

Fourth Clinical Safety Review of the Personally Controlled Electronic Health Record (PCEHR)

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

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1. Overview of findings

The key findings and recommendations from the fourth clinical safety review (review) of the Personally Controlled Electronic Health Record (PCEHR) presented in this report are based on the analysis of the qualitative and quantitative data collected across the three key review areas.

Within the three key review areas there were a total of ten findings. The findings have been classified according to the risk ratings developed for the first three reviews (a rating scale of critical, major, moderate, minor, minimum). Six findings were considered to be moderate and another three were classified as minor. The first finding was not rated as this finding was positive in nature. The ten key findings resulted in six recommendations for consideration. The key findings and recommendations are detailed below.

2. Background

The PCEHR is a nationally available electronic health record which can be accessed by consumers and clinicians to aid in clinical care and clinical decision making processes. Its intention is to provide an additional source of information, which compliments existing clinical information systems rather than replace them, enhancing the care clinicians are able to provide to health consumers. The number of consumer registrations for the PCEHR reached 1,664,136 in May 2014 and there are a small, dedicated number of clinicians uploading clinical documents into the PCEHR. The Australian Government and the jurisdictions have made a significant investment in recent times to establish a PCEHR system for all Australians who choose to register.

A clinical governance regimen has been put in place to oversee, monitor and report on clinical safety issues associated with the use of the PCEHR.

The Australian Commission on Safety and Quality in Health Care (the Commission) has been funded by the Department of Health (Health) to provide clinical safety oversight and to conduct a series of targeted reviews of the PCEHR System. The first three review reports have been completed and provided to Health. The first review report was completed in February 2013, the second June 2013 and the third in December 2013. The purpose of this program is to ensure the clinical safety of the PCEHR System, and support the Secretary of the Department of Health as the System Operator to deliver a PCEHR System which is both safe and efficient. Each review has examined different components of the System and assessed safety in terms of improving the quality and safety of clinical care.

3. Review objectives and scope

The objectives of this review as agreed by the PCEHR Clinical Governance Advisory Group (CGAG) centred around three key priority areas:

1. End-to-end investigation of the accuracy and data quality of electronic discharge summaries (EDS),
2. A review of a sample of de-identified PCEHR records, and

3. An evaluation of the implementation status of the recommendations made in the first three PCEHR clinical safety review reports.

This review builds upon the findings and recommendations from the previous three reviews.

4. Overall methodology

The approach was structured as per the three key areas of the review:

Review area 1: An end-to-end investigation of (EDS) included data analysis, site visits to three hospitals (across three jurisdictions) site visits to two general practices (in two jurisdictions).

Review area 2: Data collection and analysis of 102 de-identified PCEHR records was undertaken.

Review area 3: Reports outlining the status of recommendations from the previous three reviews were received from Health, the Department of Human Services (DHS) and the National eHealth Transition Authority (NEHTA). Teleconferences were then conducted with Health and NEHTA to discuss the reports and identify evidence to support the implementation of individual recommendations. A key agency workshop (Health, DHS, NEHTA, the PCEHR National Infrastructure Operator (NIO) and the Commission) was held to verify and agree the status of previous recommendations.

5. Key Review Areas

5.1 Review Area 1: End-to-end investigation of the accuracy and data quality of EDS

Review approach:

Three jurisdictions participated in an end-to-end review of the EDS. Specific consumer consent was sought to participate in the review which enabled the review of individual records in different clinical systems from both a hospital and general practice perspective. Stakeholder consultation was key to this review area.

Data was collected and analysed to identify any issues or inconsistencies in the presentation of information across the jurisdictions, and recommendations developed to address the issues.

Key finding 1: The review found that discharge summary information, in particular clinical information, was transferred accurately between the hospital clinical information system and the GP software system

Risk rating: -

The review found that EDS uploaded to the PCEHR were useful in enabling clinical decision making when consumers move between healthcare providers. Whilst it is important to note that the volume of records that were able to be reviewed as part of this review was low, the records examined demonstrated that information was accurately transferred from the hospital setting to general practice, and the intent of the information contained in the EDS

was retained. Specifically, clinical information was found to be accurately transferred between the hospital clinical information system and the GP software system.

Key finding 2: Information in the discharge summary varies between jurisdictions and is not displayed in any consistent order

Risk rating: Moderate

The EDS reviewed were all formatted and constructed to be consistent with the published standards. There is currently no standard format, however, for the presentation style and the order of presentation of patient information.

Each jurisdiction utilised a different clinical information system and had each developed a local template for their EDS, which led to different presentations of the information. While information is presented in EDS consistently within each jurisdiction, inconsistency between different jurisdictions and Information Technology (IT) systems may impact on the clinical utility of the PCEHR and clinicians potentially missing information when they are used to viewing information in another system or format. Differences in the presentation of information between jurisdictions and between GP software products may lead to confusion and has the potential to impact on clinical decision making.

Key finding 3: Terminology between the jurisdictions' discharge summaries and the GP software PCEHR view is inconsistent in some instances

Risk rating: Moderate

To complete the review, NEHTA eDischarge Summary Core Information Components data elements were used as a basis to transcribe and review the information in the jurisdictions' and PCEHR discharge summaries.

It was identified that this terminology can be inconsistent. Even subtle differences in terminology can lead to confusion for the reader, particularly when they are used to different terminology.

Key finding 4: Breadth of information presented in the GP software view is not consistent with the information presented in the jurisdictions' discharge summaries

Risk rating: Moderate

The analysis of the data identified instances where the general information contained within the discharge summary was missing or was presented in different formats when comparing the jurisdiction template to the PCEHR discharge summary as viewed through the GP software. For example, time was presented in 12 hour or 24 hour format and dates were presented in alphanumeric and numeric formats.

In some instances, the information provided in the GP view of the discharge summary was more comprehensive than the information provided in the jurisdictions' discharge summaries. In general it may be concluded that more information is provided in the GP software view of an EDS than the jurisdiction view of the EDS.

Key finding 5: Format of medications information across jurisdictions' discharge summary template and the GP view of the PCEHR discharge summary varies

Risk rating: Moderate

The review revealed that in general, terminology and the presentation of the information was consistent when viewing the same discharge summary through the jurisdiction's software and then the PCEHR view through GP software, however, the presentation of medications information varies. These variations include terminology for headings and by different displays between jurisdictions. It was also noted that different software interfaces are not necessarily consistent and create different views for the user. .. Inconsistencies between the terminology and presentation of medication directions may create confusion and miscommunication between clinicians and consumers. Similarly, incompleteness of information can also be misleading.

In general, when viewing a discharge summary the overarching aspiration would be to view information in the same order across different jurisdictional discharge summaries. It is recommended that consideration be given to how it may be possible to improve the standardisation of both the presentation of information and the order of information in clinical documents such as EDS.

Standardisation of the presentation of discharge information would also assist in improving usability for general practitioners and will increase user satisfaction with the system.

Recommendation 1: The Commission work with key agencies, jurisdictions, and peak clinical bodies to recommend a common presentation format for discharge summaries to the Australian Health Ministers Advisory Council (AHMAC).

5.2 Review area 2: A review of a sample of de-identified PCEHR records

Review approach

A sample of 102 de-identified records containing a range of clinical documents were analysed and assessed against published standards. Issues and inconsistencies were identified and recommendations formulated.

Key finding 6: The findings of this review have found no new issues since the third clinical safety review. Some issues continue to be evidenced in the data.

Risk rating: Moderate

Examination of the de-identified clinical documents revealed similar issues to those identified during the previous clinical safety reviews. Given the short time period between the completion of the third clinical safety review and the extraction of the data for this review it is unrealistic to expect to observe a measurable change in the data contained in the sample of clinical documents. As such the issues explained in this section of the report are intended to highlight the appropriateness and importance of continuing to implement the recommendations from the previous reviews.

The issues identified include:

- The continued presence of 'test' entries in live clinical documents,
- The transcription of a data item in one component to the data item in another component, and

- The consistency on the presentation of the information between the clinician desktop software and the PCEHR.

The continued presence of test data in the live clinical documents highlights the importance of the test environment which has been developed by NEHTA. We understand that a significant amount of work has already been completed in addressing this issue following the findings of the third clinical review.

We therefore recommend that NEHTA and the professional medical colleges continue to collaborate in developing the training and supporting materials for the PCEHR test environment. The ability for clinicians to interact with the test environment has the potential to reduce the number of live documents in individual records which do not add value to the safe clinical management of patients, as well as potentially improve the quality of the clinical information.

When looking at the transcription of data items, across both the Shared Health Summaries and Event Summaries, examples were identified where the ability to allow unstructured free text in the 'Dose Instructions' field creates the risk that ambiguous/inappropriate/abbreviated dose information can be entered. The potential for dose changes/errors and subsequent therapeutic failure/adverse events is therefore introduced.

Considering the development of standard dosage directions for high risk medications (particularly for the PINCH medications – Potassium Insulin Narcotics Chemotherapy Heparin) may assist in reducing the potential ambiguity in interpretation of dosage directions by subsequent clinicians. This is particularly true if no coding issues between the clinician desktop software and the PCEHR are identified.

Agencies are in the process of implementing, to various degrees, the recommendations to address these issues. For example, the NEHTA Clinical Usability Program (CUP) is working with both clinicians and software vendors to improve the user experience with the vendor products. As part of this it is recommended that the upload and presentation of medications is included as a key consideration. This program will also be able to reference the soon to be released National Guidelines for safer on-screen display of medications information being developed by the Commission.

It is recommended that formalised structures and processes be developed to enable the ongoing assessment and management of the PCEHR in assisting in the delivery of clinical care. The primary objectives of any such program being to create an efficient and transparent continuous quality improvement cycle that:

- facilitates appropriate feedback loops between the agencies,
- identifies and addressed an issues that arise, and
- takes a proactive approach to identifying and implementing initiatives to improve the quality of the PCEHR, based on good practice safety systems.

Recommendation 2: Key agencies continue to implement recommendations from previous clinical safety reviews and implement a formal program of continuous quality improvement for the PCEHR System.

Recommendation 3: *The Commission work with key agencies to promote the development of structured dosing directions for high risk medications, to minimise the instances of ambiguity in dosage directions.*

5.2 Review area 3: An evaluation of the implementation status of the recommendations made in the first three PCEHR clinical safety review reports

Review approach

Key agencies provided written reports and supporting evidence on the status of recommendations from the first three clinical safety reviews of the PCEHR. Stakeholders were consulted as part of this review.

Analysis of the recommendations made across Reviews 1 and 2 was undertaken together, based on the considerable overlap of the recommendations across the two reviews. It was noted that the majority of recommendations made in reviews 1 and 2 were complete. In total there were:

- 15 recommendations made in review 1 and
- 12 recommendations made in review 2.

With the exception of 3 recommendations all other recommendations were noted to be complete as supported by the commentary and documented evidence provided by relevant agencies.

Key finding 7: Recommendation 1 (review 1) and recommendations 1 and 4 (review 2) were outstanding

Risk rating: Minor

Below is a summary of the status of the outstanding recommendations from reviews 1 and 2. Whilst it was expected that these recommendations should be closed out, progress has been made and specific steps have been planned, which appear reasonable in the circumstances.

Recommendation 1 (review 1): *NEHTA finalise, implement and review the tools, templates and processes to ensure that they are aligned with PCEHR core product development, design and implementation activities.*

It was noted that the reviewed Clinical Safety Management System has been extended based on external recommendations. There is a continual Quality Management process to modify processes and related documentation and templates to reflect changes in organisational structure and product development.

Recommendation 4 (review 1): *A process of inter-rater reliability in the classification of clinical risks is established within NEHTA.*

Recommendation 1 (review 2): *The process of inter-rater reliability in the classification of clinical risks is evaluated by NEHTA following Release 4.*

For the above two recommendations, it was determined that the inter-rater reliability evaluation be performed as part of Release 5 instead of Release 4, as new clinical content in Release 4 is limited.

Key finding 8: On the whole recommendations from review 3 were a work in progress which was expected given the nature of the recommendations and the timeframe since the Third Review

Risk rating: Minor

Consultation and evidence indicated that agencies are currently working towards the implementation of recommendations from the third review and these are on track. It should be noted that while some recommendations were considered to be complete these are ongoing in nature and require continual monitoring and further improvement as required.

Recommendation 4: *Agencies continue to work towards the implementation of outstanding recommendations from reviews 1, 2 and 3.*

Key finding 9: A number of challenges associated with the implementation of recommendations were identified

Risk rating: Minor

Throughout the review a number of challenges associated with the implementation of the recommendations became evident. In the main, these challenges were common across many if not all the key agencies. The challenges relevant to the implementation of recommendations were discussed at the key agency workshop. The challenges faced fall into the broad categories below:

- vendor interpretation of conformance,
- ongoing program funding for continued implementation,
- legislation constraints including ability to review 'live' records and testing in a live environment, and
- current governance arrangements around the coordination of incident management.

Key finding 10: There is an ongoing stewardship and accountability function required by the key agencies to ensure that the recommendations implemented are monitored and maintained and further improvements made as required

Risk rating: Moderate

The implementation of effective governance structures across numerous agencies has been a key challenge confronted whilst operating the PCEHR System. Agencies have worked well together to improve governance, specifically around the incident management process. It should be acknowledged that the key agencies involved with the PCEHR have a strong commitment to improving the clinical safety of the PCEHR and addressing and implementing recommendations from previous reviews.

There are, however, still areas for further improvement. The goal now is to strike a balance between proactive system improvement, responding to issues as they arise, and ensuring future releases are built to safety and quality standards that align with good practice.

Of high priority for improvement is how agencies could work more closely together in coordination of incident management. Discussion highlighted that contractual arrangement between parties are an obstacle.

A second high priority consideration is how best to shift governance and inter-agency discussions from being focussed mainly on issues as they arise, to also proactively considering risks and issues that could be proactively addressed.

As is the case in most programs of work, continuous improvement is ongoing and does not simply finish when a recommendation has been implemented. The success of the PCEHR will depend on ensuring that there are mechanisms in place to support sustainability.

Moving forward, it is critical that the key agencies involved in operating the PCEHR continue to have an accountability role for the overarching safety and quality improvement of the PCEHR, with the focus on taking a proactive approach to identifying opportunities for improvement.

Recommendation 5: *Key agencies consider their ongoing role and accountability for the continuing clinical safety of the PCEHR and proactively address the continuous quality improvement of the PCEHR.*

Key finding 11: **Release 5 of the PCEHR is planned to include pathology and diagnostic imaging reports. Given the experience of previous releases, consideration should be given to how best to maximise quality and clinical utility, in conjunction with agreed safe standards.**

Risk rating: Minor

To date the focus of the PCEHR build has been primarily on the technical design of the System. An opportunity now exists for best practice clinical usability and utility to be a feature of future launches and embedded in the product development process. With Release 5 currently planned for late 2014, there is an opportunity for the release to include Pathology and Diagnostic Imaging functionality, based on insight into how best to deliver quality and useable health information. It is recommended that the key agencies discuss and agree on developing best practice documents for these functionalities.

Recommendation 6: *The design for pathology and diagnostic imaging incorporate specific actions designed to maximise quality and clinical utility.*

6. Conclusion

The fourth clinical safety review of the PCEHR did not find any critical or major issues related to the clinical safety of the documents viewed. Based on the findings of this review it appears that the clinical documents transferred through the system are done so accurately and that the PCEHR System is operating as intended.

In some respects, this outcome is not surprising: some issues were quickly identified and dealt with in the course of operations, and others elicited as part of the safety reviews. It is possible that as a system becomes more “business as usual” clinical safety issues are less likely to occur in existing functionality, but it is also possible that as use changes (for example with the introduction of an opt-out model) that further issues may be identified. Regardless, as greater use is achieved, ongoing and continual improvement of the clinical utility and quality associated with the use of the PCEHR will be required. This may help shape thinking on any future role for the Commission focussing upon:

1. Ongoing quality improvement that impacts upon utility of the record in supporting effective clinical care.
2. Investigation of clinical safety issues where they arise.
3. Proactive investigation and review of major new functionality (e.g. diagnostic imaging) or significantly changed functionality.