AUSTRALIAN COMMISSION
ON SAFETY AND QUALITY IN HEALTH CARE

Third Clinical Safety Review of the Personally Controlled Electronic Health Record (PCEHR)
December 2013

Undertaken by PwC on behalf of

Australian Commission on Safety and Quality in Health Care

Contents

1.   Overview of findings

The Third Clinical Safety Review of the Personally Controlled Electronic Health Record (the Third Review) was conducted in the period October to December 2013.

The key findings and recommendations presented in this report are based on the analysis of the qualitative and quantitative data collected throughout the audit across the three key review areas.

Within the three key review areas there were a total of 15 findings. The findings have been classified according to the risk ratings developed for the first two audits (a rating scale of critical, major, moderate, minor, minimum). Within the three key review areas there were 1 Critical, 4 Major, 6 Moderate, 2 Minor and 3 Minimum findings. The findings have been classified according to the risk ratings developed for the first and second audits. The 15 key findings resulted in 15 recommendations for consideration. The key findings and recommendations are detailed below.

Across the three key areas the Third Review has highlighted that for some clinicians, the PCEHR is enhancing the care they are able to provide. This is particularly the case for patients with chronic and complex conditions who attend multiple service providers. Clinicians reported that the PCEHR provided another source of information for them on which to base quality care for their patients. Most providers did not report clinical safety incidents or issues with their use of the system. However, some of the evidence collected through the audit has also drawn attention to the challenges faced in relation to the data contained within individual PCEHRs, medication safety and incident management.

Taken together, the key findings and recommendations provide key agencies with a basis for further improving the clinical safety of the PCEHR.

2.   Background

Electronic Health Records (EHRs) are an essential newer part of our health system, and the recently implemented Personally Controlled Electronic Health Record (PCEHR) aims to support improvements in the sharing and accessibility of patient information across healthcare organisation boundaries. Whilst consumer registration for the PCEHR has reached 1,178,980 [1] , there has been incremental progress in clinician enrolments, deployment capabilities and content of the PCEHR, and real-world clinical interactions with the PCEHR infrastructure by web portal and clinical software systems.

It is important to note that the PCEHR was not intended to replace current clinical information systems used by Australian health care providers; rather, it was intended to play a supportive role. Patient safety and patient centred quality have emerged as key drivers in healthcare reform, however, patients still experience needless harm and processes are not as efficient as they could be. In the area of eHealth, implementation is still inconsistent across health care systems and providers, and this inconsistency leads to equally variable implications for patient safety. Recent evidence has highlighted substantial and often unexpected risks resulting from the use of EHRs and other forms of health information

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[1] As at November 2013, Department of Health.

technology. These concerns are compounded by the pace of EHR development and implementation. It is therefore highly appropriate to be concerned about potential safety issues from the use of the PCEHR.

A clinical governance structure has been put in place to oversee, monitor and report on clinical safety issues associated with the use of the PCEHR. Given the nature of the new environment, the reality of the variable uptake and nature of clinical information and of clinical information technology, and the importance of ensuring that systems are safe and reliable in use, this is not a straight-forward challenge.

3.   Review objectives and scope

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

1. A review of a sample of de-identified PCEHR records

2. An investigation of the use by healthcare providers of the National Prescription and Dispense Repository (NPDR)

3. To review and develop incident identification, selection and review processes for the CGAG, with scenario planning and mapping for incident review and reporting.

4.   Overall methodology

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

Review area 1: Data collection and analysis of 112 de-identified PCEHR records was undertaken.

Review area 2: An investigation of the National Prescription and Dispense Repository (NPDR) included data analysis, an online survey for Pharmacists (with 12 responses), site visits to general practices and pharmacies (six site visits) and consultation with key stakeholders.

Review area 3: A desktop review of background material and current incident management processes was undertaken, stakeholder interviews were conducted with key agencies (DHS, DoH, NEHTA and UNSW), and process mapping of clinical safety incidents reported to date was completed. A workshop was held to discuss findings and propose recommendations for the way forward.

5.   Key Review Areas

5.1   Review area 1: A review of a sample of de-identified PCEHR records

Audit approach:

A sample of 112 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 1: There was a period of time where software calls to validate IHI numbers were not being processed correctly

Risk rating: Major

The audit identified an issue where the Healthcare Identifiers Service (HI Service) was not matching clinical documents to the correct PCEHR records. It is understood this primarily occurred when clinical software made business-to-business calls to utilise the historical search function in the HI Service. The consequences of this issue would be very serious if information was linked to the incorrect PCEHR, and would represent a serious PCEHR system failure. At the time of the review there was no documented investigation and analysis into this issue.

It was recommended that investigation and analysis of the IHI system failure should be undertaken and depending on the findings, appropriate protocols and management procedures may need to be created or updated.[2]

Recommendation 1: *Priority review and analysis of the issue of attribution of the IHI to PCEHRs*

Key finding 2: There is evidence to suggest there is some inconsistency in the presentation of data between the clinician desktop software and the PCEHR

Risk rating: Major

Interviews with clinicians revealed differences in the display of data between their desktop software and the provider portal of the PCEHR, particularly via the B2B view. This audit did not link the de-identified data back to the desktop software meaning an assessment of the integrity of the data could not be made, however it is vital there is consistency in the information for patient safety.

Of the Shared Health Summaries reviewed it was noted there was duplicate recording of medication information in the medicines component. Additionally, the transcription of data from a data item in one component to a data item in another component could lead to the development of incorrect clinical reasoning depending on the nature of the entry and the context of the transcription.

Recommendation 2: *The Commission seek to undertake an end-to-end examination of the presentation of the clinical data within the PCEHR.*

Key finding 3: The quality of the clinical information and data in the PCEHR could lead to misinterpretation and errors

Risk rating: Minor

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[2] Note: Subsequent information indicated that an investigation into this issue was underway when the audit commenced, which identified that it was only some software calls (i.e those utilising the historical search flag) that were affected and of the ehealth records affected by this issue, none had clinical documents associated with them at the point of investigation. Advice was provided that the resolution of the incident was completed concurrently to the finalisation of the audit.

Anomalies in the data within individual records were noted which could impact on effective and safe clinical care. These included:

- Allergies and adverse reactions (e.g. population of the 'agent description' with brand name and free text use of the therapeutic class descriptors),

- Current and past medical history (e.g. inappropriate use of abbreviations potentially leading to confusion, use of shorthand for dosing instructions, capture of past medical history in the incorrect clinical documents),

- Medication information (e.g. duplication of medication information, and use of unsanctioned status entries).

The standards for clinical documents outline the information which should be included in each of the clinical documents, and have been developed in consultation with key agencies and stakeholders. Individual clinicians determine the information included in the documents of individual patients which can impact upon the safety and quality of the records in the PCEHR.

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.

Recommendation 4: Investigate and confirm whether non-conformance with NEHTA standards in recorded clinical data is in accordance with expected clinical software performance.

Key finding 4: Restrictions on investigation of data related issues place challenging restraints on providing technical support

Risk rating: Major

Current legislative and privacy constraints of the PCEHR are impacting on how key agencies and stakeholders can work to identify and rectify issues that arise when using live data in individual records. This may be a contributing factor to some of the present issues around different user experiences of the PCEHR.

Recommendation 5: DoH review the potential to better support investigation and resolution of issues involving clinical data.

5.2 Review area 2: An investigation of the use by healthcare providers of the National Prescription and Dispense Repository (NPDR)

Audit approach

Review area 2 focused on the data related to the National Prescription and Dispense Repository (NPDR). In particular, the PBS data were analysed to identify any issues or inconsistencies and findings were explored with key agencies and stakeholders.

Key finding 5: There is evidence that medication directions, when displayed in health summaries, can be displayed in a confusing, misleading or erroneous fashion

Risk rating: Critical

Analysis of the medication lists included as part of the Shared Health Summaries (SHS) revealed a source of error. There was the potential where the directions for a medication entered by the clinician could be incorrectly interpreted when presented in the SHS. This was evident for non-standard directions for intermittent dosed medications such as three-monthly injections.

Inconsistencies between the medication directions typed into the clinician desktop software and what is displayed in the clinical documents of the PCEHR has the very real likelihood of creating confusion and miscommunication between clinicians and consumers.

Recommendation 6*: NIO, DoH and Commission to review the presentation of medication directions in all clinical documents as a high priority.*

Key finding 6: Data analysis found no evidence to suggest medication data has been attributed to the wrong PCEHR

Risk rating: Minimum

Analysis of the PBS data, prescription records and dispense records did not identify instances of inconsistency within individual patient records. Not all patients, however, had each of the three records present in the data set and the de-identification of the prescription and dispense records removed the medication descriptors. The differences in record types present in the individual PCEHRs is most likely due to the level to which individual clinicians are using the PCEHR for their patients.

Key finding 7: Clinicians lack the confidence to fully utilise the end-to-end NPDR and PCEHR solution in their everyday practice

Risk rating: Moderate

The transfer of encrypted medication information following generation of prescription and dispensing activities to the PCEHR is carried out through security measures designed to protect the integrity of the data. This means there is a small chance of corruption of the information during the transfer of information.

Sources of error are likely dependent on human factors and highlight the importance of entering the correct information at the point of both prescribing and dispensing. No recent examples were identified where there was corruption in the medication information once it had been entered into the PCEHR system.

Clinicians felt they would benefit from the ability to familiarise themselves with the functions of the PCEHR via a test site or test patient rather than on live patient records. A test environment would also be of benefit to software vendors to better understand the performance of their products.

Recommendation 7: *Development of a PCEHR test environment for clinicians and software vendors and associated education for clinicians*

Key finding 8: Medication data in the PCEHR is aiding clinical decisions

Risk rating: Moderate

The clinical utility of the PCEHR was recognised by clinicians although it was found that many had limited experience of its use. It was acknowledged that the PCEHR is not the sole source of information for a patient's medical history.

The medication information can be recorded in a range of documents in a PCEHR and clinicians access some of the records as part of the care and clinical decision making process. Understanding the benefits and limitations of the different medication information across the medication lists, prescription records and PBS data can provide a summary of the current medications used by patients.

It was identified that not all clinicians access the medication information due to a range of factors.

Recommendation 8: Education and training for clinicians in the use of the medication information in the PCEHR

Key finding 9: Different software interfaces with the PCEHR is creating different clinician experiences which may have an impact on clinical safety

Risk rating: Major

Stakeholder consultation identified the interface variations between the different software suites used by GPs and Pharmacists. If clinicians are working across multiple sites the difference between the multiple interfaces may lead to confusion in where to locate the medication information for each patient through the desktop software.

Accessing the PCEHR adds time to the work processes of both GPs and Pharmacists which may be the result of the technical processes of the systems rather than a clinical safety aspect.

Standardisation of the presentation of medicines information between the PBS data, prescription records and dispensed records would improve understanding and interpretation of the true medication use by individuals. This should also include a definition for what constitutes the PBS and MBS data and how it can be used to inform clinical decisions.

Recommendation 9: Consider greater consistency and/or standardisation of the presentation of medicines information sourced from the PCEHR

5.3 Review area 3: To review and develop incident identification, selection and review processes for the CGAG, with scenario planning and mapping for incident review and reporting

Audit approach
Documentation was provided which outlined the current incident management processes and reports. Verification of these processes were undertaken to identify issues and discuss findings from other comparative systems.

Key finding 10: Gaps in the current "PCEHR safety system" were determined based on characteristics of good practice safety systems

Risk rating: Moderate

There are a range of good practice safety systems from both national and international health systems applicable to the PCEHR which include:

- Strong core processes underpinning the incident management framework,

- Standardised design of the incident management reporting system,

- Good governance structures to support streamlined incident management processes,

- Clinical governance requirements and reporting framework.

The scope of incidents to be managed through the PCEHR incident reporting and management systems must be clearly defined and a process established for referring on issues which should be managed by the different key agencies as relevant.

Recommendation 10: *The Commission work with DoH and NEHTA to develop a performance framework and reporting system to support CGAG in their objective of providing advice on the clinical safety of the PCEHR and to support continuous quality improvement.*

Key finding 11: The clinical safety incident documentation and reports had limited and varying levels of detail on the incident investigation process, findings of the investigation and outcomes

Risk rating: Moderate

Examining the 12 reported clinical incidents, it was identified there was limited detail surrounding each of the incidents, and varying consistency in terms of the reporting process. The key findings from this analysis include:

- NEHTAs Clinical Safety Service Incident Assessments were not completed for all incidents

- There was a lack of consistency in approach and documentation provided for incidents

- There was ambiguity in the process of addressing the incident, including the communication trail

- There did not appear to be any feedback loop on the outcomes of incident reviews

- There were multiple clinical incident records relating to the same initial incident

- It remains unclear if all available and relevant supporting information was included in the appropriate system

- The risk assessment scores and frameworks used in the incident management process appear to differ.

A review of the current PCEHR incident management system and principles of good practice safety systems revealed opportunities for improvement in the PCEHR system. There is an opportunity for key agencies to work together to take immediate action to make

improvements to the incident management processes, information captured and reporting. Such a review should include:

- Governance structures

- Policies

- Consistency of information

- Timeliness of the reported information.

Recommendation 11: *DoH and NEHTA take immediate action to improve the end-to-end incident management process including the consistency of information captured, coordination of the process, timeliness of reporting and the provision of feedback.*

Key finding 12: The 1800 PCEHR1 hotline was not considered to be a convenient channel for reporting incidents by users of the system

Risk rating: Moderate

The importance of a reporting channel that is user friendly and convenient was raised. It was stated that a hotline is not necessarily convenient for all users of the system, especially if the caller is a clinician who then has to wait. Ideally an online/electronic reporting channel should be in place, even if this is in addition to other reporting mechanisms. It was considered that this would also facilitate more consistent reporting of the required information. Further, in the PCEHR system, it needs to be clearly evident how an individual may go about making an incident report.

Capturing accurate information about clinical safety and subsequent incidents is key to providing the foundation of a safe PCEHR system for all users. Additionally, it is well known that effective clinical governance must be supported by a good reporting culture.

Recommendation 12*: Relevant agencies work together to develop an online mechanism whereby incidents can be electronically reported.*

Key finding 13: Clear communication and continuing education related to reporting and the use of the PCEHR system is necessary to support the future growth of the system

Risk rating: Moderate

A number of points were raised in relation to communication and education for users on the PCEHR including:

- Clear instructions for reporting

- A certain level of literacy/confidence or empowerment on behalf of users

- Support systems in place

- Linking education sessions with continuing professional developed points.

One way to achieve a shared understanding of the clinical safety of the PCEHR across all stakeholder groups would be to develop a strategy under which targeted communication and education may be rolled out

Recommendation 13: A strategy for communication and education relevant to the clinical safety of the PCEHR be developed with input from the Commission and other key agencies.

Key finding 14: The current PCEHR legislation and protection for those reporting incidents is a deterrent to fostering a good reporting culture

Risk rating: Minimum

The legislation and protection enabling a good reporting culture are important components of driving the future success of the PCEHR system. Important elements to consider include:

- Legislation/confidentiality agreements should be in place that protect the individual reporting the incident and encourage the reporting of incidents

- Foster an environment or culture where people are encouraged to report incidents

A key component of monitoring the clinical safety of the PCEHR is a consistent approach to reporting by all system users. As in any incident reporting system the focus must be on the potential improvements to users and services that have resulted or should result from the identification of clinical safety issues. A culture of openness where errors/risk are acknowledged, reported and managed is a high priority. The limitations of the current legislation are currently considered prohibitive in achieving this.

In addition, the legislation should also allow for the auditing of clinical safety issues and enable cross matching of records with consumers (based on their consent) to further identify potential issues.

Recommendation 14: A review of the PCEHR legislation and protection for consumers/providers in reporting incidents be undertaken.

Key finding 15: The PCEHR system does not currently integrate well with GP reporting requirements or other risk management and patient safety systems

Risk rating: Minimum

Key components for the future success of the PCEHR system include its ability to integrate with other risk management and patient safety systems as well as being adaptable to the small business environment.

It would be beneficial to develop a broader, system wide incident reporting map or process that goes beyond just the PCEHR. This would highlight where there is scope overlap and to more clearly define roles/accountabilities; increase awareness of how PCEHR reporting fits into the bigger picture; drive significant change and improvement in reporting through the whole system.

Recommendation 15: The Commission, key professional bodies and other relevant stakeholders work collaboratively to discuss the future of clinical safety and the incident reporting culture in the primary care setting and the supporting governance structures.

Conclusion

Across the three priorities the audit has highlighted areas that for some clinicians, the PCEHR is enhancing the care they are able to provide. This is particularly the case for patients with chronic and complex conditions who attend multiple service providers. Clinicians reported that the PCEHR provided another source of information for them on which to base quality care for their patients. Most providers did not report clinical safety incidents or issues with their use of the system. However, some of the evidence collected through the audit has also drawn attention to the challenges faced in relation to the data contained within individual PCEHRs, medication safety and incident management.

Taken together, the key findings and recommendations provide key agencies with a basis for further improving the clinical safety of the PCEHR.