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Ninth My Health Record and national digital health infrastructure clinical safety review

**Adoption and utilisation of SNOMED
CT-AU and AMT: Safe use of
medicines – allergies and adverse
drug reactions**

Summary report

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Acronyms and abbreviations

ADR	adverse drug reaction
AMT	Australian Medicines Terminology
CDA	clinical document architecture
CIS	clinical information system
Commission, the	Australian Commission on Safety and Quality in Health Care
COTS	commercial off the shelf
ED	emergency department
EMR	Electronic Medical Record
IT	information technology
NEHTA	National E-Health Transition Authority
Semantic interoperability	the ability of computer systems to exchange data with unambiguous, shared meaning
SNOMED CT [®]	Systematized Nomenclature of Medicine, Clinical Terms
SNOMED CT-AU	SNOMED core files with Australian-developed documentation and terminology, including reference sets

A detailed glossary is provided at the end of this report.

1 Introduction

The Australian Commission on Safety and Quality in Health Care (the Commission) has undertaken a clinical safety review program for the My Health Record system since the system's implementation in 2012. In July 2016, the Australian Digital Health Agency (the Agency) was established with responsibility for all national digital health services and systems. The Agency was also appointed as the System Operator of the My Health Record system.

The purpose of the clinical safety review program is to promote and enhance the clinical safety of the My Health Record system and national digital health infrastructure. In October 2016, the Commission initiated the ninth clinical safety review under the oversight of the Digital Patient Safety Expert Advisory Group (DPSEAG). The review assessed the adoption and utilisation of SNOMED CT-AU and Australian Medicines Terminology (AMT) nationally. Specific consideration was given to mitigating clinical safety risks related to allergy and adverse drug reaction (ADR) through clinical decision support. This summary report highlights the findings and recommendations from the expanded clinical safety review report provided to the Agency.

2 Background

The need for standard terminology in clinical information systems (CISs) is recognised as a requirement for supporting the semantic interoperability of health information between different care providers. Semantic interoperability is defined as the ability of computer systems to exchange data with unambiguous, shared meaning. SNOMED CT® is such a standard, and is used globally. In 2005 state and territory governments endorsed the adoption of SNOMED CT® nationally.

The use of standard terminologies in the Australian healthcare environment, any barriers to adoption and their impact on clinical safety need to be well understood. The lack of consistent terminology between systems reduces the opportunity for semantic interoperability. This potentially puts patient safety at risk when clinical information about the patient is exchanged between systems. Currently, this exchange is predominantly occurring in acute settings within a single hospital setting, and the procedures in place around transition of care can largely mitigate these risks. But there is increasing demand for this exchange of information across the primary and acute care sectors through semantic interoperability.

The paper *Australian Medicines Terminology (AMT) Benefits Analysis 2014/15*¹ reported the benefits resulting from the implementation of electronic medications management (EMM) in Tasmania, Victoria and at the Sydney Adventist Hospital. It was identified that AMT is an enabling component of these implementations. Improved efficiency, related to decreased pharmacist interventions and decreased time to dispense, was reported. Clinical safety improvements through reduced transcription errors and increased correctly coded allergies were also observed.

The report states:

The benefits associated with AMT increase exponentially with the number of systems with incorporated AMT. The aforementioned benefits attributable to AMT implementation will directly assist each jurisdiction meet their respective health strategic objectives. As such, a priority for jurisdictions should focus on using AMT implementations as an enabler to overcome fragmentation of existing silos of clinical information.

This analysis remains accurate. It is likely the benefits from standard terminologies will only be fully realised once their adoption and use supports meaningful interoperability between systems. Currently, some systems are unable to provide outbound clinical information in a way that other systems can consume in an atomic, machine-interpretable way. Therefore, the investment made to date has only partially delivered the potential value that could accrue.

There has been significant investment in the development of standards for clinical terminology in Australia since the decision to adopt SNOMED CT® in 2005.

This investment has been made in the context of the benefits that are expected to arise. In clinical care delivery, expected benefits include:

- Improved consistency in clinical documentation through the use of common terms
- Increased interoperability between clinical systems, particularly at transitions of care
- Appropriate and actionable clinical decision support that crosses system or sector boundaries and contains granular concepts, all underpinned by robust, auditable authoring and maintenance processes, particularly in relation to drug/drug (DD) interactions, ADRs and allergies

- Opportunities for secondary use of the standardised clinical data. For example statistical analysis, population health initiatives, clinical research and monitoring the quality use of medicines.

The use of standards can enable semantic interoperability and improve clinical decision support, leading to lower risk and better outcomes. For instance, the use of health information technology (IT) to deliver the correct information to a clinician and patient has the potential to reduce 70% of adverse drug events.¹ Further, the use of standard terminologies to capture clinical content at the point of care provides a rich source of data for secondary uses.

National terminology services

The National Clinical Terminology Service (NCTS), currently operated by the Agency, is responsible for managing, developing and distributing national clinical terminologies and related tools and services to support the digital health requirements of the healthcare community.

This responsibility includes being the Australian National Release Centre for SNOMED CT® on behalf of the International Health Terminology Standards Development Organisation (IHTSDO).²

SNOMED CT-AU

SNOMED CT® is a comprehensive, multilingual clinical terminology created by a range of healthcare specialists to support clinical decision-making and analytics in software programs globally. It is owned, administered and developed by SNOMED International.

SNOMED CT-AU is the Australian extension to SNOMED CT®, which originated in 1965 and is generally considered to be the most comprehensive multilingual clinical healthcare terminology in the world with more than 350,000 active concepts. These hierarchies include clinical findings, procedures, observable features, body structures, organisms, substances and pharmaceutical/biologic products. It is a clinically validated, semantically rich, controlled vocabulary covering a wide range of clinical specialties, disciplines and requirements. Moreover, SNOMED CT-AU has been endorsed by all Australian state and territory governments as the preferred national terminology for Australia.

The adoption and use of SNOMED CT® supports the development of high-quality clinical content in Electronic Medical Record (EMR) systems and can lead to a number of benefits for individual patients and clinicians, and for the broader population and in research. These benefits are covered in more detail in the body of the report.

The content within SNOMED CT® is represented through three types of components:

1. **Concepts** – representing clinical thoughts or meanings – ‘from [abscess] to [zygote]’ – that are identified by a unique concept identifier (a number with no inherent meaning) and organised into hierarchies that run from the general to the very specific
2. **Descriptions** – that link human-readable terms to the concepts; synonyms can be recorded as associated descriptions, as can descriptions in other languages
3. **Relationships** – that link each concept to other related concepts; for example, an ‘[is a]’ relationship defines relationships within the hierarchy, and a ‘[causative agent]’ relationship is used to identify possible causality.

Reference sets are defined within both SNOMED CT® and SNOMED CT-AU for a number of purposes. The most relevant purpose for consideration in this review is the definition of subsets of concepts relevant to a particular practice area – for example, endocrinology or

emergency medicine. The rationale is that a subset of concepts relevant to a particular case facilitates use in a busy clinical setting.

Australian Medicines Terminology

The AMT identifies all commonly used medicines in Australia and can be implemented in CISs to support:

- Prescribing
- Recording
- Medicines review
- Issuing, including dispensing
- Medicines administration
- Transfer of information.³

AMT is a systematically organised, computer-readable collection of medicinal terms, modelled according to international terminology. It is part of SNOMED CT-AU and is intended to be usable by both humans (i.e. human readable) and computers, thereby enabling interoperability through provision of a standard codeset for medications.

In the AMT Implementation Plan 2011–2012), the then National E-Health Transition Authority (NEHTA) described three broad options for increasing maturity of implementation of AMT.

These are:

- Option A – mapping of AMT to an existing local medicine list
- Option B – replacing the existing local medicine list with a commercial off the shelf (COTS) medicines dictionary product that is mapped to AMT
- Option C – the goal state – native implementation of AMT where the users of the system interact directly with AMT concepts which are stored and shared throughout the system. It is acknowledged that the COTS medicines dictionary may still provide certain resources and functions; although not articulated in the paper, it is expected that this refers to the clinical decision support functions which are absent from the AMT itself.

EMR systems

There are a range of labels applied to the IT solutions used to capture clinical information relevant to the diagnosis and treatment of individuals in primary and acute care settings. For the purpose of this review, the term ‘EMR systems’ is used to cover these systems. EMR systems are in use in general practice and hospitals at the point of care to record problems, diagnoses, procedures and clinical management, and to order medications. These systems are often referred to as clinical information systems and Electronic Medications Management systems. In this review, EMR does not include Patient Administration Systems (PAS) that record information subsequent to the episode of care, primarily for administrative, reporting and billing purposes.

Objective and scope

The objective of the review was to assess the level of adoption of the national standard terminology nationally against the vision articulated by the Agency, and the contribution of the terminology to driving the safe use of medicines.

The scope of the review was to nationally evaluate the status of adoption and utilisation of the SNOMED CT-AU terminology, including the AMT (subsequently referred to in this

document as SNOMED CT-AU and AMT). The impact of terminologies in mitigating clinical safety risks, with particular regard to allergy and ADR alerts, is also assessed.

This review mapped the current status of the allergy and ADR reference sets and associated functionality in a sample of general practitioner, community pharmacy and hospital CISs, and identified clinical safety issues and areas of risk.

For the purpose of the review, 'adoption' considers the extent to which SNOMED CT-AU and AMT is supported within vendor systems during activities that involve:

- Search and display
- Recording relevant clinical findings
- Use of this information for clinical decision support
- Inclusion of this information in outgoing messages and documents.

'Utilisation' considers the extent to which clinicians use the capabilities of those systems.

3 Methods

The review assessed the adoption of SNOMED CT-AU and AMT across a broad and representative sample of stakeholders, and was undertaken in three stages:

- Stage 1 – formulation of the assessment framework
- Stage 2 – stakeholder consultations and site visits with 23 organisations and individuals in primary and acute care settings in four jurisdictions (see Appendix A)
- Stage 3 – analysis and formulation of the conclusions and recommendations.

Stage 1: Review design

There are a range of considerations that influence the adoption and utilisation of standard terminologies. Three key domains were addressed in identifying appropriate stakeholders:

- Government and other jurisdictional agencies provide the overall framework for adoption, and are relied upon for architectural, content and implementation guidance; in some countries, adoption is mandated or incentivised^{6,7}
- Vendors are a key enabler of widespread adoption of standard terminologies in clinical settings; typically commercially driven, they provide solutions that meet market demand
- Clinicians are the ultimate measure of utilisation, but are heavily dependent on the vendor products they use.

Stage 2: Consultations

The interviews were constructed around a semi-structured questionnaire that addressed each respondent organisation's adoption and utilisation of SNOMED CT-AU and AMT. The interviews used a socio-technical taxonomy, which included technology (software and hardware), people (clinicians and patients), processes (workflow), organisation (capacity, decisions about how health IT is applied, incentives), and the external environment (regulations and public opinion).² Some vendor and healthcare provider organisations were also able to provide demonstrations of the CIS functionality used for recording allergies and ADRs, and for prescribing medications.

These demonstrations were particularly useful for assessing the use of SNOMED CT-AU and AMT, and identifying any clinical risks arising from CIS functionality, with specific focus on allergies and ADRs and resulting alerts. Where no demonstration was given, a supplementary questionnaire was used to more accurately assess the conformance of SNOMED CT-AU and AMT implementation with the guidance provided by the Agency. The questionnaire specifically followed guidance for recording allergies and ADRs and prescribing medicines contained within the *Clinical Documents – My Health Record Usability Recommendations v1.3*⁹ and *Clinical Terminology – Guidance for Use in Healthcare Software v1.0*.¹⁰

Stage 3: Analysis

Results from the qualitative interviews and the more detailed questionnaire were analysed to identify key themes in each area.

4 Findings and recommendations: introduction

The approach to the implementation of SNOMED CT-AU and AMT across primary and acute care is highly heterogeneous. There is considerable variation in the way in which the national data standard is applied, utilised and consumed across the different functionalities of the various available EMR applications.

Despite no native* implementation being observed, medication and prescribing content in EMRs are reported to have coverage of AMT, albeit incomplete. For the majority of EMR vendors, their medications content is provided by (or is based on) a mature third-party COTS medicines dictionary vendor such as *MIMS, Multum or First Databank*. Medical dictionaries, in turn, interface with AMT through a 'mapping' process.

The methods across EMRs for recording allergies and ADR information are highly variable, despite standardised implementation of SNOMED CT-AU and AMT stipulated in vendor contracts. Variations exist in the different pick-lists† and also in their intended semantics of use. The extent of SNOMED CT-AU and AMT adoption for allergy and ADR content is limited, and it is unclear what level of integrity and precision could be achieved in the mapping between vendor content and SNOMED CT-AU and AMT.

For other clinical domains such as for clinical diagnosis and presenting problems, there is comparatively less content coverage. Where structured data is available for collection, there is a variety of codesets that are applied for the same fields across different EMRs.

The acute care sector typically has taken a much more systematic approach to data integrity and information model management than most primary care software vendors and services. One reason for this has been the lack of strategic direction and authority (mandate) in the use of SNOMED CT-AU and AMT in the primary health space in comparison to acute care. The impact of this is significant, as EMRs and CISs could continue to build up coded data that is of variable quality, potentially unsafe for semantic interoperability, and unreliable for comparative and population data analytics.

The following sections will outline the key findings in greater depth within the three domains assessed in this review: [Governance and intent](#); [Vendors and implementers](#); and [Clinician environment](#). Each finding has a risk rating and a related recommendation. The risk rating guide used for this review is in [Appendix B](#).

Most risks have been assessed as 'minor' because they have been assessed against the current levels of EMR use which have very limited interoperability. As most healthcare organisations operate within the confines of their own EMR, the risk to patient safety is relatively low because of existing procedures and clinician vigilance. However, it is acknowledged that the risk will increase as a greater number of patients and clinicians across health care setting begin to access information external to their own EMR or personal health record. This could lead to incorrect or missing clinical information and result in an incorrect clinical decision being made due to this variability in data standards.

* That is, accessing SNOMED CT-AU and AMT content directly through a terminology server.

† A list of items available for selection.

5 Findings and recommendations: Governance and intent

Finding 1: Vendors and implementers found the Agency to be constructive and supportive for terminology-related product development

Risk rating: Not applicable

Vendors and implementers indicated that implementation support, through existing guidance publications, phone/email support and information sessions, was informative and constructive.

Recommendation 1

The Agency should continue the current approach to support vendor and implementer communities.

Finding 2: Senior leaders, vendors and clinicians recognise SNOMED CT-AU and AMT to be a credible national and international standard

Risk rating: Not applicable

Vendors, implementers, clinicians and administrators all recognise the importance of a single authoritative terminology and recognise the benefits of such an approach. There was general consensus that the agreed Australian standard (SNOMED CT-AU and AMT) should be broadly implemented, and that there was no other standard that offered the same potential benefits.

Recommendation 2

The Agency should continue to develop SNOMED CT-AU and AMT products and promote their use.

Recommendation 3

The Agency should explore the introduction of requirements that all procurement funding and contract incentives for digital health infrastructure be contingent on systems being SNOMED CT-AU and AMT compliant for the provision of health care and to facilitate health research.

Finding 3: There is a lack of a comprehensive compliance and conformance framework from an authoritative national body

Risk rating: Minor

Despite there being guidance for terminology implementation, in the absence of a conformance description, vendors have continued to operate without any requirement to

create semantically interoperable messages. These messages need a level of granularity that supports safe clinical information exchanges between EMR systems.

With increased use of EMRs that do not utilise SNOMED CT-AU and AMT, both in new implementations and with the growth of clinical content within existing EMRs, there will be a significant volume of clinical content that will be 'new legacy' data, that is, new data that is not in line with national terminology standards. This creates further barriers to interoperability, patient safety and continuity of care, and reduces opportunities for secondary uses of clinical information.

The lack of a compliance roadmap results in vendors taking different approaches to the adoption of SNOMED CT-AU and AMT, reducing the quality of coded patient clinical data. Variation in accuracy, completeness and appropriateness in EMRs systems can:

- Compromise patient safety through lack of precision of clinical information of decision support alerts
- Prohibit safe interoperability between clinical EMR system interfaces
- Prevent data migration or historical data compatibility
- Cause accumulation of non-transferable and unusable legacy data
- Inhibit the safe provision of reliable data for information mining and analysis.

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

Finding 4: There are no assurance processes to determine clinical semantic accuracy in clinical document architecture (CDA) documents or messages from vendor EMRs

Risk rating: Minor

The quality of coded clinical information is integrally related to the semantic accuracy of the information from the point at which data was recorded in the EMR. Complex information which is common in a patient's clinical history includes contextually important concepts such as 'the patient has a past history (or diagnosis) of ...', 'the patient has a family history of ...', 'patient presented with suspected meningitis', 'the patient has an absence of ... (a clinical sign or symptom)'. These types of concepts, however, have long been a challenge to record accurately in a coded form in EMRs. In short, data items selected by the clinician from the on-screen display in the EMR must be assigned with a coded concept which has the precise clinical meaning.

The current compliance requirements of the Agency do not require a vendor EMR application to demonstrate semantic accuracy of electronic data being transmitted to the My Health Record system. The integrity of the My Health Record system therefore relies on EMR vendors to ensure that the semantics of the clinical information in electronic form is preserved between clinical data entry and the data message that is transmitted to the My Health Record system.

* At present, not all CDA messages to the My Health Record system are in SNOMED CT-AU and AMT coded form.

Currently, the Agency conducts a compliance review for vendor systems to assess their connectivity with the national My Health Record system. However, this compliance review does not include assessing the semantic integrity of the clinical content within the EMR system from which the electronic message was generated. This includes Shared Health Summaries, Event Summaries, Discharge Summaries and other clinical documents.

Example

It has already been noted by the Agency that in some CDA documents and messages, data qualifiers for example, the laterality of a clinical disease have been omitted in the CDA when they were recorded in the source EMR system. While in some cases missing laterality may not result in loss or impairment of life for example, missing laterality for knee joint replacement could be confirmed clinically with surgical scars. In other cases the missing or inaccurate laterality detail could pose significant and grave patient safety consequences for example, if the wrong side has been recorded.

Recommendation 5

The Agency to consider developing a set of clinical assurance and validation procedures for vendors to assess the semantic accuracy of coded electronic data used for system interfaces.

6 Findings and recommendations: Vendors and implementers

Finding 5: The general practice primary care sectors highly fragmented EMR environment impacts on standardised terminology adoption

Risk rating: Minor

The general practice primary care sector has a broad variety of available EMR vendors. Methods to record coded data differ and this is compounded by variations in implementation on a practice-by-practice basis. This has created a highly fragmented EMR environment from the perspective of implementation of a terminology standard.

General practice CISs in the primary care sector are implemented on a practice-by-practice basis

A general practice would typically purchase its CIS through some form of licensing agreement with the vendor company at a practice level on behalf of all the participating clinicians at that practice. In setting up the EMR, vendors usually provide technical support which includes setting up servers and databases. Beyond this point, each practice is responsible for the software's ongoing maintenance and updates. Some larger general practices employ an IT manager^{*} to maintain the software, including content releases. Some 'solo' general practitioners manage their own software implementations and updates.

Example – contributing to fragmentation

Each vendor designs and releases content sets to support clinical functionalities. These include the list of medications, and reference sets for 'reaction type' or 'immunisation type'. Vendors subsequently have no visibility of how the EMR is used, or of the quality of data recorded at the practice level.

Each practice is informed of the availability of updates, typically through an email notification. However, it is generally not mandatory for each practice to upload and implement the latest reference content set including medications list and allergic reaction types. Some practices are 'reluctant' to update their software immediately following a release due to concerns regarding the stability of the new updates.

Vendors have no access to or visibility at the practice level of individual user behaviours in selection of data, codes, or pattern of recording free text, which would allow the vendor to understand the gaps in standard codesets provided with the EMR.

Vendors have no access to information relating to data selection behaviours by clinicians which may have implications on patient safety. For example, general practitioners frequently recording medication allergy substances in free text form rather than coded lists, where free text would not trigger clinical decision support functions.^{†,10} This information would assist vendors to design EMRs to better assist with term selection.

* Variations in terms of employment may exist across practices.

† Review of clinical decision support system features is not in scope for this report – this particular point is raised as it relates to allergy substance recording.

The experience and depth of health informatics knowledge of the IT manager(s) for each general practice may vary.

It is important to note though that some vendors are in the process of rolling out new solutions that are cloud-based EMRs. Subsequently, a number of the issues identified will be resolved as the vendor will update content into the cloud solution (which will then be available to subscribers). The cloud solutions have generally incorporated SNOMED CT-AU and AMT and it is likely that this will be a significant enabler of more widespread adoption.

Reliance on third-party vendors to be compliant and conformant with SNOMED CT-AU and AMT

A number of EMR vendors rely on COTS content, particularly for medications and decision support functionalities such as MIMS, or *First Databank*. For other clinical domains such as Clinical Problems and Diagnosis, there are other content providers who maintain valid 'mappings' and 'reference subsets', and who develop easy-to-use terms and pick-lists for ease of implementation and adoption such as the International Classification of Primary Care [ICPC], and Intelligent Medical Objects [IMO].* Vendors themselves are exposed to variations in external content that is available to them commercially, over which they have little or no control.

Competing client demands

Vendors also indicated that their IT development focus is often driven by the needs of their clients (general practitioners and specialists) to meet reporting requirements. These include national incentive programs such as the Practice Incentive Payments program for the recording and reporting of immunisations.

Different primary care CIS vendors have different levels of resourcing (and priority) for SNOMED CT-AU and AMT maintenance and issues

Most primary care CIS vendors have placed the priority for SNOMED CT-AU and AMT implementation at about 'halfway' (based on an arbitrary score out of 10) among other product developmental needs. Some vendors have a dedicated clinician who leads development of terminology and is accountable to information standards. Other vendors have a product release manager who is responsible for clinical content-related products. This review recognises that this variation may be due to different implementation approaches used by vendors in the development of clinical content.

The complex primary care landscape exposes the sector to poor data quality. As discussed in previous sections, both clinical and administrative risks are associated with poor clinical data. A lack of a consistent approach risks the creation of a large volume of unusable legacy data in primary care practice systems. This in turn results in complex and unsafe data migration in the future. Practice-based IT managers may not have the necessary health informatics knowledge to recognise the importance of managing historical records, thereby impacting the quality and safety of the CIS.

* IMO is a privately held company.

Recommendation 6

The Agency to consider the following:

- Development of a terminology conformance and compliance roadmap for both primary and acute care
- Development of standard tools, operating procedures and compliance criteria to enforce semantic accuracy of coded clinical data recording and transmission
- Promotion of existing or newly developed standards, tools and operating procedures to assist vendors and implementers to assess data quality in CISs.

Recommendation 7

EMR vendors to partner with their third-party COTS medicines dictionary to co-develop a terminology implementation strategy to address national conformance and compliance requirements.

Finding 6: There are variations in the approach to adoption of SNOMED CT-AU and AMT in acute care

Risk rating: Minor

Variations and fragmentation in the approach to adoption of SNOMED CT-AU and AMT is observed across acute care providers.

Examples

Different approaches in acute care include:

- Development of fully centralised statewide terminology services supporting a single information model for all participating providers and vendors; Western Australia is implementing this model
- A statewide eHealth strategy managed through a jurisdictional authority, with devolvement of terminology implementation accountabilities to contracted vendors; this is the model New South Wales has used
- A group of related hospitals (clusters) managing its own adoption of terminology and information strategy with a view to their model providing a path forward for similar organisations; examples include Queensland Health Metro North/South, the Austin Hospital (through VicHealth) and the Royal Children's Hospital, Melbourne.

A key challenge is that EMR vendors are mainly large global companies. The priority for SNOMED CT-AU and AMT adoption is dependent on market and commercial factors external to the Australian context and influenced by the large international client base.

In addition, the review identified examples where requests to provide updated medicines catalogues for the Australian context were given very low priority by one international vendor (not included in the consultations). This resulted in sub-optimal recording of oncology treatments and was an ongoing issue. There was a view expressed that making the requests 'more official' would be beneficial.

Recommendation 6

The Agency to consider the following:

- Development of a terminology conformance and compliance roadmap for both primary and acute care
- Development of standard tools, operating procedures and compliance criteria to enforce semantic accuracy of coded clinical data recording and transmission
- Promotion of existing or newly developed standards, tools and operating procedures to assist vendors and implementers to assess data quality in CISs.

Finding 7: The private hospital sector remains predominantly paper based

Risk rating: Minor

While there are a number of smaller private hospitals that are quite advanced in the adoption of EMR, the majority of private hospital ownership groups remain largely paper based. SNOMED CT-AU and AMT are not usable where clinical records are paper based. Patient administration systems generally record allergies on admission in an unstructured form, but paper will be the source of truth for up-to-date allergy information.

Participants in the private sector often require a business case showing an expected return on investment to justify EMR investments. The 'meaningful use' incentives available in the United States have provided that impetus across sectors there, but the Australian environment does not offer such incentives.

A recurring theme on procurement of EMR systems was that functionality would always take precedence over the terminology used. While tender documents may specify that SNOMED CT-AU and AMT are desirable, some solutions do not offer this. The view was expressed that if a clinical system was functionally the best fit for the business's requirements, then that solution would still be implemented, despite SNOMED CT-AU and AMT being unavailable.

Example

One large private hospital ownership group creates an electronic documentation tool to assist with discharge letters, but this generates a largely free text based (uncoded) document for upload to the My Health Record system.

Clinical services provided in the private sector such as investigations and treatment make up a significant proportion of health services provided to our population.

Important information about a patient's care events may be missing from the My Health Record system because there is no electronic recording of health information in the private sector.

Recommendation 8

Develop strategies to support private hospitals working on adopting EMR solutions, which would include use of SNOMED CT-AU and AMT.

Recommendation 9

The Agency to consider engaging with private hospital ownership groups, possibly via the Australian Private Hospital Association and Catholic Health Australia, to provide advice and guidance on the development of a private hospital sector EMR roadmap. A key focus would be on the implementation of SNOMED CT-AU and AMT.

Finding 8: Organisations are using alternative strategies to drive interoperability in the absence of a compliance requirement or conformance model

Risk rating: Minor

Mature EMR vendors such as Cerner and Epic have developed their software over time using a centrally (and globally) maintained 'controlled medical terminology' information model. Such an approach allows for a vendor's various proprietary EMR solutions to easily 'bolt on' or 'stack', while maintaining safe transfer of semantically interoperable information across various internal applications without reliance on external reference taxonomies.

In many cases, the sophistication of such an approach creates internal system efficiencies without the resource overhead to maintain mappings; safety through decision support rules; and innovation which cannot otherwise be met by interfacing with an external taxonomy standard.

However, this approach has some limitations. Use of proprietary controlled medical terminologies by vendors means that the adoption of any external data standards will be largely limited to mapping, as opposed to natively incorporating, proprietary content to an external terminology source. The information model and knowledge inherent within SNOMED CT-AU and AMT concepts are redundant under these circumstances.

Example

Cerner's 'stacked' system includes PowerChart, SurgiNet (for operating theatres), PharmNet (for prescribing and dispensing of medicines, and for inventory and stock control), and FirstNet (for emergency departments). Cerner's internal controlled medical terminology (globally controlled) drives interoperability across each of the systems without any interface mappings. In addition, Cerner has created a set of reusable Clinical Decision Support systems for dose/weight/age prescribing, but can only meaningfully share this with other Cerner sites.

Some mature EMR systems in the market use a proprietary controlled medical terminology for integrating different components of the EMR system. This approach will continue to limit the native incorporation of SNOMED CT-AU and AMT due to the requirement to map the internal medical dictionary to external standard taxonomies.

There may be data quality issues relating to the integrity of data mapping between proprietary codesets and SNOMED CT-AU and AMT codesets, resulting in messaging and semantic interoperability anomalies. Due to dual imperatives of clinical safety and seamless operation demanded by hospital services and clinicians, EMR implementers may continue to choose a 'single stack' approach over introducing separate SNOMED CT-AU and AMT codesets for system interoperations. The data mapping overhead is highly resource intensive, and exposed to clinical risks due to data content that an EMR vendor cannot control.

For certain global EMR vendors, it may not be realistic to anticipate that a native SNOMED CT-AU and AMT implementation approach can be achieved, despite best intentions.

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

Finding 9: Difference in medications content available in different EMRs

Risk rating: Minor

For some EMRs, the structured data for entry that is available to clinician users is determined by the EMR vendor's internal team or their third-party content suppliers. It has been reported that there are differences in clinical content across the different COTS medicines dictionaries and EMR vendors.

COTS approach to data modelling differs across providers

Third-party content vendors such as *Multum*, *IMO*, *MIMS*, and *First Databank* have their own internal clinical information models. They will therefore develop and maintain their own data coverage, including code mappings and decision support rules. Due to the modelling approach by COTS medicines dictionary vendors, not all SNOMED CT-AU and AMT content will be consumed for this purpose, resulting in COTS content sets being different to SNOMED CT-AU and AMT. In addition, anecdotal suggestions are that vendors and content providers have developed 'useful' and 'clinician friendly' content sets to ease local adoption by clinicians. However, due to the variations, some clinical concepts in third-party content sets may not have a corresponding or precise mapping to SNOMED CT-AU and AMT, rendering 'orphaned' some of these proprietary concepts and creating a significant 'legacy' data issue the longer non-standardised content is sustained.

Despite this variation, the clinical decision support enabled by these external providers cannot be underestimated in terms of mitigating clinical risk. Without this content and the accompanying rules, EMR vendors would need to independently derive and manage rules themselves, or provide software with no 'out of the box' drug or allergy checking.

Timing of content release by different COTS medicines dictionaries

Due to the additional time and resources required to model SNOMED CT-AU and AMT updates into the COTS dataset, EMR vendors and other commercial consumers of COTS content may not always receive COTS content updates at the same time as SNOMED CT-AU and AMT updates. This lag time between release of SNOMED CT-AU and AMT updates and COTS content updates will invariably result in different EMRs using different versions of COTS content across certain time windows, resulting in potential conflicts arising from different EMRs using different datasets.

Timing of content release by SNOMED CT-AU and AMT

SNOMED CT-AU and AMT content updates may not meet clinician requirements. This is particularly an issue for newly approved medications from the Therapeutic Goods Administration and clinical trial medications which have not made it onto the market. These

medications typically will not have had time to be incorporated and modelled into the SNOMED CT-AU and AMT dataset for system consumption. For these reasons, clinicians will have little option in EMRs but to record such medications in non-precise coding or non-structured descriptions.

There is currently no visibility by the Agency of the variation between content sets that have been developed by different vendors and by COTS medicine dictionaries.

Recommendation 10

The Agency to develop a mechanism to resolve the gaps and overlaps between content sets of COTS medicines dictionaries, vendors, and SNOMED CT-AU and AMT.

Recommendation 11

The Agency to develop mechanisms to harmonise the difference between content available across vendors and SNOMED CT-AU and AMT content.

Recommendation 12

The Agency to develop a national terminology service which is a central reference repository for important mapped data content across EMR systems. Reference is made to Western Australia's state-based terminology service, and also Ontoserver.

Finding 10: Mapping remains the dominant approach to the adoption of SNOMED CT-AU and AMT, with no examples of native implementations

Risk rating: Minor

Vendors (in the current release of their EMR) across both primary and acute care sectors have adopted predominantly a mapping approach[†] to address the immediate requirements for sharing information with the My Health Record system.

Due to functional design of EMR systems and the atomic nature of some of the SNOMED CT-AU and AMT RefSets/subsets, vendors to date have not been able to natively use SNOMED CT-AU and AMT to drive medication prescribing. A mapping strategy has therefore been adopted by most vendors to fulfil reporting and messaging obligations.

Under some other circumstances, innovative clinical functionality and behaviours of the EMRs do not necessarily lend themselves to the native use of SNOMED CT-AU and AMT. These include an EMR's capability to create practical, convenient mechanisms to assist clinicians in prescribing, such as the local crafting of 'order sentences'[§]. For example, '0.5 mL, Intradermal, Injection, ONCE' or hand-crafted pick-lists.

Further, vendors have identified that there are limited use-cases that require native implementation of SNOMED CT-AU and AMT where mapping of content fulfils the basic business requirements for reporting and messaging. It should also be noted that sometimes not all SNOMED CT-AU and AMT can be made available in vendor EMRs due to conflicts between the SNOMED CT-AU and AMT concept model and the EMR's internal COTS

* Only for a selection of clinical content.

§ Provides ordering efficiency by allowing the user to select in one click the pertinent medication order details, including dose, route and frequency that reflect most commonly ordered medication details.

concept model. This is particularly problematic in the areas which relate to decision support rules.

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

Finding 11: Vendor EMRs are not always able to retain SNOMED CT-AU and AMT descriptions

Risk rating: Minor

Under some circumstances, vendors may need to revise the display term descriptions due to technical restrictions or to facilitate certain functional features of an EMR application.

Examples

Examples where functional features may need revision:

- Limitation in term searching capabilities; for example, the vendor has had to create new synonymous terms such as 'Class of Antibiotic – Penicillin' and 'Penicillin – Class of Antibiotic' because the EMR only has a 'begins with' search capability
- Limitation in display field length; for example, the vendor has had to create localised concatenation or abbreviations of the original SNOMED CT-AU or AMT descriptor to fit the available display field.

Any truncation, concatenation or abbreviation of SNOMED CT-AU and AMT sanctioned descriptions represents a deviation from the principles of standardisation of clinical terminology. Due to the variation of display terms against the SNOMED CT-AU and AMT descriptions, vendors may have to maintain their internal mappings, which in turn are exposed to potential errors in precision.

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

Recommendation 13

The Agency to develop tools and operating procedures to support quality assessment of semantic equivalence of the user interface design and message output.

Finding 12: There are variations in the recording of allergy substance and agent values in EMRs

Risk rating: Minor

Vendors have adopted different approaches to the recording of substance and agent values. Not all vendors are provided with the full ADR content set as specified by the Agency in the guidance provided. Vendors are not seeing this as a critical issue, as there is no requirement for compliance to the suggested dataset.

It is noted that there is a National Allergy Strategy, led by the Australasian Society of Clinical Immunology and Allergy, which is planning a broader initiative to harmonise the data recording requirements for allergy and ADR information. This strategy would be a driver towards consistent allergy and ADR information in EMRs.

Examples

Examples of inconsistent allergy and ADR information in EMRs include:

- Allergy substances for selection may vary between EMRs due to differences in content provided by other third-party COTS medicines dictionary vendors such as *Multum*, *MIMS*, and *First Databank*
- Some vendor third-party suppliers use an 'Australianised' version of the medication content, which have similar (but not identical) display names to AMT
- Some vendors have created additional acronyms or synonyms to improve usability of substances selection
- Some vendors permit the creation of a 'user-defined' list based on SNOMED CT-AU and AMT
- Some vendors permit the use of free text fields to accommodate for substances which cannot be found (but which are important to record for clinical management/communication purposes)
- Some vendors have included pharmacological 'classes' as a selection for allergic substances; however, anecdotal reports provided by vendors indicate that the modelling of decision support rules is often not congruent with the SNOMED CT-AU and AMT concept model.

There is a risk that the quality of semantic intent across allergy data could vary, particularly if atomised data items are to interoperate between EMRs in the future. This will have potential consequences of:

- Impaired data quality including accuracy, completeness, appropriateness
- Compromised patient safety through poor precision of clinical information or decision support alerts
- Restriction of semantic interoperability across system interfaces
- Restriction of future data migration or historical data compatibility
- Accumulation of non-transferable legacy data
- Incomparable information for data mining and analysis.

Recommendation 10

The Agency to develop a mechanism to resolve the gaps and overlaps between content sets of COTS medicines dictionaries, vendors, and SNOMED CT-AU and AMT.

Recommendation 11

The Agency to develop mechanisms to harmonise the difference between content available across vendors and SNOMED CT-AU and AMT content.

Recommendation 12

That a national terminology service be established as a central reference repository for important mapped data content across EMR systems. Reference is made to Western Australia's state-based terminology service, and also Ontoserver.

Finding 13: There are variations in the recording of adverse reaction type values in CISs

Risk rating: Minor

Different EMR vendors have used different strategies in the recording of different types of adverse reactions. The current list provided by the Agency is shown in Figure 1.

Figure 1: ADR hierarchy of reaction types provided by the Agency

Adverse reaction type

Allergic reaction

Hypersensitivity type I

Hypersensitivity type II

Hypersensitivity type III

Hypersensitivity type IV

Non-allergic reaction

Drug interaction

Drug interaction with drug

Drug interaction with food

Food intolerance

Medication side-effect

Toxicity

Source: Adapted from the Australian Digital Health Agency (2016)¹¹

Variations by vendor applications include:

- Different EMRs provide clinicians with their own listing of allergy type descriptions which is often a simplified list compared to the SNOMED CT-AU and AMT reference set (Figure 1)
- Frequent use of the generic label 'Allergies' as a catch-all for all different types (and subtypes) of allergies and adverse reactions, with other labels such as Drug-Intolerance and Class Allergy variably used
- Different levels of hypersensitivity types have not been observed in existing EMRs during this review (except the EMRs in development which are due for release by the vendor)
- EMRs do not all differentiate between a medication side-effect and an allergic reaction
- Free text fields are available in the majority of EMRs to qualify a reaction or provide fuller explanation of the clinical reaction if required.

Data fields in various EMRs are not identical fields; therefore, data interoperability between EMR systems will not occur without manual intervention. Lack of clear adverse reaction definitions may result in poor quality data recording.

Variation in the quality of coded clinical data (e.g. accuracy, completeness, appropriateness) in EMR systems can:

- Compromise patient safety through lack of precision of clinical information or decision support alerts
- Prohibit safe interoperability between clinical EMR system interfaces
- Prevent data migration or historical data compatibility
- Cause accumulation of non-transferable and unusable legacy data
- Prevent the safe provision of reliable data for information mining and analysis.

Recommendation 10

The Agency to develop a mechanism to resolve the gaps and overlaps between content sets of COTS medicines dictionaries, vendors, and SNOMED CT-AU and AMT.

Recommendation 11

The Agency to develop mechanisms to harmonise the difference between content available across vendors and SNOMED CT-AU and AMT content.

Recommendation 12

The Agency to develop a national terminology service which is a central reference repository for important mapped data content across EMR systems. Reference is made to Western Australia's state-based terminology service, and also Ontoserver.

Recommendation 15

The Agency to work with peak clinical groups to develop a standard set of definitions for adverse reaction types to improve precision of selection and comparability of clinical data for broader analysis. This work should be undertaken collaboratively with the National Allergy Strategy group.

Finding 14: There are variations in recording 'clinical manifestation' values in EMRs

Risk rating: Minor

There are wide variations among EMR vendors in the recording of clinical manifestations for allergies. The currently recommended (permissible) values for the recording of clinical manifestation for allergies and ADRs are from members of the following SNOMED CT-AU reference sets:

- 142341000036103 |Clinical manifestation reference set|
- 32570071000036102 |Clinical finding foundation reference set|.

Examples

Variations in vendor applications include:

- Different EMRs provide clinicians with their own listing of clinical manifestation descriptions, which often is a restricted list compared to the SNOMED CT-AU reference set (Figure 1)
- Free text fields are available to record a clinical manifestation if needed (or one which is hard to find), meaning there is no coding for decision support
- Vendors provide clinicians with a curated, or 'simplified', easy-to-use pick-list to facilitate data entry, which may be generic or poorly defined

- Some vendors have their own descriptions of clinical manifestations that do not precisely map to SNOMED CT-AU.

Recommendation 10

The Agency to develop a mechanism to resolve the gaps and overlaps between content sets of COTS medicines dictionaries, vendors, and SNOMED CT-AU and AMT.

Recommendation 11

The Agency to develop mechanisms to harmonise the difference between content available across vendors and SNOMED CT-AU and AMT content.

Recommendation 12

The Agency to develop a national terminology service which is a central reference repository for important mapped data content across EMR systems. Reference is made to Western Australia's state-based terminology service, and also Ontoserver.

Finding 15: There are variations in decision support rules, clinician interactions and system alerts across COTS medicines dictionaries, EMR vendors and implementers

Risk rating: Minor

Difference in COTS medicines dictionaries' decision support rules and the AMT concept model

Decision support rule engine vendors such as *Multum*, *MIMS*, and *First Databank* have developed clinical decision support rules using their own internal concept model.

As these commercial rule engines have been developed, used and tested by vendors in EMR systems over decades, they provide a mature solution. The introduction of SNOMED CT-AU and AMT with its own concept model has provided a challenge to vendors to reconcile the two information models to produce consistent cross-checking behaviours.

An example of this is pharmacological 'classes' of medication, where different vendors may have different approaches to how drug interaction checks are conducted. For example, applying checking at ingredient level or product level.

Difference in alert warnings when free text is entered

While alerts and decision support features are not explicitly part of this review, they are discussed because this topic needs to be considered in parallel to the implementation of SNOMED CT-AU and AMT, particularly in the recording of allergies and ADRs. The absence of this functionality would degrade the current level of patient safety enabled through these decision support tools.

Most vendor EMRs provide some form of warning to clinicians to indicate that a selected substance of allergy or ADR does not trigger decision support alerts. A number of important anomalies have been identified during discussions with participating vendors.

Examples

Updating of an EMR's reference tables with new SNOMED CT-AU and AMT allergic substances/medications in a general practice system will render a previously coded allergic substance to be a string of 'free text' data (even though the previous entry was a coded item); there is subsequently no warning to clinicians that there is now no clinical decision support against the previously coded item, even though the two texts read identically.

Due to either an absent item or an inability to find an allergic substance, clinicians enter the item as a free text field with the outcome that no decision support is available; while this was important as part of documentation at the time, clinicians are not made aware to 're-enter' the same data in coded form when it becomes available and the substance of allergy remains in free text form indefinitely.

One primary care vendor has indicated that the installation of an allergy substances reference set into an EMR could render an existing recorded allergy (previously coded with allergy cross checks) into a 'free text' form without a user's control, unknowingly leaving the clinician without decision support against that existing allergy substance item. In this situation the free text data entry will not trigger decision support alerts, and clinicians are not reminded to update the record even when the data item becomes available.

Recommendation 16

Clinical risks identified in EMRs that are then reflected in the My Health Record system should continue to be formally reported accordingly by the instigator of the issue. The Agency should consider implementation of a mechanism to collate, analyse and report on incidents and identified risks.

Recommendation 17

The Agency to conduct a detailed review of decision support approaches for allergies and ADRs by different EMR vendors.

Recommendation 18

The Agency to lead the development of best practice approaches to guide the configuration of decision support pertaining to allergies and ADRs.

Recommendation 19

Alerts and warnings should be considered for allergy and ADRs that have no decision support for example, free text recording. This consideration should be part of a broader alerts and decision support review.

Finding 16: Multiple clinical taxonomies are used across an EMR

Risk rating: Minor

Multiple clinical taxonomies are used across an EMR to address different business and reporting needs of the EMR such as My Health Record system messaging, reporting for activity-based funding and emergency department (ED) activity reporting. Taxonomies exist for domains such as problem lists, diagnoses, clinical observations, procedures, medications and allergies.

Examples

- Medication catalogue: PBS, *Multum*, *MIMS* or *First Databank*
- Non-medication allergies: Clinician defined using SNOMED CT-AU
- Problem list: ICPC or IMO provided dataset
- Diagnosis (in ED): a set of hand-crafted ICD10 codes commonly used in EDs
- Procedures: vendor hand-crafted, commonly used pick-list.

As EMRs have adopted different approaches to the taxonomies applied, semantic interoperability between systems is a significant challenge.

It is inappropriate to use classification languages that are not intended for use in clinical documentation practice

Specifically, the International Statistical Classification of Diseases and Related Health Problems (ICD10) classification coding has been used in ED-based EMRs for recording ED presentation and diagnosis. While there is merit in streamlining the recording and reporting of activity-based funding requirements by the treating clinician, ICD10 was designed principally as taxonomy for the classification of groups of related clinical conditions and it has no inherent reliable clinical precision in its descriptors.

It is acknowledged that there are initiatives underway that are addressing the mapping requirements between SNOMED CT-AU and ICD10 under the CSIRO (CSIRO SNOMAP).

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

7 Findings and recommendations: Clinician environment

Finding 17: In general, the clinical community is not cognisant of SNOMED CT-AU and AMT terminology and taxonomy and the association with EMR interoperability

Risk rating: Minor

One of the reasons cited by participants to explain the patchy and variable adoption of standard terminology is that the benefits of SNOMED CT-AU and AMT have not been presented in a clear and clinical context to clinicians. As a result, there is little evidence of clinical leaders insisting on EMRs and CISs with SNOMED CT-AU for medications, and that SNOMED CT-AU and AMT be made available for day-to-day use.

Interoperability in general has a different focus in primary and acute care settings. Interoperability in primary care is generally perceived to enable sharing of relevant patient information across a care team in different clinical settings (and hence with different EMR systems). Common terminology is a key enabler of the semantic interoperability needed to deliver this, but it is not yet the focus in general practice. General practitioners use EMRs that typically interoperate using a 'point to point', human-readable form within the same EMR system, bypassing any requirement for general practice EMRs to interoperate using external reference codes. As a result, general practitioners do not see a pressing need to use SNOMED CT-AU and AMT.

In acute settings, interoperability is most often considered in support of the patient's stay within the hospital, that is, across the continuum of care within that hospital setting. Many acute hospitals have taken a 'single stack' approach using a single vendor, and hence the vendor's proprietary controlled terminology, which allows patient data to flow across the hospital facility. For example, ED to theatres to inpatient care. As such, there may be no specific requirement for clinicians to be aware of the benefits of interoperability with systems outside the hospital and hence to understand the role of SNOMED CT-AU and AMT.

In addition, SNOMED CT-AU and AMT deliver their true value when there is a need for exchanging communication with external applications, for reporting and analysis, and as support for decision support engines. These functions are not carried out by the large majority of clinicians. Therefore, some challenges remain in communicating the benefits of SNOMED CT-AU and AMT to clinicians.

Recommendation 20

The Agency to develop communication strategies, such as education campaigns, to inform clinicians on how SNOMED CT-AU and AMT can benefit patient care and support their clinical practice. Potentially this may require further investment into development of data mining tools and other analytic and display tools.

Recommendation 21

Consider incentivising the adoption and utilisation of SNOMED CT-AU and AMT.

Recommendation 22

Consider promoting understanding of the benefits of interoperability and the role of standard terminologies as part of clinical undergraduate degrees.

Finding 18: There are variations in the consistency of structured data in EMRs to allow for SNOMED CT-AU and AMT coding

Risk rating: Minor

Navigating an EMR can be difficult for users. Vendor lists may not provide the descriptor they want or need, and consequently free text can often be perceived as an easier and faster option.

Clinicians who participated in the consultations indicated that there are sometimes practical issues in recording clinical information through a structured taxonomy, making it more time-consuming and difficult than recording free text. These concerns were echoed by the vendors.

Examples

- Inability to find the exact term description, resulting in clinicians writing in free text to supplement a 'near enough' coded term
- Clinicians not returning to replace a free text entry with a SNOMED CT-AU or AMT term, once the SNOMED CT-AU or AMT term is made available in the EMR system
- Clinicians leaving data fields incompletely filled.

These issues appear to be of more concern in the primary care sector, where the installation of each EMR is historically on a practice-by-practice basis, with no external visibility or management of the quality of the clinical content recorded.

Strategies

Strategies, as explained by vendors and hospital implementation teams, to improve data quality include:

- Running reports to help identify gaps in coding requirements in the EMR by picking up instances where free text was used
- Appointing an authoritative clinical team to update clinical records where this is required including selection and entering of coded terms to replace free text. This is, however, associated with a considerable resource and cost overhead
- Engaging third-party vendors to maintain quality data mappings and updates such as *IMO*, *Multum*, *MIMS*, or *First Databank*
- Providing a support team to work with the Agency to expedite the release of codes for EMR data recording. For example, clinical trial drugs or unique patient preparations.

Recommendation 6

The Agency to consider the following:

- Development of a terminology conformance and compliance roadmap for both primary and acute care

- Development of standard tools, operating procedures and compliance criteria to enforce semantic accuracy of coded clinical data recording and transmission
- Promotion of existing or newly developed standards, tools and operating procedures to assist vendors and implementers to assess data quality in CISs.

Finding 19: Quality documentation by clinicians in clinical systems is enabled by ease of access and navigation to the desired descriptors provided by the EMR

Risk rating: Minor

Navigating an EMR can be difficult for users. Vendor lists may not provide the descriptor they want or need, and consequently free text can often be perceived as an easier and faster option. Factors that have led to poor quality data recording, as indicated by clinicians, include:

- Lack of education and clinicians' understanding about SNOMED CT-AU and AMT and their concept model
- Difficulty in searching and navigating to the target clinical concept description efficiently
- Use of a curated or a vendor-defined pick-list can restrict precision in term selection (despite their ease of use)
- Difficulty in navigating through and finding appropriate descriptors from vendor-provided lists means it is sometimes easier to generate free text; this, in turn, prompts clinicians to create legacy, non-analysable data.

Recommendation 4

The Agency should make currently available and new conformance and compliance requirements binding for the adoption of SNOMED CT-AU and AMT. This might include compulsory accreditation, licensing or certification.

Recommendation 23

The Agency to continue to collaborate with organisations such as CSIRO to develop and make available to vendors tools that provide an easy to use and consistent way to consume SNOMED CT-AU and AMT.

8 Findings and recommendations: Specific clinical safety findings

Finding CS1: Treatment of legacy allergy and ADR data may lead to an absence of clinical decision support

Risk rating: Moderate

An example was found during a vendor demonstration of a primary care EMR system where the adoption of the Agency's guidelines for the recording of allergies had resulted in the existing 'legacy' allergies becoming the equivalent of free text.

Specifically, the updating of an EMR's reference tables with new SNOMED CT-AU and AMT allergic substances/medications in the general practice system had rendered a previously coded allergic substance to be a string of 'free text' data (even though the previous entry was a coded item). The issue was due to the way in which SNOMED CT-AU and AMT had been implemented.

As a result no clinical decision support was applied to these values. There was no alert to highlight to the clinician that allergy checking was not being performed on the value visible on screen. There was no prompt for the clinician to update allergy information using the coded list.

Recommendation 24

The Agency should promulgate guidelines for the treatment of historical data that is superseded by standard terminologies or coded lists, and actively support vendors and implementers as they migrate to standard terminologies. Data should ideally be migrated to the new form. Alternatively, the clinician should be prompted to update the data at the next review of impacted patients.

Finding CS2: The potential to use outdated third-party content is not well controlled or visible

Risk rating: Moderate

There is a risk to patient safety where it is not obvious to the clinician that the medication reference content they are using is not current, and that potentially newer products may be available or certain products have been taken off the market.

There are variable levels of control exercised by vendors to ensure that, where a COTS medicines dictionary is in use, it is updated regularly. One EMR vendor 'actively expires' the content once it is three months out of date, but the review identified one instance where the content was nine months out of date due to EMR system limitations. This meant the EMR was unable to process the update until software changes had been made. This gives rise to the risk that out-of-date information and clinical decision support rules are being applied in a clinical setting.

Recommendation 25

The Agency should seek a national mandate for the requirements for updating third-party COTS content. The mandate would cover the expected timeliness of update, and system behaviour if the content is not updated within the timeframe determined to be appropriate.

Finding CS3: Some CDA documents have omitted clinical qualifiers. For example, the laterality of a clinical disease is missing in the CDA when it was recorded in the source EMR system. In some cases, the missing laterality detail could pose significant patient safety issues.

Risk rating: Moderate

There are risks to patient safety where EMRs and general practice systems do not flag where records are incomplete. It is not clear to clinicians that the content is not complete. Examples were identified where qualifiers were appended to data coming from a coded list, but when that data was sent to a CDA document as part of a Shared Health Summary or Discharge Summary, the qualifier was omitted, resulting in the transfer of incomplete clinical notes. This situation would not be detectable by the clinician unless they actively logged on and reviewed the uploaded document in the receiving system.

Recommendation 5

The Agency to consider developing a set of clinical assurance and validation procedures for vendors to assess the semantic accuracy of coded electronic data used for system interfaces.

Recommendation 27

The Agency should review national specifications, including the existing CDA specification, and any new standards to ensure that guidance is sufficiently provided to support vendors to interface to the My Health Record system and other systems.

9 Conclusion

There is considerable benefit to be gained through the widespread use of standard terminologies within the Australian healthcare system.¹ They are a foundational enabler of better clinical outcomes and reduced risk to patients.^{12,13,14}

SNOMED CT® is widely accepted as the logical standard for clinical terminologies in Australia. An Australian version has been developed which has a comprehensive medicines catalogue. SNOMED CT-AU has strong stewardship and implementation support from the Agency. The review found widespread acceptance by jurisdictions, vendors and clinicians that SNOMED CT-AU was the logical choice for recording presenting problems, diagnoses and procedures, and the AMT should be the standard for medicines in Australia (Findings 1 and 2).

Despite this, the current level of adoption of SNOMED CT-AU and AMT can be described as patchy at best. The current approach, where the Agency provides direction and guidance to vendor and healthcare provider organisations with voluntary compliance and licensing, has manifested as an inconsistent adoption landscape. This is reflected in a number of the findings, and results in the recommendation that recurs against a number of the findings. To optimise safe and standardised uptake and implementation of SNOMED CT-AU and AMT, it is recommended that the Agency develop a binding terminology (SNOMED CT-AU and AMT) compliance and conformance roadmap that includes content coverage and data quality requirements.

SNOMED CT-AU and AMT deliver their true value when there is a need for exchanging communication with external applications, for reporting and analysis, and as support for decision support engines. There are some exemplars in clinical settings, particularly in the area of using SNOMED CT-AU for problem, diagnosis and procedure specification. In addition, there are some vendor products that are soon to be released that appear to be good examples of the use of SNOMED CT-AU and AMT for recording allergies and ADRs, and for prescribing. However, there are also examples of poor implementation. For example, in some cases, guidance provided by the Agency was followed scrupulously, but with a lack of regard to the impact on legacy data (see Finding CS1).

The review recommends identifying strategies for broad national adoption of SNOMED CT-AU and AMT. A level of conformance should be considered in order to create a consistent level of use. This, in turn, will support interoperability across healthcare settings. Improvements in the quality of data for secondary use has the potential to support research and personalised treatments. However, requiring adoption of SNOMED CT-AU and AMT in isolation of other considerations (such as closed loop medications management and a solid clinical decision support foundation) will not, in and of itself, improve clinical safety in a meaningful way.

The major recommendation from the review is that a roadmap towards national uptake, implementation and conformance assessment of SNOMED CT-AU and AMT be developed by the Agency.

The roadmap needs to address issues that will arise from:

- Local and global commercial drivers for vendors to integrate SNOMED CT-AU and AMT into their CISs used in Australia and competing priorities for solution development
- The limitations and shortcomings of existing clinical decision support rules, which are often supported through the content of third-party content providers
- Treatment of legacy data as CISs implement standard terminologies
- The need to optimise the usability and interface design of CISs.

The recording of allergies and ADRs is seen as a good candidate for initial investigation as:

- It has high clinical risk if it is not managed correctly
- It is relatively simple compared to other areas where standard terminologies can be used
- There is evidence of inappropriate drug use (particularly antibiotics) as a result of lack of clear differentiation between allergies and adverse reactions
- There is currently activity in this area to improve and standardise allergy recording, supported by the National Allergy Strategy.*

As the implementation of EMR systems progresses through the healthcare sector there is increased focus on interoperability across care settings. The review identified findings on the enablers for and barriers to adoption and utilisation of SNOMED CT-AU and AMT. The subsequent recommendations aim to address the findings across the three domains in regard to intent, enablers and implementers, and users to work towards improved standardisation and maturity. Potential clinical safety risks are currently mitigated through organisational and clinical processes. As the reliance on EMR systems grows so will the expectation around interoperability and information accuracy which in turn may introduce additional risks to clinical quality and safety.

* The National Allergy Strategy is a strategy developed by the Australasian Society of Clinical Immunology and Allergy (ASCIA) and Allergy & Anaphylaxis Australia (A&AA) (www.nationalallergystategy.org.au).

Glossary

Australian Medicines Terminology (AMT)	The national terminology that delivers unique codes to unambiguously identify originator and generic brands of medicines commonly used in Australia. It also provides standard naming conventions and terminology to accurately describe medications.
clinical document architecture (CDA)	A Health Level 7 (HL7) standard intended to specify the encoding, structure and semantics of clinical documents for exchange.
clinical documents	Documents with clinical information entered by healthcare providers in an individual's My Health Record. They include Shared Health Summaries, Event Summaries, Discharge Summaries, referral letters and specialist letters.
clinical information system (CIS)	A system used by a healthcare provider to manage patient and practice records. It may include a software component connected to the My Health Record system.
Discharge Summary (DS)	A record of an individual's hospital stay and any follow-up treatment required.
Event Summary (ES)	A clinical document that may be uploaded to an individual's My Health Record summarising one or more episodes of care.
medicine record	A summary of prescription and dispense information for My Health Record. It delivers a list of medications that have been prescribed and dispensed to the individual (previously referred to as medications view).
My Health Record	<p>A My Health Record of an individual is the record of information created and maintained by the System Operator in relation to the individual, and information that can be obtained by means of that record, including the following:</p> <ul style="list-style-type: none"> • Information that relates to the individual in the record relating to the individual's registration • Health information connected in the My Health Record system to the individual, including information included in a record accessible through the index service • Other information connected in the My Health Record system to the individual, such as information relating to auditing access to the record • Back-up records of such information.

My Health Record system	The My Health Record system is used for the operation of functions under the <i>My Health Records Act</i> by the System Operator. The system was launched on 1 July 2012 (previously known as the Personally Controlled Electronic Health Record or PCEHR) and provides a system of managing health information online that will make it more accessible to Australians who choose to sign up with the system, and to healthcare providers. The system is supported by a legislative framework consisting of the <i>My Health Records Act 2012</i> , <i>Healthcare Identifiers Act 2010</i> , <i>My Health Records Regulation 2012</i> , <i>Healthcare Identifiers Regulations 2010</i> and <i>My Health Records Rule 2016</i> .
National E-Health Transition Authority (NEHTA)	NEHTA was established by the Australian, state and territory governments to develop better ways of electronically collecting and securely exchanging health information. NEHTA was the managing agent for the design and build of the My Health Record system.
native	Accessing SNOMED CT-AU and AMT content directly through a terminology server.
prescription and dispense records	These records incorporate prescription and dispense information to provide a consolidated record of medications, which is available as two clinical documents (My Health Record Prescription Record and My Health Record Dispense Record) that are available in connecting CISs.
prescription document	<p>A document containing information about the medicine that a consumer has been prescribed by a healthcare provider. Also includes details about the healthcare provider who prescribed the medicine and the healthcare provider organisation that the consumer visited.</p> <p>Medicine-specific information recorded in the prescription record may include:</p> <ul style="list-style-type: none"> • Medicine brand name and strength prescribed • Generic medicine name • Dosage instructions • Maximum number of prescription repeats • Date the medicine was prescribed and prescription expiry date.
Shared Health Summary (SHS)	A clinical document summarising an individual's health status. Includes important information such as allergies and adverse reactions, medicines, medical history and immunisations. Only a nominated healthcare provider can create or update the SHS.
System Operator	The participant with responsibility for establishing and operating the My Health Record system. The System Operator is currently the Australian Digital Health Agency.

Source: Modified from My Health Record glossary, Australian Government Department of Health, last updated 5 December 2016, myhealthrecord.gov.au/internet/mhr/publishing.nsf/Content/glossary

Appendix A Consultations

The Commission thanks the following organisations and individuals for their contribution to the review.

- Austin Health
- Australian Digital Health Agency
- Best Practice Software
- Cerner Corporation
- Communicare Systems
- CSC (MedChart)
- eHealth NSW
- Epic Systems
- Epworth HealthCare
- Fred IT Group
- Genie Systems
- Healthscope
- Dr David Hansen (CSIRO)
- MedicalDirector
- Medtech Global
- MIMS Australia
- Dr Chris Moy
- Princess Alexandra Hospital, Brisbane
- Ramsay Health Care
- The Royal Children's Hospital, Melbourne
- Victorian Department of Health (Health Technology Services)
- Western Australia Department of Health (Health Support Services)
- Zedmed

Appendix B 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 clinical safety review risk rating matrix.

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

Risk rating	Reputation and public confidence of My Health Record / quality of service	Clinical safety harm	Control
Critical	<p>Profound influence on the My Health Record system’s reputation, resulting in a profound loss of public and healthcare provider participation</p> <p>Profound sustained degradation of service value and quality</p>	A clinical incident resulting in patient death	<p>Basic, supervisory and/or monitoring controls are inadequate and require urgent management attention</p> <p>A critical patient safety incident has occurred</p>
Major	<p>Significant influence on the My Health Record system’s reputation, resulting in significant loss of public and healthcare provider participation</p> <p>Decline in service value and quality is recognised by a majority of patients or health service providers</p>	A clinical incident resulting in major permanent loss of function	<p>Basic, supervisory and/or monitoring controls are inadequate and require prompt management attention</p> <p>A major clinical safety incident has occurred</p>
Moderate	<p>Loss of reputation affecting participation in the My Health Record system</p> <p>Decline in service value and quality is recognised by a moderate number of patients and health service providers</p>	A clinical incident resulting in permanent reduction in function	<p>Basic, supervisory and/or monitoring controls are partly inadequate and require management attention</p> <p>High potential for a clinical safety incident</p>
Minor	<p>Mild damage to reputation of the My Health Record system</p> <p>Decline in service value and quality is recognised by the System Operator and My Health Record partners</p>	A clinical incident resulting in increased level of care/intervention	<p>Basic, supervisory and/or monitoring controls are operating as intended, recommendation for improvement to strengthen control</p>

Risk rating	Reputation and public confidence of My Health Record / quality of service	Clinical safety harm	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

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