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Tenth Clinical Safety Review of the My Health Record System

**Presentation of clinical document
information from the My Health
Record system in the National
Provider Portal and clinical
information systems**

Summary report

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1 Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) has undertaken a clinical safety review program for the My Health Record system since the system's implementation in 2012. In July 2016, the Australian Digital Health Agency (the Agency) was established with responsibility for all national digital health services and systems. The Agency was also appointed as the System Operator of the My Health Record system.

The purpose of the clinical safety review program is to promote and enhance the clinical safety of the My Health Record system and national digital health infrastructure. In October 2016, the Commission initiated the 10th clinical safety review under the oversight of the Digital Patient Safety Expert Advisory Group (DPSEAG). The review examined the current presentation of clinical documents and clinical information via connected clinical information systems (CISs) in the My Health Record system. This summary report highlights the findings and recommendations to enhance clinicians' interactions with the system from the expanded clinical safety review report provided to the Agency.

2 Background

Patient care is improved by enabling clinicians to efficiently identify and utilise relevant information within clinical documents in patient records. A well-designed user interface to access this information is therefore important for clinicians, particularly when dealing with complex records with large document volumes. Difficulties in navigating and searching large volumes of clinical documents in any paper-based or electronic system can potentially impede appropriate decision-making and management and present clinical safety risks.

The My Health Record system has the potential to accumulate a large volume of clinical information captured in a range of clinical documents over time. The sixth clinical safety review of the My Health Record system (sixth review)^{*}, identified that clinicians may experience difficulties in sorting, searching and navigating large volumes of clinical documents in some My Health Records.

Clinical documents within the My Health Record system

Within the My Health Record system, clinicians may access or upload a range of clinical documents. This facilitates the sharing of information among clinicians and continuity of patient care. Some of these clinical documents are described below:

1. *Shared Health Summary* illustrates a patient's health status at a particular point in time with information on medical history, current medications, allergies and adverse reactions, and immunisations. A Shared Health Summary is likely to be the first document reviewed by a clinician other than the patient's nominated primary healthcare provider
2. *Event Summary* documents a significant healthcare event relevant to the continuation of care of a patient. An Event Summary may be created by any clinician with the intent that it will likely be accessed by another clinician(s) external to their organisation
3. *Discharge Summary* captures the details of a patient's stay in hospital. Discharge Summaries can be provided directly to the patient or carer, as well as being sent to all clinicians involved in a patient's care. It can also be uploaded to the patient's My Health Record
4. *Medication records* are uploaded to a patient's My Health Record when a clinician uses a clinical information system to prescribe and/or dispense the medication
5. *eReferral* contains important patient information to facilitate a patient's continuity of care from one clinician to another for example, from general practitioner to specialist. An eReferral may be stored in a patient's My Health Record as a copy or to be accessed directly by the referred clinician
6. *Specialist letter* is created by a specialist to respond to the referring clinician, such as a general practitioner, with relevant patient information gathered or identified during the specialist consultation, and associated recommendations.

Most CISs present these documents from the My Health Record through a clinical document list. These lists allow clinicians to sort clinical documents in chronological or alphabetical order, and filter the documents by certain parameters, such as date range. Currently, only one CIS has implemented a summary information 'page' in alignment with the Agency's Health Record Overview Presentation Guide. The Health Record Overview presents critical patient information gathered from a number of sources. This information includes vital information from the last Shared Health Summary, including current and past medical history, medicines, allergies and adverse reactions, and immunisations. It also presents a list

^{*} Sixth Clinical Safety Review of the My Health Record system, 2015. This review consisted of: 1) a review of identity management processes underpinning the My Health Record system; and 2) an end-to-end review of event summaries.

of clinical documents uploaded after the latest Shared Health Summary, as well as those uploaded in the past 12 months.

Objective and scope

The objective of the review was to examine the current presentation of clinical documents and clinical information in the My Health Record system via connected CISs. The review offers usability-focused presentation and design recommendations to enhance clinicians' interactions with the system in providing patient care.

The review also involved the following activities:

- Working with clinicians and reviewing usability and subject matter resources to identify issues with the presentation of clinical document information through connected CISs and the National Provider Portal, and through the Health Record Overview
- A review of appearance, ordering and hierarchy of reports, search and navigation functionality, titling and displayed content
- Analysis of human factors and eye tracking.

The National Provider Portal (NPP) is part of the scope of this review. However, clinicians predominantly access My Health Record clinical information via their CISs or statewide electronic Health Record (eHR) systems.

The objective of the National Provider Portal was to allow clinicians access to registered patient information on a read-only basis while CISs implemented the required capability to connect to and retrieve information from the national eHealth infrastructure. A number of CISs are now conformant with Agency specifications, and have the capability to retrieve My Health Record patient information. This means few clinicians see the need to access the National Provider Portal. The review, therefore, focused on the way My Health Record clinical document information is displayed within CISs and statewide eHR systems.

The clinicians consulted as part of this review included general practitioners in both metropolitan and regional areas, acute setting clinicians, aged care providers, pharmacists and general practice nurses.

3 Methods

The 10th review consisted of two phases involving task analysis and heuristic evaluation.

Phase 1: Task analysis

Document review and research activities

These activities focused on understanding relevant clinical document specifications as well as documentation developed by the Clinical Usability group within the Agency. Activities also included researching national and international standards and practices for the presentation of clinical document information.

Site visits and compilation of user experience samples

These activities focused on understanding the processes involved in accessing and using clinical information from the My Health Record system in both regional and metropolitan areas, noting any differences and potential for improvement across systems.

A number of clinical information systems used in primary care were reviewed to understand how clinical documents are presented.

Stakeholder interviews

Interviews were conducted across multiple clinical settings, including acute care medical professionals, general practitioners, allied health professionals, general practice nurses and pharmacists. Interviews were focused on understanding stakeholders' experiences in accessing clinical document information within the My Health Record system. Stakeholders' opinions of the presentation of information in CISs and suggestions to improve the display of this information from both clinical safety and usability perspectives were also taken into account.

Deep dive interviews

Interviews were performed with clinicians across a variety of relevant clinical settings. During these interviews, each clinician's interactions with the My Health Record system through their local CIS were observed in their normal working environment.

Phase 2: Heuristic evaluation

Behavioural experiments

Experiments consisted of eye-tracking sessions conducted with clinicians across various clinical settings, to confirm and/or validate the findings identified during the task analysis phase. During these sessions, eye-tracking technology was used to observe clinicians while they interacted with a CIS. The technology captured where the clinician's eyes landed, where their gaze lingered (indicating points of interest) and how they navigated the system. The eye-tracking technology also recorded the actual movement of the clinician's eyes on the screen and captured keystrokes and mouse movements to build a composite profile of activity.

Refinement of usability and terminology concerns

This activity focused on assessing the outcomes of the behavioural experiments to assess the validity of the initial findings, incorporating updates where necessary.

4 Findings and recommendations

There are a total of 11 findings and 15 recommendations for this review. Each finding has a risk rating and a related recommendation. The risk rating guide used for this review is in Appendix A.

No findings were assessed as critical or major. Five findings were classified as a moderate risk, and six findings were classified as a minor risk to the My Health Record system.

Finding 1: The majority of CISs display My Health Record clinical documents in a date-ordered simple list form

Risk rating: Moderate

Critical clinical information such as current medicines, allergies and adverse reactions, and medical history is usually readily available when a local patient record is retrieved in a CIS. With this in mind, clinicians have a similar expectation when retrieving a patient's My Health Record information.

The majority of CISs connecting to the My Health Record system present information as a list displaying the following details:

- Document date
- Service date
- Document name
- Organisation issuing the document
- Organisation type
- Document author
- Document size.

In July 2015, the Agency published presentation guidelines and specifications for a Health Record Overview. The Health Record Overview gathers information from the latest Shared Health Summary and displays the following patient information:

- Documents available in My Health Record since the last Shared Health Summary
- Current and past medical history
- Medicines
- Allergies and adverse reactions
- Immunisations
- A link to personal health summaries, prescription and dispense view, pathology reports, diagnostic imaging reports, Medicare information, and health check assessment schedule
- Clinical documents uploaded to the My Health Record in the past 12 months.

By September 2016, only Communicare had implemented the Health Record Overview. Consultation identified that some software vendors are not aware of this feature. Even for those software vendors who are aware of the Health Record Overview, its implementation is not considered a high priority since it is not a mandatory requirement of the Agency.

This review also noted that the functionality available within the My Health Record document list presented by most connecting systems varies. Some systems incorporate filters for the list of clinical documents, allowing documents to be searched using a date range, allowing the list to be sorted in alphabetical or chronological order, and providing a preview of the document. Other CISs only incorporate a filter. None of the systems allow for the content of clinical documents to be searched. While filtering and sorting functionalities assist with navigating clinical documents, it remains difficult for clinicians to determine which documents

contain the information they require. It can be time-consuming to repeatedly open separate clinical documents to find specific information. This is particularly problematic where a patient record contains a large number of clinical documents, especially for chronically ill or polypharmacy patients.

Recommendation 1

The Agency should promote the implementation of the Health Record Overview functionality within connecting systems.

Recommendation 2

The Agency should continue to improve the display of critical information in the Health Record Overview specification.

Recommendation 3

The Agency should work with vendors to build search functionality within connecting systems, once a minimum level of structured (coded) data is available in the system.

Finding 2: Some Shared Health Summary content in the My Health Record system does not always reflect what is in the user's CIS

Risk rating: Moderate

Some clinicians believed that other relevant information held within their local CIS should be captured in the Shared Health Summary uploaded to the My Health Record. A review of the Shared Health Summary specifications published by the Agency indicated that these specifications do not cater for the following data fields identified by clinicians as being important:

- Date of last script for medicines
- Warnings
- Family history
- Social history
- A clear distinction between current and past medical history; this section within My Health Record should be broken down into Procedures, Problem/Diagnosis and Medical History Items and clinicians are not clear of the distinction between Medical History Items and Problem/Diagnosis
- 'To do's'
- Progress notes
- Clinical items including systolic and diastolic blood pressure, weight, height, BMI, waist circumference, fasting blood glucose level, random blood glucose level, blood international normalised ratio, HbA1c and HbA1c (%).

Recommendation 4

The Agency should periodically review clinical document specifications and conduct user consultations to identify if there is a demand for additional clinical information to be included into the next versions of these specifications.

Recommendation 5

The Commission and the Agency should develop guidelines for the on-screen presentation of clinical documents (including Shared Health Summaries) in the My Health Record system, using the National Guidelines for the On-Screen Presentation of Discharge Summaries as a reference, to ensure information is presented in a manner that meets clinicians' needs.

Recommendation 6

The Agency should continue to work with the software vendor community and the clinical community to encourage implementation of new and updated specifications.

Finding 3: There is a perception that usability-related feedback from clinicians has not been incorporated into the My Health Record system specifications

Risk rating: Moderate

Some clinicians interviewed expressed concerns that usability-related feedback, provided during the development of the clinical document list specification, was not incorporated by the Agency. In addition, these clinicians indicated that they do not feel the My Health Record system readily supports their workflow or day-to-day activities.

The Department of Health and, since 1 July 2016, the Agency have undertaken a range of consultation processes with representatives of the health sector, software vendors and the broader community to inform future design of the My Health Record system and usability enhancements. While consultation is an opportunity to engage with the key stakeholders, it will raise design expectations for those having direct input to the process. It is acknowledged that there will always be potential differences among stakeholder groups in terms of workflow requirements and the challenges in adopting new workflow arrangements when moving from a paper-based system to an electronic system. Based on clinician feedback it is important that the Agency undertake a feedback process on the outcomes of the implemented design and apply this more consistently going forward.

Recommendation 7

The Agency should implement a process that gives consultation stakeholders visibility of the management and utilisation of feedback obtained for developing enhancements and new functionality in the national system.

Finding 4: It is difficult for clinicians to quickly identify new or updated information in a patient's My Health Record

Risk rating: Moderate

This finding is consistent with the results of the sixth review (Finding 11) where clinicians noted that the absence of a system for notifying them when new documents were available for a patient was considered a barrier to use.

The only way to identify new or updated information in a My Health Record is for a clinician to access each record and scroll through a list of filenames/titles of clinical documents which must then be individually clicked to access information within each document. Clinicians who

were interviewed suggested that it would be beneficial if they could more easily be made aware of new information available in the My Health Record system. This would prompt them to use the system more regularly.

Recommendation 8

The Agency should consider possible improvements to make important information, including updated and new information available in the My Health Record system, more easily identifiable (by way of a pop-up or other notification), in consideration of any medical indemnity or other stakeholder concerns.

Finding 5: Users can be confronted with intimidating and unclear warning messages when trying to access the My Health Record system in some instances

Risk rating: Minor

When a clinician selects the My Health Record icon/button in their CIS to access the My Health Record system for a patient, and the system identifies that the patient does not have a My Health Record, the following message is displayed:

An Individual Healthcare Identifier (IHI) was found for this patient. However a check for the patient's My Health Record shows that a record does not exist or is not advertised. By attempting to get access, you are declaring that you are abiding with section 66(2) of the My Health Record Act, which states that "A participant in the My Health Record system is authorised to collect, use and disclose for any purpose health information included in a healthcare recipient's My Health Record with the consent of the healthcare recipient".

Your attempt to get access will be recorded on the eHealth Record's audit log and the patient may be notified. If the patient has advised that a My Health Record does exist, use the Gain Access button above. If the patient has provided an access code, enter it in the access code field. If this is a medical emergency, then use the emergency access button. Note: If a patient does not have a My Health Record then none of the above options will result in any record being displayed.

Clinicians who were presented with this message felt it was confronting and they were concerned they did not have enough information to understand the potential consequences of asserting emergency access. Therefore, they were reluctant to perform any further actions, or to access the My Health Record system in the future.

Recommendation 9

The Agency should work with vendors to develop more user-friendly wording for warning and error messages in the My Health Record system, in alignment with the recommendations provided as part of the sixth review. This should include hyperlinks for specific terms, such as emergency access, directing clinicians to the relevant Agency's glossary webpage. Messages should also provide detail to assist the user in resolving the error, as well as contact information to obtain additional support.

This recommendation relates to both Finding 5 and Finding 6.

Finding 6: It is not clear to users whether to contact their software vendor or the System Operator when an error message is displayed in the My Health Record system

Risk rating: Minor

During a particular consultation, it was identified that the CIS displayed an error when uploading clinical documents into the My Health Record system. The general practice nurse had raised the issue with the software vendor without a resolution, and was unsure as to whether they could contact the Agency to further explore the cause of the error. This has been an intermittent issue in the practice.

The inability to resolve issues when they are first encountered reduces both users' confidence in the system and willingness to persist, especially in a busy environment.

The Commission recognises that the Agency continues to address error messaging for the My Health Record system to ensure messages are meaningful, as recommended in clinical safety reviews 6 and 7.1. However, further work is required to improve error messages generated by vendor products. There is an opportunity for the Agency to work with software vendors to develop guidelines and more user-friendly wording.

Recommendation

See Recommendation 9.

This recommendation relates to both Finding 5 and Finding 6.

Finding 7: There is a variation in clinical use and context of Event Summaries; this means they must be opened individually to identify the information contained within

Risk rating: Minor

This finding is aligned to the results of the sixth review (Finding 8) which identified a limited awareness among clinicians regarding the purpose of Event Summaries.

The work undertaken through this review reiterated the importance of clarifying the scenarios in which an Event Summary is an appropriate document to create and upload into the My Health Record system.

Recommendation 10

The Agency should raise awareness of the appropriate use of Event Summaries in the system, such as through greater dissemination of the Shared Health Summary vs Event Summary document available on their website.

Finding 8: The current titling of Event Summaries makes it difficult for clinicians to quickly ascertain the type of information contained in each document

Risk rating: Minor

Since Event Summaries can be created under different circumstances, it is difficult for clinicians to easily identify summaries that contain information critical to the patient's care.

For instance, an Event Summary created by a general practitioner or a specialist outlining that a patient was diagnosed with pneumonia is not differentiated in any way from other Event Summaries that may not contain critical or new patient information.

With this in mind, clinicians would need to open each individual Event Summary to determine if there is relevant and/or critical clinical information that they need to take into account as part of patient's consultation. When a considerable number of clinical documents (including Event Summaries) have been uploaded, it could be difficult for a clinician to open each individual document in the limited time they have available, thus creating a clinical safety risk if critical information is not able to be identified quickly.

The sixth review recommended improving heading titles (labels) in the Event Summary document to clarify its purpose.

The importance of appropriate and clear heading titles also applies to other document types in the My Health Record system, particularly pathology and diagnostic imaging reports. Improvements to titling therefore should apply to existing and new document types, as applicable.

Recommendation 11

The Commission and the Agency should develop guidelines for the on-screen presentation of clinical documents (including Event Summaries) in the My Health Record system, using the National Guidelines for the On-Screen Presentation of Discharge Summaries as a reference, to ensure information is presented in a manner that meets clinicians' needs.

The development of these guidelines should include recommendations for clearer titles, headings and filenames to be used throughout clinical documents. The titles, headings and filenames to be used and displayed in the document list should provide users with better insight into the information contained within these documents and, where necessary, changes to the specifications should be documented.

Recommendation 12

The Agency should periodically review their clinical documents specifications and conduct user consultations to identify usability issues to be addressed in updated versions of the specifications.

Finding 9: My Health Record information is displayed in separate, independent windows in some CISs which means users are required to move between their local CIS view and the My Health Record system view

Risk rating: Minor

The majority of CISs present a separate or independent user interface when displaying a My Health Record, requiring clinicians to use functionality that does not align with their CIS. This has the potential to create confusion for the user and complicate the process of accessing a patient's clinical information. Clinicians interviewed during this review indicated that a more integrated view of My Health Record information would assist in improving adoption and utilisation of the system.

Recommendation 13

The Agency should work collaboratively with vendors to encourage a more integrated presentation of My Health Record information in their CISs.

Finding 10: Clinicians are uncertain of the clinical document types and views available in the My Health Record system

Risk rating: Minor

During stakeholder consultation, clinicians displayed different perceptions of the availability of imaging reports within the My Health Record system. Some clinicians reported that these documents were available. Others did not believe this to be the case, citing this as one of the reasons for not accessing the My Health Record system. The stakeholder consultation also identified that some software vendors were not aware of the availability of the Health Record Overview presentation guidelines.

These views suggest that current mechanisms to raise awareness of My Health Record system capabilities need strengthening.

Recommendation 14

The Agency should continue to develop more effective mechanisms of communication with software vendors and the clinical community to inform the functionality available in the My Health Record system.

These communication mechanisms should also promote existing My Health Record training materials.

Finding 11: The implementation of Agency standards and specifications by vendors may be different to Agency expectations

Risk rating: Moderate

My Health Record functionality in different CISs does not always match the Agency's expectations of how their standards and specifications should be adopted. The level of understanding of the Agency's specifications varies among software vendors. As a result, the My Health Record functionality in third party clinical software may not fully meet clinicians' requirements.

Recommendation 15

The Agency should work closely with software vendors from specification development through to the implementation of specifications into vendor systems, to make sure there is a common understanding of Agency expectations.

This should also encourage awareness of the value brought by My Health Record system enhancements, and the rationale behind them.

5 Conclusion

A number of this review's findings indicate that it is difficult for clinicians to efficiently find clinical information in the My Health Record system using their CIS. This is due to CISs having limited search and presentation functionality, and a lack of awareness of new patient information. In addition, most CISs lack the facility to identify the content of a clinical document before it is opened. In line with findings in the sixth review, there is variation in clinical use and context of Event Summaries which further complicates navigation of these documents. These findings were confirmed by eye-tracking sessions that revealed the clinicians' preference for adopting the Health Record Overview in CISs, providing important patient information and updates at a glance. These outcomes indicate the need for more streamlined presentation of clinical documents. A preview function and clear titles and descriptions, for example, would allow clinicians to identify the content of the clinical document without having to open it.

In line with findings in reviews 6 and 7.1, error messages appearing in the My Health Record system were highlighted as being intimidating and unclear to some users and not user-friendly. This results in a reluctance to use the system. A nominated contact is not clearly highlighted when an error message is displayed, making it difficult for users to resolve issues they encounter when accessing the system.

To address these findings, it is recommended that the Agency:

- Promotes the implementation of the Health Record Overview by software vendors
- Works collaboratively with vendors and health jurisdictions to develop and implement new functionality into the My Health Record
- Encourages a more integrated presentation of the My Health Record information in their clinical information systems.

It is expected that achieving a more consistent 'look and feel' between the My Health Record system and clinicians' local CISs will encourage more active use. On-screen presentation guidelines for clinical documents in the My Health Record system, such as Shared Health Summaries and Event Summaries, should be developed to ensure information is presented in a manner that meets clinicians' needs. This review also supports the implementation of the recommendations provided during the sixth review. These relate to improved communication and training on the purpose of Event Summaries, and improving the clinical utility of titling in the document list and headings within Event Summaries.

Glossary

clinical documents	Documents with clinical information entered by healthcare providers in an individual's My Health Record. They include Shared Health Summaries, Event Summaries, Discharge Summaries, referral letters and specialist letters.
clinical information system (CIS)	A system used by a healthcare provider to manage patient and practice records. It may include a software component connected to the My Health Record system.
eye-tracking	Eye-tracking technologies assess user experience via a range of outputs including video and heat maps, and highlights which areas of the screen draw the eye and capture the attention of clinicians. Eye-tracking technology records the actual movement of the user's eye on the screen while also capturing keystrokes and mouse movements to build a composite profile of activity.
heuristic techniques	From the usability point of view, heuristic techniques refers to the evaluation of a user interface to determine whether it is fit-for-purpose and intuitive.
My Health Record	<p>A My Health Record of an individual is the record of information created and maintained by the System Operator in relation to the individual, and information that can be obtained by means of that record, including the following:</p> <ul style="list-style-type: none"> • Information that relates to the individual in the record relating to the individual's registration • Health information connected in the My Health Record system to the individual, including information included in a record accessible through the index service • Other information connected in the My Health Record system to the individual, such as information relating to auditing access to the record • Back-up records of such information.
My Health Record system	The My Health Record system is used for the operation of functions under the <i>My Health Records Act</i> by the System Operator. The system was launched on 1 July 2012 (previously known as the Personally Controlled Electronic Health Record or PCEHR) and provides a system of managing health information online that will make it more accessible to Australians who choose to sign up with the system, and to healthcare providers. The system is supported by a legislative framework consisting of the <i>My Health Records Act 2012</i> , <i>Healthcare Identifiers Act 2010</i> , <i>My Health Records Regulation 2012</i> , <i>Healthcare Identifiers Regulations 2010</i> and <i>My Health Records Rule 2016</i> .
National Provider Portal	The interface through which healthcare provider organisations can access the My Health Record system and view an individual's My Health Record without having to use a clinical information system. The provider portal is a view-only service.
System Operator	The participant with responsibility for establishing and operating the My Health Record system. As of 1 July 2016, the System Operator is the Australian Digital Health Agency.

Appendix A Clinical safety review risk rating matrix

Review findings have been assigned one of five risk ratings – critical, major, moderate, minor and minimum, consistent with the clinical safety review risk rating matrix.

These categories have been confirmed by the Commission’s Clinical Safety Oversight Committee and the My Health Record System Operator during the review process.

Risk rating	Reputation and public confidence of My Health Record / quality of service	Clinical safety harm	Control
Critical	<p>Profound influence on the My Health Record system’s reputation, resulting in a profound loss of public and healthcare provider participation</p> <p>Profound sustained degradation of service value and quality</p>	A clinical incident resulting in patient death	<p>Basic, supervisory and/or monitoring controls are inadequate and require urgent management attention</p> <p>A critical patient safety incident has occurred</p>
Major	<p>Significant influence on the My Health Record system’s reputation, resulting in significant loss of public and healthcare provider participation</p> <p>Decline in service value and quality is recognised by a majority of patients or health service providers</p>	A clinical incident resulting in major permanent loss of function	<p>Basic, supervisory and/or monitoring controls are inadequate and require prompt management attention</p> <p>A major clinical safety incident has occurred</p>
Moderate	<p>Loss of reputation affecting participation in the My Health Record system</p> <p>Decline in service value and quality is recognised by a moderate number of patients and health service providers</p>	A clinical incident resulting in permanent reduction in function	<p>Basic, supervisory and/or monitoring controls are partly inadequate and require management attention</p> <p>High potential for a clinical safety incident</p>
Minor	<p>Mild damage to reputation of the My Health Record system</p> <p>Decline in service value and quality is recognised by the System Operator and My Health Record partners</p>	A clinical incident resulting in increased level of care/intervention	<p>Basic, supervisory and/or monitoring controls are operating as intended, recommendation for improvement to strengthen control</p>

Risk rating	Reputation and public confidence of My Health Record / quality of service	Clinical safety harm	Control
Minimum	Minimal impact on the My Health Record system's reputation Minimal effect on service value and quality	A clinical incident resulting in no injury	Basic, supervisory and/or monitoring controls are operating effectively, a process improvement opportunity exists