Health Summary document type used – e.g. 'Shared Health Summary'
Business Document Type Version Number	Integer	1	The version number of the Shared Health Summary document type used to create the Shared Health Summary.
Document Status	Coded Text	1	The status of the document
Language	Coded Text	1	The language primarily used within the document (e.g. 'en-AU')
Structured / unstructured clinical document flag	Coded Text	1	Whilst the PCEHR Concept of Operations describes 2 options for this flag, the only permitted option is a "structured clinical document". This is a document which has all the above fields and also contain additional structured data describing the relevant clinical details (e.g. medicines, allergies, etc).

Other ACHI Comments:

There is some debate as to whether only doctors should have access / use of the summary record, however since the explanatory document (NeHTA information requirements document) is explicit in that this is a patient-controlled record for use by patients, then the updating and use of the record should be expanded to all people providing professional health care to any particular patient, i.e. complying with the 'patient centred model of care' in which the patient is the focus, not the doctor.

The patient should ideally be able to nominate a 'lead care provider' who is not necessarily a GP. For long term condition management a nurse specialist could be the chosen lead care provider who is part of the patient's care team. There should be no reason why a nurse cannot be a lead care provider for a chronic condition and the GP be selected as lead care provider for everything else. However, then the midwife also has to be given lead care provider status for pregnancy. This is somewhat confusing however if the intention is for the patient to control the summary, then there should be an option for the patient to nominate who gets to use the summary and update it for everyday use. This again comes back to trust; one needs to be able to support trust between care providers.

The fact that patients can opt in is good, however is there an argument that says all people should be given the system and opt out so that the PCEHR can be standardised and optimised? It is good that individuals can determine certain settings and give access to family members. It's also good that they can ask to view an audit trail of who's accessed their record. However, with regard to meta-data and knowledge management – if a clinician using the summary knows who last updated it, they are able to make better decisions, especially if they can contact the last person to treat the patient, e.g. suicide attempt and the medications were prescribed by a specified doctor who is contactable by the emergency care clinician to discuss future care of the patient.

What will the patient do with the meta-data? The patient should know already who made a diagnosis and intervened, prescribed medications, updated alerts, changed their demographic data (probably the GP). If someone they don't recognise changes something and it looks suspicious, then the patient should follow the process for accessing the audit trail that's already in place. Patients should be educated that clinicians are authorised to access their records without their permission under the usual clinical professional practice rules (if you're clinically responsible for a patient you have the right and obligation to view the records and change them, e.g. change a prescription).

Governance is hard; it's clear that governance will be done, however there is strong rationale to say patient representatives explicitly and overtly be present in the care governance structures in the case of emergencies etc.

There are many excellent touch points in the SHS for better patient outcomes as expressed in the intention and content of the PCEHR, however there appear to be two major issues with the detail – (1) the absence of patient input as stakeholder (as described above) and (2) an apparent conflict between the intention of the record (patient's control over the record) and the clinician's responsibility to keep the record up to date with data that's mostly relevant to doctors only. It seems illogical to tell the patient that s/he is in control of the shared record but that the doctor is the only person who can update or explicitly do anything with it. If what has been designed is a shared EHR it should not be called a patient controlled EHR as the specifications do not seem to align with the name.

Data quality could be an issue in the future if free text fields are available in the summary record. Using the principle of 'make it easy to do the right thing the right way' all the data pulled into the summary record should be structured. Transcribing is not something that people do well – again, one doesn't know if data is missing because it was omitted or there was nothing to insert. It's nice that the free text comments field is available in the summary document, however trusting the content may become an issue; trust is one of

those things that's easy to lose and almost impossible to retrieve. The risk of trust being lost due to a misleading or ambiguous free text comment is high. If trust isn't supported the whole endeavour may fail.

11 Shared Health Summary Scenario

An example scenario is as follows:

A patient John has a complex chronic illness and is regularly managed by his usual GP. The usual GP has regularly maintained an up-to-date SHS for John, which has been published to John's PCEHR.

John has a holiday interstate, falls ill and needs to see a GP for management. The new GP reviews John's SHS and gets acquainted with John's available history. As a result of the new problem, the GP makes some changes to John's medications and decides to create an Event Summary which is published to the PCEHR.

On return to home, John is seen by his usual GP and rather than relying upon John's memory of the recent event, he reviews the Event Summary written by the other GP. The usual GP decides to incorporate the new medications listed in the Event Summary into her own clinical records and then updates John's SHS if appropriate.

Definitions

This section explains the specialised terminology used in this document.

Shortened Terms

This table lists abbreviations and acronyms in alphabetical order.

Term	Description
AMT	Australian Medicines Terminology
CDA	Clinical Document Architecture
GP	General Practitioner
HI	Health Identifiers
HL7	Health Level 7
HPI-I	Healthcare Provider Identifier of the individual
HPI-O	Healthcare Provider Identifier of the organisation
IHI	Individual Healthcare Identifier
LOINC	Logical Observation Identifiers Names and Codes
MMRG	NEHTA Medication Management Reference Group
NCTIS	NEHTA's National Clinical Terminology and Information Service
PCEHR	Personally Controlled Electronic Health Record
SNOMED CT	Systemised Nomenclature of Medicine, Clinical Terminology

Glossary

This table lists specialised terminology in alphabetical order.

Term	Description
Business Architect	A Business Architect is anyone who looks at the way work is being directed and accomplished, and then identifies, designs and oversees the implementation of improvements that are harmonious with the nature and strategy of the organisation. Source: http://www.businessarchitects.org
Development Team	The Developer writes the code for the specifications that the Development leads provide. Source: http://www.developer.com
Interoperability	The ability of software and hardware on multiple machines from multiple vendors to communicate. Source: The Free On-line Dictionary of Computing. Denis Howe. 21 Apr. 2008. From: Dictionary.com - http://dictionary.reference.com/browse/Interoperability
Solutions Architect	The Solutions Architect is typically responsible for matching technologies to the problem being solved. Source: http://www.developer.com
Technical Architect	The technical architect is responsible for transforming the requirements into a set of architecture and design documents that can be used by the rest of the team to actually create the solution. Source: http://www.developer.com

References

At the time of publication, the document versions indicated are valid. However, as all documents listed below are subject to revision, readers are encouraged to use the most recent versions of these documents.

References

The documents listed below are non-package documents that have been cited in this document.

Reference Documents			
[REF]	Document Name	Publisher	Link
[PCO-2011]	DRAFT Concept of Operations PCEHR System, April 2011 Release, Version 0. 13.6 — 8 April 2011	DOHA & NEHTA	http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/Content/pcehr-document

Related Reading

The documents listed below may provide further information about the issues discussed in this document.

Related Documents			
[REF]	Document Name	Publisher	Link
[NEHTAWEB]	NEHTA Web Site	NEHTA	http://www.nehta.gov.au/