

Fifth Clinical Safety Review of the My Health Record system

Undertaken by PwC on behalf of
Australian Commission on Safety and Quality in Healthcare

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1. Background

The My Health Record system (formerly the Personally Controlled Electronic Health Record or PCEHR) is a national system that allows both consumers and healthcare practitioners to securely access a consumer's health information to aid in clinical care and decision making processes. The intention of the My Health Record system is to provide an additional source of information for clinical decision making and enhance the care provided by healthcare practitioners to consumers.

The Australian Commission on Safety and Quality in Health Care (the Commission) has been funded by the Department of Health to provide clinical safety oversight and a series of targeted clinical safety reviews of the My Health Record system. The purpose of the clinical safety program is to promote and enhance the clinical safety of the My Health Record system. To date, the Commission has conducted four clinical safety reviews of the My Health Record system. These reviews have examined a variety of aspects of the system, including clinical safety management processes and the review of de-identified records to identify potential clinical safety issues.

This review focused on six review areas, looking at a broad spectrum of My Health Record system functionality from Shared Health Summaries (SHS) to the use of clinical safety principles in rolling out new functionality. These objectives are outlined more detail in section 3.

2. Overview of findings

The findings of the fifth clinical safety review of the My Health Record system cover the review period incorporating December 2014 through to June 2015.

The findings and recommendations presented in this report are based on the analysis of the qualitative and quantitative data collected across the six review areas. The six review objectives were aligned into four workstreams to address the review areas.

Within the six review areas, there were a total of twelve findings. The findings have been classified according to the risk ratings developed for the first four clinical reviews (a rating scale of critical, major, moderate, minor, minimum). The review found no critical issues. Two findings were considered to be moderate, eight were classified as minor and a further two findings were not rated as these findings were positive in nature. The twelve findings resulted in 13 recommendations for consideration. The findings and recommendations are detailed below.

3. Review objectives and scope

The objectives of this clinical safety review are listed below:

1. To conduct an end-to-end analysis of the accuracy and data quality of Shared Health Summaries (SHSs) prepared in local clinical information systems and submitted to the My Health Record system,
2. To review the rigour and consistency of applying best practice clinical safety principles in the design and build of new functional aspects for the My Health Record system, during the My Health Record Release 5 development process,
3. To review the usability of a sample of SHSs, including the degree to which healthcare practitioners have the ability to find the information they need within a SHSs,
4. To review the current use of Medicare Benefits Schedule (MBS) and Pharmaceutical Benefits Scheme (PBS) administrative data by participants accessing the My Health Record system for clinical purposes, and how potential safety implications of using this information are being managed,
5. To conduct a review of a sample (approximately 500) de-identified My Health Records for general data quality and consistency, and
6. To review and report against the implementation progress of the recommendations made in the third and fourth My Health Record system clinical safety reviews, particularly in relation to usability improvements.

4. Overall methodology

The clinical review approach was structured by aligning the six review areas into four workstreams:

Workstream 1 – SHS review: An end-to-end analysis of SHSs, including a review of a “real-world” SHS journey, data analysis, and site visits to one hospital, one community pharmacy (across two jurisdictions) and five general practices (in three jurisdictions).

Workstream 2 – My Health Records data review: Data collection and analysis of 500 de-identified My Health Records.

Workstream 3 – Release 5 review: Desktop review of processes related to Release 5 of the My Health Record system and the clinical safety standards, key agency workshop and stakeholder consultations with participants involved in the release.

Workstream 4 – Previous recommendations: Reports outlining the status of recommendations from the previous third and fourth clinical reviews were received from Health on behalf of National eHealth Transition Authority (NEHTA) and the Department of Human Services (DHS). A workshop with key agencies was held to verify and agree the status of previous recommendations, while implementation challenges and issues were also noted.

Workstreams 1 and 2 also addressed review area 4, relating to current use of MBS and PBS data by healthcare providers.

5. Review Areas

5.1. Workstream 1: End-to-end investigation of the accuracy and data quality of SHSs and the usability of a sample of SHSs (Objectives 1,3 and 4)

Review approach:

Three jurisdictions participated in the end-to-end review of the SHSs. Specific consumer consent was also sought, which enabled the analysis of individual records in different clinical information systems from a hospital, pharmacy and general practice perspective. Stakeholder consultation was key to this review area.

De-identified shared health summaries were collated and analysed to identify any issues or inconsistencies, to enable recommendations to be developed against the issues identified.

Finding 1: There were no discrepancies in the information in the SHS between the three software and two end viewing platforms included in this review

Risk rating: N/A

The review found that the presentation of information in the SHS was displayed in the same manner across each of the sites visited¹. The reviewed shared health summary presentation style and order of presentation of consumer information and clinical data adhered to the NEHTA standards for clinical documents in the My Health Record system.

Finding 2: The time taken to create a SHS varies significantly across authors

Risk rating: Minor

There was a large variation in the time taken to author an SHS, from 3 minutes up to 40 minutes. These time differences can be explained to some degree by the quality of consumer notes in the local clinical information system, the experience of the author with the creation of SHS, the discussions with the consumer regarding their SHS and the level of detail the GP incorporated.

During the site visits with GPs the reasons underpinning the creation of a SHS for their patients was discussed. The commonly reported underlying reason was their desire to improve the care for patients with a number of chronic conditions where they may see multiple healthcare providers and/or be on complex treatment regimens. It was thought that having important clinical information readily available through the SHS would improve clinical decision making processes and thereby lead to enhanced clinical outcomes for consumers.

Having noted this, there was only one instance identified through interviews where a GP was aware that their SHS had been viewed by another clinician. Given the small number of active healthcare practitioners interacting with the system, there are opportunities to work with the different professional groups to improve the utilisation of the system and contribute to

¹ Not all clinical desktop software products were included in this review and therefore this finding applies only to those reviewed during the site visits

enhanced clinical outcomes for consumers. Whilst SHSs have been used, the lack of significant use as consumers transition across care settings limits the “real world” conclusions that can be drawn from this review.

Recommendation 1: Identify and encourage ‘communities’ of providers to actively use the SHS, as consumers transition across the care continuum.

Finding 3: MBS and PBS views are not useful to healthcare providers in their present state and currently do not appear to add value to the GPs review of the consumer’s record

Risk rating: Minor

The five GPs interviewed for this workstream had access to MBS and PBS views for the SHS creation. Two of the GPs visited were unaware that this information was available.

The GPs expressed that their preference was still to review the consumer’s medication list from their local clinical system and to update the list themselves. The absence of automated population functionality in the My Health Record system meant that the GPs did not want to duplicate information and therefore referred to their current medications listings per consumer to provide the current and ceased medication list.

The information presented in the MBS and PBS view within a consumer’s digital health record often differed with the medicines information captured for that consumer within the local clinical system. DHS advised that the time of upload for MBS and PBS data is dependent on the Medicare claiming process. That is, uploading time is driven by when the MBS or PBS rebates are claimed by the individual or healthcare organisation/pharmacy, and subsequently processed by Medicare. Therefore, data arising from the consumer MBS or PBS claim process will not always be in synchronisation with the view in the GP software at the time of consultation.

Recommendation 2: Take this finding into account in the context of considering a more detailed assessment on the usefulness of MBS and PBS data in a person’s My Health Record.

Finding 4: There is a lack of clarity regarding SHS technical support and feedback mechanisms

Risk rating: Minor

During the review four of the GPs expressed concern regarding the lack of direction as to how to provide feedback on the usability and functionality of the SHS, or how to seek technical support. For example, with regard to SHS functionality they cited the required fields and the transmission of information to the My Health Record system. A co-ordinated approach is recommended to keep GPs updated with regards to changes to the My Health Record system and compliant software products. A Frequently Asked Questions (FAQs) page which directs them to contacts for feedback and follow up on concerns is one solution to this issue.

Recommendation 3: Consider whether existing communication to providers on where to seek help and lodge feedback needs to be revised or renewed.

5.2. Workstream 2: Review of a sample of de-identified My Health Record records

Review approach

A sample of 500 de-identified individual My Health Records containing a range of clinical documents were analysed and assessed against published standards. A new extraction and de-identification process was completed for this review. This allowed for enhanced linkage between the documents within the individual records, leading to different perspectives on the usage of the My Health Record system when compared to prior reviews. Issues and inconsistencies were identified and recommendations then formulated.

Finding 5: Improvements have been identified resulting from the recommendations of the third and fourth clinical safety reviews

Risk rating: N/A

The previous clinical safety reviews of the My Health Record system have identified a number of recommendations for improving the clinical safety of the information uploaded to the system. Through this review and the sample of de-identified records it appears improvements have been made in the presentation of medication strengths.

Of the documents reviewed, no instances of leading zeros or floating decimal points were identified. Further no examples of incorrect attribution of dosages between multiple medications for a single consumer were present in the summary documents reviewed.

Finding 6: Examples of inconsistent persistence of adverse reactions and medical history across summary documents for individual consumers appear to be related to healthcare practitioners working from different information sources across multiple practice sites

Risk rating: Moderate

A number of examples were identified during the review where there was inconsistent persistence between key information categories for individual consumers. The processes followed during this review allowed for enhanced longitudinal linking of documents for individual consumers. This revealed in a number of cases that discrepancies existed in the information recorded in these documents, despite short time intervals between the posting of the documents to the individual's My Health Record.

In one example, across 12 months, 13 SHSs were uploaded by ten healthcare practitioners at eight different organisations for one consumer. When attributing the summaries to individual healthcare practitioners, consistency was observed in the information presented by healthcare practitioners of the same organisation. This is to be expected, as these clinicians work off the same local information sources. However there were differences in the recording of information between healthcare practitioners, even when that information was available in SHSs already uploaded. For example, there were differences in the recording of the consumer's allergy status in that one clinician in one practice noted adverse reactions to peanuts, latex and penicillin (no event description provided) while a different practice indicated the consumer had no adverse reactions.

This example indicates that the source of the inconsistency is in the quality of clinician entered information rather than a limitation within the My Health Record system. However it is also apparent that users may not be referring to previous SHSs created by other organisations as another information source to augment their existing information. Coupled with this and the frequency of uploads of SHSs, there is an indication that healthcare practitioners may be utilising the SHSs for the purpose intended by the ESs. This merits further discussion with appropriate professional bodies and clinical advisors, for consideration in future training and change management strategies.

Additionally, it could be the case that healthcare practitioners are unaware of the presence of the previous SHSs prior to uploading their document. The importance of reviewing an individual consumer's My Health Record prior to the posting of documents should be highlighted for healthcare practitioners to aid their clinical decision making processes.

Recommendation 4: Key agencies work together to enhance the training and understanding of healthcare practitioners in the appropriate use of the different document types within the My Health Record to support consumer care.

A further example was identified where a consumer was noted to have developed muscle pain while taking atorvastatin. An ES noted that rosuvastatin had been "ceased – the change has been made" against the change status column of the medication section. A SHS was posted within a minute of the ES, where no 'statin' therapy was listed in the current medication list and the atorvastatin adverse event was noted. A PBS report was created two months later for rosuvastatin which was then followed by a prescription record a further six months later for continuing therapy. All clinical documents were uploaded to the individual's My Health Record by the same clinician.

There are a number of hypotheses to explain the content of these clinical documents including:

- The rosuvastatin is replacing the atorvastatin and the "ceased" status in the ES may have been intended by the clinician to relate to the atorvastatin.
- The non-persistence of rosuvastatin in the SHS is due to the clinician not indicating that this is a long-term medication at the time of recording in the clinical information system, and therefore the systems has recorded it as a one-off prescription.

Further exploration of the possible reasons for these series of clinical documents relating back to clinician workflows would be beneficial in understanding the source of the inconsistencies.

Recommendation 5: NEHTA utilise the My Health Record test environment to test different clinician workflow processes to identify any possible sources for medications information presenting differently across systems.

Finding 7: Evidence was found of circumstances where an ES was posted very shortly after an SHS – most likely as part of the same consultation – and the information from the ES was not reflected in the SHS. Whilst this may have been intended, it appears more likely that a healthcare provider would intend the most up-to-date information to be in the SHS.

Risk rating: Minor

This review incorporated an enhanced ability to examine the flow of information uploaded for individual consumers. With this information, it was possible to see a number of circumstances where a SHS was uploaded, followed very quickly by an ES. It is reasonable to assess that these each occurred within a single consultation.

Where this sequence occurs, the implication is that, if there has been a change in medication therapy or additional diagnosis recorded in the ES, the SHS information becomes outdated as soon as it is uploaded. This observation suggests that this practice is unintended by the clinician, and is most likely explained by healthcare practitioners not being aware of the implications of the uploading sequence.

Recommendation 6: Key agencies work with professional colleges and, potentially, software vendors to develop appropriate training and education tools (e.g. through continuing professional development activities) and resources for healthcare providers to highlight the importance of posting an ES prior to a SHS.

Finding 8: There is room for improvement in the quality of information contained in the clinical documents as the information uploaded appears not to conform to the NEHTA standards

Risk rating: Minor

There is an overall sense that the My Health Record system is being populated with data that is created by a clinician for their own use, rather than for use and consideration by other healthcare practitioners and consumers. My Health Record information uploaded by healthcare practitioners will be of most use to other health professionals who do not normally have access to that information. Creating records and clinical documents with the understanding that the consumer and other healthcare practitioners will use them to inform clinical decision is likely to require both cultural and behavioural change.

A number of examples were identified where the curation of medication records appear to still require improvement. In these examples, multiple prescribing events continue to appear in a single medication history, resulting in duplicate drug records with the potential for dose duplication. Additionally, non-current medications appear to persist in medication histories, which may result in inappropriate re-prescription and potentially impacting clinical safety for the patient.

Test data continues to appear in the My Health Record system. This information could be misinterpreted by healthcare practitioners and consumers and thereby impact clinical safety and quality of care. The impact of inaccurate test data and documents can create assumptions with respect to issues that do not exist or the opposite case, where assumptions are made that the data contained in a test record is fictional when in fact it is not.

Recommendation 7: Key agencies work together with professional colleges to develop and implement appropriate training and education material for healthcare practitioners in utilising the My Health Record.

5.3. Workstream 3: Evaluation of the use of best practice clinical safety principles in the design and build of Release 5

Review approach

One of the foundational elements of rigorous and consistent application of best practice clinical safety principles in the design and build of new functional aspects of the My Health Record system is consultation with appropriate experts and the broader stakeholder community. Understanding the consultation process for Release 5 of the system was the primary purpose of this workstream.

For this review, the team undertook an initial workshop with key agencies (Department of Health and NEHTA) to understand the consultation processes followed for Release 5. We then interviewed selected key stakeholders from NEHTA, the Commission, Health and individual participants involved in the Release 5 process to gain their feedback on improvements for future releases.

Finding 9: The size of the stakeholder group was too large, and differing levels of understanding of the My Health Record system resulted in prolonged consultation for the Release 5 development process.

Risk rating: Minor

When undertaking the development of Release 5, stakeholder engagement activities (involving participants such as representatives of professional colleges and individual providers) were conducted to inform the development. This was welcomed by stakeholders.

During the review, however, the group was identified by a number of stakeholders as being too large. The number of people and their diverse positions and interests resulted in a protracted journey towards achieving the agreed outcome. The Department of Health noted that the stakeholder group was large due to the need for the model to adequately reflect the variations in clinical practice, patterns of use and the range of technologies in use.

Differing levels of understanding of the capabilities and functional architecture of the My Health Record system across the group also contributed to the prolonged consultation, although this issue ameliorated as the group became better informed.

Stakeholders felt the delays could have been somewhat mitigated by providing the group with key decision logs to take them on a journey of how decisions had been made for the release.

Recommendation 8: Consider whether a smaller stakeholder group with key representatives providing feedback from craft groups, professional associations and providers, can better support release consultations

Finding 10: Lack of clarity on My Health Record system technical constraints and the provision of only two use cases caused frustration amongst stakeholders

Risk rating: Minor

During the review, stakeholders reported that they were frustrated by technical constraints with the My Health Record system and felt that the constraints should have been more clearly articulated at the commencement of consultation on functionality. It was suggested

that more than two use cases should be made available to provide the stakeholder group with a deeper level of understanding on the complexities of the process.

Recommendation 9: An outline of current My Health Record system technical capabilities needs to be circulated to stakeholders prior to consulting on forthcoming releases

5.4. Workstream 4: Evaluation of the implementation status of the recommendations made in the third and fourth reviews

Review approach

The purpose of Workstream 4 was to perform a review of the progress made against the recommendations made in the third and fourth My Health Record system clinical safety reviews. Evaluation of the recommendations from the third and fourth reviews was undertaken independently of each other. With the exception of three completed recommendations from the third review, all other recommendations were noted to be in progress by the commentary and documented evidence provided by the relevant agencies.

Finding 11: Recommendations 1, 3 and 7 (of 15) from the third review have been completed while the remaining recommendations from the third and fourth reviews (6 recommendations) are at various stages of completion

Risk Rating: Moderate

Findings on completed recommendations from the third review

Recommendation 1: Workstream review and analysis of the issue of attribution of the IHI to My Health Records

This recommendation was based on an issue occurring when some calls from the My Health Record system to the Healthcare Identifier (HI) Service to validate Individual Healthcare Identifier (IHI) numbers were not being processed correctly. The HI Service has now been updated to ensure that the search functionality works as intended to return a correctly matched IHI.

Recommendation 3: Consider, in collaboration with professional colleges, how awareness of actions taken in creating clinical records could lead to unintended safety and quality issues

The Department of Health has funded both key agencies and professional bodies to develop and promote guidelines on electronic information exchange and data quality requirements for the My Health Record system. These guidelines are available for viewing by healthcare practitioners via the RACGP website as well as on the My Health Record website.

Recommendation 7: Development of a My Health Record test environment for healthcare practitioners and software vendors and associated education for healthcare practitioners

NEHTA and the Department of Health have made substantial progress in the creation of the test environment which is now available through the NEHTA “For Providers” website. It was reported that the NEHTA Board approved funding to support testing functionality as a key workstream. NEHTA was to launch the ‘on demand’ test environment on 1 July 2015.

Status of remaining recommendations

It is acknowledged that the key agencies have devoted considerable effort in the development of the Clinical Incident Management Framework (CIMF). This framework spans a number of the recommendations of the third and fourth clinical safety reviews and has required collaboration between the key agencies.

Documented evidence together with consultation with the key agencies indicated that despite the ongoing status of the majority of the recommendations, each are still tracking according to their intended time schedules.

Recommendation 10: Key agencies continue to address the outstanding recommendations from the third and fourth clinical reviews through periodic check points.

Significant effort has been directed towards the implementation of the recommendations from the third and fourth clinical safety reviews and no major obstacles or barriers were identified to the completion of the remaining recommendations.

Establishing periodic review or check points where all key agencies meet to assess progression against the recommendations will provide opportunity for discussion of overall achievement of the objectives of the recommendations.

Recommendation 11: Health and the Commission undertake regular reviews of clinical incident management processes against pre-determined metrics to assess impact and effect of the clinical incident management framework.

Assessing the impact and effectiveness of the clinical incident management processes and the potential introduction of the CIMF (clinical incident management framework) periodically into the future will assist the key agencies in further refining the framework. The framework will benefit from a continuous improvement cycle which will contribute to enhancing the quality and safety of the My Health Record system.

Recommendation 12: Ongoing funding for the My Health Record system should include funding for ongoing quality and safety activities to optimise the outcomes for consumers

Finding 12: Key agencies continue to collaborate with the implementation of the identified recommendations through appropriate governance and monitoring structures

Risk rating: Minor

This review found that significant progress has been made in the development of the CIMF and it was reported that it is on-track to be finalised in late-2015, with implementation spanning 2015 - 16 and beyond.

Each of the key agencies consulted as part of this review expressed their ongoing commitment to improving the clinical safety of the My Health Record system and progressing the recommendations of the previous reviews.

Recommendation 13: Key agencies continue to monitor and enhance the clinical safety of the My Health Record system through a proactive continuous improvement quality cycle.

6. Conclusion

The review team has identified 12 findings across the four workstreams undertaken for this review, resulting in 13 recommendations. There were no critical findings. Two of the findings have been ranked as being of moderate risk, eight as minor and two as unrated, in accordance with the risk matrix used for these clinical safety reviews. The findings highlight that the SHS document, which is often cited as the key clinical document (being a curated health summary of the person concerned), is presenting without any identified discrepancies when accessed across a range of secondary users' systems (e.g. pharmacists and hospitals). The review of 500 de-identified My Health Record records has also identified positive developments in that improvements seem to have been made following recommendations arising from the third and fourth clinical safety reviews. For example, no instances of leading zeros or floating decimal points were identified. Further no examples of incorrect attribution of dosages between multiple medications for a single consumer were present in the summary documents reviewed.

This review has identified areas where further improvements could be made to improve the overall clinical safety of the system. In particular, further detailed assessment surrounding the clinical utility and inclusion of the MBS and PBS data within the My Health Record system would be useful, from both a consumer and healthcare provider perspective. It is important that information uploaded and viewable through the My Health Record system aids clinical decision making processes. As it was found (based on those interviewed for this review) that few healthcare practitioners are utilising this data and the number of clinical documents uploaded to the system is increasing, the ongoing provision of MBS and PBS data may not be as important as originally identified in the initial stages following go-live of the My Health Record system.

Findings made through the review of de-identified records review also highlight the need for a focus on improving the quality of adverse reactions and medicines history information for consumers within the My Health Record system. It is recognised that this cannot be improved by technology nor by the system alone, but in collaboration with broader efforts to improve local data quality across contributing systems and greater awareness and training on using the My Health Record system as effectively as possible. This may be achieved through the key agencies collaborating with the professional societies in the development and delivery of education and training for healthcare practitioners in the use of the My Health Record system (e.g. continuing professional development modules). The focus of this should be on incorporating the My Health Record system into the workflow of individual healthcare practitioners to enhance the quality of information recorded for an individual consumer. This would contribute to further enhancing the clinical utility of the system, resulting in improved quality and safety across the care continuum for consumers.