

Australian Core Data for Interoperability Release 1

Version 1.0 - February 2024

Draft for Community Comment

Sparked AU FHIR Accelerator

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1. Document Information

1.1. Document Information

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We look forward to the community continuing to grow and working with you all to share resources and specifications to enable the meaningful use, exchange, and reuse of clinical information.

Table of Contents

| 1. | Doc | ument Information | 3 |
|----|----------------------|--|----|
| | 1.1. | Document Information | 3 |
| | 1.2. | L.2. Distribution | |
| 2. | Intro | oduction | 11 |
| | 2.1. | Purpose of document | 11 |
| | 2.2. | Intended Audience of the document | |
| | 2.3. | How to read the document | |
| 3. | - | ut the Sparked program | |
| 5. | | Sparked program overview | |
| | 3.1. | | |
| | 3.2. | Sparked program deliverables | |
| | 3.3. | Sparked program community approach | |
| 4. | Abo | ut Australian Core Data for Interoperability | 14 |
| | 4.1. | Background | 14 |
| | 4.2. | Role and purpose of AUCDI | 14 |
| | 4.3. | AUCDI data groups | 15 |
| | 4.3.1 | | |
| | 4.3.2 | | |
| | 4.4. 4.4.1 | Understanding the scope of AUCDI R1 | |
| | 4.4.2 | | |
| | 4.4.3 | | |
| | 4.4.4 | . A Case Study | 19 |
| | 4.5. | AUCDI, FHIR, and AU Core Implementation Guide | 20 |
| | 4.6. | Design of the AUCDI | 21 |
| | 4.7. | AUCDI and implementations | 25 |
| 5. | Ном | r to read the AUCDI | 25 |
| | 5.1.1 | . <data group="" name=""> (e.g., Adverse reaction risk summary)</data> | 25 |
| 6. | The | AUCDI library at a glance | 29 |
| 7. | AUC | DI Release 1 Draft for Comment Library | 30 |
| | 7.1. | Adverse reaction risk summary | 30 |
| | 7.1.1 | | |
| | 7.1.2 | | |
| | 7.1.3 | | |
| | 7.1.4 7.1.5 | | |
| | 7.2. | Problem/Diagnosis summary | |
| | 7.2. 7.2.1 | | |
| | 7.2.1 | | |
| | 7.2.3 | | |
| | 7.2.4 | . Specific alignment to AUCDI design principles | 41 |

| 7.2.5. | For future consideration | |
|--------|--|----|
| 7.3. | Procedure completed event | 44 |
| 7.3.1. | Context | |
| 7.3.2. | Concept representation | 45 |
| 7.3.3. | | |
| 7.3.4. | | |
| 7.3.5. | For future consideration | |
| 7.4. | Vaccination administered event | 51 |
| 7.4.1. | Context | |
| 7.4.2. | Concept representation | |
| 7.4.3. | Information model | |
| 7.4.4. | Specific alignment to AUCDI design principles | |
| 7.4.5. | For future consideration | |
| 7.5. | Tobacco smoking summary | |
| 7.5.1. | | |
| 7.5.2. | | |
| 7.5.3. | Information model | |
| 7.5.4. | Specific alignment to AUCDI design principles | |
| 7.5.5. | For future consideration | |
| 7.6. | Measurements and vital signs | |
| 7.6.1. | | |
| 7.6.2. | | |
| 7.6.3. | Body temperature | |
| 7.6.4. | Respiration | |
| 7.6.5. | Body height | |
| 7.6.6. | Body weight | |
| 7.6.7. | Waist circumference | |
| 7.7. | Biomarkers | 83 |
| 7.7.1. | Lipids | |
| 7.7.2. | | |
| 7.7.3. | | |
| 7.7.4. | | |
| 7.7.5. | All biomarkers - for future consideration | |
| 7.8. | Medication use statement | 96 |
| 7.8.1. | Context | |
| 7.8.2. | Concept representation | |
| 7.8.3. | Information model | |
| 7.8.4. | Specific alignment to AUCDI design principles | |
| 7.8.5. | For future consideration | |
| 7.9. | Encounter – clinical context | |
| 7.9.1. | Context | |
| 7.9.2. | Concept representation | |
| 7.9.3. | | |
| 7.9.4. | | |
| 7.9.5. | | |
| 7.10. | Sex and gender | |
| | ext | |
| 7.10.1 | 1. Concept representation | |
| 7.10.2 | 2. Information model | |
| 7.10.3 | 3. Specific alignment to AUCDI design principles | |
| 7.10.4 | 4. For future consideration | |

| 8. | Арр | endix A – Definition of Terms114 | | | |
|-----|--------------------------------|--------------------------------------|--|-----|--|
| 9. | Арр | endix B – Data groups at a glance116 | | | |
| 9. | .1. | Adverse reaction risk summary | | | |
| 9. | 0.2. Problem/Diagnosis summary | | | 116 | |
| 9. | .3. | Proc | edure completed | 116 | |
| 9. | .4. | Vacc | ination administered | 116 | |
| 9. | .5. | Toba | cco smoking summary | 116 | |
| 9. | .6. | Mea | surements and vital signs | 116 | |
| 9. | .7. | Bion | narkers | 116 | |
| 9. | .8. | Med | ication use statement | 117 | |
| 9. | .9. | Enco | unter – clinical context | 117 | |
| 9. | .10. | Sex a | and gender | 117 | |
| 10. | App | endix | C – Sparked collaborative processes | 118 | |
| 1(| 0.1. | Snar | ked Clinical and Technical Design Groups | 118 | |
| - | 10.1. | - | Sparked Clinical Design Group | | |
| | 10.1. | | Sparked Technical Design Groups | | |
| 1 | 0.2. | Ope | n feedback process | | |
| 1 | 0.3. | Core | Design Principles | 120 | |
| 11. | App | | c D – National and International initiatives | | |
| | | | | | |
| 1: | | | ralia | 123 | |
| | 11.1.1 Dena | | The Digital Health Blueprint and Action Plan 2023–2033 – Australian Government It of Health and Aged Care | 173 | |
| | 11.1. | | Connecting Australian Healthcare – National Healthcare Interoperability Plan 2023-202 | | |
| | | | Digital Health Agency | | |
| | 11.1. | | My Health Record – Australian Digital Health Agency | | |
| | 11.1.4 | 4. | National primary care data development, Australia Institute of Health and Welfare | | |
| | 11.1. | | Primary Care Data Quality Foundations - Australia | | |
| 1 | 1.2. | Inter | national | 125 | |
| | 11.2. | | USCDI HL7 FHIR accelerators - USA | | |
| | 11.2. | | HL7 FHIR accelerators - USA | | |
| | 11.2. | | Core Information Standard – NHS England | | |
| | 11.2.4 | | The pan-Canadian Health Data Content Framework - Canada | | |
| | 11.2. | | International Patient Summary | | |
| | 11.2. | 6. | openEHR International | | |

| Figure 1. Sparked partnership | 12 |
|--|--------|
| Figure 2. Sparked deliverables | 13 |
| Figure 3. AUCDI scope | 18 |
| Figure 4. Maria's care journey | 20 |
| Figure 5. Focus points of AUCDI and AU Core. | |
| Figure 6. Relationship between AUCDI and FHIR AU Core | 22 |
| Figure 7. Design of AUCDI and relationship with AU Core | 23 |
| Figure 8. Example mind map structure. | |
| Figure 9. Example data group mind map depicting data element nodes and legend | 28 |
| Figure 10. Draft AUCDI R1 data groups | |
| Figure 11. Adverse reaction risk summary mind map. | 32 |
| Figure 12. Proposed roadmap for further development of the 'Adverse reaction risk summary | ' data |
| group | 37 |
| Figure 13. Problem/diagnosis summary mind map | 39 |
| Figure 14. Proposed roadmap for developing the 'Problem/Diagnosis summary' data group | 43 |
| Figure 15. Procedure completed event mind map | 45 |
| Figure 16. Proposed roadmap for developing the 'Procedure completed' data group | 50 |
| Figure 17. Vaccination administered event mind map. | 51 |
| Figure 18. Proposed roadmap for developing the 'Vaccination administration' data group | |
| Figure 19. Tobacco smoking summary mind map. | |
| Figure 20. Proposed roadmap for the future development of the 'Tobacco smoking summary' | |
| group | |
| Figure 21. Measurements and vital signs (blood pressure) mind map | 62 |
| Figure 22. Proposed roadmap for developing the 'Blood Pressure' data group | |
| Figure 23. Measurements and vital signs (pulse) mind map. | |
| Figure 24. Proposed roadmap for the future development of the 'Pulse' data group | |
| Figure 25. Measurements and vital signs (body temperature) mind map. | |
| Figure 26. Proposed roadmap for developing the 'Body temperature' data group | 71 |
| Figure 27. Measurements and vital signs (respiration) mind map. | 72 |
| Figure 28. Proposed roadmap for the future development of the 'Respiration' data group | 74 |
| Figure 29. Measurements and vital signs (body height) mind map | 75 |
| Figure 30. Proposed roadmap for developing the 'Height' data group | 77 |
| Figure 31. Measurements and vital signs (body weight) mind map | 78 |
| Figure 32. Proposed roadmap for developing the 'Body weight' data group | 80 |
| Figure 33. Measurements and vital signs (waist circumference) mind map. | |
| Figure 34. Proposed roadmap for developing the 'Waist circumference' data group | 82 |
| Figure 35. Biomarkers (lipids) mind map | |
| Figure 36. Biomarkers (Haemoglobin A1c) mind map | |
| Figure 37. Estimated glomerular filtration rate mind map. | |
| Figure 38. Urine albumin-creatinine ratio mind map. | 92 |
| Figure 39. Proposed roadmap for the future development of the 'Laboratory test result' data | |
| | |
| Figure 40. Medication use statement mind map | 98 |
| Figure 41. Proposed roadmap for developing the 'Medication Statement' data group | |
| Figure 42. Encounter (clinical context) mind map. | |
| Figure 43. Sex and gender mind map. | |
| Figure 44. Proposed roadmap for developing the 'Sex and Gender' data group based | |
| Figure 45. Purpose of the Sparked Clinical Design Group and the Sparked Technical Design Group | |
| Figure 46. Sparked Clinical Design Group and Sparked Technical Design Group high-level proce | • |
| feedback loop | |
| | |

| Figure 47. High-level AUCDI R1 development, review, and publication process. | 120 |
|---|-----|
| Table 1. Core design principles. | 23 |
| Table 2. Example context | 25 |
| Table 3. Example information model | 26 |
| Table 4. Design principles topic headings | 27 |
| Table 5. Adverse reaction risk summary – context | |
| Table 6. Adverse reaction risk summary information model | |
| Table 7. Adverse reaction risk summary alignment to design principles | |
| Table 8. Problem/diagnosis summary context. | 38 |
| Table 9. Problem/diagnosis summary information model. | 39 |
| Table 10. Problem/diagnosis summary alignment to design principles. | 41 |
| Table 11. Procedure completed event context | |
| Table 12. Procedure completed event information model | 46 |
| Table 13. Procedure completed event alignment to design principles | 48 |
| Table 14. Vaccination administered event context | |
| Table 15. Vaccination administered event information model | 52 |
| Table 16. Vaccination administered event alignment to design principles | 53 |
| Table 17. Tobacco smoking summary context | |
| Table 18. Tobacco smoking summary information model. | 57 |
| Table 19. Tobacco smoking summary alignment to design principles | 57 |
| Table 20. Measurements and vital signs (blood pressure) context. | 61 |
| Table 21. Measurements and vital signs (blood pressure) information model. | |
| Table 22. Measurements and vital signs (blood pressure) alignment to design principles | 62 |
| Table 23. Measurements and vital signs (pulse) context | 65 |
| Table 24. Measurements and vital signs (pulse) information model | 66 |
| Table 25. Measurements and vital signs (pulse) alignment to design principles | 66 |
| Table 26. Measurements and vital signs (body temperature) context. | 69 |
| Table 27. Measurements and vital signs (body temperature) information model. | 69 |
| Table 28. Measurements and vital signs (body temperature) alignment to design principles | 70 |
| Table 29. Measurements and vital signs (respiration) context | 72 |
| Table 30. Measurements and vital signs (respiration) information model | 72 |
| Table 31. Measurements and vital signs (respiration) alignment to design principles | |
| Table 32. Measurements and vital signs (body height) context. | 75 |
| Table 33. Measurements and vital signs (body height) information model. | 75 |
| Table 34. Measurements and vital signs (body height) alignment to design principles | 76 |
| Table 35. Measurements and vital signs (body weight) context. | |
| Table 36. Measurements and vital signs (body weight) information model. | |
| Table 37. Measurements and vital signs (body weight) alignment to design principles | 79 |
| Table 38. Measurements and vital signs (waist circumference) context. | |
| Table 39. Measurements and vital signs (waist circumference) information model. | 81 |
| Table 40. Measurements and vital signs (waist circumference) alignment to design principles | |
| Table 41. Biomarkers (lipids) context | |
| Table 42. Biomarkers (lipids) information model. | |
| Table 43. Biomarkers (lipids) alignment to design principles. | |
| Table 44. Biomarkers (Haemoglobin A1c) context | |
| Table 45. Biomarkers (Haemoglobin A1c) information model | |
| Table 46. Biomarkers (Haemoglobin A1c) alignment to design principles. | |
| Table 47. Estimated glomerular filtration rate context. | |
| Table 48. Estimated glomerular filtration rate information model | |
| Table 49. Estimated glomerular filtration rate alignment to design principles | 91 |

| Table 50. Urine albumin-creatinine ratio context | 92 |
|---|-----|
| Table 51. Urine albumin-creatinine ratio information model | 92 |
| Table 52. Urine albumin-creatinine ratio alignment to design principles | 93 |
| Table 53. Medication use statement context. | 96 |
| Table 54. Medication use statement information model. | 98 |
| Table 55. Medication use statement alignment to design principles | |
| Table 56. Encounter (clinical context) context | |
| Table 57. Encounter (clinical context) information model | |
| Table 58. Encounter (clinical context) alignment to design principles. | 108 |
| Table 59. Sex and gender context | 109 |
| Table 60. Sex and gender information model | 110 |
| Table 61. Sex and gender alignment to design principles | 111 |
| Table 62. Core design principles | |
| | |

2. Introduction

2.1. Purpose of document

The purpose of this document is to outline the contents of the Australian Core Data for Interoperability (AUCDI) and to provide insights into its development context.

2.2. Intended Audience of the document

The intended audience of this document is stakeholders interested in improving health data interoperability in Australia. This includes consumers, clinical and technical subject matter experts, healthcare organisations, peak bodies, technology and software industry partner organisations, jurisdictions, and government organisations.

2.3. How to read the document

This document is organised into two main sections: Sections 3 and 4 offer background information on the Sparked Program and the AUCDI, respectively, while Section 5 and subsequent sections details the specifics of the AUCDI.

3. About the Sparked program

3.1. Sparked program overview

As part of 2023-24 Federal Budget funding to implement new initiatives to improve digital health information sharing, the Australian Government provided \$15.7 million over two years to progress national health information sharing priorities. This funding included \$9.3 million over two years for Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO) to work with all Australian Governments, the Australian Digital Health Agency, HL7 Australia and the health technology industry to develop and adopt national data standards, including clinical information models, terminology value sets and Fast Healthcare Interoperability Resources (FHIR) standards.

Australia's first FHIR accelerator, '*Sparked*', was launched in August 2023 to deliver national core clinical data for interoperability to support health information sharing, the AUCDI. Over the next two years, aligned FHIR standards to support the implementation of AUCDI in Australian settings will be developed by the technical community.

The Sparked program is a community-driven collaboration comprising government, technology and software industry partners, provider organisations, clinical and industry peak bodies, healthcare practitioners, and domain experts with a common goal – to accelerate the creation and use of national FHIR standards in healthcare information exchange.

The program is led by CSIRO's Australian e-Health Research Centre (AEHRC) as the community coordinator in partnership with the Department of Health and Aged Care (DOHAC), the Australian Digital Health Agency (Agency) and HL7 Australia (HL7 AU).

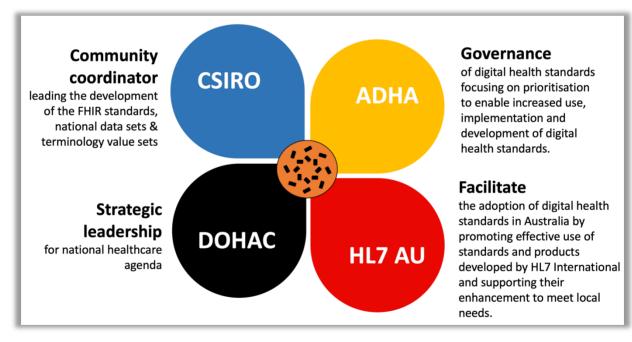


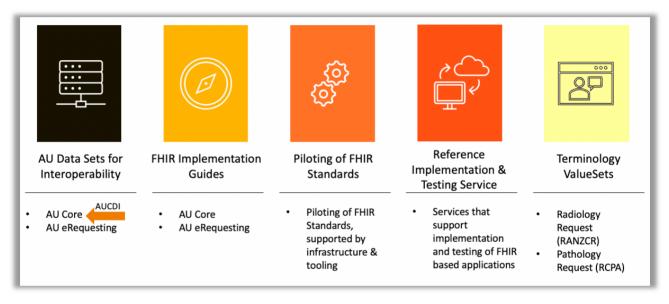
Figure 1. Sparked partnership.

3.2. Sparked program deliverables

CSIRO is leading the clinical and technical community collaboration and consensus for developing the AUCDI and AU Core FHIR implementation guides, which are expected to be ready by mid-2025.

The FHIR AU program will create the following products during the two-year program:

- Australian Core Data for Interoperability (AUCDI),
- AU eRequesting Data for Interoperability,
- AU Core FHIR Implementation Guide,
- AU eRequesting FHIR Implementation Guide,
- Royal College of Pathologists Australasia (RCPA) ValueSets,
- Royal Australian and New Zealand College of Radiologists (RANZCR) ValueSets,
- Target Operating Model for Standards development, and
- Standards development roadmap to highlight priorities and sequence going forward.





This document describes the first release of the AUCDI.

3.3. Sparked program community approach

Using an open and transparent standards development approach, the Sparked Program is developing an active community of clinicians, software industry vendors, private and public healthcare organisations, and government agencies to co-design and validate nationally agreed health data standards.

This community-centric and consensus-driven approach will ensure standards are driven by community needs and are more readily understood, adopted, and implemented. This builds on the successful approach adopted globally through US-based HL7 FHIR Accelerators such as the Argonaut project. More information on these projects is in 11.2.2.

To participate in our Sparked community – visit our registration page on <u>Confluence</u>.

4. About Australian Core Data for Interoperability

4.1. Background

The Australian health IT landscape is characterised by isolated health information systems, often confined within single clinics or organisations. This fragmentation is prevalent across primary, acute, and tertiary care sectors. The consistency in health data structure is generally limited to systems provided by the same technology industry partner, leading to a lack of alignment between different clinical systems.

This situation poses significant challenges in sharing and exchanging information across systems, impacting the development of value-added services like clinical decision support. The local and often proprietary development of these systems has necessitated the mapping or transformation of health data between systems, increasing the risk of errors and potential loss of critical clinical data.

The fragmented nature of these systems complicates the capture and reuse of health data. Data captured in one system often cannot be efficiently or accurately reused in another, leading to redundant data entry and potential inconsistencies in electronic health records. This not only increases the workload for healthcare providers but also poses risks to clinical safety and quality of care. Inaccurate or incomplete data can lead to misinformed clinical decisions and compromised health outcomes.

Additionally, the focus on developing data sets for secondary rather than primary clinical use adds to the data collection burden for care providers. This approach often overlooks the immediate clinical needs and usability, potentially compromising the effectiveness of clinical decision support systems and the overall quality of health care delivered.

4.2. Role and purpose of AUCDI

The AUCDI is changing the approach to health data and is set to become a national asset focused on creating an independent foundation of reusable, standardised information models and related artefacts.

It is intentionally agnostic of:

- Any single **clinical use case** while being constructed as a foundation for many clinical use cases,
- Any single **clinical system vendor** while being strongly informed by functionality and data available in current clinical systems, and
- Any single **technical implementation or exchange approach** while providing the clinical data requirements for developing the FHIR AU Core specifications and subsequent Implementation Guides (IG).

The AUCDI:

• Will provide the initial foundation for an evolving ecosystem of agreed data groups, purposebuilt to reflect clinical requirements for the data required to support the provision of care, exchange, aggregation for analysis, and to support clinical decision support.

- Describes and defines a set of data groups comprising one or more data elements, forming the foundation of a common language to allow systems to exchange semantically accurate data more efficiently.
- Will act as an agent for change by bridging fragmented silos of data and providing a foundation of building blocks of standardised data applicable to multiple use cases across a variety of clinical specialties, geographical locations, and professional contexts and problems.
- Incorporates and builds upon existing standards and prior work from national and international programs and initiatives. It has not been developed in isolation.
- Is a living artefact that will evolve and grow in future iterations to support additional use cases adding breadth by including new clinical data groups and depth by expanding with further granular detail.

AUCDI Release 1 (R1) is focused on an agreement of "the core of the core" common data elements, meaning the absolute minimum data required to support standardised clinical information capture at the point of care as well as enable the safe and meaningful exchange of information to other care providers.

4.3. AUCDI data groups

The AUCDI data groups are comprised of two components – clinical information models and terminologies.

4.3.1. Clinical information models

An information model is a technical term commonly used in software engineering to describe the representation of data semantics. It is like a blueprint or map of how information and its meaning and relationships are managed and organised within a system.

Each clinical information model describes a single, discrete clinical concept and its clinically agreed data structure, pattern, and content. Some information models will be simple; others will represent a more complex grouping of related data. However, each information model includes:

- Metadata descriptions about the clinical concept and its intended purpose, purpose, and use,
- One or more component data elements, each associated with attributes such as data types¹, recommended values and constraints, and
- Relationships between data elements.

Within this document, groups of clinical information models are referred to as 'data groups'. Examples include:

- 'Adverse reaction risk summary',
- 'Procedure completed', and
- 'Blood Pressure'.

¹The AUCDI references defined data types from https://build.fhir.org/datatypes.html

Each clinical information model is designed to be reused across many data sets, projects, clinical scenarios, and geographical locations. Each one will vary in detail, growing in granularity over time as requirements for applications in different contexts are further understood.

This core data for interoperability will grow towards providing a master set of information models inclusive of all relevant data elements and their attributes. Existing projects and priorities informed the development of these models and intended to be agnostic to any use case, project, application, or intent. As projects and clinical systems increasingly use the same clinical information models, data interoperability becomes significantly more straightforward because of these shared information models, minimising the need for data transformation and mapping, which can lead to errors or data loss.

4.3.2. Terminologies, SNOMED CT-AU and value sets

Within the information model, capturing data as text can be done through free text narrative or structured, coded text by selecting a word or phrase from a controlled terminology value set. A standardised set of terms is called a ValueSet. Selection from an agreed value set from a standardised clinical terminology can dramatically improve the quality and consistency of data recording. Benefits include correct spelling, acceptable synonyms and limiting data entry selection to clinically appropriate values based on the context. Reusing agreed and validated terminology value sets within the clinical information models further enhances data exchange, clinical decision support, querying, and analysis of health data.

In Australia, SNOMED CT-AU is an adopted standard for recording structured clinical data in health records. In the Sparked program, SNOMED CT-AU is the primary terminology from which value sets are derived to support standardised coded data entry in the AUCDI's clinical information models. Other code systems, such as LOINC, may also be used where agreed through consultation with the community of practice. Standardised terminologies have been selected because they are internationally recognised with an existing global implementation footprint.

Many SNOMED CT-AU value sets have already been developed and published by the National Clinical Terminology Service (NCTS). These nationally agreed and published value sets are maximal in nature to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI value sets.

4.4. Understanding the scope of AUCDI R1

The AUCDI focuses on core health data required to support high quality healthcare delivery. The first release of AUCDI, R1, is the foundation from which we will grow more comprehensive information models as standards, policies, technical implementations, and user requirements mature and evolve.

Key considerations in determining the scope of R1 were to:

- Include data that is well understood, commonly used, and well supported by existing clinical systems,
- Identify incremental change that will create benefits and support broad reuse across multiple use cases,
- Create a starting block to build upon, avoiding breaking changes in the future as much as possible, and

• Support clinical safety and best practices.

4.4.1. Scope drivers

In designing national data standards, finding the balance between supporting current clinical practice and system implementations that are safe and scalable is crucial. There is also a tension to ensure that the design of the AUCDI can be extended to support future best practices and clinical workflow and leverage the potential for smart use of health data (e.g. CDS and AI), simultaneously avoiding the risk of backwardly incompatible changes and the cost of clinical system rework in subsequent AUCDI releases. This balance helps form a foundation to build on and evolve to become more extensive over time.

Due to the extensive international engagement and acceptance of the International Patient Summary (11.2.5) and the need for health summary information across many clinical use cases, it was agreed² that the clinical content for a generic health summary would be used to identify many of the data groups and data elements to be included in AUCDI R1. Guided by the clinical concepts from the International Patient Summary, this content underpins any health summary or referral, supports chronic disease health assessment and management, and is a common approach to standardised clinical decision support tools such as a cardiovascular risk calculator or other health assessments (e.g., Aboriginal and Torres Strait Island Health Assessment).

4.4.2. Scope of AUCDI R1

The R1 scope of AUCDI includes:

- Adverse reaction risk summary (allergies and intolerances),
- Problem/Diagnosis summary,
- Procedure completed,
- Vaccination administration (immunisations),
- Vital signs, measurements and other biomarkers for chronic disease and preventative health with an initial scope of cardiovascular risk calculation and diabetes care,
- Medication use statement,
- Sex and gender, and
- Encounter information required to provide clinical context,

The focus of the AUCDI is the representation of the clinical content required for each of the data groups. System information, or system-derived information, is deliberately excluded from the scope of AUCDI unless it is also of clinically significant and requires clinical validation. Information related to technical aspects of recording data (such as author and record date/timestamp) will be managed in the technical implementation specifications (e.g., FHIR IG).

Each data group is designed as a standalone module. The data groups can be mixed and matched to represent larger clinical data sets for use in different contexts.

² See Confluence for details

In each data group, most data elements are optional. Only a limited number of data elements within a specific data group are deemed mandatory, usually designated to identify a key data element necessary for ensuring the clarity and comprehension of the remaining data elements in that group.

Some data elements, for example, 'Comment' or 'Clinical Indication,' might share names and be present in several data groups to promote coherence across the data groups. 'Comment' serves as a universal data element with a uniform description across all data groups where it is found. Conversely, 'Clinical Indication' is encountered in a select few data groups. It ensures uniformity in naming and purpose across the data groups it appears in, such as 'Procedure Completed' and 'Medication Use Statement.' However, the specific semantics of each instance may be tailored to fit the concept, reusing value sets where clinically appropriate.

In R1, the scoped data models mark the foundational beginnings, "the core of the core", on which to further build upon and fill out as the AUCDI progresses, and as further use cases and requirements mature.

Data elements needing further community consultation or those not widely implemented and lacking significant clinical importance were omitted from the initial release (R1) and deferred to a backlog for consideration in future updates.

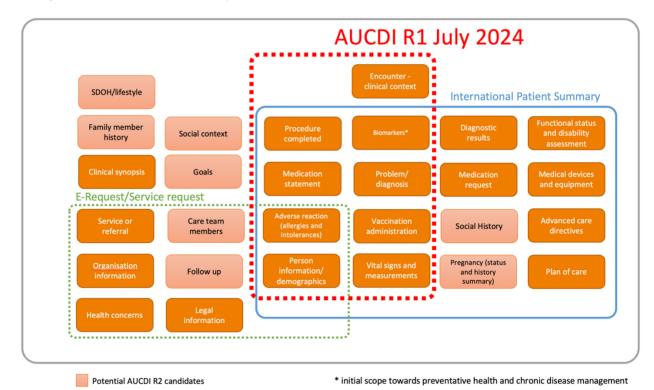


Figure 3. AUCDI scope.

4.4.3. AUCDI Use cases

The community identified several priority use cases to inform the scope of AUCDI R1. These include:

- Transfer of care summary (e.g., discharge summary),
- Chronic disease management (e.g., care plan),
- Decision support (e.g., cardiovascular disease risk), and

• Referral.

4.4.4. A Case Study

The care journey, below, describes how the different AUCDI data groups can be reused to support multiple use cases, for a fictional woman named Maria.

| "Maria is 65-year-old women, living in regional Australia. She leads a sedentary lifestyle, has a diet high in carbohydrates and sugars, and smokes cigarettes. She rarely consults with any Health professionals, unless her health issue is no longer self-manageable." | | |
|--|--|--|
| 1. GP Visit - Maria visits h | er GP after experiencing worsening symptoms of Type 2 diabetes. During | |
| consultation, GP reviews | her medical history, measures her BP, and orders some pathology tests lucose levels and HbA1c, to assess her current diabetes control. | |
| Related documents • Patient summary • Clinical notes • Pathology request | Example data groups and terminology Problem/Diagnosis (E.g. SCT Code 44054006 Diabetes Mellitus Type 2), Vaccination Administered, Adverse reaction risk, Sex and Gender, Tobacco smoking summary, Biomarkers (E.g. LOINC Code 4548-4: HbA1c,), Vital signs (LOINC Code 55284-4: BP), Measurements, Encounter – clinical context, Reason for test*, Test name* | |
| | gement - Based on the test results, GP prescribes Metformin to icose control. Maria fills her prescription at a local pharmacy and begins her medication regimen. | |
| Related documents | Example data groups and terminology | |
| Pathology results | Problem/Diagnosis, Procedure completed, Adverse reaction risk, Medication statement (E.g. Medicine Name: AMT MP Code 21614011000036102 Metformin), Sex and Gender, Clinical indication | |
| that she requires hospi | eeks later, Maria's blood glucose control deteriorates to the point talisation. She is admitted as an inpatient for stabilisation and also lergoes a procedure for an untreated foot ulcer | |
| Related documents •Hospital admission •Discharge summary | Example data groups and terminology • Problem/Diagnosis (E.g. SCT Code 237623001 Acute hyperglycaemia , 371087003 Diabetic foot ulcer), Procedure Completed (E.g. SCT-AU Code: 312733004 Debridement of foot ulcer), Vaccination Administered, Adverse reaction risk, Medication statement, Sex and Gender, Tobacco smoking summary | |
| | GP - Maria is discharged from the hospital. The discharge plan s for medication management and follow-up appointments. | |
| Related documents: | Example data groups and terminology: | |
| • Discharge summary | Problem/Diagnosis (E.g. 237623001 Acute hyperglycaemia , 371087003 Diabetic foot ulcer), Procedure Completed (E.g. SCT-AU Code: 312733004 Debridement of foot ulcer), Medication statement, Biomarkers, Vital signs | |

| 5. Allied Health Referral - As part of her ongoing care, GP refers Maria to a Podiatrist to treat her foot ulcer and for advice regarding foot care. | | |
|--|--|--|
| Related documents: | Examples data groups and terminology: | |
| Referral to Allied Health Clinical notes | Problem/Diagnosis (E.g. SCT-AU Code 371087003 Diabetic foot ulcer), Procedure Completed (E.g. SCT-AU Code: 312733004 Debridement of foot ulcer), Sex and Gender, Medication statement, Encounter – clinical context | |
| | to the complexity of her condition, Maria is also referred to an nion and management of her diabetes and its complications | |
| Related documents: | Example data groups and terminology: | |
| Referral to specialist Clinical notes | •Problem/Diagnosis (E.g. SCT-AU Code 44054006 Diabetes Mellitus Type 2 , 371087003 Diabetic foot ulcer), Procedure Completed, Sex and Gender, Medication statement, Encounter – clinical context | |
| medications, lifestyle mod | a comprehensive care plan for Maria, outlining her treatment, ifications, and scheduled follow-ups with her healthcare team | |
| Related documents: •Care plan | Example data groups and terminology: Problem/ Diagnosis (E.g. SCT-AU Code 44054006 Diabetes Mellitus Type 2 , Procedure Completed, Adverse reaction risk, Sex and Gender, Medication statement | |
| | GP – Maria relocates, necessitating a transfer of her care. Her her care plan and recent hospitalisation details are transferred to her new GP. | |
| Related documents: | Example data groups and terminology: | |
| Patient summary Care plan | Problem/Diagnosis, Procedure completed, Vaccination Administered, Adverse reaction risk, Sex and Gender, Medication statement, Tobacco smoking summary (E.g. SCT-AU code 77176002 Current smoker , Biomarkers, Vital signs, Measurements, Encounter – clinical context | |
| reviews her medical records | D risk - Maria continues her regular check-ups with her new GP, who c, coordinates her care with the podiatrist and endocrinologist, and based on available health records as a preventative measure. | |
| Related documents: | Example data groups and terminology: | |
| •Care plan •CVD risk score | •Sex and Gender, Medication statement, Tobacco smoking summary (e.g., SCT- AU code 77176002 Current smoker), Biomarkers, Vital signs, Measurements | |
| Figure 4. Maria's care journey * Items marked with an asterisk are not sup | oported by R1, but are potential candidates for AU eRequesting Data for Interoperability R1 | |

4.5. AUCDI, FHIR, and AU Core Implementation Guide

The primary intent of the AUCDI is to design and govern a collection of coherent, reusable building blocks known as 'data groups'. These data groups specify "what" the clinical requirements of the clinical information that should be included for data entry, data use, and sharing of information supporting healthcare delivery. However, it does not specify "how" the data is exchanged; this is the role fulfilled by the FHIR standard.

FHIR is the next-generation HL7 standard for exchanging healthcare data electronically. It is based on the lessons learnt from the many years of developing previous HL7 standards for healthcare data exchange.

The basic building blocks of FHIR, Resources, can be tailored to suit specific use cases by "profiling". Whilst FHIR is an international standard, national and regional projects can provide localisation of resources and profiles. HL7 Australia's "AU Base" IG provides localised resources extensions in the Australian context. AU Core specifies minimum data element support and system behaviour capability for a system to record, update, search, and retrieve core health and administrative information.

AU Core FHIR IG has been developed in reference to the AUCDI, representing the AUCDI data groups as FHIR artefacts. The Sparked HL7 AU Core Technical Design Group (AU Core TDG) has been tasked to co-design the AU Core FHIR IG under the governance framework of the <u>HL7 AU Australian FHIR</u> <u>Management Framework</u>.

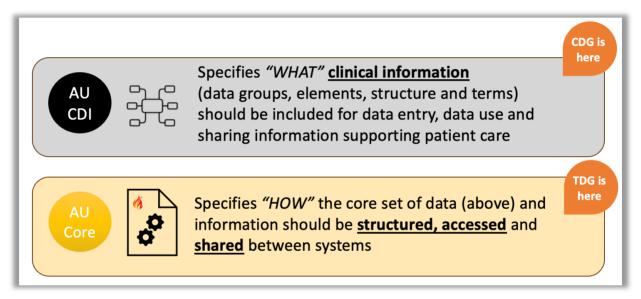


Figure 5. Focus points of AUCDI and AU Core.

4.6. Design of the AUCDI

The AUCDI has been developed in collaboration with the community and is informed by the key data drivers such as data entry, clinical documentation, clinical decision support, data use and reporting requirements.

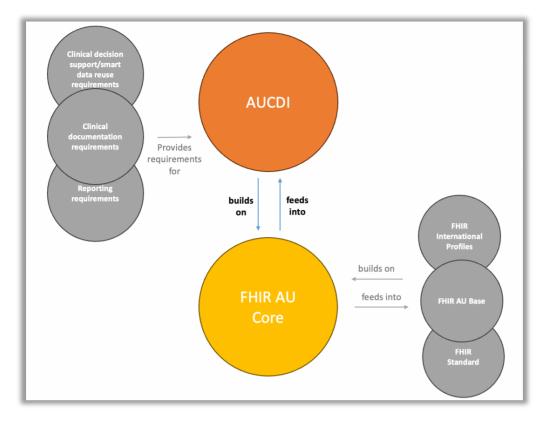


Figure 6. Relationship between AUCDI and FHIR AU Core.

In order to support maximum reuse and leveraging previous investment, the data model has been informed by other key local and international initiatives and programs such as previous Australian specifications and international standards. This includes:

- My Health Record Specifications,
- CSIRO Primary Care Data Quality Foundations (PCDQF),
- AIHW Minimum Data Sets,
- International Patient Summary (IPS),
- The pan-Canadian Health Data Content Framework,
- United States Core Data for Interoperability (USCDI), and
- UK Professional Record Standards Body (PRSB).

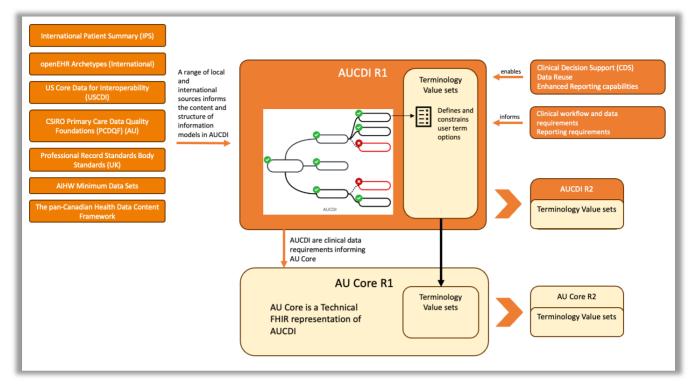


Figure 7. Design of AUCDI and relationship with AU Core

The initial design of the AUCDI commenced in 2018 during the PCDQF project with an analysis of existing data in primary care clinical systems and national standards. The AUCDI has built upon this foundation, referencing a broader range of national and international standards and initiatives described in 11.

The AUCDI is deliberately designed with a focus on clinicians and stakeholders, ensuring that the conceptual data models represent common, well-defined requirements identified from agreed use cases. The AUCDI direction and scope were established through in-person workshops involving clinicians, informaticians, software engineers, and other stakeholders, conducted over a period of months across 2023 and 2024. The structured representation of the AUCDI concepts in R1 has been informed by established clinical information model standards, particularly openEHR archetypes (see 11.2.6), which have been purposely developed by clinicians and informaticians focused on ensuring high-quality structured clinical data that is clinically safe and fit for purpose.

Core Design principles were developed to assist the development of AUCDI and to allow prioritisation by the Sparked team and the community. Table 1 sets out the design principles used and how the clinical information model has been aligned.

| Design Principles | Alignment |
|--|---|
| Reduce duplication - single entry, single development (multiple use and reuse) | Data collected in a structured and coded manner enables data to be reused for clinical decision support, population of summary information, forms, and letters, and for secondary uses like population health analytics. |

Table 1. Core design principles.

| Supports person-centred care - driven by a clinical quality and safety use case | Using standardised coded structured data for health information will support good clinical care, unambiguous transfer of clinical information and clinical decision support. This allows delivery of the right care to the right person at the right time. | |
|--|--|--|
| No data for data's sake | Every proposed data element has a practical purpose. | |
| Driven by primary clinical data use not secondary data use needs | Data models are intentionally minimal to start with, incorporating the minimum data elements to support safe and effective care, rather than collecting a comprehensive data set. In future releases, new data group concepts will be added and the level of detail of existing data groups will be increased to support clinical priorities and data requirements. | |
| Supports best practice care, clinical guidelines, and clinician workflow | Having standardised coded structured data for clinical information will support clinical care delivery and clinical decision support. This supports best practice care, clinical guidelines, and clinician workflow. | |
| Systems can support now or with minimal effort, supporting a strategic roadmap with an agile iterative process | Most systems can support the minimal model proposed although additional data elements for recording of health information is inconsistent across existing systems. | |
| Alignment with national health data standards and initiatives | Reference national standards and initiatives, such as: SNOMED CT-AU and the Australian Medicines Terminology (AMT) My Health Record | |
| Alignment with international standards and initiatives | Reference international standards and initiatives, such as: International Patient Summary HL7 Gender Harmony Project Information models FHIR Resources openEHR archetypes | |
| Involve and consider all healthcare domains and care modalities | The data groups are agnostic of any specific use case and needs to support usage in all healthcare domains and across healthcare modalities. Stakeholders engaged include primary, acute, and tertiary care and specialised domains and professions such as aged care and allied health. | |

More information on the rationale and approach to these design principles can be found in 10.3 and how they align with AUCDI R1 in Table 1.

4.7. AUCDI and implementations

The AUCDI does not need to be implemented as a whole single product. Sections can be implemented as required for specific use cases. This is true for both the data model and the recommended terminology value sets.

It is intended that AUCDI will continue to evolve to provide a foundation for future uses. For example it will both inform and be incorporated into the eRequesting use case, and any new common data elements may also be added to AU Core if determined to be foundational, for example Pregnancy Status. When combined with eRequesting specific requirements, the result will be the eRequesting Data for Interoperability. All future projects will commence with the AUCDI at their core.

5. How to read the AUCDI

Each data group represents one or more data elements about a single, discrete concept. The sections below (5.1.1 through to 5.1.1.5) provide examples of how the data groups and elements are represented in the AUCDI.

5.1.1. <Data group name> (e.g., Adverse reaction risk summary)

5.1.1.1. Context

Every data group contains a table that explains the general attributes, or metadata, of the data group as a whole, comprising:

| Clinical description | A definition or description of the data group concept. |
|---------------------------|--|
| Data group purpose | An explanation of the reason and objective for the data group. |
| Data group representation | A description of how a clinician might anticipate the data might be recorded within a clinical information system. |
| Data group alias | A list of synonyms for the name of the data group |
| Considerations for use | A description of factors that may impact the implementation or use of this data group within a clinical system. |
| Misuse | Guidance for implementers about possible scenarios or use cases in which this specific data group (as a whole) is not recommended, incorrect or inappropriate. Where applicable, a suitable alternative data group will be suggested. |

Table 2. Example context.

In addition, every data group contains an introductory narrative framing the concept by highlighting design, use, and implementation considerations.

Note the two exceptions, 'Measurements and Vital signs' and 'Biomarkers' where a set of data groups have been grouped into a collection of similar concepts, framed by a shared context.

5.1.1.2. Concept representation

Data element name 1

Cata group name>
Data element name 2

Data cluster name 3

An image of a mind map for each data group showing all R1 data elements.

Figure 8. Example mind map structure.

5.1.1.3. Information model

Every data group also contains a table that explains the specific attributes for each data element comprising:

Table 3. Example information model.

| Data element name | Description | A description or definition of the name of the data element |
|----------------------|-----------------------------------|--|
| | Element occurrence | Optional or mandatory: single occurrence only or allows more than one occurrence, for example, to record more than one coded value |
| | Data type | An indication of the type of data allowed to be captured; a choice of data type is allowed if more than one data type is noted. |
| | Proposed code system/value set | For CodeableConcept data types, a proposed value set will be recommended or proposed. For example: an agreed value set of SNOMED CT-AU terms limited to the context of the data element |
| | Examples | Examples of acceptable data entries may be provided to clarify what information could be recorded in this data element. |
| | Alias | A list of synonyms for the name of the data element. |
| | Considerations | A description of factors that may impact the implementation or use of this data element within a clinical system. |

5.1.1.4. Specific alignment to AUCDI design principles

All data groups are designed to align with the data design principles outlined in Table 1. These principles apply equally to every data group. Additional information on how the design principles were followed depending on the specific concept for the data group and specific alignment with

national clinical and technical standards, projects, and legislation that support the rationale for the data group and its component data elements may be highlighted in a table in this section.

The topic headings for each of these design principles are:

Table 4. Design principles topic headings.

| Reduce duplication, single entry, single development (multiple use and reuse) | Identifies known or anticipated opportunities to reuse the health information, recorded as per the data group specification, within other contexts or specifications. |
|--|---|
| Driven by a clinical quality and safety use case supporting person-centred care | Identifies known or anticipated benefits of using the data group in patient outcomes. |
| Aligns and leverages agreed national standards and initiatives | Identifies relevant Australian standards, specifications, or projects. |
| Aligns with international standards and initiatives | Identifies relevant international standards, specifications, or projects. |
| Inclusive engagement to involve all healthcare domains and modalities | Identifies the applicability of the data group to specific healthcare domains, peak bodies, or types of data recording. |

5.1.1.5. For future consideration

Each data group or collection contains a description of how the Release 1 content might evolve. Specific considerations may be highlighted, and issues that may have been identified as controversial may require further investigation and discussion.

A mind map of a proposed, comprehensive data group is considered a potential road map for future AUCDI releases and clinical information system evolution is included.

Each mind map has a legend:

- Nodes displayed as black text on an orange background and containing a green star icon are included in R1,
- Nodes displayed as grey text on a grey background and containing an orange star are candidate data elements for Release 2, and
- Nodes displayed as grey text on a grey background and containing a grey flag are candidate data elements for future AUCDI releases.

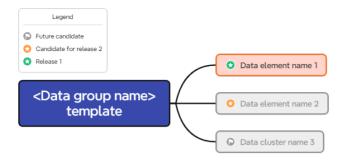


Figure 9. Example data group mind map depicting data element nodes and legend.

6. The AUCDI library at a glance

The scope of the AUCDI R1 Draft for Comment library of data groups (as clinical information models) is focused on commonly used clinical concepts, comprising of data elements confirmed by clinicians as 'core' for their clinical documentation and broadly supported by existing clinical information systems. The library is composed of the data groups and their component elements shown in Figure 10.

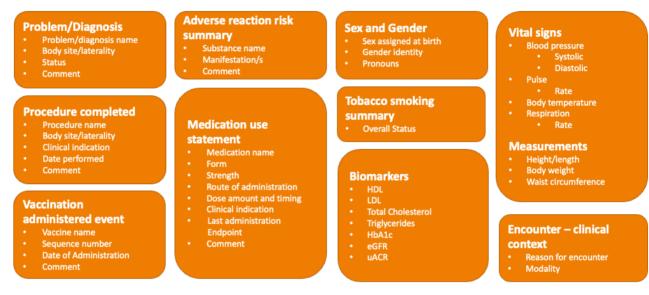


Figure 10. Draft AUCDI R1 data groups.

7. AUCDI Release 1 Draft for Comment Library

The clinical content scope and granularity in Release 1 are primarily driven and approved by clinicians and informaticians to ensure utility and clinical safety. As a result, depending on the specific concept, some data groups in this initial release feature only a single data element while others include multiple. Additionally, the selection of most data elements has been guided by an underlying principle of ensuring alignment with existing data structures available in clinical systems. Any new data elements proposed have been carefully chosen for their clinical significance or safety purposes.

7.1. Adverse reaction risk summary

7.1.1. Context

Table 5. Adverse reaction risk summary – context.

| Concept description | A summary or overview of a clinical assessment that identifies the potential for a harmful or undesirable physiological reaction unique to an individual and associated with exposure to a specific substance. |
|---------------------------|---|
| Data group purpose | To record: An assessment of the risk or propensity of a future adverse reaction if exposed, or re-exposed, to an identified substance. A summary of each exposure event, including details about the reaction experienced, as evidence supporting the risk assessment. |
| Data group representation | • Record one summary instance per substance within a health record. |
| Data group alias | Adverse reaction Allergy Intolerance Hypersensitivity |
| Considerations for use | Substances include but are not limited to: A therapeutic substance administered correctly at an appropriate dosage for the individual, Food, Material derived from plants or animals, or Venom from insect stings. Manifestations include any symptom, sign, or diagnosis. It is also possible to record the absence of a reaction on re-exposure to a substance where an existing adverse reaction summary exists. This may trigger further investigation to |

| confirm whether the previously assumed causal relationship to the substance is correct or mistaken. |
|--|
| • This data group is intended to provide a single place within the health record to document the propensity for the full range of adverse reactions, from trivial to life-threatening, irrespective of the underlying physical mechanism. This includes but is not limited to: |
| Immune-mediated: Types I-IV (including allergic reactions and hypersensitivities); or |
| Non-immune-mediated: such as pseudo-allergic reactions, side effects, intolerances, and drug toxicities in individuals with impaired excretion. |
| • In Release 1, all adverse reactions are assumed active in the context of a summary for exchange. |
| • In future updates, it is anticipated this data group will be extended to incorporate additional detail. |
| Not to be used to record a diagnosis of an adverse reaction as the conclusion of a clinical consultation or investigation – use the Problem/Diagnosis data type for this purpose. |
| Not to be used for recording physiological reactions to physical agents, such as heat, cold, sunlight, vibration, exercise activity, by infectious agents, or food contaminants. |
| Not to be used to record adverse events, including failures of clinical processes, interventions, or products. For example, abnormal use, incorrect dosage or maladministration of an agent or substance, mislabelling, overdose, or poisoning. |
| |

This data group documents a clinician's recommendation to avoid future exposure to a particular substance, emphasising the assessment of exposure risk and its substantiating evidence.

While highlighting the critical importance of accurately recording adverse reactions for safety, it is also crucial to recognise that documenting such reactions in a clinical system is not always limited to reactions categorised as true allergies, hypersensitivities, or intolerances. In practice, clinicians may encounter situations where the underlying pathophysiology of a reaction may not be known. Despite this, they still need to document that, in their judgment, the patient should avoid a specific substance. Such an entry is vital to prompt clinical safety alerts that prevent re-exposure, with previous manifestations offering insights into the risk of potential future harm, regardless of the unknown physiological mechanisms involved.

Use cases include, but are not limited to:

• 'Adverse Reaction List', or similar document, containing one or more 'Adverse reaction summary' data groups,

- Triggering clinical decision alerts when prescribing, and
- To exchange safety-critical adverse reaction information with other healthcare providers.

7.1.2. Concept representation

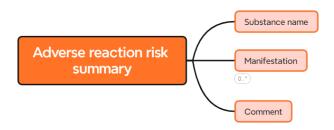


Figure 11. Adverse reaction risk summary mind map.

In this mind map, 'Manifestation' is represented as 0..*, indicating that more than one reaction manifestation per substance can be recorded, if necessary.

7.1.3. Information model

Table 6. Adverse reaction risk summary information model.

| Data elements | | |
|-------------------|---|--|
| Substance name | Description | Identification of a specific substance, compounded product, combination therapy product, or class of substances that is considered to have a causal link to the adverse reaction. |
| | Occurrence | Mandatory, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Adverse Reaction Agent value set</u> published by the NCTS currently includes all Substances (and classes) within SNOMED CT-AU and all AMT Product (notable) concepts. |
| | Examples | AMT provides concepts at various granularities from brand to specific ingredient: |
| | | • TP: 3738011000036101 Amoxil |
| | | • TPUU: 4542011000036104 Amoxil Forte Sugar Free oral liquid |
| | | MP: 27658006 Product containing amoxicillin |
| | | Note: The above examples reflect the future state of AMT, v4. |
| | | Specific ingredients and non-medicinal substances from SCT-AU: |
| | | • 372687004 Amoxicillin |
| | | • 111088007 Latex |

| | Alias Considerations | 256259004 Pollen 762952008 Peanut 1222501000168103 Vegemite 348608005 Surgical adhesive tape 'Band-Aid' Agent, Class, Product In this context, appropriate values for 'Substance name' include, but are not limited to: A therapeutic substance administered correctly at an appropriate dosage for the individual, Food, |
|---------------|---|--|
| | | Material derived from plants or animals,Venom from insect stings, and |
| | | • Physical objects commonly recorded as the proxy for a substance, such as Band-Aids or surgical tape. |
| | | It is strongly recommended that 'Substance name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate terminology is available. |
| Manifestation | Description | Symptom or sign observed or associated with the reaction. |
| | Occurrence | Optional, multiple occurrences |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Clinical Finding value set</u> published by the NCTS currently includes all Clinical findings within SNOMED CT- AU that could manifest as the result of an adverse reaction. |
| | | Additionally, the <u>Clinical manifestation reference set</u> is a subset of Clinical Findings that is published as part of SNOMED CT-AU that was developed collaboratively with a number of different health jurisdictions to identify the most commonly encountered reactions. |
| | Examples | 247472004 Hives 267038008 Oedema 62315008 Diarrhoea 422587007 Nausea 39579001 Anaphylaxis |
| | Alias | Reaction |

| | | Nature of reaction |
|---------|----------------|---|
| | | Clinical manifestation |
| | Considerations | It is strongly recommended that 'Manifestation' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate terminology is available. This data element has multiple occurrences to allow the recording of more than one manifestation per substance. |
| Comment | Description | Additional narrative about the adverse reaction risk not captured in other fields. |
| | Occurrence | Optional, single occurrence |
| | Data type | string |
| | Alias | Note |

7.1.4. Specific alignment to AUCDI design principles

Table 7. Adverse reaction risk summary alignment to design principles.

| Poduce duplication Single | |
|--|---|
| Reduce duplication, Single entry, single development (multiple use and reuse) | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Referrals My Health Record Adverse drug reaction reporting to the Therapeutic Goods Administration (TGA) Research data registry |
| Driven by a clinical quality and safety use case supporting person- centered care | A standardised, comprehensive, and shareable record of adverse reaction risks will: Enhance consistency and continuity of care across various healthcare settings Serve as a foundation for standardised clinical decision support systems, especially clinical alerts during prescribing or related to diet Support efforts to improve clinical safety by reducing prescribing and diet-related errors Facilitate consistent use of clinical guidelines and protocols, especially pharmacogenomic risk management Reduce errors in diagnosis, treatment, and management |

| Aligns and leverages national standards and initiatives | Recommended terminology leverages national SNOMED CT-AU and AMT value sets |
|---|--|
| Aligns and leverages international standards and initiatives | Adverse reaction risk, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.7022 Adverse reaction event, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.5795 AllergyIntolerance, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/allergyintolerance.html. AllergyIntolerance, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care; [cited: 2024 Feb 05]. Available from: https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition- AllergyIntolerance-uv-ips.html. |
| Inclusive engagement to involve all healthcare domains and modalities | As well as broad engagement, specific input has been sought from peak specialist bodies, such as the National Allergy Council. |

7.1.5. For future consideration

The openEHR 'Adverse reaction risk' archetype and the FHIR 'AllergyIntolerance' resource are mature information models that have been used globally in a broad range of implementations over many years. They form the basis for this initial AUCDI R1 data group and provide guidance for potential future augmentation.

The 'Adverse reaction risk summary' data group is expected to be expanded in future updates to include more detail. Additional information will be required to support broad use across common clinical settings, focusing on the assessment of active risk and the evidence underpinning the risk assessment. Further consideration will need to be given to enhancing and extending this model towards support for specific use cases, such as management of changes in the status and additional detail required by allergy specialists or for use in pharmaceutical trials.

The mind map below demonstrates a proposed roadmap for further development of the 'Adverse reaction risk summary' data group, based on the published openEHR 'Adverse reaction risk' and 'Adverse reaction event' archetypes. The framework of the mind map demonstrates the data elements that describe the overall risk assessment of an adverse reaction on future exposure. Within that framework, one or more reaction events can be recorded to support cumulative information gathering related to each exposure.

Potential candidate data elements for Release 2:

- Active/inactive status adding an 'Active/Inactive status' can be considered part of a broader consideration of ongoing management of adverse reaction lists, including reconciliation of new or updated adverse reaction instances.
- Clinical verification status for example, unconfirmed/confirmed/refuted.
- Onset of first reaction.
- Onset of last/most recent reaction.
- Recording details about each separate exposure/reaction event for example, urticarial rash following initial exposure in 1985 and anaphylaxis following a second exposure on January 1, 2024.
- Last updated the timestamp indicates whether the information is current or outdated, serving as a critical marker of its timeliness.

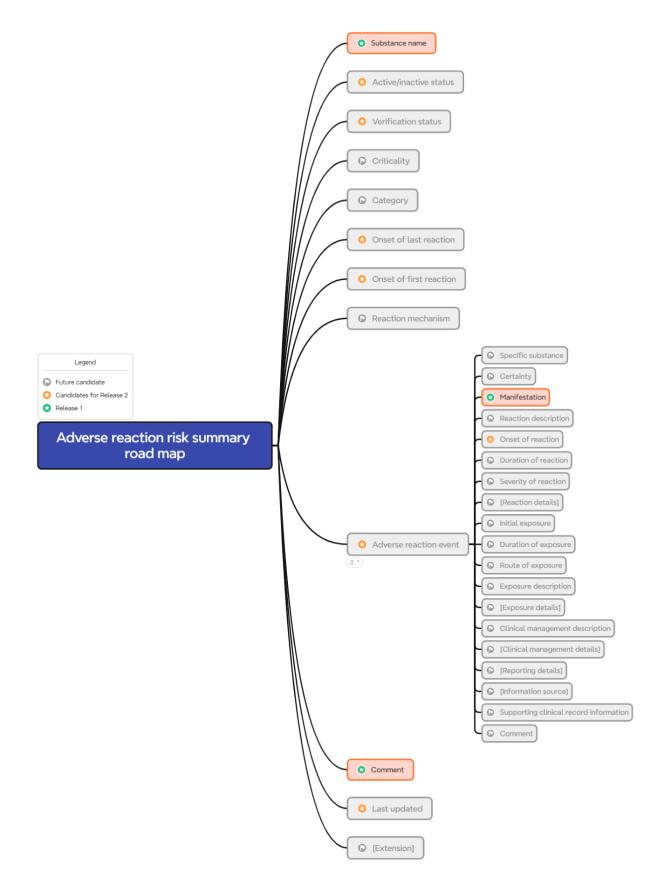


Figure 12. Proposed roadmap for further development of the 'Adverse reaction risk summary' data group.

7.2. Problem/Diagnosis summary

7.2.1. Context

Table 8. Problem/diagnosis summary context.

| Concept description | A summary or overview of a single health condition, injury, disability, or any other issue that impacts the physical, mental and/or social well-being of an individual. | |
|---------------------------|---|--|
| Data group purpose | To record summary information about a single problem or diagnosis. | |
| Data group representation | Record one instance per problem or diagnosis within a health record; changes or updates over time are captured as a revision rather than a new entry. | |
| Data group alias | condition | |
| Considerations for use | Both problems or diagnoses can be recorded using this same data model without distinguishing and labelling them as one or the other. The recording pattern is closely aligned, and what may initially be considered a 'soft' problem may evolve towards a formal diagnosis as more clinical evidence is discovered. In future updates, it is anticipated this data group will be extended to incorporate additional detail. | |
| Misuse | Not to be used to record summary information about a single pregnancy. | |

This data group documents a summary or overview of a single active, inactive, or resolved problem or diagnosis, gathered and integrated from various information sources, including multiple consultations and other activities, accumulated, and updated over time. An exception is summary information about a specific pregnancy; a condition that requires a very different data structure.

Traditionally, differentiating between problems and diagnoses has been difficult because they often exist at opposite ends of the same spectrum, both conceptually and in practice. As clinical evidence accumulates, what begins as a 'problem' may develop into a definitive 'diagnosis.' Adopting a unified data group for both facilitates the collection of clinical evidence and recognises the dynamic and interconnected nature of their relationship.

Use cases include, but are not limited to:

- Recording a diagnosis as the conclusion of a Consultation note,
- A 'Problem List', 'Medical history' or similar document, containing one or more 'Problem/Diagnosis summary' data groups,
- Triggering clinical decision alerts related to preventive health and chronic disease management, or
- To exchange critical information about problems or diagnoses with other healthcare providers.

7.2.2. Concept representation

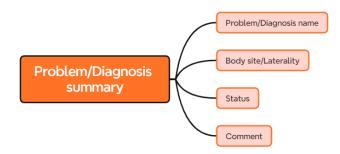


Figure 13. Problem/diagnosis summary mind map.

7.2.3. Information model

Table 9. Problem/diagnosis summary information model.

| Data elements | | |
|--------------------------------|---|--|
| Problem / Diagnosis name | Description | Identification of the problem or diagnosis by name. |
| | Occurrence | Mandatory, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Clinical Condition value set</u> value set published by the NCTS currently includes all members of the <i>Problem/Diagnosis reference set</i> in SNOMED CT-AU. This includes (most) subtypes of |
| | | 272379006 Event |
| | | 243796009 Situation with explicit context |
| | | 404684003 Clinical Finding |
| | Examples | SNOMED CT-AU: |
| | | • 195967001 Asthma |
| | | 46635009 Diabetes Mellitus Type 1 |
| | | • 13746004 Bipolar disorder |
| | | 307608006 Ewing's sarcoma of bone |
| | | • 44465007 Sprain of ankle |
| | | 112981000119107 Bilateral osteoarthritis of knees |
| | | • 20902002 Fall from bed |
| | | 315604002 Missed contraceptive pill |
| | Alias | Condition name |

| | Considerations | It is strongly recommended that the 'Problem/Diagnosis name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate terminology is available. |
|-----------|---|--|
| Body site | Description | The anatomical location or body structure where the 'Problem or diagnosis' is manifested. |
| | Occurrence | Optional, multiple occurrences |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Body Site value set</u> published by the NCTS is a subset of the SNOMED CT-AU Body structure hierarchy. It includes anatomical structures (including acquired structures) with laterality but excludes morphologic abnormalities and cellular/intercellular structures. |
| | Examples | 761920005 Bone structure of shaft of right humerus |
| | | • 51636004 Left ankle |
| | | 38033009 Amputation stump |
| | Alias | Anatomical location |
| | Considerations | Specification of 'Body site' is only required when the 'Problem/Diagnosis name' does not include or imply a specific body site. |
| | | This data element has multiple occurrences to allow the recording of more than one body site for each problem or diagnosis – for example, to record multiple skin sites affected by a rash. |
| | | It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. |
| Status | Description | An assertion whether a problem or diagnosis is currently active or inactive. |
| | Occurrence | Optional, single occurrence |
| | Data type | Coding |
| | Recommended code system/value set | Coded terms for 'Status' will be selected from a value set, yet to be determined, and limited to the following two values: • Active – a current, ongoing health condition that |
| | | requires active treatment or management; or |

| | | Inactive – a health condition that has resolved, is in remission, or no longer requires active treatment or management. |
|---------|----------------|---|
| | Alias | Clinical status |
| | Considerations | None |
| Comment | Description | Additional narrative about the problem or diagnosis not captured in other fields. |
| | Occurrence | Optional, single occurrence |
| | Data type | string |
| | Alias | Note |
| | Considerations | None |

7.2.4. Specific alignment to AUCDI design principles

Table 10. Problem/diagnosis summary alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Supports collection of data for Practice Incentives Program Quality Improvement Measures The proportion of patients with diabetes with a |
|---|---|
| | current HbA1c result |
| | The proportion of patients with diabetes with a blood pressure result. |
| | Supports the Australian guideline and calculator for assessing and managing cardiovascular disease risk |
| | • Data captured using this data group could potentially be re- used, with appropriate authority and consent, for: |
| | • Referrals |
| | My Health Record |
| | Research data registry |
| Driven by a clinical quality and safety use case | A standardised, comprehensive and shareable record of problems and diagnoses will: |
| supporting person- centered care | Enhance consistency and continuity of care across various healthcare settings |
| | Serve as a foundation for standardised clinical decision support systems |
| | Streamline monitoring and management of conditions |
| | Support efforts to improve clinical safety |
| | • Facilitate consistent use of clinical guidelines and protocols |
| | |

| Aligns and leverages national standards and initiatives | Enable tailored, personalised preventive health plans Reduce the variability in healthcare delivery Reduce errors in diagnosis, treatment, and management Recommended terminology leverages national SNOMED CT-AU value sets |
|--|---|
| Aligns and leverages international standards and initiatives | Problem/Diagnosis, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [v]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.169 Condition, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/condition.html. Condition, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care; [cited: 2024 Feb 05]. Available from: https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition- Condition-uv-ips.html. |

7.2.5. For future consideration

The openEHR 'Problem/Diagnosis' archetype and the FHIR 'Condition' resource are mature information models that have been used globally in a broad range of implementations over many years. They form the basis for this initial AUCDI R1 data group and provide guidance for potential future augmentation.

In addition, the 'Problem/Diagnosis name' value set can be extended to include problems identified from an allied health or Social Determinants of Health (SDOH) perspective, such as 'Food insecurity' and 'Financial insecurity'.

The mind map below demonstrates a proposed roadmap for developing the 'Problem/Diagnosis summary' data group based on the published openEHR 'Problem/Diagnosis' archetype.

Potential candidate data elements for Release 2:

- Date/time clinically recognised this equates to the 'Date of diagnosis' for a formal diagnosis, but is deliberately framed more loosely to support a date related to a softer problem.
- Last updated the timestamp indicates whether the information is current or outdated, serving as a critical marker of its timeliness.

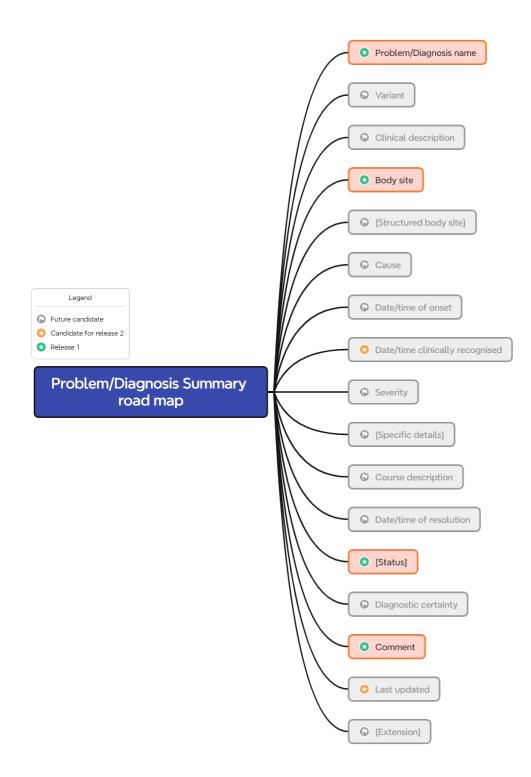


Figure 14. Proposed roadmap for developing the 'Problem/Diagnosis summary' data group.

7.3. Procedure completed event

7.3.1. Context

Table 11. Procedure completed event context.

| Concept description | A clinical procedure is an intentional intervention to diagnose, treat or manage a health condition, often involving invasive or potentially harmful techniques requiring skin or mucosal penetration or tissue manipulation. | |
|---------------------------|--|--|
| Data group purpose | To record details about a procedure that has been performed or carried out. | |
| Data group representation | Record one instance per procedure event within a health record. | |
| Data group alias | operationinterventionsurgery | |
| Considerations for use | Significant procedures can be persisted within a curated Procedure or Surgical History list (or similar). In future updates, it is anticipated this data group will be extended to incorporate additional detail. | |
| Misuse | Not to be used to record vaccination administration – use the 'Vaccination administration' data group for this purpose. Not to be used to record problem/diagnosis – use the 'Problem/Diagnosis Summary' data group for this purpose. Not to be used to record non-invasive procedures found in some terminology coding hierarchies, such as patient transportation, day care services, home modification or exercise. | |

This data group documents details about a single procedure event that has been performed and/or completed.

The definition of procedures can be challenging. In clinical terminologies such as SNOMED CT, the scope of a procedure can be extremely broad, including clinical activities such as patient transportation, day care services, home modification, or exercise. However, the data structure for the 'Procedure completed data group' is specifically designed to capture activities performed on an individual to diagnose, treat, or manage a health condition, usually involving invasive or potentially harmful techniques. In this context, there is no precise definition of what exactly is and is not a procedure; there will likely be some 'grey zones' that require clinical documentary discretion, depending on the clinical context – for example, procedures related to diagnostic investigations or proctoscopy.

The structure for documenting a procedure markedly differs from that required to capture details about a medication condition. This distinction becomes more apparent when comparing the

'Procedure completed' data group to the 'Problem/Diagnosis summary', and the divergence is even more apparent on reviewing the extended, future roadmap models. It is noted that some clinical systems currently use a generic data structure to record both completed procedures and manage active and inactive problems or diagnoses. Vendors of clinical systems will need to consider the shift towards the separated modelling patterns.

The differentiation of models is necessary because of the inherent differences in each type of data; the 'Problem/Diagnosis summary' serves as an evolving overview of an ongoing condition, whereas the Procedure data represents a historical account of a past event. Implementing this separation of models will not only improve the accuracy and clarity of electronic health records but also significantly support more accurate clinical decision support systems.

Use cases include, but are not limited to:

- Recording a procedure completed as part of a Consultation note or Operation note, for example:
 - Taking a blood sample,
 - Repair of a laceration or suture removal,
 - o Insertion of an intravenous cannula or a urinary catheter,
 - Endoscopy or laparoscopy,
 - Biopsy of a skin lesion,
 - o Manual manipulation of a fracture or dislocation,
 - External version of a foetus,
 - o Electrical cardioversion, or
 - Coronary artery bypass graft operation.
- A 'Procedure list', 'Surgical history' or similar document containing one or more 'Procedure completed' data groups, or
- To exchange critical information about past operations or procedures with other healthcare providers.

7.3.2. Concept representation

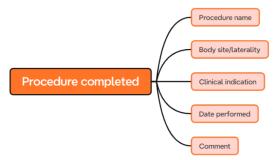


Figure 15. Procedure completed event mind map.

7.3.3. Information model

Table 12. Procedure completed event information model.

| Data elements | | |
|------------------------|---|--|
| Procedure | Description | Identification of the procedure by name. |
| name | Occurrence | Mandatory, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Procedure value set</u> published by the NCTS currently includes all Procedure concepts within SNOMED CT-AU. Groupers that are considered artefacts of the terminology and not useful for clinical records are excluded. |
| | Examples | SNOMED CT-AU: |
| | | • 232722009 Coronary artery bypass grafts x 4 |
| | | 312681000 Bone density scan |
| | | 239592001 Forefoot amputation |
| | | 34309001 Drainage of tonsil |
| | | • 307998000 Excision of pigmented skin lesion |
| | Alias | Operation name |
| | Considerations | It is strongly recommended that 'Procedure name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be permitted if no appropriate terminology is available. |
| Clinical indication | Description | The clinical symptom, sign or diagnosis that necessitates the procedure. |
| | Occurrence | Optional, multiple occurrences |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Reason For Encounter value set</u> published by the NCTS is a broad reference set including (most) clinical findings, situation with explicit context, and event concepts. |
| | Examples | 4557003 Unstable angina |
| | | 59848001 Obstructive jaundice |
| | | 46635009 Diabetes Mellitus Type 1 |
| | | 33261009 Abscess of tonsil |
| | | 80201000119103 Atypical pigmented lesion |
| | | 289916006 Family history of kidney disease |
| | | 772150003 Diphtheria suspected |

| | | • 422181004 Antibiotic prophylaxis |
|-------------------|--|---|
| | | |
| | | 274920002 Jellyfish sting |
| | Alias | Reason for procedure |
| | Considerations | This data element has multiple occurrences to allow the recording of more than one clinical indication per medication. |
| Body site | Description | The anatomical location or body structure where the procedure was performed. |
| | Occurrence | Optional, multiple occurrences |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Body Site value set</u> published by the NCTS is a subset of the SNOMED CT-AU Body structure hierarchy. It includes anatomical structures (including acquired structures) with laterality but excludes morphologic abnormalities and cellular/intercellular structures. |
| | Examples | 761920005 Bone structure of shaft of right humerus 51636004 Left ankle |
| | | 38033009 Amputation stump |
| | | |
| | Alias | Anatomical location |
| | Alias | Anatomical location |
| | Alias Considerations | Anatomical location Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. |
| | | • Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a |
| | | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of |
| Date | | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no |
| Date performed | Considerations | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. |
| | Considerations | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. The date when the procedure was performed. |
| | Considerations Description Occurrence | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. The date when the procedure was performed. Optional, single occurrence |
| | Considerations Description Occurrence Data type | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. The date when the procedure was performed. Optional, single occurrence March 15, 2024 |
| | Considerations Description Occurrence Data type | Specification of 'Body site' is only required when the 'Procedure name' does not include or imply a specific body site. This data element has multiple occurrences to allow the recording of more than one body site for each named procedure – for example, to record multiple related skin sites requiring excision of pigmented lesions in one procedure. It is strongly recommended that the 'Body site' be coded with a terminology, where possible. Free text entry should only be permitted if no appropriate terminology is available. The date when the procedure was performed. Optional, single occurrence date |

| | Alias | Date completed |
|---------|----------------|--|
| | Considerations | Partial dates are allowed. |
| Comment | Description | Additional narrative about the procedure not captured in other fields. |
| | Occurrence | Optional, single occurrence |
| | Data type | string |
| | Alias | Note |
| | Considerations | None |

7.3.4. Specific alignment to AUCDI design principles

Table 13. Procedure completed event alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Referrals My Health Record Research data registry |
|--|--|
| Driven by a clinical quality and safety use case supporting person- centered care | A standardised, comprehensive, and shareable record of procedures will: Enhance consistency and continuity of care across various healthcare settings Improve the precision of clinical decision-making processes, potentially underpinned by an accurate organ inventory Serve as a foundation for standardised clinical decision support systems Support efforts to improve clinical safety Facilitate consistent use of clinical guidelines and protocols Reduce errors in diagnosis, treatment, and management |
| Aligns and leverages national standards and initiatives | Recommended terminology leverages national SNOMED CT-AU value sets |
| Aligns and leverages international standards and initiatives | Procedure, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.204</u> |

| Procedure, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org/fhir/R5/procedure.html</u>. |
|---|
| Procedure, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care; [cited: 2024 Feb 05]. Available from: <u>https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-Procedure-uv-ips.html</u>. |

7.3.5. For future consideration

The openEHR 'Procedure' archetype and the FHIR 'Procedure' resource are mature information models that have been used globally in a broad range of implementations over many years. They form the basis for this initial R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Procedure completed' data group based on the published openEHR 'Procedure' archetype.

Potential candidate data elements for AUCDI Release 2:

• None proposed at the time of publication.

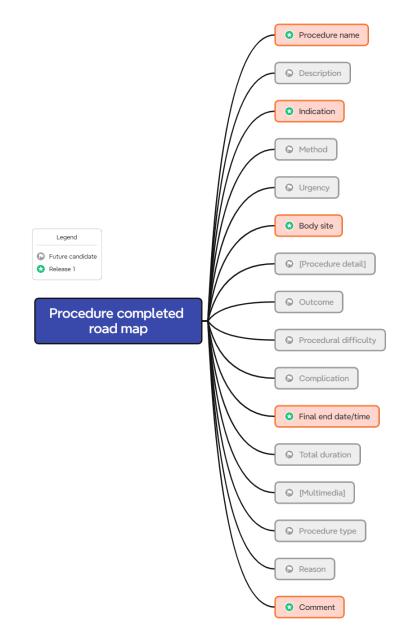


Figure 16. Proposed roadmap for developing the 'Procedure completed' data group.

7.4. Vaccination administered event

7.4.1. Context

Table 14. Vaccination administered event context.

| Concept description | Intentional introduction of a substance into the body to stimulate the body's immune response against a disease. | |
|---------------------------|---|--|
| Data group purpose | To record details about a vaccine that has been administered. | |
| Data group representation | Record one instance per vaccination administration event within a health record. | |
| Data group alias | immunisation administered | |
| Considerations for use | Each vaccination can be included within a curated Vaccination or Immunisation list (or similar). In future updates, it is anticipated this data group will be extended to incorporate additional detail. | |

This data group documents details about a single vaccine administration event that has been performed and/or completed.

Accurate documentation of administered vaccinations in clinical systems is invaluable in maintaining an individual's vaccination history over their lifetime. However, the current approach to recording this information varies significantly between clinical systems, especially in clinical systems that do not participate in the Australian Immunisation Registry (AIR), resulting in inconsistent data. This lack of standardisation is a significant barrier to the safe exchange of a vaccination history between healthcare providers, particularly as individuals move through the health system and require them to repeat their history to each new healthcare provider and organisation.

Use cases include, but are not limited to:

- Recording a vaccination administered during a Consultation,
- A 'Vaccination list', 'Immunisation history' or similar document containing one or more Vaccination completed' data groups, or
- To exchange a history of vaccination with other healthcare providers.

7.4.2. Concept representation

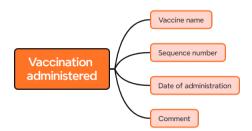


Figure 17. Vaccination administered event mind map.

7.4.3. Information model

Table 15. Vaccination administered event information model.

| Data elements | | |
|----------------|---|--|
| Vaccine name | Description | The name of the vaccine administered. |
| | Occurrence | Mandatory, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Australian Vaccine value set</u> published by NCTS includes all Australian Medicines Terminology vaccine product concepts and Australian Immunisation Register vaccine codes available for recording a vaccine product. |
| | Examples | SNOMED CT-AU: |
| | | • 709541000168107 Fluvax 2015 |
| | | 38598009 MMR vaccination |
| | Alias | Immunisation name |
| | Considerations | It is strongly recommended that the 'Vaccine name' be coded with terminology capable of triggering decision support where possible. Free text entry should only be permitted if no appropriate terminology is available. |
| Sequence | Description | The sequence of the vaccine administration within a series of administrations. |
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept or Positive integer |
| | Recommended code system/value set | Recommendations about the code system and value set are under development. |
| | Examples | • First, Second, Third, '2,' or '2 of 3'. |
| | Alias | • sequence number, |
| | | dose number |
| | Considerations | None |
| Date of | Description | The date on which the vaccine was administered. |
| administration | Occurrence | Optional, single occurrence |
| | Data type | date |
| | Example | • 14 January, 2024 |
| | Alias | date of immunisation, |

| | | performed date, date given |
|---------|----------------|--|
| | Considerations | None |
| Comment | Description | Additional narrative about the vaccination administration, not captured in other fields. |
| | Occurrence | Optional, single occurrence |
| | Data type | • string |
| | Alias | Note |
| | Considerations | None |

7.4.4. Specific alignment to AUCDI design principles

Table 16. Vaccination administered event alignment to design principles.

| Reduce duplication, Single entry, single development | Supports collection of data for Practice Incentives Program Quality Improvement Measures: |
|--|---|
| (multiple use and reuse) | Proportion of patients aged 65 and over who were immunised against influenza |
| | Proportion of patients with diabetes who were immunised against influenza |
| | Proportion of patients with COPD who were immunised against influenza |
| | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: |
| | Australian Immunisation Register |
| | Referrals |
| | My Health Record |
| | Research data registry |
| | Infant/child health records |
| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of vaccinations will: |
| supporting person- centered care | Enable tailored, personalised vaccination care plans, including both schedule-driven protocols plus catch-up doses, as appropriate |
| | Facilitate consistent use of clinical guidelines and protocols, such as identifying missed or delayed vaccination administration according to age-appropriate vaccination protocols |

| Aligns and leverages | Enhance consistency and continuity of care across various healthcare settings Improve the precision of clinical decision-making processes Serve as a foundation for standardised clinical decision support systems Foster active health consumer engagement Reduce the variability in healthcare delivery |
|--|---|
| Aligns and leverages national standards and initiatives | Recommended terminology leverages national SNOMED CT- AU and AMT value sets Meets requirements of the Australian Immunisation Register Vaccinations recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Immunization, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/procedure.html. Vaccination management, Proposed archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypeproposals/1013.38.273 Immunization, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care; [cited: 2024 Feb 05]. Available from: https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition- Immunization-uv-ips.html |

7.4.5. For future consideration

The FHIR 'Immunization' resource is a mature information model used globally in a broad range of implementations. The openEHR 'Vaccination management' archetype is a proposed archetype based on global patterns and specifications underpinning implementations. They form the basis for this initial AUCDI R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Vaccination administration' data group based on the published openEHR 'Vaccination management' archetype.

Potential candidate data elements for Release 2:

- Batch/Lot ID.
- Vaccine serial ID.

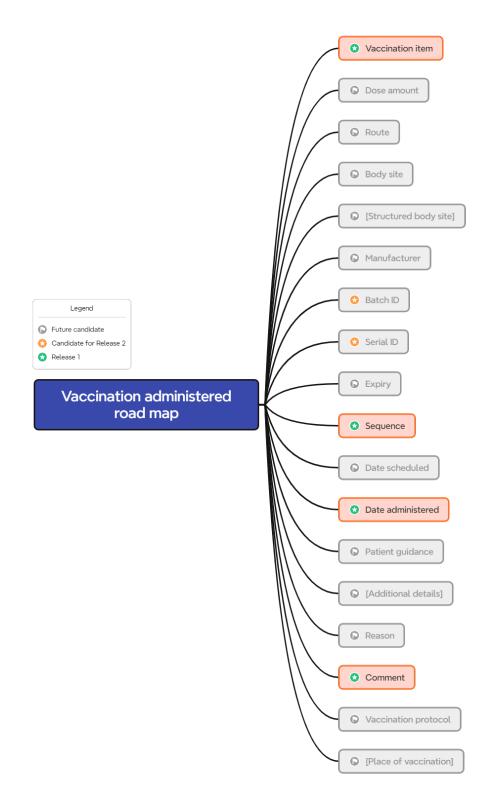


Figure 18. Proposed roadmap for developing the 'Vaccination administration' data group.

7.5. Tobacco smoking summary

7.5.1. Context

Table 17. Tobacco smoking summary context.

| Concept description | Summary information about an individual's pattern of smoking tobacco and tobacco-containing products. | |
|---------------------------|--|--|
| Data group purpose | To record summary information of tobacco smoking behaviour. | |
| Data group representation | Record only once in the health record; changes or updates over time are captured as revisions rather than new entries. | |
| Data group alias | smoking | |
| Considerations for use | Tobacco smoking summary is one component of a larger group of models recording lifestyle risk factors and related behaviour, such as alcohol consumption and other substance use. In future updates, it is anticipated this data group will be extended to incorporate additional detail. | |

Lifestyle factors represent important information about Individual behavioural factors that are likely to influence their health and well-being. For the AUCDI R1, stakeholders agreed to limit the scope to include the 'Overall status' within the 'Tobacco smoking summary' data group. It is understood that data groups for other lifestyle factors, such as alcohol consumption, other substance use, nutrition, physical activity, etc, will be added to the AUCDI in future releases.

Accurate documentation of an individual's tobacco smoking history and behaviour in clinical systems is essential for assessing their future risk of serious disease and making informed decisions to mitigate the risk. However, the current approach to recording this information varies significantly between clinical systems, resulting in inconsistent data. This lack of standardisation is a significant barrier to the safe exchange of medical history between healthcare providers, particularly as individuals move through the health system and require them to repeat their medical history to each new healthcare provider and organisation.

Adopting a simple, standardised data framework for documenting a summary of tobacco smoking behaviour will support the provision of coordinated and integrated health care.

The clinical concept has been limited to an overview of tobacco smoking behaviour to support potential tobacco smoking behaviour change interventions. This data group does not include smoking of other substances, smokeless tobacco use, nicotine consumption, or vaping; all of which require separate purpose-specific data groups.

7.5.2. Concept representation



Figure 19. Tobacco smoking summary mind map.

7.5.3. Information model

Table 18. Tobacco smoking summary information model.

| Data elements | | |
|----------------|---|---|
| Overall status | Description | Statement about current smoking habits for all types of tobacco. |
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Smoking Status value set</u> published by NCTS includes concepts from SNOMED CT-AU that may be used to represent an individual's current behaviour of tobacco smoking. |
| | Examples | SNOMED CT-AU |
| | | • 266919005 Lifetime non-smoker |
| | | • 77176002 Current smoker |
| | | • 8517006 Ex-smoker |
| | Alias | overall smoking status |
| | | tobacco smoking status |
| | Considerations | Some proposed value sets for 'Smoking status' also include values such as 'Occasional smoker' or 'Heavy tobacco smoker'. However, these values represent complementary data elements about the frequency of smoking, or the amount smoked. In this context, these values relate to other clinical concepts which may be represented in future releases for this data group. |

7.5.4. Specific alignment to AUCDI design principles

Table 19. Tobacco smoking summary alignment to design principles

| Reduce duplication, Single | Supports collection of data for Practice Incentives Program Quality |
|----------------------------|---|
| entry, single development | Improvement Measures Proportion of patients with a smoking status Data captured using this data group could potentially be re-used, |
| (multiple use and reuse) | with appropriate authority and consent, for: |
| | Australian cardiovascular disease risk assessment tool and guideline Referrals |

| | My Health Record |
|---|---|
| | |
| | Research data registry |
| Driven by a clinical quality and safety use case supporting person- | A standardised, comprehensive, and shareable record about tobacco smoking will: Serve as a foundation for standardised clinical decision |
| centered care | support systems, especially for chronic disease management |
| | Foster active health consumer engagement |
| | Support efforts to improve clinical safety by identifying individuals at risk of significant clinical disease due to tobacco smoking behaviour |
| | • Facilitate consistent use of clinical guidelines and protocols, for example, cardiovascular risk assessment |
| Aligns and leverages national standards and initiatives | Recommended terminology leverages national SNOMED CT- AU value sets |
| muatives | Smoking status recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Tobacco smoking summary, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.2466</u> |
| | SH Tobacco Use, International Patient Summary Implementation Guide, [Internet]. HL7 International / Patient care; [cited: 2024 Feb 05]. Available from: <u>https://build.fhir.org/ig/HL7/fhir-ips/StructureDefinition-Observation-tobaccouse-uv-ips.html</u>. |

7.5.5. For future consideration

It is anticipated that this data group will be expanded over time to incorporate additional detail about smoking habits, including the type/form of tobacco, typical use, and episodes of use.

The openEHR 'Tobacco smoking summary' archetype is a peer-reviewed and published information model, and the FHIR 'Tobacco use' profile has been implemented in many situations as part of the International Patient Summary. They form the basis for this initial AUCDI R1 data group, with the archetype providing guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the future development of the 'Tobacco smoking summary' data group, based on the published openEHR 'Tobacco smoking summary' archetype. The framework of the mind map demonstrates the data elements that describe overall tobacco smoking information. Nested within that framework, it is possible to record more detailed smoking summaries per type of tobacco, for example for cigarettes or a pipe.

Potential candidate data elements for AUCDI Release 2:

- Identifying each form of use, then details the current typical amount and pattern of use, and record summary information about previous episodes of use, for example, while pregnant.
- Last updated the timestamp indicates whether the information is current or outdated, serving as a critical marker of its timeliness.

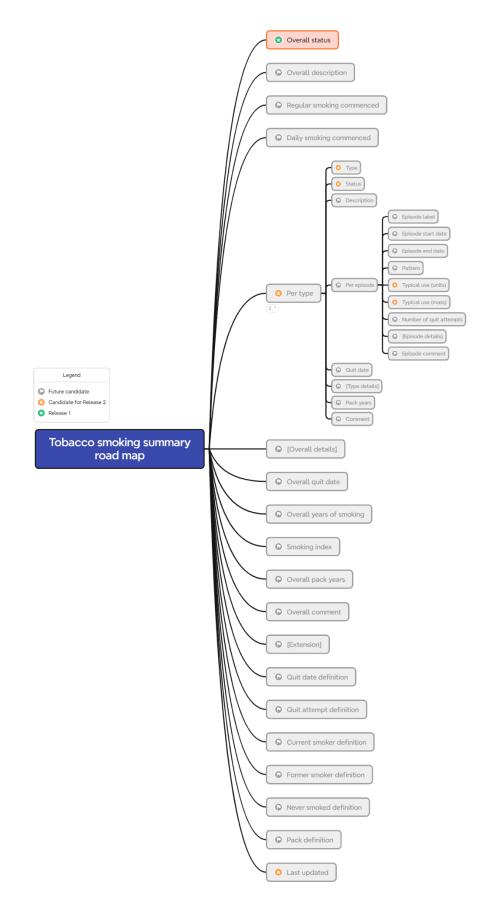


Figure 20. Proposed roadmap for the future development of the 'Tobacco smoking summary' data group.

7.6. Measurements and vital signs

A collection of data groups representing common anthropometric measurements and critical physiological parameters, initially comprising:

- Blood pressure
- Pulse
- Body temperature
- Respiration
- Height/Length
- Body weight
- Waist circumference

As new use cases are identified in scope for AUCDI, the range of the Measurements and Vital signs collection is expected to expand.

7.6.1. Blood pressure

7.6.1.1. Context

Table 20. Measurements and vital signs (blood pressure) context.

| Concept description | Measurement of the blood pressure in a single artery as a proxy for systemic arterial pressure. |
|------------------------------|--|
| Data group purpose | To record details of a single blood pressure measurement and its associated parameters. |
| Data group representation | Record one instance per observation event within a health record. |
| Data group alias | BP |
| Considerations for use | The measured pressure can be recorded using a device. In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the measurement context. |

This data group documents details of observed and measured parameters related to blood pressure at a point in time. In R1, the parameters recorded are constrained only to measurements of the Systolic and Diastolic pressures.

7.6.1.2. Concept representation

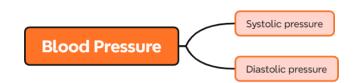


Figure 21. Measurements and vital signs (blood pressure) mind map.

7.6.1.3. Information model

Table 21. Measurements and vital signs (blood pressure) information model.

| Data elements | | |
|-----------------------|----------------|--|
| Systolic pressure | Description | The peak systemic arterial blood pressure, measured during c |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity (pressure) |
| | Example | • 140 mm[Hg] |
| | Alias | Systolic |
| | Considerations | Units: mm[Hg] |
| Diastolic pressure | Description | The minimum systemic arterial blood pressure, measured during the relaxation phase of the heart. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity (pressure) |
| | Example | • 85 mm[Hg] |
| | Alias | Diastolic |
| | Considerations | • Units: mm[Hg] |

7.6.1.4. Specific alignment to AUCDI design principles

Table 22. Measurements and vital signs (blood pressure) alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Supports collection of data for Practice Incentives Program Quality Improvement Measures Proportion of patients with the necessary risk factors |
|---|---|
| | assessed to enable CVD assessment Proportion of patients with diabetes with a blood pressure result |

| | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: |
|--|--|
| | Australian cardiovascular disease risk assessment tool and guideline |
| | Emergency transfer of care summary |
| | My Health Record |
| | Research data registry |
| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of blood pressure measurements will: |
| supporting person- centered care | Enhance consistency and continuity of care across various healthcare settings, especially in emergency transfer of care |
| | Serve as a foundation for standardised clinical decision support systems |
| | Streamline monitoring and management of cardiovascular conditions |
| | Foster active health consumer engagement through home monitoring |
| | Support efforts to improve clinical safety by alerting to extreme measurements or persistent outlier measurements |
| | Facilitate consistent use of clinical guidelines and protocols |
| | Reduce errors in diagnosis, treatment, and management |
| Aligns and leverages national standards and initiatives | Blood pressure, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org.au/fhir/4.0.0/StructureDefinition-au- bloodpressure.htm</u>. |
| | • Blood pressure recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Blood pressure, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.3574</u> |

7.6.1.5. For future consideration

The openEHR 'Blood Pressure' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation. The mind map below demonstrates a proposed roadmap for developing the 'Blood Pressure' data group, based on the published openEHR 'Blood Pressure' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad-hoc measurement events and a specific event that explicitly records data relevant to the measurements recorded as part of a '24-hour average' assessment.

Potential candidate data elements for AUCDI Release 2:

• Context of the measurement, such as the body site (location) of the measurement, body position, and method of measurement.

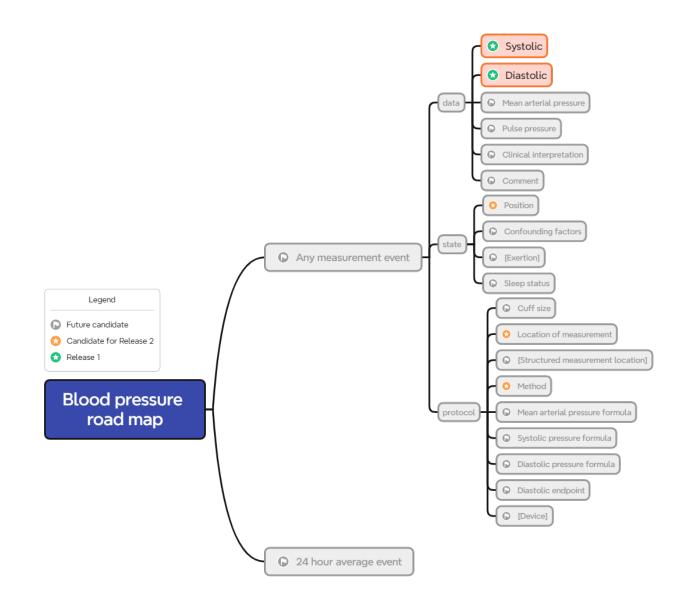


Figure 22. Proposed roadmap for developing the 'Blood Pressure' data group.

7.6.2. Pulse

7.6.2.1. Context

Table 23. Measurements and vital signs (pulse) context.

| Concept description | The rate and associated findings related to the pressure wave of blood as it is pumped through an artery by the heart. | |
|---------------------------|---|--|
| Data group purpose | To record details from a single observation of an arterial pulse. | |
| Data group representation | Record one instance per observation event within a health record. | |
| Data group alias | None | |
| Considerations for use | The measured rate can be recorded using a device. In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional observable parameters related to the pulse and details regarding the measurement context. | |
| Misuse | Not to be used to record information about the heartbeat, including heart rate, which should only be recorded at the heart. | |

This data group documents details of observed and measured parameters related to an arterial pulse at a point in time. It is important to note that observations about an arterial pulse need to be recorded in a separate model from observations about the heartbeat. Clinicians commonly compare the heart and pulse rates to identify or exclude diagnoses.

In AUCDI R1, the only parameter recorded is the pulse rate measurement. Future releases may extend the level of detail for this data group.

7.6.2.2. Concept representation



Figure 23. Measurements and vital signs (pulse) mind map.

7.6.2.3. Information model

Table 24. Measurements and vital signs (pulse) information model.

| Data elements | | |
|---------------|----------------|---|
| Pulse rate | Description | The measured rate of an arterial pulse. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity (frequency) |
| | Example | • 72 beats/min |
| | Alias | • pulse |
| | Considerations | Units: /min or {beats}/min |

7.6.2.4. Specific alignment to AUCDI design principles

Table 25. Measurements and vital signs (pulse) alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Event summary Emergency transfer of care summary Research data registry |
|--|---|
| Driven by a clinical quality and safety use case supporting person- centered care | A standardised, comprehensive, and shareable record of pulse measurements will: Enhance consistency and continuity of care across various healthcare settings, especially in emergency transfer of care Serve as a foundation for standardised clinical decision support systems Streamline monitoring and management of cardiovascular conditions Foster active health consumer engagement through home monitoring Support efforts to improve clinical safety by alerting to extreme measurements or persistent outlier measurements Facilitate consistent use of clinical guidelines and protocols Reduce errors in diagnosis, treatment, and management |
| Aligns and leverages national standards and initiatives | None. Note the similar, but conceptually separate, FHIR profile for heart rate - Heart rate, HL7 AU Base FHIR Profile [Internet]. |

| | Health Level Seven Australia; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org.au/fhir/4.0.0/StructureDefinition-au-</u> <u>heartrate.html</u> |
|--|--|
| Aligns and leverages international standards and initiatives | Pulse, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 08]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.7153.</u> |

7.6.2.5. For future consideration

The openEHR 'Pulse' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the future development of the 'Pulse' data group, based on the published openEHR 'Pulse' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events and a specific event that explicitly records data relevant to the maximal pulse measurements recorded over a specified time interval as a 'Maximum event'.

Potential candidate data elements for AUCDI Release 2:

- Characteristics of the pulse, including the regularity.
- Context of the measurement, such as the body site (location) of the measurement and method of measurement.
- Clinical interpretation of the findings, e.g. identifying a rhythm.

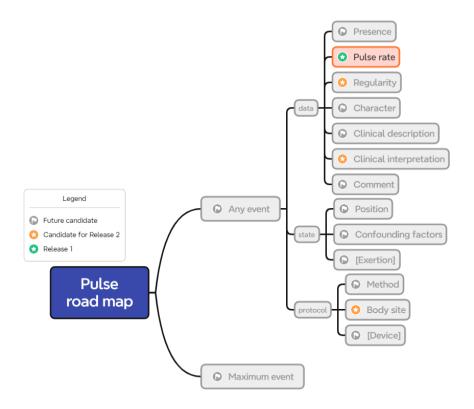


Figure 24. Proposed roadmap for the future development of the 'Pulse' data group.

7.6.3. Body temperature

7.6.3.1. Context

Table 26. Measurements and vital signs (body temperature) context.

| Concept description | Measurement of body temperature as a proxy for the core body temperature of an individual. | |
|---------------------------|---|--|
| Data group purpose | To record details of a single body temperature measurement and its associated parameters. | |
| Data group representation | Record one instance per observation event within a health record. | |
| Data group alias | temperature | |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the measurement context. | |

This data group documents details of observed and measured parameters related to body temperature at a point in time. In AUCDI R1, the only parameter recorded is constrained to the temperature measurement.

7.6.3.2. Concept representation



Figure 25. Measurements and vital signs (body temperature) mind map.

7.6.3.3. Information model

Table 27. Measurements and vital signs (body temperature) information model.

| Data elements | | |
|---------------|----------------|--------------------------------|
| Temperature | Description | The measured body temperature. |
| | Occurrence | Mandatory, single occurrence |
| | Data type | Quantity (temperature) |
| | Examples | • 37.5 Cel |
| | Alias | body temperature |
| | Considerations | Units: [Cel] |

7.6.3.4. Specific alignment to AUCDI design principles

Table 28. Measurements and vital signs (body temperature) alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Event summary Emergency transfer of care summary Research data registry |
|---|---|
| Driven by a clinical quality and safety use case supporting person-centred care | A standardised, comprehensive, and shareable record of pulse measurements will: Enhance consistency and continuity of care across various healthcare settings, especially in emergency transfer of care Serve as a foundation for standardised clinical decision support systems Foster active health consumer engagement through home monitoring Support efforts to improve clinical safety by alerting to extreme measurements or persistent outlier measurements |
| Aligns and leverages national standards and initiatives Aligns and leverages international standards and initiatives | Body temperature, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org.au/fhir/4.0.0/StructureDefinition-au- bodytemp.html</u>. Body temperature, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.2796</u>. |

7.6.3.5. For future consideration

The openEHR 'Body temperature' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Body temperature' data group, based on the published openEHR 'Body temperature' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events.

Potential candidate data elements for AUCDI Release 2:

• None proposed at the time of publication.

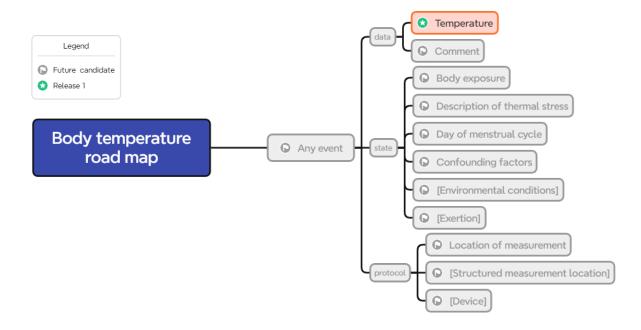


Figure 26. Proposed roadmap for developing the 'Body temperature' data group.

7.6.4. Respiration

7.6.4.1. Context

Table 29. Measurements and vital signs (respiration) context.

| Data group description | The rate and characteristics of spontaneous breathing by an individual. | |
|---------------------------|---|--|
| Data group purpose | To record details from a single observation of respiration. | |
| Data group representation | Record one instance per observation event within a health record. | |
| Data group alias | None | |
| Considerations for use | In future updates, this data group is anticipated to be extended beyond a single data element to incorporate additional observable parameters related to respiration and details regarding the measurement context. | |

This data group documents details of observed and measured parameters related to respiration at a point in time. In R1, the only parameter recorded is constrained to the respiratory rate measurement.

7.6.4.2. Concept representation



Figure 27. Measurements and vital signs (respiration) mind map.

7.6.4.3. Information model

Table 30. Measurements and vital signs (respiration) information model.

| Data elements | | |
|---------------|----------------|--|
| Rate | Description | The measured frequency of spontaneous breathing. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity (frequency) |
| | Example | • 16 /min |
| | Alias | respiration rate |
| | | respiratory rate |
| | Considerations | Units: /min |

7.6.4.4. Specific alignment to AUCDI design principles

| Reduce duplication, Single entry, single development (multiple use and reuse) | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Event summary Emergency transfer of care summary Research data registry |
|--|---|
| Driven by a clinical quality and safety use case supporting person- centered care | A standardised, comprehensive, and shareable record of respiration observations will: Enhance consistency and continuity of care across various healthcare settings, especially in emergency transfer of care Serve as a foundation for standardised clinical decision support systems Support efforts to improve clinical safety by alerting to extreme measurements or persistent outlier measurements |
| Aligns and leverages national standards and initiatives | Respiration rate, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org.au/fhir/4.0.0/StructureDefinition-au-</u> <u>resprate.html</u>. |
| Aligns and leverages international standards and initiatives | Respiration, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.4218</u> |

Table 31. Measurements and vital signs (respiration) alignment to design principles.

7.6.4.5. For future consideration

The openEHR 'Respiration' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the future development of the 'Respiration' data group, based on the published openEHR 'Respiration' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events.

Potential candidate data elements for AUCDI Release 2:

• None proposed at the time of publication.

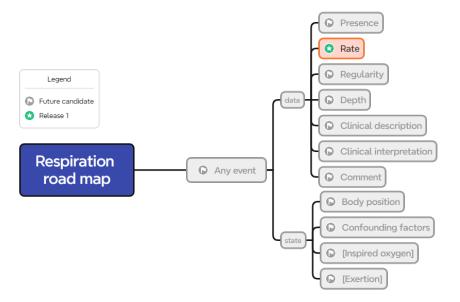


Figure 28. Proposed roadmap for the future development of the 'Respiration' data group.

7.6.5. Body height

7.6.5.1. Context

Table 32. Measurements and vital signs (body height) context.

| Data group description | Measurement of the height, or length, of the body measured from the crown of the head to the sole of the foot |
|---------------------------|--|
| Data group purpose | To record details of a single body height or length measurement and its associated parameters. |
| Data group representation | Record one instance per measurement event within a health record. |
| Data group alias | height,length |
| Considerations for use | The height of an adult or child is measured with the individual in a standing position; the length of an infant is usually measured lying down. |
| | In future updates, this data group is anticipated to be extended beyond a single data element to incorporate additional details regarding the measurement context, such as the state of the individual at the time of measurement and the specific attributes required to identify body length at birth. |

This data group documents details of observed and measured parameters related to the height or length of the body at a point in time. In AUCDI R1, the only parameter recorded is constrained to measurement of the height of a standing child or adult, or the length of a supine infant.

The level of detail for this data group may be extended in future releases.

7.6.5.2. Concept representation



Figure 29. Measurements and vital signs (body height) mind map.

7.6.5.3. Information model

Table 33. Measurements and vital signs (body height) information model.

| Data elements | | |
|--------------------|-------------|---|
| Height / Length | Description | The measured length of the body from the crown of the head to the sole of the foot. |
| | Occurrence | Mandatory, single occurrence |

| Data type | Quantity (length) |
|----------------|-------------------|
| Examples | • 45 cm |
| | • 165 cm |
| Alias | height |
| | • length |
| Considerations | Units: cm |

7.6.5.4. Specific alignment to AUCDI design principles

Table 34. Measurements and vital signs (body height) alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse)Supports the Australian guideline and calculator managing cardiovascular disease risk. Data captured using this data group could poter with appropriate authority and consent, for: • Event summary | - |
|--|-------------------------------------|
| with appropriate authority and consent, for: | tially be re-used, |
| Event summary | |
| | |
| Emergency transfer of care summary | |
| Research data registry | |
| Driven by a clinical quality and safety use caseA standardised, comprehensive, and shareable r length will: | ecord of height or |
| • Enhance consistency and continuity of c healthcare settings, especially during ch | |
| Serve as a foundation for standardised of support systems | linical decision |
| Streamline monitoring, especially relate patterns | d to child growth |
| Facilitate consistent use of clinical guide | lines and protocols |
| Aligns and leverages national standards and initiativesBody height, HL7 AU Base FHIR Profile [I Level Seven Australia; [cited: 2024 Feb C https://hl7.org.au/fhir/4.0.0/StructureD bodyheight.html | 5]. Available from: |
| Body height recommended for collection Australian College of General Practitione preventive activities in general practice. updated. East Melbourne, Vic: RACGP, 2 | ers. Guidelines for 9th edition, |
| Aligns and leverages international standards and initiatives • Height/Length, Published archetype [Int Foundation, openEHR Clinical Knowledg | |

2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.3210.

7.6.5.5. For future consideration

The openEHR 'Height/Length' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Height' data group, based on the published openEHR 'Height/Length' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events and a 'Birth' event to explicitly distinguish the first measured length after birth from any other measurement.

Potential candidate data elements for AUCDI Release 2:

• Birth length – first measurement of an infant's length, recorded at or around the time of birth.

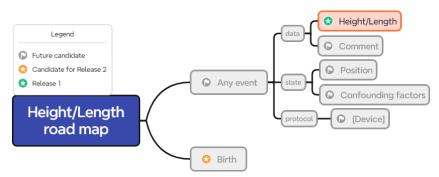


Figure 30. Proposed roadmap for developing the 'Height' data group.

7.6.6. Body weight

7.6.6.1. Context

Table 35. Measurements and vital signs (body weight) context.

| Concept description | Measurement of the weight of the body. | |
|---------------------------|--|--|
| Data group purpose | To record details of a single body weight measurement and its associated parameters. | |
| Data group representation | Record one instance per measurement event within a health record. | |
| Data group alias | • bodyweight | |
| Considerations for use | In future updates, this data group is anticipated to be extended beyond a single data element to incorporate additional details regarding the measurement context, such as the state of the individual at the time of measurement and the specific attributes required to identify body weight at birth. | |

This data group documents details of observed and measured parameters related to body weight at a point in time. In AUCDI R1, the only parameter recorded is constrained to measuring body weight.

The level of detail for this data group may be extended in future releases.

7.6.6.2. Concept representation

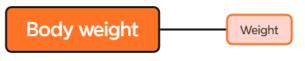


Figure 31. Measurements and vital signs (body weight) mind map.

7.6.6.3. Information model

Table 36. Measurements and vital signs (body weight) information model.

| Data elements | | |
|---------------|----------------|--|
| Weight | Description | The measured weight of the individual. |
| | Occurrence | Mandatory, single occurrence |
| | Data type | Quantity (mass) |
| | Examples | • 3300 g |
| | | • 89.2 kg |
| | Alias | • bodyweight |
| | Considerations | • Units: kg or g |

7.6.6.4. Specific alignment to AUCDI design principles

Table 37. Measurements and vital signs (body weight) alignment to design principles.

| Reduce duplication, Single entry, single development | Supports collection of data for Practice Incentives Program Quality Improvement Measures |
|--|---|
| (multiple use and reuse) | Proportion of patients with a weight classification |
| | Supports the Australian guideline and calculator for assessing and managing cardiovascular disease risk |
| | Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: |
| | Event summary |
| | My Health Record |
| | Referrals |
| | Transfer of care summary |
| | Research data registry |
| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of body weight will: |
| supporting person- centered care | Enhance consistency and continuity of care across various healthcare settings, especially during childhood |
| | Serve as a foundation for standardised clinical decision support systems |
| | Streamline monitoring, especially related to child growth patterns |
| | • Facilitate consistent use of clinical guidelines and protocols |
| | Foster active health consumer engagement, especially with at-home monitoring |
| | • Support patient safety, especially in drug dosing calculations |
| Aligns and leverages national standards and initiatives | Body weight, HL7 AU Base FHIR Profile [Internet]. Health Level Seven Australia; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org.au/fhir/4.0.0/StructureDefinition-au-</u> <u>bodyweight.html</u> |
| | • Body weight recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Body weight, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: |

2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.2960

7.6.6.5. For future consideration

The openEHR 'Body weight' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Body weight' data group, based on the published openEHR 'Body weight' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events and a 'Birth' event to explicitly distinguish the first measured weight after birth from any other measurement.

Potential candidate data elements for AUCDI Release 2:

• Birth weight – first measurement of an infant's weight, recorded at or around the time of birth.

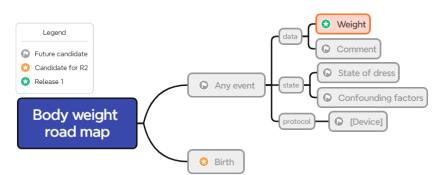


Figure 32. Proposed roadmap for developing the 'Body weight' data group.

7.6.7. Waist circumference

7.6.7.1. Context

Table 38. Measurements and vital signs (waist circumference) context.

| Concept description | Measurement of the distance around the waist | |
|---------------------------|---|--|
| Data group purpose | To record details of a single waist circumference measurement and its associated parameters as an indicator for assessing body fat distribution and associated cardiovascular risk and mortality. | |
| Data group representation | Record one instance per measurement event within a health record. | |
| Data group alias | None | |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the measurement. | |

This data group documents details of observed and measured parameters related to the circumference of the waist at a point in time.

The level of detail for this data group may be extended in future releases.

7.6.7.2. Concept representation



Figure 33. Measurements and vital signs (waist circumference) mind map.

7.6.7.3. Information model

Table 39. Measurements and vital signs (waist circumference) information model.

| Data elements | | |
|---------------|----------------|--|
| Waist | Description | The measured circumference of the waist. |
| circumference | Occurrence | Mandatory, single occurrence |
| | Data type | Quantity (length) |
| | Examples | • 108 cm |
| | Alias | • girth |
| | Considerations | Units: cm |

7.6.7.4. Specific alignment to AUCDI design principles

Table 40. Measurements and vital signs (waist circumference) alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Supports the monitoring and management of cardiovascular disease risk related to abdominal fat. Data captured using this data group could potentially be reused, with appropriate authority and consent, for: Research data registry |
|--|--|
| Driven by a clinical quality and safety use case supporting person-centred care | A standardised, comprehensive, and shareable record of waist circumference will: Enhance consistency and continuity of care across various healthcare settings |
| | Serve as a foundation for standardised clinical decision support systems, especially related to cardiovascular risk assessment |
| | Streamline monitoring and management of obesity-related conditions |

| Aligns and leverages | Foster active health consumer engagement Facilitate consistent use of clinical guidelines and protocols Waist circumference recommended for collection by the |
|--|---|
| national standards and initiatives | Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Waist circumference, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.2814</u> |

7.6.7.5. For future consideration

The openEHR 'Waist circumference' archetype is a mature information model that has been used globally in a broad range of implementations over many years. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for developing the 'Waist circumference' data group, based on the published openEHR 'Waist circumference' archetype. The mind map is divided into sections recording the measured 'data', along with the 'protocol' describing how the measurement was measured and the 'state' of the individual at the time of measurement. It also proposes an 'Any event' supporting ad hoc measurement events.

Potential candidate data elements for AUCDI Release 2:

• None proposed at the time of publication.

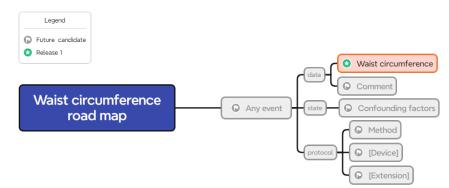


Figure 34. Proposed roadmap for developing the 'Waist circumference' data group.

7.7. Biomarkers

This collection of data groups represents the measurements of common biomarker analytes used to manage or monitor chronic diseases and to drive decision support, initially comprising four data groups:

- Lipids
- Haemoglobin A1c (HbA1c)
- Estimated glomerular filtration rate (eGFR)
- Urine albumin-creatinine ratio (uACR)

These initial data groups are designed to align with common practice, where clinical systems either extract this data from laboratory test results or clinicians enter it manually. Each data group is designed separately, representing only the analyte measurements for each biomarker, serving as a temporary measure until a more formal 'Laboratory test result' data group is established in future AUCDI updates.

As new use cases are identified in scope for AUCDI, the range of the Biomarker collection is expected to expand.

7.7.1. Lipids

7.7.1.1. Context

Table 41. Biomarkers (lipids) context.

| Concept description | Blood tests used to measure blood lipid concentrations. | |
|---------------------------|--|--|
| Data group purpose | To record the measured values for each component within a collection of lipid biomarkers, excluding details about the measurement event or recording context. | |
| Data group representation | Record one instance per measurement event within a health record. | |
| Data group alias | lipid profile | |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the context of the laboratory test. | |

This data group documents analyte results that are components of a lipid profile.

7.7.1.2. Concept representation

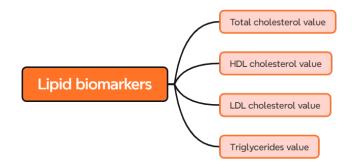


Figure 35. Biomarkers (lipids) mind map.

7.7.1.3. Information model

Table 42. Biomarkers (lipids) information model.

| Data elements | | |
|---------------|----------------|--|
| Total | Description | The measured total cholesterol concentration in the blood. |
| cholesterol | Occurrence | Optional, single occurrence |
| | Data type | Quantity (concentration) |
| | Example | • 5.5 mmol/L |
| | Alias | • TC, Chol |
| | Considerations | Units: mmol/L |
| HDL | Description | The measured HDL concentration in the blood. |
| cholesterol | Occurrence | Optional, single occurrence |
| | Data type | Quantity (concentration) |
| | Example | • 1.3 mmol/L |
| | Alias | HDL, HDLC, HDL-C, High-density lipoprotein cholesterol |
| | Considerations | Units: mmol/L |
| LDL | Description | The calculated LDL concentration in the blood. |
| cholesterol | Occurrence | Optional, single occurrence |
| | Data type | Quantity (concentration) |
| | Example | • 1.8 mmol/L |
| | Alias | LDL, LDLC, LDL-C, Low-density lipoprotein cholesterol |
| | Considerations | Units: mmol/L |
| Triglycerides | Description | The measured triglyceride concentration in the blood. |

| Occurrence | Optional, single occurrence |
|----------------|-----------------------------|
| Data type | Quantity (concentration) |
| Example | • 1.6 mmol/L |
| Alias | • Trigs |
| Considerations | Units: mmol/L |

7.7.1.4. Specific alignment to AUCDI design principles

Table 43. Biomarkers (lipids) alignment to design principles.

| Reduce duplication, Single entry, single development | Supports collection of data for Practice Incentives Program Quality Improvement Measures |
|---|---|
| (multiple use and reuse) | Proportion of patients with the necessary risk factors assessed to enable CVD assessment. |
| | • Data captured using this data group could potentially be re- used, with appropriate authority and consent, for: |
| | Australian cardiovascular disease risk assessment tool and guideline |
| | Preventing duplication of laboratory testing |
| | Referrals |
| | My Health Record |
| | Research data registry |
| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of lipid biomarker values will: |
| supporting person- centered care | Enhance consistency and continuity of care across various healthcare settings |
| | Serve as a foundation for standardised clinical decision support systems |
| | Support monitoring and management of hypercholesterolaemia and cardiovascular disease |
| | Facilitate consistent use of clinical guidelines and protocols |
| | Enable tailored, personalised preventive health plans |
| | Reduce errors in diagnosis, treatment and management |
| Aligns and leverages national standards and initiatives | • Lipids recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| | |

| Aligns and leverages | Laboratory analyte result, Published archetype [Internet]. |
|-------------------------|--|
| international standards | openEHR Foundation, openEHR Clinical Knowledge Manager |
| and initiatives | [cited: 2024 Feb 05]. Available from: |
| | https://ckm.openehr.org/ckm/archetypes/1013.1.2881 |

7.7.1.5. For future consideration

See 7.7.5 for future considerations for biomarkers.

7.7.2. Haemoglobin A1c (HbA1c)

7.7.2.1. Context

Table 44. Biomarkers (Haemoglobin A1c) context.

| Concept description | A blood test measuring a form of haemoglobin is used to monitor average plasma glucose concentrations over prolonged periods of time. | |
|---------------------------|--|--|
| Data group purpose | To record the value for a single HbA1c measurement, excluding details about the measurement event or recording context. | |
| Data group representation | Record one instance per measurement event within a health record. | |
| Data group alias | HBA1c glycated Hb GHB glycosylated haemoglobin glycohaemoglobin | |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the context of the laboratory test. | |

This data group documents a single analyte result for haemoglobin A1c.

7.7.2.2. Concept representation



Figure 36. Biomarkers (Haemoglobin A1c) mind map.

7.7.2.3. Information model

Table 45. Biomarkers (Haemoglobin A1c) information model.

| Data elements | | |
|---------------|-------------|--|
| HbA1c | Description | The measured HbA1c concentration in the blood. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity (concentration) or Proportion |
| | Example | • 40 mmol/mol |
| | | • 5.9% |
| | Alias | • HBA1c |

| | glycated Hb |
|----------------|--------------------------|
| | • GHB |
| | glycosylated haemoglobin |
| | glycohaemoglobin |
| Considerations | Units: mmol/mol or % |

7.7.2.4. Specific alignment to AUCDI design principles

Table 46. Biomarkers (Haemoglobin A1c) alignment to design principles.

| Reduce duplication, Single entry, single development | Supports collection of data for Practice Incentives Program Quality Improvement Measures |
|---|---|
| (multiple use and reuse) | Proportion of patients with diabetes with a current HbA1c result. |
| | • Data captured using this data group could potentially be re- used, with appropriate authority and consent, for: |
| | Australian cardiovascular disease risk assessment tool and guideline |
| | Preventing duplication of laboratory testing |
| | Referrals |
| | My Health Record |
| | Research data registry |
| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of HbA1c biomarker values will: |
| supporting person-centred care | Enhance consistency and continuity of care across various healthcare settings |
| | Serve as a foundation for standardised clinical decision support systems |
| | Streamline monitoring and management of diabetes and pre-diabetes |
| | Facilitate consistent use of clinical guidelines and protocols |
| | Enable tailored, personalised preventive health plans |
| | Reduce errors in diagnosis, treatment and management |
| Aligns and leverages national standards and initiatives | HbA1c recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| | |

| Aligns and leverages | • Laboratory analyte result, Published archetype [Internet]. |
|-------------------------|--|
| international standards | openEHR Foundation, openEHR Clinical Knowledge Manager |
| and initiatives | [cited: 2024 Feb 05]. Available from: |
| | https://ckm.openehr.org/ckm/archetypes/1013.1.2881 |

7.7.2.1. For future consideration

See 7.7.5 for future considerations for biomarkers.

7.7.3. Estimated glomerular filtration rate (eGFR)

7.7.3.1. Context

Table 47. Estimated glomerular filtration rate context.

| Concept description | A calculated measure used to assess the glomerular filtration rate as an indicator of kidney function. |
|---------------------------|--|
| Data group purpose | To record the value for a single eGFR measurement, excluding details about the measurement event or recording context. |
| Data group representation | Record one instance per measurement event within a health record. |
| Data group alias | EGFR estimated glomerular filtration rate estimated GFR |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the context of the laboratory test. |

This data group documents a single analyte result for eGFR.

7.7.3.2. Concept representation



Figure 37. Estimated glomerular filtration rate mind map.

7.7.3.3. Information model

Table 48. Estimated glomerular filtration rate information model.

| Data elements | | |
|---------------|----------------|--|
| eGFR | Description | The calculated eGFR measurement. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity |
| | Example | • 104 mL/min/1.73m2 |
| | Alias | estimated glomerular filtration rate |
| | | estimated GFR |
| | Considerations | Units: mL/min/1.73m2 |
| | | Usually calculated using the CKD-EPI formula |

7.7.3.4. Specific alignment to AUCDI design principles

Table 49. Estimated glomerular filtration rate alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Supports collection of data for Practice Incentives Program Quality Improvement Measures Proportion of patients with the necessary risk factors assessed to enable CVD assessment. Supports the Australian guideline and calculator for assessing and managing cardiovascular disease risk. |
|---|---|
| Driven by a clinical quality and safety use case supporting person- centered care | A standardised, comprehensive and shareable record of eGFR biomarker values will: Enhance consistency and continuity of care across various healthcare settings Serve as a foundation for standardised clinical decision support systems Streamline monitoring and management of renal conditions Facilitate consistent use of clinical guidelines and protocols Enable tailored, personalised preventive health plans Reduce errors in diagnosis, treatment and management |
| Aligns and leverages national standards and initiatives Aligns and leverages international standards and initiatives | eGFR recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 Laboratory analyte result, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.2881 |

7.7.3.1. For future consideration

See 7.7.5 for future considerations for biomarkers.

7.7.4. Urine albumin-creatinine ratio (uACR)

7.7.4.1. Context

Table 50. Urine albumin-creatinine ratio context.

| Concept description | A calculated ratio between albumin and creatinine levels in urine, used to screen for microalbuminuria as an early indicator of kidney disease or to monitor the progress of known kidney disease. | |
|---------------------------|--|--|
| Data group purpose | To record the value for a single uACR ratio, excluding details about the measurement event or recording context. | |
| Data group representation | Record one instance per measurement event within a health record. | |
| Data group alias | uACR | |
| Considerations for use | In future updates, it is anticipated this data will be extended beyond a single data element to incorporate additional details regarding the context of the laboratory test. | |

7.7.4.2. Concept representation



Figure 38. Urine albumin-creatinine ratio mind map.

7.7.4.3. Information model

| Table 51. Urine d | albumin-creatinine | ratio information model. |
|-------------------|--------------------|--------------------------|
|-------------------|--------------------|--------------------------|

| Data elements | | |
|---------------|----------------|--------------------------------|
| uACR | Description | The calculated uACR ratio. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity |
| | Example | • 25mg/mmol |
| | Alias | Urine albumin-creatinine ratio |
| | Considerations | Units: mg/mmol |

7.7.4.4. Specific alignment to AUCDI design principle

Table 52. Urine albumin-creatinine ratio alignment to design principles.

| Reduce duplication, Single entry, single development | Supports collection of data for Practice Incentives Program Quality Improvement Measures |
|--|---|
| (multiple use and reuse) | Proportion of patients with the necessary risk factors assessed to enable CVD assessment |
| | Supports the Australian guideline and calculator for assessing and managing cardiovascular disease risk |
| Driven by a clinical quality and safety use case | A standardised, comprehensive and shareable record of uACR biomarker values will: |
| supporting person- centered care | Enhance consistency and continuity of care across various healthcare settings |
| | Serve as a foundation for standardised clinical decision support systems |
| | Streamline monitoring and management of renal conditions |
| | Facilitate consistent use of clinical guidelines and protocols |
| | Enable tailored, personalised preventive health plans |
| | Reduce errors in diagnosis, treatment and management |
| Aligns and leverages national standards and initiatives | • uACR recommended for collection by the Royal Australian College of General Practitioners. Guidelines for preventive activities in general practice. 9th edition, updated. East Melbourne, Vic: RACGP, 2018 |
| Aligns and leverages international standards and initiatives | Laboratory analyte result, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.2881</u> |

7.7.4.5. For future consideration

See 7.7.5 for future considerations for biomarkers.

7.7.5. All biomarkers - for future consideration

The FHIR 'Diagnostic Report' resource and the openEHR 'Laboratory test result' are information models that have been used globally in a broad range of implementations.

See:

• DiagnosticReport, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: <u>https://hl7.org/fhir/R4/diagnosticreport.html</u>. The scope of

this generic information report model is broad and intended to represent Laboratory and Pathology reports, Imaging reports and other diagnostic reports.

 Laboratory test result, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [[cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.2191</u>. The scope of this test result information model is constrained to represent the full range of laboratory test results, including biochemistry, haematology, anatomical pathology, cytology, and microbiology. Imaging and other test results are intended to be represented using other information models, specific for each purpose.

However, despite the apparent differences in scope, they are sufficiently aligned to form the basis for this initial AUCDI R1 data group and provide guidance for potential future augmentation.

The mind map below demonstrates a proposed roadmap for the future development of the 'Laboratory test result' data group, based on the published openEHR 'Laboratory test result' archetype as the framework. It also contains several nested archetypes representing 'Laboratory analyte result' and 'Specimen' that are reused across a range of other laboratory test-related archetypes and will provide more detail than is required for a current use case.

Potential candidate data elements for AUCDI Release 2:

• None proposed at the time of publication.

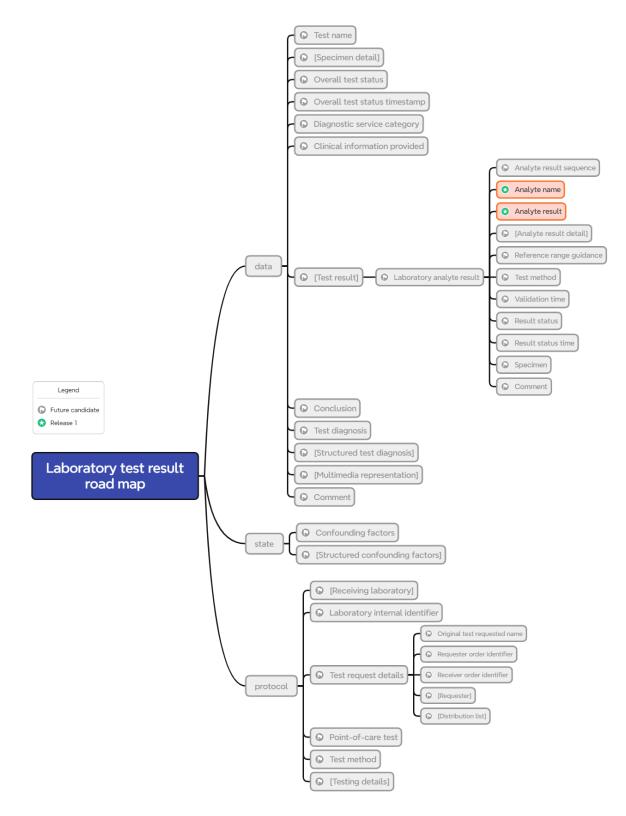


Figure 39. Proposed roadmap for the future development of the 'Laboratory test result' data group.

7.8. Medication use statement

A range of complementary data groups will be required to capture the full range of information needed for safe and effective medication management, including but not limited to:

- An order for a medication,
- A curated list of medications within a clinical system,
- Capturing activities in the management of a single medication, such as administration or dispensing,
- A summary or overview of usage of a single medication to capture usage patterns and cumulative dosing,
- Questionnaires about medication use (e.g. have you ever used 'medication A'?),
- Medicines reconciliation, compliance, and adherence, and
- This data group a point-in-time snapshot of current medication use.

7.8.1. Context

Table 53. Medication use statement context.

| Concept description | An assertion about the current use of a single medication by an individual. | |
|---------------------------|---|--|
| Data group purpose | To record an assertion about the current use of a single medication. | |
| Data group representation | Record one instance per medication, including complex medication regimes that require a sequence of varying therapeutic directions. | |
| Data group alias | medication statement | |
| | medication snapshot | |
| Considerations for use | In this context, 'medication' describes a wide range of items that may be prescribed or obtained 'over the counter'. This includes: | |
| | • A single pharmaceutical item or agent, | |
| | An extemporaneous preparation, A combination therapy product, A nutritional product, or Another therapeutic item used to treat or prevent disease, such as a bandage or dressing containing an antimicrobial agent. In Release 1, the inclusion of extemporaneous or compounded preparations is restricted to simple formulations where the 'Medication name', 'Strength', and 'Form' can be precisely recorded with the current data group. More complex preparations, particularly those that require separate specification of each ingredient's name, strength, and quantity, fall outside the scope. | |
| | | |
| | | |
| | | |
| | | |

| | The source of information may be an individual, their carer or a clinician. | |
|--------|--|--|
| | This data group is designed to align with data groups representing medication orders or administrations. However, it has been constrained to represent only essential information necessary for exchange or summary purposes, plus the addition of other data elements to support clinical safety and communication, especially as part of a transition of care – in Release 1, this is limited to 'Last administered' and 'Endpoint'. | |
| | The data group should be considered up to date only at the time of authoring. | |
| | In future updates, it is anticipated this data group will be extended to incorporate additional detail. | |
| Misuse | Not to be used to record summary or persistent information about past use of a medication. | |
| | Not to be used to record a medication order. | |
| | Not to be used to record information about a specific medication administration or dispensing activity. | |
| | Not to be used to record vaccination administration – use the 'Vaccination administration' data group for this purpose. | |
| | Not to be used to record information about medical devices that are used or implanted. | |

This data group documents an assertion about current medication use by an individual, which can be made by the individual themselves, their carer, or a clinician. Despite the goal of AUCDI R1 to recommend minimal data groups, 'Medication use summary' is necessarily more detailed than most other data groups, mainly to ensure the minimum data elements to support clinical safety, especially within an exchange or transfer of care context.

In the mind map below (Figure 40), the dosage of a medication is represented by the 'Dose amount and timing' concept. It is depicted as a repeatable group, comprising both dose amount and the timing of administration. For AUCDI R1, this 'Dose amount and timing' structure has been constrained to support medication administrations that require one or more dose/timing combinations, such as the administration of 100mg of an identified medication in the morning and 50mg in the evening.

This data model is designed to be extended in future AUCDI releases to support complex dosage regimens, including variable doses and timings. For example, incorporating direction sequences and durations will enable accurate representation of structured tapering dose orders, such as 'Take three tablets per day for seven days, then two tablets per day for seven days, then one tablet per day for seven days'.

Use cases include, but are not limited to:

• A 'Current medication list' or similar document containing one or more 'Medication use statement' data groups,

- Exchange a snapshot of current medications, highlighting the expected endpoint of a medication regimen during a transition of care,
- Document a list of current medications on admission to hospital, including the last dose of a medication in a fasting, pre-operative patient,
- The medication component of a specialist referral, and
- The basis for a medication review.

7.8.2. Concept representation

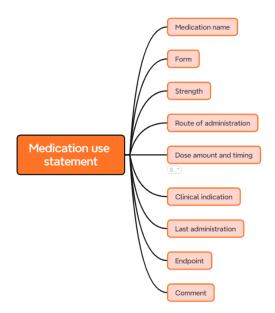


Figure 40. Medication use statement mind map.

In Figure 40, 'Dose amount and timing' is represented as 0..*, indicating that more than one dosage can be recorded, if necessary.

7.8.3. Information model

Table 54. Medication use statement information model.

| Data elements | | |
|---------------|---|---|
| Medication | Description | Name of the medication. |
| name | Occurrence | Mandatory, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Australian Medication value set</u> published by the NCTS includes all Australian Medicines Terminology (AMT) product concepts that may be used for the identification of a medicine, vaccine or other therapeutic good. |
| | Examples | Australian Medicines Terminology:4126011000036109 Plaquenil |

| | | 3322011000036101 Coumadin 1400851000168100 brutinih 420 mg tablat |
|----------|---|---|
| | | • 1490851000168109 Ibrutinib 420 mg tablet |
| | | 81001011000036103 Rectinol ointment, 50 g, tube |
| | | 169071000036106 dressing hydrofibre with silver 10 cm x 10 cm dressing |
| | Alias | Drug name, Medicine name |
| | Considerations | It is strongly recommended that 'Medication name' be coded with a terminology capable of triggering decision support, where possible. Free text entry should only be used if there is no appropriate terminology available or for customised extemporaneous preparations. |
| Form | Description | The physical presentation or formulation of the medication. |
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Medication Form value set</u> published by the NCTS includes values that represent the physical dose form of a medication from SNOMED CT-AU. |
| | Examples | SNOMED CT-AU: |
| | | • 63011000036109 Tablet |
| | | • 111011000036103 Cream |
| | | • 201011000036102 Inhalation powder |
| | Alias | None |
| | Considerations | Record only if not specified within a coded 'Medication name' value. |
| Strength | Description | The amount of the active ingredient in the medication. |
| | Occurrence | Optional, single occurrence |
| | Data type | Ratio or Quantity |
| | Examples | • 2mg/5ml |
| | | • 100mg/tablet |
| | Alias | Concentration |
| | Considerations | Record only if not specified within a coded 'Medication name' value. |

| Route of administration | Description | The route by which the medication is administered into the body. |
|-------------------------|---|---|
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Route of Administration value set</u> published by NCTS includes concepts from SNOMED CT-AU that describe the route by which a medication may be administered. |
| | Examples | SNOMED CT-AU: |
| | | 47625008 Intravenous route |
| | | • 26643006 Oral route |
| | | • 6064005 Topical |
| | Alias | Route |
| | Considerations | None |
| Dose amount | Description | The amount of medication administered at one time. |
| | Occurrence | Optional, single occurrence |
| | Data type | Quantity |
| | Examples | 1 mg1.5 ml |
| | | • 0.125 g |
| | | • 1-2 |
| | Alias | Dosage |
| | Considerations | The combination of dose amount and dose frequency are both required to represent a single dose of a medication. While more than one dose amount/dose frequency combinations may be needed to represent a medication order accurately, each combination can only comprise one instance of a 'Dose amount' with one instance of a 'Dose frequency'. |
| Dose timing | Description | The intended timing or frequency of medication administration. |
| | Occurrence | Optional, single occurrence |
| | Data type | Timing |
| | Examples | three times a day |
| | | • PRN |
| | | before bedtime |

| | Alias | • Timing |
|------------------------|---|---|
| | Considerations | The combination of dose amount and dose frequency is required to represent a single dose of a medication. While more than one dose amount/dose frequency combinations may be needed to represent a medication order accurately, each combination can only comprise one instance of a 'Dose amount' with one instance of a 'Dose frequency'. |
| Clinical indication | Description | The clinical symptom, sign or diagnosis that necessitates medication use. |
| | Occurrence | Optional, multiple occurrences |
| | Data type | Codeable text |
| | Recommended code system/value set | The <u>Reason For Encounter value set</u> published by the NCTS is a broad reference set including (most) procedures, clinical findings, situation with explicit context, and event concepts. |
| | Examples | • 3723001 Arthritis |
| | | 128053003 Deep venous thrombosis |
| | | • 40993007 Burn of ankle |
| | | 105629000 Chlamydial infection |
| | | 444400000 Exposure to Streptococcus |
| | Alias | Reason for medication, |
| | | Reason for prescription |
| | | Reason for prescribing |
| | Considerations | This data element has multiple occurrences to allow the recording of more than one clinical indication per medication. |
| Last administration | Description | The date and time when the medication was last taken by, or administered to, the individual. |
| | Occurrence | Optional, single occurrence |
| | Data type | DateTime |
| | Example | • 14 January 2024 at 1430 |
| | Alias | last administered |
| | | last dose |
| | Considerations | Partial dates are permitted. |

| Endpoint | Description | The intended absolute end date for the use of the medication or a textual indication that the medication will be used indefinitely. |
|----------|-------------------|---|
| | Occurrence | Optional, single occurrence |
| | Data type | Choice of DateTime or Code |
| | Recommended | SNOMED CT-AU: |
| | code system/value | • 89557005 Indefinite time |
| | Examples | • March 15, 2024 |
| | | • 0830, March 15, 2024 |
| | | • 'Indefinite' |
| | Alias | Long term indicator |
| | Considerations | • The DateTime datatype can indicate a precise, absolute date and optional time for the intended end of a limited course of medication - for example, the endpoint of a course of antibiotics the sender has just initiated. |
| | | The coded text option can also be used to record that the medication is intended for indefinite use, for example, potentially lifelong use of an antihypertensive medication. |
| | | • Inclusion of relative endpoints within Release 1 is not supported, but this feature could be added in future releases. Recording 'after seven days' or 'on completion of 14 doses' will require additional data elements to pinpoint the start of treatment or monitor the progression through a prescribed course. |
| Comment | Description | Additional narrative about the medication item not captured in other fields. |
| | Occurrence | Optional, single occurrence |
| | Data type | string |
| | Examples | • "Gets confused if prescribed a generic brand." |
| | Alias | • Note |
| | Considerations | Should not be used for free text duplication or alternative to other data elements |

7.8.4. Specific alignment to AUCDI design principles

Table 55. Medication use statement alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) Data captured using this data group could potentially be re-used, with appropriate authority and consent, for: Referrals Transfer of care summaries, for example, admission and discharge summaries Medication review As the medication list component of an Adverse drug reaction report to the Therapeutic Goods Administration (TGA) Research data registry Driven by a clinical quality and safety use case supporting person-centred care Enhance consistency and continuity of care across various healthcare settings Improve the precision of clinical decision-making processes Serve as a foundation for standardised clinical decision support systems Streamline monitoring and management of conditions Foster active health consumer engagement Support efforts to improve clinical safety Facilitate consistent use of clinical guidelines and protocols Reduce ethe variability in healthcare delivery Reduce ether variability in healthcare delivery Reduce etheroris in diagnosis, treatment, and management Aligns and leverages national standards and initiatives MedicationStatement, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/medicationstatement.html. Medication statement, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openeh.org/ckm/archetypes/1013.1.4949. Medication details, Published archetype [Internet]. | | |
|--|---------------------------|--|
| Reterrats Transfer of care summaries, for example, admission and discharge summaries Medication review As the medication list component of an Adverse drug reaction report to the Therapeutic Goods Administration (TGA) Research data registry Driven by a clinical quality and safety use case supporting person-centred care Improve the precision of clinical decision-making processes Serve as a foundation for standardised clinical decision support systems Streamline monitoring and management of conditions Foster active health consumer engagement Support efforts to improve clinical safety Facilitate consistent use of clinical guidelines and protocols Reduce the variability in healthcare delivery Reduce errors in diagnosis, treatment, and management Aligns and leverages MedicationStatement, HL7 FHIR Resource [Internet]. Health Level Seven International SINOMED CT-AU and AntT value sets Medication statement, Draft archetype [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hT.org/fhir/R5/medicationstatement.html. Medication statement, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetype/[Internet]. | entry, single development | |
| discharge summaries.Medication reviewAs the medication list component of an Adverse drug reaction report to the Therapeutic Goods Administration (TGA) Research data registryDriven by a clinical quality and safety use case supporting person-centred careA standardised, comprehensive, and shareable record of current medications will: | (multiple use and reuse) | Referrals |
| As the medication list component of an Adverse drug reaction report to the Therapeutic Goods Administration (TGA) Research data registryDriven by a clinical quality and safety use case supporting person-centred careA standardised, comprehensive, and shareable record of current medications will: • Enhance consistency and continuity of care across various healthcare settings • Improve the precision of clinical decision-making processes • Serve as a foundation for standardised clinical decision support systems • Streamline monitoring and management of conditions • Foster active health consumer engagement • Support efforts to improve clinical safety • Facilitate consistent use of clinical guidelines and protocols • Reduce the variability in healthcare delivery • Reduce the variability in healthcare delivery • Reduce errors in diagnosis, treatment, and managementAligns and leverages national standards and initiatives• MedicationStatement, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hI7.org/fhir/R5/medicationstatement.html. • Medication statement, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.4949. • Medication details, Published archetype [Internet]. | | |
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| Driven by a clinical quality and safety use case supporting person-centred careA standardised, comprehensive, and shareable record of current medications will: Enhance consistency and continuity of care across various healthcare settingsImprove the precision of clinical decision-making processesServe as a foundation for standardised clinical decision support systemsStreamline monitoring and management of conditionsFoster active health consumer engagementSupport efforts to improve clinical safetyFacilitate consistent use of clinical guidelines and protocolsReduce the variability in healthcare deliveryReduce errors in diagnosis, treatment, and managementAligns and leverages international standards and initiativesMedicationStatement, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hI7.org/fhir/R5/medicationstatement.html.Medication statement, Oraf archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openeh.org/ckm/archetypes/1013.1.4949.Medication details, Published archetype [Internet]. | | |
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| Reduce the variability in healthcare delivery Reduce errors in diagnosis, treatment, and management Aligns and leverages national standards and initiatives MedicationStatement, HL7 FHIR Resource [Internet]. Health | | Support efforts to improve clinical safety |
| Reduce errors in diagnosis, treatment, and management Aligns and leverages national standards and initiatives Aligns and leverages international standards and initiatives MedicationStatement, HL7 FHIR Resource [Internet]. Health Level Seven International; [cited: 2024 Feb 05]. Available from: https://hl7.org/fhir/R5/medicationstatement.html. Medication statement, Draft archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.4949. Medication details, Published archetype [Internet]. | | • Facilitate consistent use of clinical guidelines and protocols |
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| | | Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: |
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| [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.5947. Therapeutic direction, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.2753. |
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| 2024 Feb 05]. Available from: https://ckm.openehr.org/ckm/archetypes/1013.1.2245. |

7.8.5. For future consideration

The FHIR 'Medication Statement' resource is an information model that has been used globally in a broad range of implementations and the openEHR 'Medication Statement' archetype is a draft archetype that has been informed by the FHIR Medication Statement resource and known use cases. They form the basis for this initial AUCDI R1 data group and provide guidance for potential future augmentation.

Potential candidate data elements for AUCDI Release 2:

- 'Instructions' further clarification is required to determine what instructions are pertinent for an exchange use case. For example:
 - o Describe and represent a partially completed tapering dose regime,
 - Instructions to receiving clinicians, such as 'Needs repeat renal function test in one month', and
 - Administration-focused instructions to the individual, such as 'Take with food' or 'Avoid grapefruit'.
- Timings further clarification regarding useful timings to complement 'Last administered' and 'Endpoint' in an exchange or transfer of care use case.

The mind map below demonstrates a proposed roadmap for developing the 'Medication Statement' data group, based on the published openEHR 'Medication Statement' archetype. It also contains nested archetypes for 'Medication details', 'Therapeutic direction', 'Dosage', 'Timing - daily', and 'Timing - non-daily' that are reused across other medication-related archetypes and, as such, will provide more detail than is required for a current medication snapshot use case.

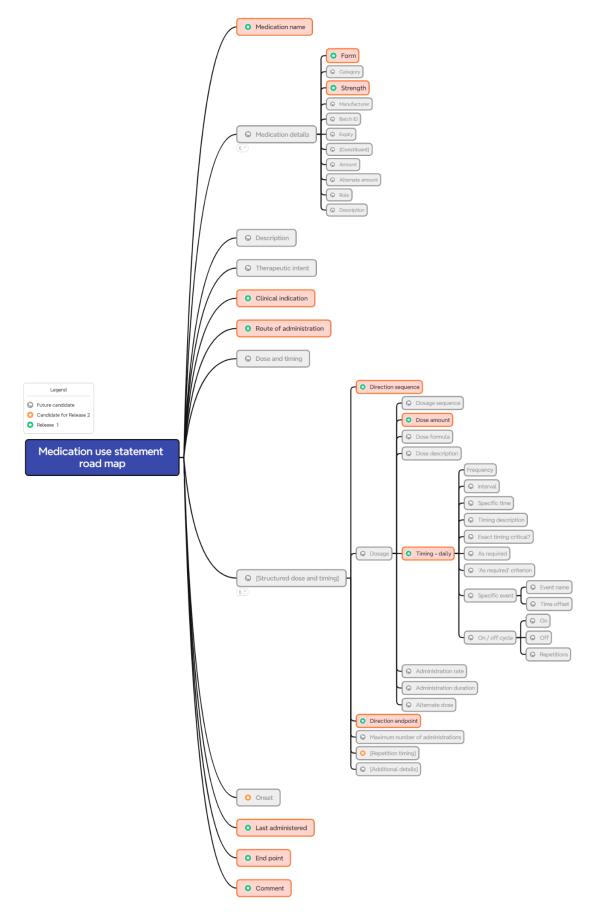


Figure 41. Proposed roadmap for developing the 'Medication Statement' data group.

7.9. Encounter – clinical context

7.9.1. Context

Table 56. Encounter (clinical context) context.

| Concept description | Information about the clinical context for a single, discrete clinical consultation or contact with a healthcare provider. |
|---------------------------|--|
| Data group purpose | To record relevant clinical context as part of the documentation of any clinical encounter event. |
| Data group representation | Record one instance per encounter event within the health record. |
| Data group alias | consultation |
| Considerations for use | In R1, the scope of an encounter is intentionally limited to a single, discrete encounter event between an individual and a clinician, excluding an ongoing inpatient episode of care. |

This data group documents only two data elements - 'Reason for encounter' and 'Modality.'

Within clinical systems, additional information will be captured about each clinical encounter:

- System information, including the encounter date, participants, type of encounter, location, etc. These technical attributes are outside the scope of this data group.
- Clinical information, including but not limited to history, examination findings, measurements, test results and a plan of care. These clinical details will be captured in other data groups.

It is anticipated that this data group will be extended to include more detail in future AUCDI releases as specific use cases are defined and common data elements are identified (for example: care plans, transfer of care documents, etc.)

7.9.2. Concept representation

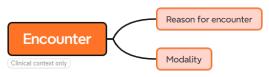


Figure 42. Encounter (clinical context) mind map.

7.9.3. Information model

Table 57. Encounter (clinical context) information model.

| Data elements | | |
|-------------------------|-------------|---|
| Reason for encounter | Description | The reason for initiating a healthcare encounter or contact by an individual, as recorded by the clinician during or after the encounter. |

| | Occurrence | Optional, multiple occurrences |
|----------|---|---|
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Reason For Encounter value set</u> published by the NCTS is a broad reference set including (most) procedures, clinical findings, situation with explicit context, and event concepts. |
| | Examples | 267036007 Dyspnoea 30549001 Removal of suture 171351004 Driving license medical examination 183517000 Referral to paediatrician 18876004 Pain in finger 418399005 Motor vehicle accident |
| | Alias | Reason for contact Presenting Problem Reason for Visit Chief Complaint |
| | Considerations | Use to record one or more reasons an individual initiated a healthcare encounter, recorded by the clinician during or after the encounter. The reason may be for clinical, social, or administrative purposes. 'Reason for Encounter' is a common phrase used in clinical practice; however, the term is often used in one of two ways - one that refers to an administrative category for the provision of healthcare and the other that reflects clinical or social problems that motivate individuals to seek healthcare. Not to be used as a de facto diagnosis by the clinician or a conclusion at the end of an encounter. Not to be used as the 'reason for booking' of any healthcare encounter by the individual before the commencement of the encounter. |
| Modality | Description | The method used to conduct the encounter. |
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |

| Recommended code system/value set | Recommendations for the code system and value set are under development. |
|---|--|
| Examples | Face-to-face Telephone Consultation Video consultation SMS Email |
| Alias | MethodApproachEncounter type |
| Considerations | None |

7.9.4. Specific alignment to AUCDI design principles

Table 58. Encounter (clinical context) alignment to design principles.

| Driven by a clinical quality and safety use case supporting person- centered care | Standardised documentation of the context of a clinical encounter will: Provide valuable insight into the nature of encounters, unresolved issues and emerging modalities and methods of care Reduce the variability in healthcare delivery |
|--|---|
| Aligns and leverages national standards and | Recommended terminology leverages national SNOMED CT-AU value sets |
| initiatives | |
| Aligns and leverages | Reason for encounter, Published archetype [Internet]. |
| international standards | openEHR Foundation, openEHR Clinical Knowledge Manager |
| and initiatives | [cited: 2024 Feb 05]. Available from: |
| | https://ckm.openehr.org/ckm/archetypes/1013.1.290. |

7.9.5. For future consideration

The focus for AUCDI R1 has been to include only 'Reason for encounter' and 'Modality' data elements, however, requirements to support location category (e.g. hospital, residential aged care home, community clinic, home) and encounter classes (e.g. ambulatory (outpatient), inpatient, emergency department) may need to be considered in the future.

Potential candidate data elements for AUCDI Release 2:

- Location category.
- Encounter class.

7.10. Sex and gender

Context

Table 59. Sex and gender context.

| Concept description | A collection of clinically significant concepts related to the sex and gender of an individual. | | |
|---------------------------|--|--|--|
| Data group purpose | To record information related to sex and gender to ensure safe and appropriate clinical care and support respectful communication. | | |
| Data group representation | Record one instance per data group within a health record; changes or updates over time are captured as a revision rather than a new entry. | | |
| Data group alias | sexgender | | |
| Considerations for use | This data group may be expanded in future updates to include more concepts as related data elements. In future updates, this data group may be extended to incorporate additional related concepts. | | |

This data group records information regarding an individual's sex assigned at birth and their selfidentified gender preferences.

The current approach to recording sex and gender information varies significantly across clinical systems, with some not yet capturing self-identified gender preferences. Historically, data has often been collected within a generic 'Sex' or 'Administrative sex' field without clear definitions and guidance for collection. This has resulted in the accumulation of ambiguous data. It is not possible to tell if the data reflects biological sex, gender identity, legal sex, or other representations and is not suitable for use in either administrative or clinical contexts.

Use cases for this data group include, but are not limited to:

- As a foundation for personalised medical treatment, supporting both biological- and genderspecific health needs, and improving assessment of disease risk and outcomes,
- Facilitate healthcare accessibility, delivery and communication that acknowledges and incorporates the differences in health needs, experiences, and outcomes across different genders, and
- Facilitate research and public health monitoring.

7.10.1. Concept representation

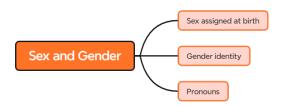


Figure 43. Sex and gender mind map.

7.10.2. Information model

Table 60. Sex and gender information model.

| Data elements | | |
|--------------------------|---|---|
| Sex assigned at birth | Description | The sex of an individual, as determined by inspection of external genitalia or diagnostic testing at birth or early infancy. |
| | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Biological Sex value set</u> published by NCTS includes SNOMED CT-AU concepts that represent the biological sex of an individual. |
| | Examples | SNOMED CT-AU: |
| | | • 248152002 Female |
| | | • 32570681000036106 Indeterminate |
| | | • 32570691000036108 Intersex |
| | Alias | Birth sex, natal sex |
| | Considerations | Sex assigned at birth is assumed to be stable unless an error is determined by genetic testing at a later date. |
| | | Other designations related to sex, such as types of 'Legal sex', can change throughout the individual's lifetime and can differ from 'Sex assigned at birth'. |
| Gender | Description | The individual's internal perception of their gender. |
| identity | Occurrence | Optional, single occurrence |
| | Data type | CodeableConcept |
| | Recommended code system/value set | The <u>Gender Identity Response value set</u> published by NCTS includes SNOMED CT-AU concepts that may be used to represent a response for an individual's gender. |
| | Examples | SNOMED CT-AU: |
| | | 446151000124109 Identifies as male gender |
| | | 33791000087105 Identifies as nonbinary gender |
| | Alias | • gender |
| | | gender identification |
| | Considerations | It is strongly recommended that 'Gender identity' be coded, where possible. Free text entry should |

| | | be permitted if no appropriate terminology is available. | |
|-----------|---|---|--|
| Pronoun/s | Description | Pronouns specified by the individual. | |
| | Occurrence | Optional, multiple occurrences | |
| | Data type | CodeableConcept | |
| | Recommended code system/value set | The <u>Personal Pronouns value set</u> published by HL7 included codes from LOINC (LOINC Parts) that be used when communicating with or about an individual. This is a still under discussion see: <u>https://confluence.hl7.org/pages/viewpage.action?pageId</u> =212730453 | |
| | Examples | she/her/hers/herself; | |
| | | • they/them/their/theirs/themselves; or | |
| | | • xe/xem/xyr, ze/hir/hirs, and ey/em/eir | |
| | Alias | Neopronouns | |
| | Considerations | To be used when speaking directly to the individual or referring to the individual in written documentation. | |
| | | This data element has multiple occurrences to allow the recording of more than one group of pronouns to be used. | |
| | | • Free text entry is permitted if the suggested terms are not appropriate. | |

7.10.3. Specific alignment to AUCDI design principles

Table 61. Sex and gender alignment to design principles.

| Reduce duplication, Single entry, single development (multiple use and reuse) | Supports the Australian guideline and calculator for assessing and managing cardiovascular disease risk Data captured using this data group could potentially be reused, with appropriate authority and consent, for: Health risk assessment, especially where genetic/biological sex can impact presentations, management, and outcomes |
|---|--|
| | Referrals Transfer of care summaries, for example, admission and discharge summaries Research data registry Reporting, especially population health |

| Driven by a clinical quality and safety use case | A standardised, comprehensive, and shareable record of sex- and gender-related data elements will: | | |
|--|--|--|--|
| supporting person- centered care | Promote the cultural and psychological safety of individuals by ensuring that they can be identified and addressed appropriately. | | |
| | Enhance consistency and continuity of care across various healthcare settings | | |
| | Improve the precision of clinical decision-making processes | | |
| | Serve as a foundation for standardised clinical decision support systems | | |
| | Support efforts to improve clinical safety | | |
| | • Reduce errors in diagnosis, treatment, and management | | |
| Aligns and leverages national standards and | Recommended terminology leverages national SNOMED CT- AU value sets | | |
| initiatives | Australian Bureau of Statistics. (2020). Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables. ABS. <u>https://www.abs.gov.au/statistics/standards/standard-sex-gender-variations-sex-characteristics-and-sexual-orientation-variables/latest-release</u>. | | |
| | Collecting and recording information about patient sex, gender, variations of sex characteristics and sexual orientation - RACGP Standards for general practices (5th edition) fact sheet | | |
| | Guidance note: Inclusive collection and reporting of sex and gender data, Department of Health, Victoria October 2023, www.health.vic.gov.au/populations/understanding-lgbtiq- health | | |
| Aligns and leverages international standards and initiatives | Gender, Published archetype [Internet]. openEHR Foundation, openEHR Clinical Knowledge Manager [cited: 2024 Feb 05]. Available from: <u>https://ckm.openehr.org/ckm/archetypes/1013.1.3715</u> | | |
| | McClure RC, Macumber CL, Kronk C, Grasso C, Horn RJ, Queen R, Posnack S, Davison K. Gender harmony: improved standards to support affirmative care of gender-marginalized people through inclusive gender and sex representation. J Am Med Inform Assoc. 2022 Jan 12;29(2):354-363. doi: 10.1093/jamia/ocab196. Erratum in: J Am Med Inform Assoc. 2021 Nov 25;: PMID: 34613410; PMCID: PMC8757317. HL7 Cross Paradigm Implementation Guide: Gender | | |
| | Harmony - Sex and Gender Representation, Edition 1 | | |

[Internet]. HL7 International; [cited: 2024 Feb 05]. Available from: <u>https://build.fhir.org/ig/HL7/fhir-gender-</u> <u>harmony/branches/main/index.html</u>.

7.10.4. For future consideration

The openEHR 'Gender' archetype is a peer-reviewed and published information model that aligns well with most recommendations from the HL7 Gender Harmony Project. It forms the basis for this initial AUCDI R1 data group and provides guidance for potential future augmentation.

The HL7 FHIR community has recommended that the new Gender Harmony project concept of 'Sex Parameter for Clinical Use (SPCU)' be included in Australian specifications. This potential addition requires a broader national evaluation of its clinical utility and clinical safety implications.

The mind map below demonstrates a proposed roadmap for developing the 'Sex and Gender' data group based on the published openEHR 'Gender' archetype.

Potential candidate data elements for AUCDI Release 2:

• Last updated – the timestamp indicates whether the information is current or outdated, serving as a critical marker of its timeliness.

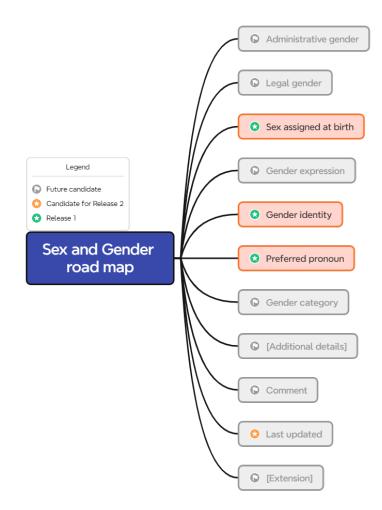


Figure 44. Proposed roadmap for developing the 'Sex and Gender' data group based.

| 8. | Appendix | A – Definition | of Terms |
|----|----------|----------------|----------|
|----|----------|----------------|----------|

| Term / Acronym | Definition | |
|-------------------------|--|--|
| AIR | Australian Immunisation Register (AIR) is a national register that records | |
| | vaccines given to all people in Australia. There are legislative requirements | |
| | n what information is required to be recorded ³ | |
| Archetype | openEHR clinical information model for a certain clinical concept | |
| AU Core | FHIR Implementation guide supporting the technical | |
| AUCDI | Australian Core Data for Interoperability | |
| AUCDI R1 | Australian Core Data for Interoperability Release 1 | |
| CodeableConcept | A text description and/or a list of codings (i.e. a list of references to codes defined by code systems) | |
| Coding | A simple direct reference to a code defined by a code system | |
| Data groups | Standalone clinical content specifications containing information models and terminology | |
| FHIR | Fast Health Interoperability Resources ⁴ – Standard supporting health | |
| | information sharing and exchange. Owned by HL7 | |
| HL7 | Heath Level 7 ⁵ – a standards development organisation responsible for a | |
| | range of health information exchange standards, including FHIR | |
| IG | FHIR Implementation Guide – it is the mechanism that describes how FHIR is used to meet a specific Use Case or cases. | |
| IPS | International Patient Summary – a minimal and non-exhaustive set of basic clinical data of a patient, specialty-agnostic, condition-independent, but readily usable by all clinicians for the unscheduled (cross-border) patient care. | |
| LOINC | LOINC ⁶ is a terminology for identifying health measurements, observations, and documents. | |
| openEHR | Standards development organisation responsible for governance of standardised clinical information models ⁷ | |
| PIP QI | Practice Incentives Program Quality Improvement Measures ⁸ . This includes a PIP QI Incentive which is a payment to general practices that participate in quality improvement activities to improve patient outcomes and deliver best practice care. | |
| SNOMED CT- AU/SCT-AU | Systematised Nomenclature of Medicine ⁹ – Clinical Terms (Australian Extension). Australia's national terminology ¹⁰ for clinical terms. | |
| Sparked AU Core TDG | Sparked AU Core Technical Design Group – responsible for the development of the FHIR AU Core implementation guide for Sparked | |
| Sparked CDG | Sparked Clinical Design Group – responsible for the clinical definition of data | |
| | requirements to inform the technical | |

³ https://www.legislation.gov.au/Details/F2021C00679

⁴ https://fhir.org/

⁵ https://www.hl7.org/

⁶ https://loinc.org/

⁷ https://openehr.org/

⁸ https://www.health.gov.au/sites/default/files/2022-12/practice-incentives-program-quality-improvement-measures 0.pdf

⁹ https://www.snomed.org/

¹⁰ https://www.healthterminologies.gov.au/

| string | A sequence of Unicode characters (e.g. free text) |
|-----------|---|
| Value set | An agreed, defined list of coded terms to support standardised data capture |
| | and use (often using a standardised terminology system, e.g., SNOMED CT) |

9. Appendix B – Data groups at a glance

9.1. Adverse reaction risk summary

This data group documents:

- An assessment of the risk or propensity of a future adverse reaction if exposed, or reexposed, to an identified substance.
- A summary of each exposure event, including details about the reaction experienced, as evidence supporting the risk assessment.

9.2. Problem/Diagnosis summary

This data group documents summary information about a single problem or diagnosis.

9.3. Procedure completed

This data group documents details about a procedure that has been performed or carried out.

9.4. Vaccination administered

This data group documents details about a vaccine that has been administered.

9.5. Tobacco smoking summary

This data group documents summary information of tobacco smoking behaviour.

9.6. Measurements and vital signs

This collection of data groups collection of data groups representing common anthropometric measurements and critical physiological parameters used to assess health status, initially comprising:

- Blood pressure
- Pulse
- Body temperature
- Respiration
- Height/Length
- Body weight
- Waist circumference

9.7. Biomarkers

This collection of data groups represents the measurements of common biomarker analytes used to manage or monitor chronic diseases and to drive decision support, initially comprising:

- Lipids
- Haemoglobin A1c (HbA1c)

- Estimated glomerular filtration rate (eGFR)
- Urine albumin-creatinine ratio (uACR)

9.8. Medication use statement

This data group documents an assertion about the current use of a single medication.

9.9. Encounter – clinical context

This data group documents relevant clinical context as part of the documentation of any clinical encounter event.

9.10. Sex and gender

This data group documents information related to sex and gender to ensure safe and appropriate clinical care and support respectful communication.

10. Appendix C – Sparked collaborative processes

10.1. Sparked Clinical and Technical Design Groups

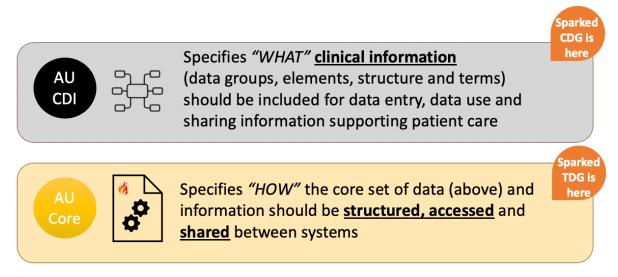


Figure 45. Purpose of the Sparked Clinical Design Group and the Sparked Technical Design Group.

10.1.1. Sparked Clinical Design Group

The Sparked Clinical Design Group (CDG) brings together key stakeholders with expertise and experience in clinical practice and those who have health industry and practice knowledge to work in partnership to develop and validate the data artefacts for the Sparked FHIR Accelerator Core AU programme, including the AUCDI.

The Sparked CDG has an open membership.

The purpose of Sparked CDG was to:

- Assist in the prioritisation and development of the Data Sets for Interoperability
- Meet quarterly in person
- Meet monthly to understand clinical requirements for the AUCDI/AUeReqDI and review draft AUCDI/AUeReqDI and to address the consultation objectives and consider the content of the AUCDI/AUeReqDI, implementation considerations and risks
- Interact with the Sparked AU Core TDG and Sparked eRequesting TDG as required to ensure as much alignment as possible between the groups

At time of publication, the Sparked CDG had:

- 243 members, and
- Held one in-person and five virtual meetings.

For more information about the Sparked CDG, see the Sparked program reports published on <u>Confluence</u>.

10.1.2. Sparked Technical Design Groups

The Sparked Technical Design Group (TDG) is to precisely articulate the requirements and specifications necessary to promote seamless interoperability among clinical and non-clinical systems within the Australian context. This includes setting clear standards and profiling the necessary FHIR resources to ensure systems can effectively record, update, search, and retrieve core digital health clinical and administrative information.

There are currently two Sparked Technical Design Groups, one for AU Core and one for AU eRequesting.

At time of publication, the Sparked AU Core TDG had:

- 235 members, and
- Held one in-person and 11 virtual meetings.

At time of publication, the Sparked AU eRequesting TDG had:

- 202 members, and
- Held one webinar and five virtual meetings.

For more information about the Sparked AU Core TDG and AU eRequesting TDG, see the Sparked program reports published on <u>Confluence</u>.

10.2. Open feedback process

To support the development of the AUCDI R1, an open feedback process was utilised to ensure suitable engagement with stakeholders and wider digital health community. Continuous feedback was welcome throughout the process, through the community confluence page and through the Sparked CDG workshops and meetings.

In addition to the designated AUCDI R1 review process, there is an ongoing engagement and feedback process between the Sparked AU Core TDG and Sparked CDG. This is outlined at a high-level in Figure 46.

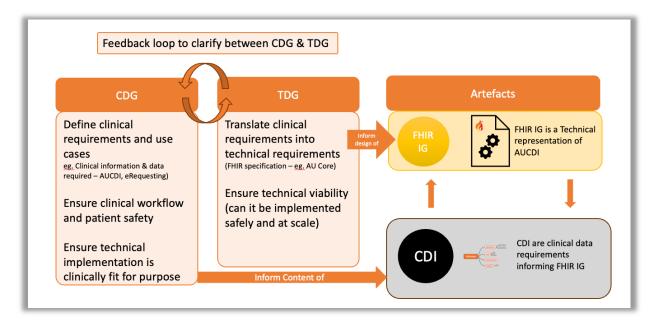


Figure 46. Sparked Clinical Design Group and Sparked Technical Design Group high-level process and feedback loop.



Figure 47. High-level AUCDI R1 development, review, and publication process.

If there was no consensus regarding a concept or data element, or the specification was not mature, it was pushed toward a future release, pending further discussion and agreement.

The AUCDI is intended to gradually build a collection of re-usable clinical information models and associated SNOMED CT-AU value sets that will provide a foundation for a standardised health data ecosystem.

10.3. Core Design Principles

To assist the development of AUCDI and to allow prioritisation by the Sparked team, Sparked CDG, and its collaborators, eight design principles were developed at the first Sparked CDG workshop in September 2023¹¹. The details of the design principles are outlined below in Table 62.

| Design Principles | Rationale | Approach |
|---|---|--|
| Reduce duplication - Single entry, single development (multiple use and reuse) | Well-structured clinical data defined at the point of collection should be able to be reused for multiple use cases (e.g. clinical decision support, reporting and analytics). This reduces burden of effort on care providers to record similar versions of the same information in multiple different locations. It can also help reduce the need for an individual to share their information multiple times in different settings. | Supporting preventative care/chronic disease management to drive clinical decision support, considering secondary use data sets e.g. AIHW primary care data model, PIP QI |
| Driven by a clinical quality and safety use | Person-centred care is widely recognised as a foundation to safe, high-quality health care. It is care that respects and responds to the | Engaging with clinicians from the beginning |

Table 62. Core design principles

¹¹ See Confluence for details

| case supporting person-centred care | preferences, needs and values of healthcare consumers. | across the health ecosystem |
|--|---|--|
| | | Looking at agreed national clinical standards and guidelines |
| No data for data's sake | Before collecting data, it should be important to understand what use case it serves so as not to burden the care provider with collecting data that is of little to no value | Starting with "core of the core" and growing iteratively |
| Driven by clinical data use first | Clinical data collection should be driven by primary use first – clinical use; however secondary use should still be considered. If data collection for primary use is designed | Considering secondary use data sets e.g. AIHW primary care data model, PIP QI, etc. |
| | correctly, it should be able to be reused and aggregated for most secondary use cases | Looking towards data that can be reused for secondary uses |
| Supports best practice care including supporting clinical decision support, | Provision of care must be in accordance with minimum evidence-based standards, guidelines and protocols. | Engaging with clinicians across the health ecosystem from the beginning Looking at |
| clinical guidelines and clinician workflow | Standardised health data should support best practice care, clinical guidelines and care provider workflow. | agreed national clinical standards and guidelines |
| Systems can support now or with minimal effort, supporting a | A priority was placed on data elements that would give highest return of effort; currently well supported by most systems, of industry | Alignment with US Core FHIR IG, US CDI Validation with |
| strategic roadmap with an agile iterative process | importance and requiring minimal standards development. The standard would then gracefully evolve as implementations mature. | HealthCare Industry |
| Aligns and leverages agreed national standards and initiatives | To seamlessly exchange or access health information and ensure consistent understanding, it is essential to use nationally agreed digital health standards, specifications and terminology | Using agreed national clinical and technical standards – FHIR, SNOMED CT, LOINC, clinical standards e.g. RACGP Clinical guidelines |
| Aligns with international standards and initiatives | Aligning international standards and building on similar international initiatives ensures consistent understanding, and allows reuse of technology development from international vendors | Looking at international standards and as initiatives as a base for the work done in AUCDI |
| Inclusive engagement to involve all healthcare domains and modalities | There is an increasing use of additional care modalities, particularly since the COVID-19 pandemic (e.g. telehealth, video consultations). It is also important to support all healthcare domains, particularly those domains that have not traditionally been the | Engaging with clinicians, jurisdictions and industry from across the health ecosystem |

| focus of national digital/electronic transition programs (e.g. allied health, aged care) | |
|--|--|
| | |

11. Appendix D – National and International initiatives

Many programs, both nationally and internationally, concentrate on health interoperability. Instead of beginning anew, Sparked has utilised these existing programs as a foundation to initiate and guide the development of the AUCDI.

11.1. Australia

There are several initiatives in Australia that have both informed the Sparked program and will leverage Sparked deliverables.

11.1.1. The Digital Health Blueprint and Action Plan 2023–2033 – Australian

Government Department of Health and Aged Care¹²

The Digital Health Blueprint outlines the Australian Government's ten-year vision for Australia's digital health to continue providing a more connected and sustainable health system. The Action Plan highlights the initiatives the Australian Government are investing in to meet the outcomes outlined in the Blueprint.

Developed through consultations and research with consumers, clinical healthcare providers, and non-clinical healthcare staff, the blueprint has four key target outcomes:

- Australians have choice in how they manage their health and wellbeing and can navigate the health system knowing their story follows them.
- Australia's health workforce is digitally empowered to provide connected care with confidence, whenever or wherever it is needed.
- Data and information are shared and reused securely to deliver a sustainable learning health system.
- Modern digital foundations underpin and strengthen a collaborative, standards-based health system that is safe and secure.

11.1.2. Connecting Australian Healthcare – National Healthcare Interoperability

Plan 2023-2028 – Australian Digital Health Agency¹³

The Australian Digital Health Agency's National Healthcare Interoperability Plan 2023-2028 defines a shared vision for long-term interoperability in the Australian healthcare environment. It explores current barriers and enablers to interoperability between organisations. It recommends priority actions across government, the health technology sector and private healthcare organisations to increase interoperability and improve workflows, accessibility, and outcomes within the healthcare sector.

¹² See the https://www.health.gov.au/resources/publications/the-digital-health-blueprint-and-action-plan-2023-2033?language=enDepartment of Health and Aged Care for more detail

¹³ See the Australia Digital Health Agency for more detail

11.1.3. My Health Record – Australian Digital Health Agency¹⁴

The Australian Digital Health Agency operates the My Health Record (MHR) system, providing Australians with a secure digital health record supporting their clinical care. Healthcare providers can access the system to view and add information.

The MHR provides:

- Healthcare providers access to information about consumers, including vaccinations; allergies; medical conditions; medications; advance care documents; and test or scan results.
- Consumers with control over what information is in their My Health Record including the ability to permanently delete it at any time.

The MHR stores a wide range of health information, including:

- Shared health summary (from your doctor)
- Current medicines and prescriptions (scripts)
- Referral letters
- Allergies (including past adverse reactions)
- Immunisation history (including routine childhood immunisations)
- Test and scan reports such as ultrasound scans or X-rays
- Pathology reports such as blood test results
- Hospital discharge information
- Medicare and Pharmaceutical Benefits Scheme (PBS) claims history
- Organ donation status
- Advance care planning document or contact details of advance care custodian
- Emergency contact details
- Personal health notes

The MHR specifications published by ADHA were used to build the foundation of the Primary Care Data Quality Foundations data dictionary (see 11.1.5), which formed the basis of the AUCDI.

11.1.4. National primary care data development, Australia Institute of Health and Welfare¹⁵

The Primary Health Care Data Development at the Australian Institute of Health Welfare (AIHW) is developing processes for initiating enduring national primary care data collections, including the data governance framework, guiding standards, and demonstrating data quality and value in population health reporting.

Work is currently in progress, and AIHW is developing a draft data model to explain the structure of a proposed data set for primary care data collection. Early consultation has occurred to ensure

¹⁴ See the Australia Digital Health Agency for more detail

¹⁵ See the Australian Institute of Health and Welfare for more detail

alignment between the AUCDI and draft data model for future reusability of data collected through the AUCDI and the AIHW draft data model.

11.1.5. Primary Care Data Quality Foundations - Australia

CSIRO was commissioned in 2018 by the Australian Government Department of Health to undertake a series of projects known as the Primary Care Data Quality Foundations (PCDQF) Program. This work was delivered through collaboration with the clinical profession, the software industry, the Australian Digital Health Agency (ADHA), and the Australian Institute of Health and Welfare (AIHW). The objectives were to define the foundation data standards in primary care and drive the adoption of these data standards in primary care to support better clinical outcomes, enhance the usefulness of the information in the practice record and improve interoperability of health information shared with other health care providers and organisations. More information on the PCDQF Program is available via <u>Confluence</u>.

The Primary Care Data Dictionary that came out of this work has formed the initial foundation of the AUCDI. Release 1 of the Data Dictionary focused on the agreement of the core common data elements to enable quality use of information within the record at the practice and enable the safe and meaningful exchange of information to other care providers. This was enhanced and extended in the second release to support a range of health assessment clinical scenarios. Decisions about the level of detail included had been pragmatic and intended to align or extend existing vendor data models where possible and to support clinical priorities for adding structured data that will impact patient care. The content of SNOMED CT-AU informed the clinical information models and provided the value sets.

11.2. International

There are several similar government initiatives to develop agreed healthcare standards to underpin interoperability. Given our common healthcare industry, the efforts of the Office of the National Coordinator in the US, NHS UK, and Canada Health Infoway are of particular interest. In addition to the national programs, global collaboration around the development of the International Patient Summary (IPS) and openEHR International's clinical modelling efforts were important in the development AUCDI.

11.2.1. USCDI HL7 FHIR accelerators - USA

The Office of the National Coordinator for Health Information Technology (ONC) in the US has established the United States Core Data for Interoperability¹⁶ (USCDI) as part of the 21st Century Cures Act (Cures Act), which set broad healthcare mandates. The Cures Act is particularly known for its Anti-Information Blocking Rule, which facilitates and requires the sharing of healthcare data.

The USCDI is a standardised set of health data classes and constituent data elements for nationwide, interoperable health information exchange. USCDI v1 is adopted as a standard in the ONC Cures Act Final Rule. The USCDI sets a foundation for electronic health information sharing.

The USCDI has been periodically updated to reflect the evolving needs of the healthcare system and technological advancements. These updates ensure that the standard remains relevant and comprehensive. USCDI v4 has been recently published, and the ONC continues to solicit feedback and suggestions for future versions of USCDI.

¹⁶ See the Office of the National Coordinator for Health Information Technology for more detail

11.2.2. HL7 FHIR accelerators - USA

FHIR accelerators have been established to assist communities and collaborative groups across the health care spectrum in creating and adopting FHIR Implementation Guides or other standard artifacts to enable health data interoperability.

In the US, the Argonaut Project¹⁷ provides FHIR guidance for the ONC's USCDI through the US Core. It was established as an implementation community that was established in 2014 by the private sector, to advance industry adoption of modern, open interoperability standards. The Argonaut Project rapidly developed a first-generation FHIR-based API and Core Data Services specification to enable expanded information sharing for electronic health records and other health information technology based on Internet standards and architectural patterns and styles. The project published the FHIR DSTU2 Data Query Implementation Guide in 2016, and promoted support for SMART on FHIR, which laid the foundation for deploying FHIR-based API in the healthcare industry.

The Argonaut Project has continued to advance artifacts foundational to healthcare exchange including CDS Hooks, Bulk Data, Subscriptions, Clinical Notes, and US Core which provides formal FHIR guidance for ONC's USCDI.

Since the launch of the Argonaut Project, there have been other FHIR accelerators established to focus on different use cases including:

- The HL7 da Vinci project¹⁸ focusing on accelerating interoperability standards to support value-based care,
- The CARIN alliance¹⁹ working with government stakeholders to overcome barriers in consumer-directed exchange,
- The Gravity Project²⁰ a national public collaborative that develops consensus-based data standards to improve information on social determinants of health are shared and used, and
- The Helios HL7 Accelerator for Public Health²¹ ensure public health needs are at the forefront as the US Core FHIR profiles evolve and rollout nationwide by focusing on extending and adopting existing HL7 specifications.

11.2.3. Core Information Standard – NHS England

In the UK, the Professional Records Standards Body²² (PRSB) develops and helps implement standards for the structure and content of health and social care records. The PRSB was commission by NHS UK to develop the Core Information Standard in consultation with the people who use services, health, and care professionals.

The Core Information Standard²³ is a standard for sharing information in health and care record. It is a consensus and evidence-based standard that defines a set of information that can potentially be shared between systems in different sites and settings, among professionals and people using services.

¹⁷ https://confluence.hl7.org/display/AP

¹⁸ https://build.fhir.org/ig/HL7/davinci-ehrx/

¹⁹ https://www.carinalliance.com/

²⁰ https://thegravityproject.net/

²¹ https://confluence.hl7.org/display/PH

²² https://theprsb.org/

²³ https://theprsb.org/core-information-standard-v2-0/

The PRSB Is working closely with the NHS Digital interoperability team to align V2.0 to the UK core R4 FHIR profiles. This is in progress and with work completed on many areas such as person demographics, allergies and adverse reactions, medications, and medical devices.

The Core Information Standard is set to be reviewed and updated to version 3.0. PRSB is currently welcoming suggestions for this upcoming version, indicating an ongoing process of refinement and enhancement based on stakeholder input.

11.2.4. The pan-Canadian Health Data Content Framework - Canada

In Canada, the Canadian Institute for Health Information (CIHI) and Canada Health Infoway are partnering to modernise health information flows and create a connected health system. This involves both defining the underlying data content and data structure to be exchange and building the technical exchange standards through the pan-Canadian Health Data Content Framework.

The pan-Canadian framework is a cohesive product with many deliverables including data models, data sets, a data content standard and value sets. Version 1.0 is due to be delivered after community engagement, consultation, and feedback in September 2024 with a scope to support the International Patient Summary, Patient Summary-CA and eReferral-eConsult.

11.2.5. International Patient Summary

The International Patient Summary²⁴ (IPS) is a standard for sharing essential health information and supported by global programs for digital health, such as the Global Digital Health Partnership (GDHP). The IPS was also endorsed by the G7 and G20 as key focus for interoperability.

The International Patient Summary is a minimal and non-exhaustive set of basic clinical data of a patient, specialty-agnostic, condition-independent, but readily usable by all clinicians for the (un)scheduled patient care away from the patient's home health system.

Created originally by a CEN/TC 251 Project Team in 2015, in close collaboration with HL7 and IHE, the International Patient Summary is getting a lot of attention across the globe and several countries are starting to implement the IPS within and across jurisdictions. The IPS is gaining traction within Europe, in support of the cross-border patient summary exchange in MyHealth@EU, based on the European Guideline as published by the eHealth Network.

11.2.6. openEHR International

openEHR International's Clinical Program and global community has developed a library of information models, known as archetypes. Each archetype is a computable specification inclusive of all relevant data elements for a single clinical concept. Over 600 archetypes, comprising approximately 6000 data elements that define and describe common clinical concepts, can be found in the online openEHR Clinical Knowledge Manager (CKM) tool²⁵. The CKM functions as a library of archetypes and other openEHR artefacts, as a collaboration portal, and to provide knowledge and technical governance across the artefacts during simultaneous collaborative design, content publication, and technical versioning processes.

²⁴ https://international-patient-summary.net/

²⁵ https://ckm.openehr.org/ckm/

The archetypes are intentionally designed as a coherent ecosystem of standardised health- and carerelated information models, including ontology-based classes and clinical design patterns to support consistent health data design with minimal data overlaps or gaps.

The openEHR archetypes have been referenced in the AUCDI.