AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Seventh clinical safety review of the My Health Record system

Review 7.2: Assessing the presentation to healthcare providers of the My Health Record system 'medications views'

October 2016

Contents

BACKGROUND	3
REVIEW OBJECTIVES AND SCOPE	4
METHODOLOGY	5
FINDINGS	
FINDING 1: THERE IS NO READILY AVAILABLE PLATFORM TO TEST THE CLINICAL SAFETY OF MEDICINES INFORMATION HELD WITH THE SYSTEM	
FINDING 2: THE NPDV DOES NOT PRESENT A SINGLE 'MEDICINE HOME' OF THE MY HEALTH RECORD SYSTEM	
FINDING 4: THE NPDV NEEDS TO BE CONSISTENTLY INTEGRATED INTO THE CIS OF HEALTHCARE PROVIDERS	8
ADVERSE DRUG REACTIONS IN THE SYSTEM	9
FINDING 8: OF THE 19 REVIEWED POLYPHARMACY NPDVs, A MEDIAN CLINICAL USABILITY SCORE OF 3 OUT OF 10 WAS REPOR	RTED
FINDING 9: THERE IS THE POTENTIAL FOR 'ORPHAN' OR UNNAMED NPDV TABS TO REMAIN OPEN WITHIN A CIS WHEN THE USE CLOSES A PATIENT RECORD AND MOVES TO THE NEXT PATIENT	11
FINDING 10: A MISMATCH BETWEEN A PRESCRIPTION AND A DISPENSE RECORD WAS IDENTIFIED	ORD
FINDING 12: HEALTHCARE PROVIDERS CAN SEE 3 MONTHS OF MEDICINES IN THE NPDV, WHEREAS SOME PRESCRIPTIONS LAST UP TO 12 MONTHS	
CONCLUSION	14
APPENDIX A CLINICAL SAFETY REVIEW RISK RATING MATRIX	15

Background

The Australian Commission on Safety and Quality in Health Care (the Commission) has undertaken a clinical safety program for the My Health Record system since the system's implementation in 2012. In July 2015, the Australian Government Department of Health appointed the Commission to conduct the seventh clinical safety review of the system, with the oversight of the Commission's Clinical Safety Oversight Committee (CSOC).

The aim of the Commission's clinical safety reviews is to proactively identify potential clinical safety risks to, and arising from, the My Health Record system and to recommend suggested mitigation strategies. This will improve the overall safety and quality of the system over time.

Copies of the Commission's completed clinical safety reviews and the System Operator status reports against review recommendations to date are available on the Commission website at www.safetyandguality.gov.au/our-work/safety-in-e-health.

The seventh clinical safety review of the My Health Record system, conducted by the Commission, comprises:

- review 7.1 assessing the impact and safety of the use of the My Health Record system in emergency departments (the hospital emergency department review)
- review 7.2 assessing the presentation to healthcare providers of the My Health Record system 'medications views' (the medications view review)
- review 7.3 assessing downtime management best practices for clinical safety in health IT systems (the downtime management review).

This report presents the findings of clinical safety review 7.2. This review component assessed the medication information displayed by the My Health Record system through the National Prescription and Dispense View (NPDV), with a focus on the presentation of the information from a clinical safety perspective.

Review objectives and scope

My Health Record presents healthcare providers and participating organisations with a series of records of patient medication events, through the NPDV. The NPDV collates and displays prescription and dispense record information in general practitioner clinical information systems (CIS), and the My Health Record consumer and provider portals. The NPDV does not present medicines information in documents such as Shared Health Summaries (SHS) and Discharge Summaries (DS). Also, it does not present Medicare data including Pharmaceutical Benefit Scheme administrative medicines information nor Medicare Benefits Schedule data, as these are presented in a separate view – the Medicare Overview.

Concern has been expressed that using the medicines view generated by the NPDV can be time consuming for healthcare providers reviewing the medicines history of polypharmacy patients. This is because a patient with a chronic condition or conditions may have many prescription and dispense records for the same medicine over time that are uploaded to the My Health Record system and displayed in the NPDV.

Methodology

The review evaluated the presentation of medicines information through NPDV functionality. The review was designed to assess the safety and usability of the current medicines view, using a cohort of polypharmacy patients whose chronic disease profiles are typical of high-volume users, whom My Health Record was intended to support.

The NPDV, as presented in five general practitioner CISs, was evaluated.

The review findings reflect the presentation of information in each product version that was available via the eHealth Reference Platform at the time of the review.

A three-stage approach was undertaken:

- stage 1 formulation of the review design
- stage 2 extraction of de-identified data by the System Operator, and development of the review tool with the National E-Health Transition Authority (NEHTA)
- stage 3 analysis and formulation of the conclusions and recommendations.

As part of stage 2, the NPDVs and associated clinical documents for the polypharmacy cohort were reviewed by Commission officers, and by a panel of clinical safety and informatics experts, and healthcare providers. The panel included clinicians who were familiar with one or more of the general practitioner CIS. Structured interviews were also conducted with the clinicians, using a questionnaire developed by the Commission to determine their views on the overall usability of the NPDV.

Findings

The review produced 12 findings and 13 recommendations. Each finding has a risk rating. The risk rating guide is shown in Appendix A.

No findings were assessed as critical or high risk. Six findings were assessed as moderate risk. The remainder were classified as a minor risk to the system.

The findings can be broadly categorised into the following themes:

- clinical safety testing capabilities
- issues relating to minimising unintended user errors in accessing the NPDV
- clinical usability of the NPDV in the clinical workflow setting
- on-screen presentation of medicines information.

Finding 1: There is no readily available platform to test the clinical safety of medicines information held within the system

Risk rating: Moderate

An appropriately established and maintained stand-alone My Health Record clinical safety test environment, and data extraction processes and protocols, would provide the required platform for specific and ongoing clinical safety hazard and risk assessments of system data and tools. The test environment should be available for more CIS, including hospital CIS and pharmacy dispensing systems.

Recommendation 1: Extend the capability of the national training and testing environment based on the work undertaken for this review to support other use cases for clinical safety testing using anonymised records. This requires:

- updating the data extraction process used in this review to exclude superseded documents, allowing the rendering of all system views and documents to be consistent with NEHTA specifications
- extending the existing platform to include the consumer and healthcare provider portals; hospital CIS and viewers; and CIS in residential aged care, and community and hospital pharmacies.

Finding 2: The NPDV does not present a single 'medicine home' of the My Health Record system

Risk rating: Minor

Although information available in the NPDV was regarded as clinically valuable, it was considered challenging to use and interpret efficiently and effectively in the fast-moving clinical environment. The low usability of the NPDV was mainly attributed to the lack of interoperability between the NPDV and the healthcare provider's CIS. This was compounded by the lack of a single standard medicines terminology for prescription and dispense records, which would be necessary to establish a single medicine home from the information in the NPDV.

A significant amount of a consumer's prescription and dispense information is missing from the NPDV, even when it is visible in other clinical documents. This could be due to a number of factors, such as the dispensing pharmacy not participating in the system. Medicines information labelled 'unavailable' in the NPDV, and missing medicines information for some polypharmacy patients reduced user confidence in the NPDV and the system as a reliable source of medicines information.

There was strong reviewer support for more medicines information to be made available for NPDV use, or at least a new product to be investigated or considered that would allow a fully interoperable and interactive 'medicines list' of curated information to support the NPDV. A curated medicines list was presented by some reviewers as an option to assist in reconciling a consumer's NPDV with Medicare View administrative information and other clinical documents.

Recommendation 2: The Medications View project, being led by the Australian Digital Health Agency, consider the development of an eventual single 'medicine home' – or curated medicines list – in the system. This would require:

- increasing the adoption of Australian Medicines Terminology (AMT) in CIS
- achieving compatibility of the NPDV and CIS with machine-readable medicine management and reconciliation tools
- specifying the minimum set of information to be provided or used in a curated list of medicines.

Finding 3: Communication and guidance material for healthcare providers accessing the NPDV needs to be improved

Risk rating: Moderate

Interpreting the NPDV medicines information was challenging. Other clinical documents, such as SHS and DS (with medicines information not available in the NPDV), had to be used to make more clinical sense of the polypharmacy NPDVs reviewed. The on-screen management of these multiple documents can be complex for users, and the potential for user-interface errors, and wrong document and date selections was observed.

Users noted that the multiple, unlinked sources of medicines information in the system hindered efficient medicines reconciliation for the patient and presented new workflow issues.

The limitations of medicines information displayed by the NPDV can lead to uncertainty for users.

Recommendation 3: Improve training and support materials for healthcare providers to enhance their understanding of the NPDV and its limitations, by:

- developing and promoting targeted education materials about the system's medicines information, and how it can be accessed, used and updated
- requiring the developers of CIS to develop a support or help screen to provide these messages.

Finding 4: The NPDV needs to be consistently integrated into the CIS of healthcare providers

Risk rating: Minor

Dissatisfaction was expressed about the lack of guidance and tips within CIS about how to navigate to, and display, the medicines information needed.

The NPDV is one of the system's medicines information tools, and reviewers identified the need for greater integration between CIS and the NPDV to assist medication history and reconciliation activities. Reviewers noted that further involvement with health practitioners on the co-design and integration of the NPDV within clinical practice software would be beneficial.

The less embedded the system was in the CIS, the greater the concern expressed over how better to incorporate the system medicines information into healthcare providers' workflow for clinical safety and efficacy.

Recommendation 4: The System Operator works with vendors and healthcare providers to define how best to present the NPDV within general practitioner, hospital, residential aged care and pharmacy CIS.

Finding 5: There is insufficient use of structured and coded information on medicines, medicine allergies and adverse drug reactions in the system

Risk rating: Minor

There is a large amount of uncoded medicines information in the system's clinical documents, which are clinically useful but not displayed in the NPDV – only around 30 per cent of the system's medicines information reviewed was structured or coded. Viewing a patient's SHS or DS (where available) was regarded by some reviewers as a prerequisite to gain a more reliable understanding of the patient's NPDV medication history and current medication list. However, medicines information found in clinical documents is not easily transferred into other CIS applications and electronic medication management tools.

The need for more AMT-coded medicines information, as well as medicine allergy information, was emphasised by the reviewers. AMT-coded medicines information enables both medicines information and medicine allergies information to be tightly integrated with health providers' CIS. This was regarded as the single most important way to allow the ready curation and exchange of medicines information and medicine allergies information for enhanced digital health safety and quality.

Recommendation 5: The System Operator continues to work with contributors to the My Health Record system to increase the provision of coded (AMT) medicines content, including medicine allergies and adverse drug reactions that will improve the quality, presentation and utility of the data held within the system.

Finding 6: There is no medicines or medicine allergies search function for the NPDV

Risk rating: Minor

There is no search function in the NPDV that allows health practitioners to search for a medicine of interest or concern, or for medicine allergies.

Concern was expressed by reviewers about the need to 'deep dive' for more relevant medicines information and medicine allergies information, which might be contained in a patient's discharge summary, event summary, shared health summary.

This finding is related to finding 5.

Recommendation 6: Enable a medicines and medicine allergies search function in CIS presenting the NPDV.

Finding 7: There is inconsistent on-screen presentation of medicines in the NPDV and CIS

Risk rating: Moderate

Unclear, incomplete or confusing presentation of medicines information can increase the opportunity for health practitioners to make errors and cause patient harm.

There was strong support for a more consistent and unambiguous presentation of medicines information in the NPDV. It is important to note that the Commission and NEHTA, with funding from the System Operator, developed *National guidelines for on-screen display of clinical medicines information* in 2014 and 2015 to enable consistent and safe presentation of medications.

More consistency, particularly for long and combination medicine names, was highlighted by some reviewers. The use of non-English abbreviations (e.g. for administration directions) was regarded by some users as unhelpful in clinical care situations where users may be unfamiliar with certain contractions and acronyms. These abbreviations were also presented in the consumer's view, and do not provide consumers with a plain-English guide to their medicines information.

Specific on-screen NPDV display issues noted by the reviewers included a number of recommendations that are generally consistent with the national guidelines:

- Display full medicine names.
- Display active ingredient names and brand names using consistent font styles for both prescription and dispense records.
- Do not use abbreviations.
- Display prescription details in full.
- Use consistently formatted, approved units.
- Use a space between numbers and units of measure for ease of reading.
- Unambiguously position related elements when using text wrapping.

Some users highlighted the need for clearer definition of dose and strength information to increase readability and prominence. For example, highlighting of a dose using visually distinctive type or font to differentiate dose from strength was noted as being useful for onscreen readability.

Recommendation 7: The System Operator continues to work with vendors, jurisdictions and healthcare provider peak bodies/groups to increase the consistency of the on-screen presentation of medicines. This can be achieved through adoption and uptake of the National guidelines for on-screen display of clinical medicines information.

Finding 8: Of the 19 reviewed polypharmacy NPDVs, a median clinical usability score of 3 out of 10 was reported

Risk rating: Moderate

For the 19 polypharmacy NPDVs reviewed, healthcare providers completed a survey questionnaire on the overall usability of the NPDV. Around half of the 19 NPDVs reviewed scored 5 or more for clinical usability; 10 scored 3 or less.

Some specific results of the survey are outlined below:

- Around one-third scored less than 2 out of 10, as a result of lack of available relevant medicines information.
- Usability scores improved as availability of medicines information (of any category) increased in the NPDV, and when the NPDV was supported by trustworthy secondarysource information such as SHS and DS.
- Users sought more interactive NPDV IT tools and on-screen display options to aid onscreen readability, and clinical interpretation and use (particularly for multi-medicine entries).
- Using the polypharmacy NPDVs for medicine reconciliation was considered a challenge, because it required 'manual' (visual) on-screen sorting of multiple medicine entries; there was no option to quickly identify the first and last prescription or dispense entries, nor to search for and sort medicines of clinical interest or concern.
- The majority of the usability scores were between 0 and 6 out of 10 (standard deviation 3).
- Around half of the NPDVs could not be readily reconciled with medicines information contained in relevant system clinical documents such as an SHS.

However, medicines information in other sources – such as SHS, DS and Event Summaries (ES) – greatly assisted in understanding the NPDV medicines information.

Clinical user-based testing and co-design were considered important for increasing NPDV clinical usability.

Errors were observed in the interpretation of polypharmacy patients' NPDV medication histories, as a result of the narrow default date ranges used in some CIS – for example, a 3-month search returning no NPDV medication history compared with multiple medications at 6–12 months.

Lack of health practitioner confidence in the system's medicines information was also observed when no prescription and dispense records for polypharmacy patients were

available for NPDV use, but the patients' other My Health Record documents held medicines information.

How the NPDV is accessed from within general practitioner software differs among CIS systems. The extent of user-centred design testing undertaken by software vendors as part of their implementation of the My Health Record system is uncertain.

User-centred design – that is, including users in the design process – can improve system usability by applying research, factoring in user behaviour, and iterating the design to meet objectives. Part of usability testing is assessing screen design effectiveness – that is, assessing whether a user can effectively navigate an interface to accomplish their clinical tasks. This assessment can include looking at whether or not the clinical user was able to complete their intended task, the amount of time it took the user to meet their goals, and the manner in which clinical tasks were achieved.

Recommendation 8: The System Operator and vendors of medical software make user-based design and testing of medicines presentation and functionality in My Health Record and CIS a central element of future releases.

Finding 9: There is the potential for 'orphan' or unnamed NPDV tabs to remain open within a CIS when the user closes a patient record and moves to the next patient

Risk rating: Moderate

When clicking on the Prescription and Dispense View button in one of the CIS, a separate window opened up containing the NPDV and the search parameters. This window does not include the patient's name in the title bar, only 'Prescription and Dispense View'.

If the healthcare provider used certain key strokes (e.g. 'Alt + Tab') to move on to a new patient, the original patient's NPDV remained open as an 'orphan' view. This meant that two different patients' clinical information was being presented to the healthcare provider at the same time. The lack of patient name in the title bar of the orphan window further increased the potential clinical safety risk posed in this situation.

This matter was reported to the System Operator and the general practitioner CIS vendor. The vendor responded without delay to resolve the matter, and the Commission supported the System Operator to verify that this issue was no longer occurring in the latest release of the software concerned.

Recommendation 9: The System Operator works with the CIS vendor to remove the potential for 'orphan' or unnamed NPDV tabs to remain open within the CIS when the user closes a patient record and moves to the next patient.

Finding 10: A mismatch between a prescription and a dispense record was identified

Risk rating: Moderate

The review found an unexpected grouping of medicines within an NPDV. A dispense record was detected showing a different medicine dispensed (aspirin) from the one prescribed (paracetamol). One of the prescribed medications listed also showed a zero supply.

Once observed as part of the review, this matter was referred to the System Operator for further investigation, and assessment of how widespread this issue was in the production environment. The System Operator confirmed that the misaligned prescription and dispense linkage was due to a coding error in a connecting system, outside of the My Health Record system. The System Operator advised that the coding error has now been rectified.

Recommendation 10: The System Operator investigates and rectifies the mismatch identified in the prescription and dispense record grouping in the NPDV and confirms that the fix applied successfully addresses this issue

Recommendation 11: The System Operator confirms whether the fix applied to address Recommendation 10 rectifies the zero supply issue and if not, develops a system specification to prevent prescriptions specifying no or nil (zero) supply being uploaded into the system

Finding 11: The NPDV header row is not visible when the user scrolls down through a patient's medicines record

Risk rating: Minor

When scrolling down a list of medications, grouped by prescription, in the NPDV, the header row containing the column title information disappears from view. This can lead to users not being able to readily identify what the medicines information relates to in each column. Healthcare provider reviewers identified this as a usability issue, requiring additional time for scrolling back and forth to identify the corresponding column header.

Recommendation 12: Change the NPDV header row to ensure it remains static, enabling the user to view the header (containing column title information) at all times when scrolling down the NPDV list for easier readability of the medicines information

Finding 12: Healthcare providers can see 3 months of medicines in the NPDV, whereas some prescriptions last for up to 12 months

Risk rating: Minor

The healthcare providers who reviewed the NPDVs noted that the default date range for the medicines displayed (usually three months) does not provide a comprehensive view of current medicines for some patients. It was suggested that relevant CIS vendors increase the default date range so that healthcare providers are more likely to obtain a comprehensive view of the current medications available in the NPDV.

Recommendation 13: The System Operator works with software providers to increase the default date range search for system medicines information and documents, to enable users to view appropriate NPDV medicine histories, once tested with healthcare providers

Conclusion

The NPDV was seen as a useful tool by the clinical users engaged during the review, who noted its importance as a reliable and trustworthy source of medicines information. Efficient access to clear, reliable and up-to-date medicines information is regarded by the clinical users as one of the most important uses of the system in their practice.

Increasing use of AMT and the *National guidelines for on-screen display of clinical medicines information* across the My Health Record system and CIS will increase the utility, usability and safety of electronic medicines management.

Building on the NPDV and My Health Record functions for eventual development of a single 'medicine home', or curated medicines list, should be a system goal. The Commission will work closely with the System Operator and NEHTA on the design of a single 'Medications View' project, which has started and aims to improve the display of medications information in the My Health Record system.

Appendix A Clinical safety review risk rating matrix

Review findings have been assigned one of five risk ratings: critical, major, moderate, minor and minimum, consistent with the review's clinical safety risk rating matrix (Table A1).

These categories have been confirmed by the Commission's Clinical Safety Oversight Committee and the My Health Record System Operator during the review process.

Table A1 Clinical safety review risk rating matrix

Risk	Reputation and public	Clinical safety	Control
rating	confidence of My Health Record / quality of service	harm	
Critical	Profound influence on the My Health Record system's reputation, resulting in a profound loss of public and healthcare provider participation Profound sustained degradation of service value and quality	A clinical incident resulting in patient death	Basic, supervisory and/or monitoring controls are inadequate and require urgent management attention A critical patient safety incident has occurred
Major	Significant influence on the My Health Record system's reputation, resulting in significant loss of public and healthcare provider participation Decline in service value and quality is recognised by a majority of patients or health service providers	A clinical incident resulting in major permanent loss of function	Basic, supervisory and/or monitoring controls are inadequate and require prompt management attention A major clinical safety incident has occurred
Moderate	Loss of reputation affecting participation in the My Health Record system Decline in service value and quality is recognised by a moderate number of patients and health service providers	A clinical incident resulting in permanent reduction in function	Basic, supervisory and/or monitoring controls are partly inadequate and require management attention High potential for a clinical safety incident
Minor	Mild damage to reputation of the My Health Record system Decline in service value and quality is recognised by the System Operator and My Health Record partners	A clinical incident resulting in increased level of care/intervention	Basic, supervisory and/or monitoring controls are operating as intended, recommendation for improvement to strengthen control
Minimum	Minimal impact on the My Health Record system's reputation Minimal effect on service value and quality	A clinical incident resulting in no injury	Basic, supervisory and/or monitoring controls are operating effectively, a process improvement opportunity exists