AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Second Clinical Safety Review of the Personally Controlled Electronic Health Record (PCEHR) June 2013

Undertaken by KPMG on behalf of

Australian Commission on Safety and Quality in Health Care

Contents

1. Overview of findings

The Second Clinical Safety Review of the Personally Controlled Electronic Health Record (the Second Review*)* was conducted in June 2013. Across 16 review areas, 16 findings were made and these were risk stratified as six major, one moderate, four minor and five minimum findings. As a result of these findings, a total of 12 recommendations were made.

There has been demonstrable progress with implementation of some of the recommendations from the First Review. There has been evaluation, refinement and endorsement of supporting documentation and governance structures with greater alignment between agencies. The Programme Committee Charter has been implemented and a clinical utility program is being established to provide assurance on the end useability of products, including the PCEHR.

Major risk findings for the Second Review include the absence of a mechanism for joint review of clinical risk. There is a need for a PCEHR worksite test and training environment and the potential clinical safety and staff privacy risks associated with the absence of a training environment has been raised. Urgent strategic and financial evaluation, including a conceptual design and development of a business case, will be required. Identification of clinical incidents is not possible through the centralised telephone number and there is variable awareness of the Department of Health and Ageing (DoHA) clinical incident management processes by system users.

The findings and recommendations from the Second Review will be utilised to inform the priorities for ensuring clinical safety for the operation of the PCEHR system.

2. Background

The Australian Government has made significant investment in the establishment of a Personally Controlled Electronic Health Record (PCEHR) system for all Australians who choose to register. The PCEHR is intended to support the better provision of access to health information relating to consumers through:

- helping overcome the fragmentation of health information
- improving the availability and quality of health information
- reducing the occurrence of adverse medical events and the duplication of treatment
- improving the coordination and quality of healthcare provided to consumers by different healthcare providers.

The Australian Commission on Safety and Quality in Health Care *(*the Commission*)* was contracted by the Commonwealth Government in order to establish an independent Clinical Governance Advisory Group (CGAG) and a clinical safety audit program (the program) under the guidance of CGAG. The purpose of this program is to ensure clinical safety for the operation of the PCEHR system and to support the delivery of a safe and efficient PCEHR system.

The Commission conducted the Second Review in June 2013, as part of the series of four planned reviews of the PCEHR.

3. Review objectives and scope

In February 2013, the Commission conducted the First PCEHR Clinical Safety Review (the First Review) to assess the implementation of the PCEHR. This review assessed progress against earlier recommendations generated from a review of the National eHealth Transition Authority's (NEHTA) clinical safety management (the *Report*), and assessed the clinical incident management process for the PCEHR.

The purpose of the Second PCEHR Clinical Safety Review was to examine the progress made against the 16 recommendations from the First Review, across five specific areas including:

- clinical safety management tools
- risk registers
- Compliance, Conformance and Accreditation (CCA) and V model processes[1]
- processes to manage clinical safety across and within organisations
- clinical incident management.

A detailed examination of the PCEHR clinical incident management and investigation processes was also undertaken.

4. Overall methodology

The Second Review included a document review of policies, processes and supporting tools and templates. Consultations were conducted with key stakeholders from NEHTA, DoHA, the Department of Human Services (DHS), the National Infrastructure Operator (NIO), health service providers and a jurisdictional Department of Health. NEHTA, DHS and DoHA were requested to provide documentation to support their responses with respect to their progress and activity undertaken to address the findings of the First Review. The findings outlined in the Second Review have been risk rated, in order to stratify the findings.

5. Key review areas

Sixteen areas have been assessed as part of the Second Review and the findings risk stratification (rating) and recommendations will described in this section.

5.1 Review Area 1: Implementation of clinical safety management tools

Audit approach

The First Review noted that NEHTA's Clinical Safety Management System (CSMS) had been reviewed, with rationalisation of documentation requirements. Documents were available to provide guidance on clinical safety management processes

[1] The V Process Model is an approach to software development that integrates verification and validation activities throughout the development lifecycle. These activities help in discovery and correction of defects in an application and in assessing if an application is ready for operational use.

throughout product design, development and implementation activities including supporting tools and templates.

There is a process for the development, ratification, publication and dissemination of tools and templates, however, at the time of the review, the full suite of tools, templates and processes had not been finalised, with implementation therefore incomplete.

The First Review put forward two recommendations:

- tools, templates and processes be finalised, implemented and reviewed to ensure that they are aligned with PCEHR core product development, design and implementation activities
- ensure that there is a process to collect feedback about the effectiveness of the new suite of materials and undertake further refinement based on this feedback where applicable.

Findings

The clinical safety tools were revised and endorsed by NEHTA's Clinical Governance Committee and presented to the NEHTA Executive in March 2013. The Executive made several recommendations for improvement. It is expected that there will continue to be improvements and amendments to the tools and templates following implementation.

NEHTA has identified that the application and utilisation of the new tools has assisted in raising issues earlier in the development cycle than previously may have occurred. The new tools have highlighted risks and issues earlier, which, in turn, have made the final safety cases easier to develop (and be accepted) at the time of product release.

Risk rating: Minimum

Recommendation: *No recommendation was identified for Review Area 1.*

5.2 Review Area 2: Assessment of clinical safety management tool effectiveness

Findings

As identified in Review Area 1, the tools and templates are subject to modification following their application in the operational setting. Positive feedback was received from various stakeholders about their application in the development and release cycle for new products.

Whilst no formal mechanism for feedback had been established, direct feedback through a governance committee and working group has taken place. It is expected that the current corporate governance processes for feedback on, and modification of, all tools and templates, and the involvement of the Executive in the endorsement process, is sufficiently robust to ensure ongoing review and modification of clinical safety tools as required.

Risk rating: Minimum

Recommendation: *no recommendation was identified for Review Area 2.*

5.3 Review Area 3: Evaluation of the CSMS to ensure identified risks have mitigating strategies and that these strategies are implemented

Audit approach

New processes and systems had been put in place to address the issue of concurrent risk registers. This has included the establishment of a clinical risk classification matrix, which defines both the consequence and frequency of risks. A new process to support the integration of clinical risk assessment into broader risk identification, analysis and mitigation activities in other areas, such as Conformance, Compliance and Accreditation (CCA), or design units, has been put in place. At the time of the First Review, it was unclear as to the extent to which these processes were effective in supporting the management of clinical risks. There had also been no inter-rater reliability testing of the new matrix to ensure consistency in the classification of risks.

The First Review made three recommendations in relation to the use of risk registers to:

- evaluate the newly developed CSMS to ensure that identified risks have mitigating strategies and that these mitigating strategies are implemented
- establishment of a process of inter-rater reliability in the classification of clinical risks
- a process of shared access to and joint review of PCEHR clinical safety risk registers be established between partner agencies as a priority.

Findings

The CSMS is primarily focussed on activities undertaken in the process of development, building and testing, and deployment of software that results in a mitigation of identified risks. The Clinical Safety Unit (CSU) provides advice to software development teams and to the Operational Management Committee (OMC) for decisions about mitigation effectiveness and residual risk. It is acknowledged that not all mitigating strategies are within the direct influence or management of NEHTA, but may reside with the System Operator or in fact with individual clinicians. Whilst the CSMS may nominate mitigation strategies, it is not within the remit of NEHTA to implement or monitor their effectiveness.

There is a scheduled review of the CSMS and planned update of all documented risks, identification of new risks and associated mitigation strategies as part of Release 4 of the PCEHR. This review is also planned to occur as required for other product development and release activities.

Risk rating: Minor

Recommendation: *see recommendation 2.*

5.4 Review Area 4: Establishing a process of inter-rater reliability in classifying clinical risks

Audit approach

As identified in Review Area 3, there was a need to implement a process for inter-rater reliability testing of the new matrix to ensure consistency in the classification of risks (noted as a recommendation in the First Review).

Findings

There is no documented process for inter-rater reliability in the classification of clinical risks. Working group meetings allow discussion regarding risks and classification of risks. This provides a valuable mechanism by which convergence in the classification of risks can be reached. NEHTA has outlined planning for the development of draft processes for formal inter-rater reliability testing for Release 4 of the PCEHR.

Risk rating: Minimum

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

5.5 Review Area 5: Shared access to and joint review of clinical safety risk registers between partner agencies

Audit approach

As the System Operator, DOHA is responsible for the management of the PCEHR Program and, in this capacity, holds overall accountability for its delivery, including clinical safety. A comprehensive clinical risk register is maintained by NEHTA, however, as outlined in Review Area 3, not all the mitigating strategies are under its control. Given the multiple partner organisations responsible for the development of, communication about and monitoring of all risk mitigation strategies, the importance of a shared approach to risk mitigation is paramount.

Findings

The Second Review notes that there has been no progress on the recommendation for shared access to, and joint review of, PCEHR clinical safety risk registers between partner agencies. A mechanism by which a joint review of clinical risks identified on risk registers occurs as matter of routine has not been established.

During the conduct of this review, a residual risk (i.e. a risk still present once the project was completed) with the date order in which rendered documents appeared in the PCEHR was identified by two health care organisations.

Risk rating: Major

Recommendation 2: *As a priority, a process of shared access to, and joint review of, PCEHR clinical safety risk registers be established by partner agencies. This joint review should include identifying the agency responsible for the risk and any mitigating strategies and monitoring required as a result of the risk identification.*

5.6 Review Area 6: NEHTA evaluate the newly developed Programme Committee Charter (PCC)

Audit approach

Prior to the First Review, a PCC for managing all aspects of the Work Programme was developed and implemented by NEHTA. Clinical safety has been integrated into the charter to ensure that design and implementation activities include an integrated clinical safety approach.

The First Review recommended that, given its significance in the governance of the program, the newly developed Programme Committee Charter should be evaluated once it had been fully implemented.

Findings

At the time of the Second Review, the Programme Committee Charter was being evaluated, as were all risk management practices across NEHTA. Whilst there has been no formal evaluation of the Programme Management Committee (PMC) as part of this process, anecdotal information indicates that the PMC has created a mechanism for more uniform reporting on project progress and project risks. Documents that are developed for the PMC are forwarded to the NEHTA Board including a 'watch list' to facilitate Executive involvement (where required) in critical aspects of projects during the project life cycle. Whilst the terms of reference (TOR) of several committees have been reviewed in line with the implementation of the Programme Committee Charter, it is understood that the review of the TOR of the Clinical Governance Committee has not been finalised.

Risk rating: Minor

Recommendation 3*: NEHTA continue to review the terms of reference of the Clinical Governance Committee in line with the new Programme Committee Charter.*

5.7 Review Area 7: NEHTA progress the development and implementation of a PCEHR work site test environment

Audit approach

The First Review made a recommendation for development and implementation of a PCEHR work site test environment to undertake simulation testing and training to understand the implications of the PCEHR on work flow and clinical service delivery.

This could address the reported limitations in the current testing environment of the software, which does not allow testing of a large number of sample patients with complex profiles and multiple shared health summaries. The limited test environment has meant that the ability to run scenarios and test scripts on multiple test clients may result in failure points not being identified, except in real cases in the production environment. In addition, the current legislation does not allow for complex 'dummy' patient records to be created and tested in the full production environment.

Findings

The Second Review identified that there has been little progress on the recommendation to implement a PCEHR work site test environment.

In addition to the limitations in the test environment, there is no training environment which mirrors the production environment. This has resulted in situations where system provider, clinical and administrative staff register and utilise their own PCEHR in order to demonstrate functionality to General Practitioners (GPs) which raises privacy implications. PCEHR call centre operators were noted to have not received training in the PCEHR production environment.

An end-to-end testing environment has been developed, which provides the ability to view another endpoint, i.e. what a product (e.g. a discharge summary) might look like elsewhere (e.g. in a GP's software). However, it is not sufficient to model the production environment of the PCEHR, which would require the development of a much more sophisticated environment.

In order to progress the development of a PCEHR test environment, a scoping paper was prepared in May 2013. It is acknowledged that a test environment, which mirrors the functionality of the production environment, has financial implications for development and implementation. However, its importance in simulation testing and training, implications on clinical workflow and clinical safety require ongoing strategic and financial evaluation, including a conceptual design and development of a business case.

Risk rating: Major

Recommendation 4: *NEHTA progress the development and implementation of a PCEHR work site test environment in order to undertake simulation testing and training in order to understand the implications of the PCEHR on work flow and clinical service delivery.*

5.8 Review Area 8: NEHTA risk register include mitigation strategies for time periods of increased volume

Audit approach

The First Review identified concerns regarding the ability of the testing environment to support the requirements for development, end-to-end testing and deployment phases as the volume increased, resulting in a recommendation for the development of mitigation strategies in the event of periods of increased volume.

Findings

The risk register has been updated to include strategies for time periods of increased volume related to product release. Processes are in place to identify forward adoption milestones in relation to new releases to assist with planning for surge capacity and supporting increased peaks in activity. Risk mitigation strategies have been documented and include communication with both product owners and user communities in order to support forward planning. In addition, provision has been

made to roster additional staff immediately following a new release or when a new vendor is due to connect to the system.

Risk rating: Minimum

Recommendation: *No recommendation was identified for Review Area 8.*

5.9 Review Area 9: Finalise and evaluate the draft Incident Management Framework and Response Plan for the PCEHR

Audit approach

In response to an earlier recommendation to formalise processes to manage clinical safety across the partner organisations involved in the implementation of the PCEHR, a draft Incident Management Framework and Response Plan was developed. The First Review noted that this draft plan outlined both DoHA's and each partner agency's requirements for incident management. It also raised concerns in relation to the role of NEHTA*'s* Clinical Leadership and Engagement Unit (CLEU). Prior to implementation, the CLEU is required provide sign-off for the release of products. This process had not been formalised however, and there had been instances in which clinical lead sign off for software release had been withheld to ensure that issues were resolved.

The First Review recommended that, as a priority, the draft Incident Management Framework and Response Plan for the PCEHR be finalised and the processes be evaluated via scenario testing following implementation.

Findings

The Incident Management Framework and Response Plan for the PCEHR (the Framework) has been finalised and endorsed. At the time of the Second Review, five clinical safety incident referrals had been actioned in accordance with the Framework, which included an assessment of the potential clinical safety impact and potential controls and mitigations.

Whilst the Framework has been endorsed, and has been actioned in relation to the five reported clinical incidents, the processes have not been evaluated. Scenario testing, and a review of the processes outlined in the Framework, will be important to determine the robustness of the processes for clinical safety of the PCEHR.

Risk rating: Minor

Recommendation**:** *see recommendation 11.*

5.10 Review Area 10: Review of the TOR for the PCEHR Clinical Safety Officers Working Group

Audit approach

The PCEHR Clinical Safety Officers Working Group has been established to collect, discuss and document clinical safety issues that have inter-agency dependencies.

The Working Group activities facilitate regular discussions between the agencies to inform CGAG and System Operator deliberations.

Findings

At the time of this Second Review, the fourth meeting of the PCEHR Clinical Safety Officers Working Group was scheduled to be held. A review of the TOR will be undertaken after the sixth meeting, expected to occur prior to end of calendar year 2013.

Risk rating: Minimum

Recommendation 5: *The TOR for the PCEHR Clinical Safety Officers Working Group be reviewed after six meetings, or in December 2013, whichever comes first.*

5.11 Review Area 11: Formal process for Clinical Lead sign-off of software releases

Audit approach

A CLEU has been established to ensure clinical safety during product implementation by authorising the clinical release of products.

At the time of the First Review, this process had not yet been formalised, and there had been instances in which authorisation for software release had been withheld in order to ensure issues were resolved. The roles of the Clinical Leads had also been articulated, however, this was not widely communicated. It was recommended that a formal process for the sign off of PCEHR software release by the CLEU be documented to ensure roles and responsibilities are clearly articulated.

Findings

The roles and responsibilities of Clinical Leads were formalised in March 2013. Clinical Leads are members of a working group that is responsible for formal sign off on Clinical Safety Case Reports (CSCRs). The CSCRs include a summary of recommendations on the release of software. Documentation to support an end-to-end process for Clinical Leads sign off has not been finalised. It was noted that although Clinical Leads provide a sign off prior to release, the Clinical Safety Case Report had not been provided for Release 3 of the PCEHR, several weeks following the go-live date.

The development of a Clinical Utility program to provide assurance on the end usability of products, including the PCEHR is being explored. It is anticipated that the program will result in the development of a report, similar to the CSCR, to provide sign off for both the safety and useability of software. A single clinical sign-off process is being developed that includes consideration of clinical safety, clinical functional assurance and adoption, benefits and change.

Risk rating: Moderate

Recommendation 6: *NEHTA continues to explore the development of the Clinical Utility program.*

Recommendation 7: *A formal process for the sign off of software release by the CLEU be documented to ensure roles and responsibilities are clearly articulated.*

5.12 Review Area 12: Alignment of DOHA and NEHTA clinical incident management documents for the PCEHR

Audit approach

The First Review examined the processes in place for the identification and management of clinical incidents. Available documentation was reviewed for alignment and adequacy to support clinical incident management processes.

A number of anomalies in content, relating to incident definition, incident classification and incident resolution were noted. Whilst assessed as not significant, these anomalies demonstrated the need to further align processes across partner organisations.

Findings

A gap analysis has been conducted to ensure consistency in definitions, clinical incident classification and risk ratings across a range of documents. A formal method for clinical incident investigation has not been documented, however there are a number of existing methods to identify root causes and the development of recommendations that can be used.

Risk rating: Minor

Recommendation: *See recommendation 11.*

5.13 Review Area 13: Update of 1800 PCEHR1 complaint script to include a clinical incident scenario

Audit approach

The First Review raised concerns regarding the lack of call centre complaint scripts to support call centre staff in managing and directing complaints related to clinical safety issues. For example, if a consumer called with a concern about a clinical safety issue, they would need to use the specific term ‘clinical safety’ in order to trigger an escalation of the complaint. Whilst it was unlikely that a health service provider would contact 1800 PCEHR1 to raise a concern, call centre staff could be unaware of how to escalate the issue.

Findings

The Framework has been finalised to include a definition of a clinical incident. However, without a suite of complaint scenarios and training in clinical incidents, the 1800 PCEHR1 call operators may still not recognise clinical safety issues. The need for complaint scripts to include clinical incident scenarios was highlighted during the course of the Second Review.

Additional training is also required to educate call operators on clinical incident scenarios.

The purpose of the 1800 PCEHR1 telephone number, as the primary point of contact for all issues, including clinical safety concerns of clinicians and consumers, is not clearly defined or understood, with variable knowledge amongst system providers of the existence and/ or purpose of the number.

Risk rating: Major

Recommendation 8: *The 1800 PCEHR1 complaint script continue to be updated to include a PCEHR clinical incident scenario. In addition, training for telephone operators in 1800 PCEHR1 to be updated to include additional PCEHR clinical incident scenarios.*

Recommendation 9: *The role of the 1800 PCEHR1 telephone number as the primary point of notification of all clinical safety and incident issues be clarified and broadly communicated to system users.*

5.14 Review Area 14: Ensure the process for notification of PCEHR clinical safety concerns is clearly outlined in clinician information packs for PCEHR registration

Audit approach

When clinicians register for the PCEHR, they receive an information pack which includes guidance about how to make a complaint. The First Review recommended that the information pack be revised to ensure processes for clinical safety concern notification were clearly outlined.

Findings

As outlined in Review Area 13, there is variable understanding by system users and providers about the purpose of the 1800 PCEHR1 telephone number. Information distributed to system providers states that the first point of contact for PCEHR issues is the software vendor. Clinician reference materials need to be made consistent. System users do not receive information regarding the clinical incident management process in DoHA. The information distributed to clinicians is currently under review by DoHA, and NEHTA will be consulted during the review to ensure consistency.

Risk rating: Major

Recommendation 10: *The DoHA and NEHTA information packs for clinicians registering for the PCEHR be reviewed and aligned in order to ensure the process for notification of PCEHR clinical safety concerns is clearly outlined.*

5.15 Review Area 15: Interagency scenario testing of PCEHR critical incident management processes

Audit approach

At the time of the First Review, the critical incident management process remained untested, and the need to undertake scenario testing of the process and determination of a clinical incident management investigation method was identified as a priority.

Findings

A facilitated clinical incident process mapping workshop was conducted during the course of the Second Review in order to undertake comprehensive end-to-end mapping of the clinical incident management processes. The findings are as follows:

- Terms such as 'clinical incident', 'near miss' and 'clinical safety hazard' are still not consistently interpreted.
- Notification processes are inconsistently defined, call operators are not trained in clinical incident scenarios and there are multiple sources through which a trigger may be notified.
- Reported issues are classified as 'technical', even though they may have clinical safety implications. A matrix is used to assess risks, however classification may be inconsistent given that assessment of risk is not always undertaken by clinical staff.
- Whilst processes are in place to investigate incidents, there is no formal method for clinical incident investigation, nor expected timeframes for investigation conclusion.
- There is a lack of clarity regarding the obligation that individuals, agencies and system users have to participate in incident investigations.
- System activity data could be used proactively, to identify clinical incidents, given the likelihood of incomplete data capture through formal notification processes.

Risk rating: Major

Recommendation 11: *Interagency scenario testing of clinical incident management processes for the PCEHR, including notification, stratification, escalation, investigation, and development of recommendations be undertaken as a priority in order to address identified process gaps.*

5.16 Review Area 16: Development of a reporting template for PCEHR clinical safety incidents to CGAG to access expert clinical advice

Audit approach

The First Review identified the need to develop a template for reporting PCEHR clinical safety incidents to CGAG to facilitate access to expert clinical advice.

Findings

The Second Review found that a template has not been developed in order to report PCEHR clinical safety incidents to the CGAG. A variety of PCEHR functionality information is collected and, whilst this information may not specifically include clinical incidents, some of the information could be indicative of potential clinical risk and, as such, could be aggregated into a report to CGAG. There is also potential for clinical risk associated with clinician access to information resulting from system outages, document upload failures and document rendering issues

Incident summary documents and Clinical Safety Service Incident Assessments (CSSIAs) have been created following the five reported incidents. These include an assessment of the potential clinical safety impact and potential controls and

mitigations. The information in these documents could also be collated and reported to CGAG.

Risk rating: Major

Recommendation 12: *A reporting template be developed for reporting selected PCEHR clinical safety incidents, and aggregated system information to the CGAG in order for expert clinical advice to be accessed.*

6. Conclusion

There has been demonstrable progress with implementation of some of the recommendations from the First Review. There has been evaluation, refinement and endorsement of supporting documentation and governance structures with greater alignment between agencies. The Programme Committee Charter has been implemented and a clinical utility program is being established to provide assurance on the end useability of products, including the PCEHR.

The findings and recommendations from the Second Review will be utilised to inform the priorities for ensuring clinical safety for the operation of the PCEHR system. Progress against the recommendations will be assessed as part of the Third Review.