

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

February 2013

Undertaken by KPMG on behalf of

Australian Commission on Safety and Quality in Health Care

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1. Overview of findings

The First Clinical Safety Review of the Personally Controlled Electronic Health Record (the First Review) was conducted in February 2013. Across the 10 review areas, 10 findings were made and these were risk stratified as four moderate, two minor and four minimal findings. As a result of these findings, a total of 16 recommendations were made.

At the time of the First Review, governance arrangements and processes have been documented, with the majority of documents either in draft, or ratified and recently implemented. In addition, the clinical incident management process remains untested, and the need to undertake scenario testing of the process and determination of a clinical incident management investigation method has been identified as a priority. Other recommendations related to the need to finalise supporting documentation and governance arrangements, and the need to evaluate processes over time.

The findings and recommendations from the First 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 First Review in February 2013, as the first of a series of four planned reviews. This report will describe the first, in a series of four clinical safety reviews for the PCEHR.

3. Review objectives and scope

In May 2012, prior to the First Review, the Commission undertook a review of the National eHealth Transition Authority's (NEHTA) clinical safety management (the Report). This was undertaken to assess the clinical safety management approach to

implementation of the PCEHR by the organisation responsible for supporting eHealth solutions and initiatives.

The Report found a number of issues including the use of risk registers, clinical safety assessment processes, documentation and roles and responsibilities in relation to the PCEHR, and resulted in nine recommendations made. The recommendations are grouped into the following categories:

- clinical safety management tools
- risk registers
- clinical safety management processes in the PCEHR system
- inter-agency clinical safety management processes.

The purpose of the first PCEHR clinical safety review was to examine the progress made on the nine Report recommendations. An additional area for review was requested by the CGAG. This was a review and assessment of the clinical incident management process for the PCEHR.

4. Overall methodology

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

5. Key review areas

Ten areas have been assessed as part of the First Review and the findings, risk stratification (rating) and recommendations are described in this section.

5.1 Review Area 1: Clinical safety management tools

Audit approach

Implementation and monitoring of the PCEHR system requires a comprehensive clinical safety program that includes processes to investigate the occurrence of clinical incidents. A recommendation arising from the Report was the need to demonstrate rationalisation and refinement of the suite of clinical safety management process tools that aligned with product development phases for PCEHR.

Findings

Guidance documentation supported by tools and templates have been developed and implemented to reduce duplication and complexity and heavy time burden. Notably, documentation articulates how clinical safety issues are linked and integrated into the system design, development and implementation process. These include:

- Overview of the Clinical Safety Management System
- Managing Clinical Safety Requests.

A process has been established for the development, ratification, publication and dissemination of tools and templates to mitigate the risk of tool development that is duplicative in nature or developed in isolation. At the time of the review, the full suite of tools, templates and processes had not been finalised, with implementation therefore incomplete.

Risk rating: Minimum

Recommendation 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.*

Recommendation 2: *NEHTA to 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.*

5.2 Review Area 2: Use of risk registers

Audit approach

Risk registers are an important tool for identification and monitoring of clinical risk. The Report identified that there were issues with systems that rely on a qualitative (and therefore variable) assessment of risk. In addition, multiple registers were found to be in use which raised the possibility that issues would not be transferred from one source to another. Formal feedback mechanisms and documentation of activities to mitigate risk were identified as needing improvement. This included a need for clarity of responsibility for identifying, actioning and monitoring identified risks. A recommendation was made to review the use of concurrent risk registers to enable more streamlined risk mitigation, issue management, escalation and resolution, and minimisation of fragmented recording and assessment of hazards.

Findings

In response to this recommendation, a dedicated Clinical Safety Management System (CSMS), supported by a specific clinical risk classification matrix was implemented. The new matrix defines both the consequence and frequency of risks as well as enabling a more detailed means of developing recommendations arising from identified risks.

A new risk register process has been established that requires working group review to enable clinical and technical consideration and development of actions to address or mitigate risk. At the time of the review, processes were relatively new and were not yet able to be evaluated.

Risk rating: Minor

Recommendation 3: *NEHTA evaluate the newly developed CSMS to ensure that identified risks have mitigating strategies and that these mitigating strategies are implemented.*

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

Recommendation 5: *As a priority, a process of shared access to and joint review of PCEHR clinical safety risk registers be established between partner agencies.*

5.3 Review Area 3: Conformance, Compliance and Accreditation (CCA) and V model processes' contribution to clinical safety management

Audit approach

A range of clinical safety management processes have been established across product design, development and implementation phases of the PCEHR system implementation. This included CSMS as the core system, as well as the CCA and V model¹ processes.

The Report noted that the CCA and V model processes enabled clinical consultation to inform the requirement analysis and specification processes, and that technical and behavioural testing occurred to identify risks (including clinical risks). At the time however, the CCA and V model processes were not subject to assessment or verification. This gave rise to the recommendation to verify the consistent application of the CCA and V model processes, with respect to their contribution to clinical safety management.

Findings

Since the Report in May 2012, changes have been made to ensure that there is a process for clinical consultation and endorsement of requirement analysis and specifications. This has included the establishment of a new Programme Committee Charter for managing all aspects of the Work Programme being delivered through approved projects. Clinical safety is integrated into the charter to ensure all aspects of design and implementation include an integrated clinical safety approach.

It is acknowledged that during release waves, risk can increase with integration into existing software, system utility, handover between processes and end user education. Test scripts integrating clinical safety components have been developed and modified for each new release. Capability for connecting systems via gateways to download and render documents from the PCEHR, and send Discharge Summaries simultaneously to other IT systems and the PCEHR were being developed. Concerns were raised regarding the ability of the testing environment to support the requirements for development, end to end testing and deployment phases as the volume increased.

It was felt that patient safety implications would need to be considered with each release of the PCEHR and that an additional work site test environment to understand the implications on work flow for health service providers could serve to mitigate risk.

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.

Risk rating: Moderate

Recommendation 6: *Given its significance in the governance of the program, NEHTA evaluate the newly developed Programme Committee Charter once it has been fully implemented.*

Recommendation 7: *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.*

Recommendation 8: *The risk register include mitigation strategies for time periods of increased volume, e.g. when acute services come on line, or when new releases are due, as these are recognised periods of increased risk.*

5.4 Review Area 4: Integration of the CSMS with CCA and systems development processes

Audit approach

It was noted in the Report that product development, CCA and CSMS cycles were operating independently, resulting in a risk that clinical safety issues would not be identified as early as possible. The Report also identified that the clinical safety processes were viewed as ‘a final quality assurance’ that risks were being adequately mitigated, however noted a lack of integration of the clinical safety unit’s activities in the core design and development activities.

There was also a reliance on staff outside the CSU to identify clinical safety risks and the lack of a common view of what constituted a clinical safety risk. Clarity about the full process in relation to the discovery of issues, quality assurance and mitigation of risks, and approval of changes across the organisation was varied. CSU resourcing was noted, at the time, to be inadequate to address the quantum of issues that arise from the use of eHealth products, resulting in the introduction of a triaging process to determine which products would be reviewed and which assessments would be applied. This resulted in a recommendation to revise, redesign and appropriately resource the integration of the CSMS with CCA and systems development processes to ensure optimal practice.

Findings

Improvements in clinical safety management have resulted in the development of a core document that identifies how clinical safety issues are linked and integrated into the system design, development and implementation process for eHealth products and systems. The establishment of an Implementation Support Working Group (ISWG) has also resulted in greater integration of clinical safety into the CCA processes.

Participating vendors in the PCEHR must undergo an observed self-assessment process that includes running and reporting on test scripts prior to authorisation to participate. Additionally, as risks and issues are identified, modified and newly developed test scripts and cases can be sent to the vendors.

There is currently no requirement for vendors to undergo accreditation processes that would formally recognise facilities that produce reliable technical results. It is understood that the requirement for vendors of the PCEHR to undertake a formalised accreditation process in order to participate is due for review in 2013.

Risk rating: Minimum

Proposed Approach: *Await the outcome of the draft National eHealth ICT roadmap, deployment plan and the development of the national business case for eHealth, which was due for release in 2013.*

5.5 Review Area 5: Formalised processes to manage clinical safety across organisations

Audit approach

A number of partner organisations involved in the ongoing development and implementation of the PCEHR have a role in ensuring the safety of implemented PCEHR products. It was noted in the Report that there was a lack of clearly defined processes and responsibilities to ensure that effective clinical safety is supported across all organisations, particularly during product implementation. It was noted that the quality assurance was segmented, with fragmented responsibility for addressing risks.

Findings

Regular and formal means of information exchange and work programme briefings have been established to enable service quality improvement. A working group collects, discusses and documents clinical safety issues that have inter-agency dependencies.

A draft Incident Management Framework and Response Plan has been developed by DoHA. The framework and response plan defines a coordinated process for effective clinical safety incident management across all partner organisations.

A Clinical Leadership and Engagement Unit (CLEU) aims to ensure clinical safety during product implementation by authorising the clinical release of products. This process has not yet been formalised, and there have been instances in which authorisation for software release has been withheld in order to ensure issues are resolved.

Risk rating: Moderate

Recommendation 9: *As a priority, the draft DoHA Incident Management Framework and Response Plan for the PCEHR be finalised and the processes be evaluated via scenario testing following implementation.*

Recommendation 10: *The Terms of Reference for the PCEHR Clinical Safety Officers Working Group be reviewed after six meetings.*

Recommendation 11: *A formal process for the sign off of PCEHR software release by the Clinical Leadership and Engagement Unit be documented to ensure roles and responsibilities are clearly articulated.*

5.6 Review Area 6: Use of a Project Management Office approach

Audit approach

Multiple risk management processes that were noted to be running in parallel included: CCA, the V model process, consultation teams, reference groups and a project management approach. This was further complicated by multiple reporting lines.

Whilst there was a view that the parallel processes complemented each other, the Report suggested this could be done in a more structured and integrated way. Further, as identified in Review Area 2, the concurrent use of multiple risk and hazard registers presented a number of risks.

Findings

As outlined in Review Area 10, an overarching comprehensive CSMS has been developed, along with supporting tools and templates. An ISWG provides an opportunity for consultation to occur between multiple work streams in order to ensure a coordinated clinical safety approach. A Project Management Office (PMO) for the overall development of the PCEHR has been established in line with the recommendations, however this is not inclusive of partner organisations.

Risk rating: Minimum

Recommendation: *See Recommendation 11.*

5.7 Review Area 7: Quality management accountabilities, roles and responsibilities of the executive, Clinical Leadership and Engagement Executive and Clinical Leadership and Engagement Unit (CLEU)

Audit approach

The Report identified some concerns with governance of clinical safety management, including:

- An apparent lack of documentation about how the CSU and the CLEU work together to ensure the clinical safety of all products being released
- Stakeholder reports that the significance of risks were not always being assessed consistently with inconsistent escalation processes
- Ongoing confusion of functions and sign off responsibilities between CSU and the Clinical Leadership and Engagement Executive.

This resulted in a recommendation that specific quality management accountabilities, articulation of formal gating and escalation points, and roles and responsibilities of the Executive, Clinical Leadership and Engagement Unit and CLEU be defined and documented.

Findings

A new Programme Committee Charter has been developed to ensure that there is a governance process for managing all aspects of the Work Programme. Clinical safety is integrated into the charter to ensure that it is considered in all aspects of design and

implementation. At critical junctures of the design, release and implementation, risks are reviewed and authorisation to proceed to the next stage is required. If risks are accepted at these junctures, mitigating controls are developed and communicated in clinical safety case reports.

There are a number of committee structures that define roles and responsibilities in relation to clinical safety. Various advisory roles, reporting lines and working relationships are in place, including issues escalation and resolution processes. Whilst job descriptions for Clinical Engagement Leads outlined explicit responsibility for quality management, this was not necessarily known by partner organisations and raised the possibility of a lack of clarity in identification of the appropriate lead with which to raise specific issues.

Risk rating: Minimum

Recommendation: See recommendation 12.

5.8 Review Area 8: Roles, responsibilities and accountabilities for clinical safety for the full implementation of products

Audit approach

The Report noted that a number of parties have responsibilities with respect to risk mitigation, including clinical safety risk. As such, risk mitigation cannot be the sole responsibility of one organisation, and there should be a system for clinical safety risk mitigation across the development and implementation lifecycle involving all partner organisations. Roles and responsibilities for clinical safety were not clearly documented and clarity regarding responsibility for testing, change management and training was lacking.

It was recommended that roles, responsibilities and accountabilities for clinical safety be documented for the full implementation of products, including jurisdictional hospital, clinical and consumer responsibilities.

Findings

A draft Incident Management Framework and Response Plan has been developed. It outlines the incident management requirements for government and partner organisations to ensure a coordinated approach to effective clinical safety. This document is supported by a Clinical Safety Service Safety and Incident Management document.

Risk rating: Moderate

Recommendation: See recommendation 15.

5.9 Review Area 9: National clinical governance structure for implementation of National eHealth programs

Audit approach

At the time of the Report, responsibility for third party implementation and for maintenance activities was not held by one organisation, with uncertainty about ongoing responsibility for the coordination and management of clinical safety activities. There was also a lack of clarity of roles and responsibilities for government bodies, clinicians, consumers and vendors and no clearly articulated system for the national management of clinical risk in eHealth implementation.

A recommendation identified the need to establish a formal national clinical governance structure for implementation of national eHealth programs to monitor performance of systems, identify risks, investigate and resolve issues.

Findings

The review noted that an organisational chart has been developed to outline the reporting and governance arrangements in PCEHR development, implementation and monitoring. In addition, a draft national eHealth ICT roadmap, deployment plan and the development of the national business case for eHealth is under development.

Risk rating: Minor

Recommendation: *Nil, await finalisation of the business case due for release in 2013.*

5.10 Review Area 10: Clinical incident management systems

Audit approach

Concerns were raised at the time of the Report with respect to the management processes for any clinical safety incidents which may occur after implementation of the PCEHR.

The review of the clinical incident management processes requested by the CGAG included the following domains: culture; preparedness; information collection; investigation; response and monitoring.

Findings

At the time of the review, as no clinical safety incidents had been reported, a review of the processes and documentation to support the processes was undertaken.

A draft Incident Management Framework and Response Plan has been developed. This document is supported by a Clinical Safety Service Safety and Incident Management document and an Incident Management Process document. Some anomalies relate to incident definition, risk management approach, incident classification and incident resolution which were noted in the documents.

The establishment of a government administered call centre for consumers to make complaints or raise issues in relation to registering with the PCEHR was found to lack clinical safety scripts for call system operators.

There is an opportunity for interagency scenario testing and process mapping in order to identify issues in the clinical incident management system.

Risk rating: Moderate

Recommendation 12: *A gap analysis and refinement of PCEHR clinical incident management documents between DoHA and NEHTA be undertaken to ensure further alignment of processes. The analysis and refinement should include addressing recommendations from the Report. In addition, the refinement should include a defined clinical incident investigation method.*

Recommendation 13: *The government administered call centre complaint script be updated to include a PCEHR clinical incident scenario. In addition, there should be training for telephone operators to include a PCEHR clinical incident scenario.*

Recommendation 14: *The DoHA information packs for clinicians registering for the PCEHR be reviewed to ensure the process for notification of PCEHR clinical safety concerns is clearly outlined.*

Recommendation 15: *Interagency scenario testing of PCEHR critical incident management processes, including notification, stratification, escalation, investigation, and development of recommendations be undertaken as a priority.*

Recommendation 16: *A reporting template be developed for reporting of selected PCEHR clinical safety incidents to the CGAG in order for expert clinical advice to be accessed.*

6 Conclusion

Significant progress in the implementation of the recommendations from the Report have been made, with evidence of strong executive support for clinical safety of the PCEHR across government and partner organisations. This has included a comprehensive review and refinement of the suite of clinical safety documents, development of a comprehensive risk framework, development and publication of a Safety Case Report and development of a draft Incident Management Framework.

The findings and recommendations from the First 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 Second Review.