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Shared Health Summary
PCEHR Usability Recommendations v1.1

5 May 2014

Approved for external use

Document ID: NEHTA-1563:2014

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Product version history

Product version	Date	Release comments
1.0	25 Nov 2013	Extracted from Clinical Usability Program (CUP) R1 PCEHR Clinical Usability Software Requirements v1.0
1.1	5 May 2014	Revised version, incorporating usability recommendations from both CUP R1 and CUP R2

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1 Introduction

1.1 Purpose

It has been recognised that developers of software systems that access the personally controlled electronic health record (PCEHR) system need usability recommendations to complement the software requirements provided by other eHealth specifications. These usability recommendations are designed to achieve greater consistency between software that accesses the PCEHR system, thereby improving clinical usability.

The usability recommendations are provided to all software developers interested in improving the usability of their software systems. They are *not* part of the set of software conformance requirements for clinical information systems accessing the PCEHR system; however, conformance to these usability recommendations is strongly encouraged by clinical system users. More information about conformance to the usability recommendations is provided in section 1.4.

These recommendations were prepared as part of NEHTA's Clinical Usability Program (CUP) in consultation with clinicians.

1.2 Intended audience

This document is intended for:

- healthcare providers;
- vendors and developers of eHealth systems; and
- software test laboratories.

1.3 Scope

This document provides usability recommendations for clinical information systems and contracted service provider systems authoring or rendering information contained in shared health summary documents exchanged with the PCEHR system.

It is focused on recommendations applicable specifically to shared health summary documents. Additional usability recommendations for *all* types of clinical documents are published in the *Clinical Documents PCEHR Usability Recommendations v1.1* [NEHTA-1564:2014].

The usability recommendations in this document are chiefly intended for adoption by clinical software used by medical general practitioners. However, developers of software for other types of healthcare providers are also encouraged to adopt the usability recommendations.

This document does *not* provide usability recommendations for:

- document types other than shared health summary;
- PCEHR functions not related to the authoring and rendering of shared health summary documents exchanged with the PCEHR system; or
- display and management of clinical terminology.

1.4 Conformance

Software developers may want to claim that their software implements these usability recommendations. For such claims to be meaningful and for the healthcare community to have a shared understanding of these claims, the usability recommendations have been documented in the form of software conformance requirements using the standard conformance verbs **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT** and **MAY**.

Conformance to the recommendations in this document is not a prerequisite for software to be granted access to the PCEHR system. However, conformance to these usability recommendations is strongly encouraged by clinical software users. A software developer wanting to claim conformance to the clinical usability recommendations must have software that conforms to all mandatory and applicable conditional recommendations in this document. These are the recommendations using the verbs **SHALL** and **SHALL NOT**. Achievement of conformance to the mandatory and applicable conditional recommendations may be recognised by inclusion in the eHealth Register of Conformity operated by the National E-Health Transition Authority (NEHTA) on behalf of the Commonwealth Department of Health.

Software that implements the usability recommendations also needs to conform to the requirements listed in the *Shared Health Summary PCEHR Conformance Profile v1.5* [NEHTA-1452:2013].

2 Attesting a shared health summary

Applies to: Document authoring systems (shared health summary clinical documents).

The *Shared Health Summary PCEHR Conformance Profile* (conformance profile) states that:

> A Clinical Information System shall display the final version of a Shared Health Summary to the author and prompt the author to attest to the content of the Shared Health Summary before the Clinical Information System uploads the Shared Health Summary to the PCEHR System and to assert the healthcare provider individual (i.e. the author of the Shared Health Summary) is a Nominated Healthcare Provider as defined by the *Personally Controlled Electronic Health Records Act 2012.* [COM2012]

There are multiple ways to implement this requirement. The conformance profile states:

> One option for meeting this requirement is for a Clinical Information System to display the Shared Health Summary along with a user interface button with the statement "By uploading this Shared Health Summary, I acknowledge that I am a Nominated Healthcare Provider for this patient as defined by the *Personally Controlled Electronic Health Records Act.*

Software vendors have taken a variety of approaches to implementing these requirements; some have introduced extra steps or checks concerning accuracy and patient consent.

There is no legal requirement for a provider to obtain the consent of a consumer each time a shared health summary is uploaded, as the provider can rely on the standing consent given by the consumer at registration.

The following professionals are eligible to be nominated healthcare providers as defined by the *Personally Controlled Electronic Health Records Act*:

- medical practitioners
- registered nurses
- Aboriginal and/or Torres Strait Islander health practitioners (with a Certificate IV in Aboriginal and/or Torres Strait Islander Primary Health Care (Practice)

The shared health summary authoring software is not required to enforce that the author falls into one of these categories, and doing so reliably may not be possible.

The usability recommendations in this section address how the shared health summary authoring review should be presented to the user.

ID	Recommendation	Status
SHS.01	The software **SHALL** present a statement on shared health summary review and attestation as follows: • I am the patient's nominated healthcare provider in accordance with the *Personally Controlled Electronic Health Records Act 2012*. • I am providing ongoing care to this patient. • I have prepared this shared health summary in consultation with the patient. *Note: The above wording meets the requirements of the conformance process, addresses and encourages best clinical practice as agreed by clinicians consulted during the Clinical Usability Program, and does not intrude on the natural workflow of a clinician.* *The wording does not ask the clinician to confirm that the document is either complete or accurate, since the patient may ask to withhold information from the document.*	*Mandatory*
SHS.02	The software **SHALL** have one and only one confirmation step for shared health summary review and attestation. *Note: The recommendation reduces the key strokes needed to submit a shared health summary. A single upload button is sufficient to meet this recommendation. It is not necessary to display a checkbox to record consent, nor is it necessary to display the acknowledgement as a separate pop-up window.*	*Mandatory*
SHS.03	The software **SHALL NOT** upload the authored clinical document without an explicit confirmation from the user. *Note: A generic keystroke such as "Tab" or "Enter" is liable to be pressed automatically by the user, so it would not count as an explicit confirmation. Examples of explicit confirmations include a mouse click on an "Upload" button, or a dialog with "Y" or "N" responses.*	*Mandatory*

3 Populating a shared health summary

Applies to: Document authoring systems (shared health summary clinical documents).

When creating a shared health summary, it should be possible for the clinician to readily manage the relevant clinical data items to be included. Current implementations typically present lists of data items drawn from the patient record with a check box against each list item denoting inclusion or exclusion in the shared health summaries. Each list corresponds to a health summary document section – that is, adverse reactions, medications, medical history or immunisations.

The methods and rules that determine the initial check box state (that is, whether a data item is included by default) have not been specified. Consequently, there are considerable differences between software products. Various inconsistent approaches based on clinical entry "shared data flags" (for example, include in summary, include in correspondence) and direct selection on authoring have been implemented in systems.

The *Shared Health Summary Structured Content Specification v1.1* [NEHTA-0997:2011] provides information about the sections of a shared health summary. In brief:

- *Adverse Reactions:* Information about adverse reactions or propensity to adverse reaction of the patient (including allergies and intolerances), and any relevant reaction details.
- *Medications:* Medicines which the healthcare consumer is using. This includes self-prescribed, clinician-prescribed and non-prescription medicines. This section must not be used to record vaccine administration records of the healthcare consumer. The "Administered immunisation" section must be used for this purpose.
- *Medical History:* The past and current medical history of the healthcare consumer which is relevant to the episode of care. This includes problem/diagnosis and medical or surgical procedures performed.
- *Immunisations:* Information about the immunisation history of the healthcare consumer.

ID	Recommendation	Status
SHS.04	The software **SHALL** display four complete lists of data items sourced from the local patient record: 1 Adverse Reactions 2 Medications 3 Medical History 4 Immunisations The list headings **SHALL** be as given above. Information in these lists **SHALL** be in accordance with the definition of Adverse Reactions, Medications, Medical History and Immunisations, stated in in the *Shared Health Summary Structured Content Specification*.	*Mandatory*

ID	Recommendation	Status
SHS.05	If the software allows an individual data item to be attributed with a "Confidentiality" flag and the flag is set to "true", then the software **SHALL** disallow the selection and inclusion of that data item. *Note: Some clinical systems incorporate confidentiality settings that restrict sharing of sensitive information or particular health information (for example, HIV status) outside the healthcare organisation. Such items will still appear in the shared health summary review authoring screen; however, their status should be clearly indicated to the user. Furthermore, the software may implement controls to prevent inadvertent inclusion in a shared health summary by disabling selection when authoring a shared health summary.*	*Conditional*
SHS.06	If the software has one or more item-level shared data flags for an entry type, those items that have been flagged for sharing **SHALL** be marked for inclusion in the shared health summary by default. *Note: Entry types are: adverse reactions, medications, medical history and immunisations. Clinical systems commonly attribute medical history entries with shared data flag(s). When authoring a shared health summary, it must be possible to de-select any item marked for default inclusion.*	*Conditional*
SHS.07	If the software does not have an item-level shared data flag for an entry type, all items of that entry type **SHALL** be marked for inclusion by default. *Note: Clinical systems typically do not attribute adverse reactions, medications and immunisations with shared data flags. When authoring a shared health summary, it must be possible to de-select any item marked for default inclusion.*	*Conditional*
SHS.08	The software **SHALL** support selection and de-selection of clinical items for shared health summaries, regardless of whether the shared data flag is marked or unmarked on entry.	*Mandatory*

4 Presentation and selection of medical history items

Applies to: Document authoring systems (shared health summary clinical documents).

The clinical requirements for the Medical History Section (as specified by the *Shared Health Summary Information Requirements v1.0* [NEHTA-0990:2011]) describe a single list of medical history items, with a single exclusion statement. However the *Shared Health Summary CDA Implementation Guide v1.3* [NEHTA-0988:2012] separates medical history into three sub-groupings: Problems/Diagnosis, Procedures, and Medical History Items. There are two exclusion statements: one for Problems/Diagnosis and another for Procedures. The need for two statements is due to the way the information is modelled and handled internally – it was not intended to impact on the way that the information was gathered from the user, nor how it was displayed. However, the CDA implementation guide does not directly address the question of how documents are presented and, since it suggests separate lists, this is how the shared health summary has been implemented.

Information on a patient's medical history is to be presented to the user so that they can select the items to record in a shared health summary.

ID	Recommendation	Status
SHS.09	The software **SHALL** present to the user a combined medical history list containing all applicable procedures, problems/diagnosis and other medical history entries.	*Mandatory*
SHS.10	The software **SHALL** present a medical history item for each entry in the local health record that corresponds to a procedure, problem/diagnosis or other medical history entry. *Note: It is not expected that the software presents history items contained in progress notes or similar narrative entries.*	*Mandatory*

5 Medical history narrative

Applies to: Document authoring systems (shared health summary clinical documents).

The *Shared Health Summary CDA Implementation Guide* states that the shared health summary medical history section has one narrative for problems/diagnosis, procedures and medical history items and three sub-sections for the structured data for problems/diagnosis, procedures and medical history items. The intent is for the medical history narrative to be formatted as a table according to the recommendations listed below.

ID	Recommendation	Status
SHS.11	The software **SHALL** populate the narrative of the medical history section of the CDA document with a single table containing all procedures, problem/diagnoses or other medical histories that are to be included in the document.	*Mandatory*
SHS.12	The software **SHALL** create a medical history table with an "Item" column containing a textual description of the problem/diagnosis, procedure or other medical history item.	*Mandatory*
SHS.13	If the software supports a date entry associated with medical history items, then the software **SHALL** create a medical history table with a "Date" column containing a point in time or time period for the entry. *Note: The date displayed could be:* • *a specific date corresponding to a point in time occurrence, such as a procedure date or date of onset;* • *a date range, such as date of onset to date of remission; or* • *"(ongoing)" to indicate that the condition is ongoing.*	*Conditional*
SHS.14	If comments associated with medical history items are supported, then the software **SHALL** create a medical history table with a "Comment" column containing additional comments about the entry.	*Conditional*
SHS.15	The software **SHALL** create entries in the medical history table in reverse chronological order based on the Date field. Medical history items with the most recent dates **SHALL** be listed higher in the table. Any medical history items with no corresponding date (e.g. where no date of onset has been recorded) **SHALL** be displayed at the top of the table. *Note: When a history item has a date range recorded (e.g. date of onset to date of resolution), the start of the date period is used for sorting.*	*Mandatory*

6 Exclusion statements for medical history items

Applies to: all systems authoring shared health summaries that record exclusion statements.

The medical history section of shared health summary clinical documents allows three possible types of medical history entry (problem/diagnosis, procedure and other medical history item) and two types of global exclusion statements (for problems and diagnoses and for procedures) as shown below.

Medical History Entry

- Problem/Diagnosis
- Procedure
- Other Medical History Item

Global Exclusion Statement

- Exclusion Statement – Problems and Diagnoses
- Exclusion Statement – Procedures

A clarified definition of "Other Medical History Item" based on the *Shared Health Summary Structured Content Specification* definition is:

> *"A medical history entry which cannot be categorised into one of the categories such as Procedure and Problem/Diagnosis."*

This covers cases where the source system cannot automatically classify an entry as a Problem/Diagnosis or a Procedure, including cases where:

- The coding system used for medical history item cannot structurally support adequate concept classification.
- The medical history item is maintained as free-text and thus has never been classified.

Appropriate use is defined here based on the existence of medical history entries of each type.

Since it is not known whether an "Other Medical History Item" entry is conceptually a procedure or a problem/diagnosis, exclusion statements cannot be used when an "Other Medical History Item" entry is present, as the entry may, in fact, be a procedure or a problem/diagnosis. Therefore, the following explicit constraints apply based on the *Shared Health Summary CDA Implementation Guide.*

ID	Recommendation	Status
SHS.16	When there are no entries for both "Procedure" and "Other Medical History Item" the software **SHALL** create an "Exclusion Statement – Procedures". *Example:* **Medical History Entry**: Problem/Diagnosis; Procedure **No entry**; Other Medical History Item **No entry** **Global Exclusion Statement**: Problems and Diagnoses; Procedures **Required**	*Mandatory*

ID	Recommendation	Status
SHS.17	When there are no entries for both "Problem/Diagnosis" and "Other Medical History Item" the software **SHALL** create an "Exclusion Statement – Problems and Diagnoses". *Example:* **Medical History Entry** Problem/Diagnosis **No entry** Procedure Other Medical History Item **No entry** **Global Exclusion Statement** Problems and Diagnoses **Required** Procedures	*Mandatory*
SHS.18	When there are no entries for all of "Procedure", "Problem/ Diagnosis" and "Other Medical History Item" the software **SHALL** create both an "Exclusion Statement – Procedures" and "Exclusion Statement – Problems and Diagnoses". *Example:* **Medical History Entry** Problem/Diagnosis **No entry** Procedure **No entry** Other Medical History Item **No entry** **Global Exclusion Statement** Problems and Diagnoses **Required** Procedures **Required**	*Mandatory*
SHS.19	When there are any entries for "Other Medical History Item" the software **SHALL NOT** create an exclusion statement. *Example:* **Medical History Entry** Problem/Diagnosis Procedure Other Medical History Item **Entry** **Global Exclusion Statement** Problems and Diagnoses **Not allowed** Procedures **Not allowed** *Note: The reason for this recommendation is that if "Other Medical History Item" is present, it may be either a problem/diagnosis, or a procedure, so there should not be an exclusion statement for either of these.*	*Mandatory*
SHS.20	The software **SHALL NOT** use the "not asked" exclusion statement in the context of Shared Health Summary clinical document authoring.	*Mandatory*

Note: In the example tables above, the blank cells in Medical History Entry indicate either an entry or blank. A medical history section is allowed to contain procedures, problem/diagnosis, and other medical history items.[1] Having both categorised items (procedures and problem/diagnosis) and uncategorised medical history items would be unusual, because generally if a system is able to differentiate some items, it is able to differentiate them all. However a system may be able to categorise some, and not others – because of legacy data, or partial classification in the underlying terminology, for instance. For this reason, the rules allow a mix of categorised and uncategorised items.

[1] Page 5 of the *Shared Health Summary Release Note* v1.3 [NEHTA-1076:2012] says "Use EITHER "Problem/Diagnosis" and "Procedure" OR "Other Medical History Item", but NOT both". This should be understood as product guidance and is consistent with these usability recommendations.

Abbreviations and terminology

Term or abbreviation	Description
CDA	Clinical Document Architecture; an XML-based mark-up standard intended to specify the encoding, structure and semantics of clinical documents exchanged between health software systems. Specifications for clinical documents are based on CDA Release 2 [HL72005].
clinical document	A digital file containing personal health information about an individual, containing unstructured (narrative) information and optionally structured (atomic) information.
clinical information system (CIS)	A system that deals with the collection, storage, retrieval, communication, and use of health related data, information and knowledge pertaining to subjects of care [AS5021]. The system may comprise one or more applications or components.
contracted service provider (CSP)	An entity that may offer health software as a service, and support access to the PCEHR system on behalf of healthcare organisations. A CSP provides under a contract with the healthcare provider organisation: a) information technology services relating to the PCEHR system; or b) health information management services relating to the PCEHR system (Section 5 *Personally Controlled Electronic Health Records Act*).
healthcare consumer	A person who is the subject of care.
PCEHR system	Personally controlled electronic health record system (eHealth record system). National eHealth infrastructure for managing records in eHealth. The eHealth record system includes the PCEHR repository, and the National Prescription and Dispense Repository.
SCS	structured content specification

References

NEHTA references

The references below are published on www.nehta.gov.au.

If viewing this as a printed document, use the NEHTA-XXXX:YYYY identifier to search for the exact reference online.

NEHTA-0988:2012 *Shared Health Summary CDA Implementation Guide v1.3*, 7 March 2012.

NEHTA-0990:2011 *Shared Health Summary Information Requirements v1.0,* 29 November 2011

NEHTA-0997:2011 *Shared Health Summary Structured Content Specification v1.1*, 30 November 2011.

NEHTA-1076:2012 *Shared Health Summary Release Note v1.3*, 10 September 2012

NEHTA-1452:2013 *Shared Health Summary PCEHR Conformance Profile v1.5*, 9 October 2013.

NEHTA-1564:2014 *Clinical Documents PCEHR Usability Recommendations v1.1,* 5 May 2014.

Other references

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

[AS5021] *AS 5021:2005 - The language of health concept representation*, Standards Australia, 2005.

[COM2012] *Personally Controlled Electronic Health Records Act 2012*, Australian Government ComLaw, 2012

[HL72005] *Clinical Document Architecture, Release 2*, ISO/HL7 27932:2008, 21 Apr 2005