



# Sparked

Version 1.0 – 25 June 2024

**Sparked AU FHIR Accelerator**

Australian E-Health Research Centre Office

Level 7

297 Herston Road

Herston QLD

Australia.

**Document Control**

This document is maintained in electronic form and is uncontrolled in printed form. It is the responsibility of the user to verify that this copy is of the latest revision.

## 1. Document Information

### 1.1. Document Information

Name	Australian Core Data for Interoperability Release 1: Feedback from Community Comment
Release Date	25 June 2024
Version	V1.0
Release Status	Final
Author	Sparked AU FHIR Accelerator

### 1.2. Distribution

Name	Title	Date	Version
Sparked Community	N/A	25 June 2024	V1.0

## Community Acknowledgement

*We thank all community members, in particular, the Sparked Clinical and Technical Design Groups, the Clinical Leads and our founding members who contributed their time, expertise, passion, resources and energy to deliver the first release of the Australian Core Data for Interoperability.*

*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

<b>1. Document Information .....</b>	<b>3</b>
1.1. Document Information .....	3
1.2. Distribution .....	3
<b>2. Introduction .....</b>	<b>8</b>
2.1. Purpose of document .....	8
2.2. Intended audience of the document .....	8
2.3. How to read this document .....	8
<b>3. Overall Feedback Themes and Actions .....</b>	<b>9</b>
<b>4. AUCDI R1 Section: Adverse Reaction Risk.....</b>	<b>11</b>
4.1. Overall Recommendations.....	11
4.2. Substance Name.....	11
4.3. Manifestation/s.....	13
4.4. Adverse Reaction Risk Comment .....	16
4.5. Adverse Reaction Risk General Feedback .....	18
<b>5. AUCDI R1 Section: Problem/Diagnosis Summary .....</b>	<b>31</b>
5.1. Overall Recommendation .....	31
5.2. Problem/Diagnosis Name .....	31
5.3. Body Site/Laterality .....	34
5.4. Status .....	36
5.5. Problem/Diagnosis Summary Comment .....	37
5.6. Problem/Diagnosis Summary General Feedback .....	38
<b>6. AUCDI R1 Section: Procedure Completed .....</b>	<b>43</b>
6.1. Overall Recommendation .....	43
6.2. Procedure Name.....	43
6.3. Body Site/Laterality .....	47
6.4. Clinical Indication .....	49
6.5. Date Performed .....	51
6.6. Procedure Completed Comment.....	52
6.7. Procedure Completed General Feedback .....	52
<b>7. AUCDI R1 Section: Vaccine Name .....</b>	<b>58</b>
7.1. Overall Recommendation .....	58
7.2. Vaccine name .....	58
7.3. Sequence.....	60
7.4. Date of Administration .....	61

7.5.	Vaccine Administered Event Comment.....	62
7.6.	Vaccine Administered Event General Feedback .....	63
<b>8.</b>	<b><i>AUCDI R1 Section: Tobacco Smoking Summary .....</i></b>	<b>66</b>
8.1.	Overall Recommendation .....	66
8.2.	Overall Status .....	66
8.3.	Tobacco Smoking Summary General Feedback.....	67
<b>9.</b>	<b><i>AUCDI R1 Section: Measurements and Vital Signs.....</i></b>	<b>72</b>
9.1.	Overall Recommendation .....	72
9.2.	Blood Pressure: Systolic Pressure.....	72
9.3.	Blood Pressure: Diastolic Pressure .....	74
9.4.	Blood Pressure: General Feedback .....	75
9.5.	Pulse Information: Rate .....	77
9.6.	Pulse Information: General Feedback .....	78
9.7.	Body Temperature: Temperature .....	79
9.8.	Body Temperature: General Feedback .....	80
9.9.	Respiration Information: Rate.....	81
9.10.	Respiration Information: General Feedback .....	82
9.11.	Body Height: Height/Length .....	82
9.12.	Body Height: General Feedback .....	83
9.13.	Body Weight: Body Weight .....	84
9.14.	Body Weight: General Feedback .....	85
9.15.	Waist Circumference: Waist Circumference.....	86
9.16.	Waist Circumference: General Feedback .....	86
9.17.	Measurements and Vital Signs: General Feedback .....	86
<b>10.</b>	<b><i>AUCDI R1 Section: Biomarkers .....</i></b>	<b>90</b>
10.1.	Overall Recommendation .....	90
10.2.	Lipids: HDL Cholesterol .....	90
10.3.	Lipids: LDL Cholesterol.....	91
10.4.	Lipids: Total Cholesterol.....	91
10.5.	Lipids: Triglycerides .....	91
10.6.	Lipids: General Feedback .....	92
10.7.	Haemoglobin A1c: hbA1c.....	93
10.8.	Haemoglobin A1c: General Feedback.....	94
10.9.	Estimated Glomerular Filtration Rate: eGFR.....	94
10.10.	Estimated Glomerular Filtration Rate: General Feedback .....	95
10.11.	Urine Albumin Creatinine: uACR .....	96

10.12.	Urine Albumin Creatinine: General Feedback.....	97
10.13.	Biomarkers: General Feedback .....	97
<b>11.</b>	<b><i>AUCDI R1 Section: Medication Use Statement.....</i></b>	<b>107</b>
11.1.	Overall Recommendation .....	107
11.2.	Medication Name.....	107
11.3.	Form.....	108
11.4.	Strength .....	108
11.5.	Route of Administration .....	109
11.6.	Dose Amount and Timing .....	109
11.7.	Clinical Indication .....	110
11.8.	Last Administration .....	111
11.9.	Endpoint.....	112
11.10.	Medication Use Statement: General Feedback.....	113
<b>12.</b>	<b><i>AUCDI R1 Section: Encounter – Clinical Context .....</i></b>	<b>119</b>
12.1.	Overall Recommendation .....	119
12.2.	Reason for Encounter .....	119
12.3.	Modality.....	121
12.4.	Encounter – Clinical Context: General Feedback.....	123
<b>13.</b>	<b><i>AUCDI R1 Section: Sex and Gender .....</i></b>	<b>126</b>
13.1.	Overall Recommendation .....	126
13.2.	Sex assigned at birth.....	126
13.3.	Gender Identity .....	129
13.4.	Pronouns.....	131
13.5.	Sex and Gender: General Feedback.....	132
<b>14.</b>	<b><i>General Feedback .....</i></b>	<b>136</b>
14.1.	General Feedback.....	136

## 2. Introduction

### 2.1. Purpose of document

The purpose of this document is to outline the feedback received during the Australian Core Data for Interoperability Release 1 Community Comment period and provide reflections, commentary and summary of actions.

### 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 this document

This document is broken into two key sections:

- **Section 3:** high-level summary of the feedback received, and action taken
- **Sections 4 – 14:** detailed feedback as received throughout the community comment period, with responses.

In addition to specific feedback, reviewers were also asked to provide an overall recommendation for each data group. The votes for each of the options were tallied for each data and included in this document. The options provided to reviewers were:

- **Accept** – if you have no suggestion for further improvement and consider the data group ready for publication without further review or if the suggested changes are trivial (e.g., spelling)
- **Minor revision** – if you consider that there are only small changes required to make the data group ready for publication
- **Major revision** – if you consider the data group needs large or significant modifications such as addition/removal of data elements
- **Reject** – if you consider the data group is not suitable for publication – for example that it is “unfit for purpose” or fundamentally flawed
- **Abstain** – if you feel you need to deliberately refrain from participating in the recommendation process. We encourage you to contribute from your unique point of view as the collaborative review process is intended to be inclusive of all points of view and not requiring specific skill sets or professional background.



### 3. Overall Feedback Themes and Actions

The following are the high-level feedback themes and actions taken as part of the AUCDI Release 1 community comment review.

Section	Feedback theme	Action
Overall document	Questions around rationale for optional vs mandatory	Updated document for clarity
	Request for additional national references and international FHIR references	Updated document with additional references
	Questions around datatypes	Added an explanatory table into document
	Need for data elements capturing date/time to be explicitly included	Addition of new data elements to capture last updated (summaries) and date of observation, date of measurement (measurements, vital signs and biomarkers) and date of assertion (medication use summary)
Adverse reaction risk	More information around adverse reaction risk e.g. severity, clinical verification status etc. to be included	Added identified data elements to backlog
	Need for other data groups e.g. Adverse events, Drug-drug interactions	Added identified data groups to backlog
Problem/diagnosis summary	Need for additional data elements	Added identified data elements to backlog
Procedure completed	Need for additional data elements	Added identified data elements to backlog
Vaccine administered event	Need for additional data elements	Added identified data elements to backlog
Tobacco smoking summary	Need for additional data elements	Added identified data elements to backlog
	Need for additional data groups e.g. Vaping	Added identified data groups to backlog
Measurements and vital signs (general comments)	Need for dates of observation/measurement	Added to the relevant data groups
	Questions around specific structure	Document updated for clarity
	Questions around specific units (UCUM)	Document updated for clarity
Blood pressure	Need for additional data elements	Added identified data elements to backlog
Pulse information	Need for additional data groups e.g. Rhythm	Added identified data groups to backlog
Body temperature	Need for additional data elements	Added identified data elements to backlog
Respiration information	No other additional themes	None
Body height/length	Questions around allowed decimal places	Document updated for clarity

Body weight	Need for additional data elements	Added identified data elements to backlog
Waist circumference	No other additional themes	None
Biomarkers general feedback	Need for dates of measurement	Added to the relevant data groups
	Need for additional data groups	Added identified data groups to backlog
Lipids	Need for additional data elements	Added identified data elements to backlog
HbA1c	Questions around units	Document updated for clarity
eGFR	No other additional themes	None
uACR	No other additional themes	None
Medication use statement	Issues with Last administration and Endpoint	Removed from AUCDI R1 and placed on backlog for further discussion
	Issues relating to Medication use statement vs medication order vs administration record	Document updated for clarity, added identified data groups to backlog
	Need for additional data elements	Added identified data elements to backlog
Encounter - clinical context	No other additional themes	None
Sex and gender	Questions around sex assigned at birth and sex parameter for clinical use	Document updated with details of discussions and other details added for clarity
	Need for additional data groups	Added identified data groups to backlog
	Need for additional data elements	Added identified data elements to backlog

## 4. AUCDI R1 Section: Adverse Reaction Risk

### 4.1. Overall Recommendations

Accept	Minor	Major	Reject	Abstain	No vote
23	11	5	0	9	4

### 4.2. Substance Name

Responder	Community Comment Feedback	Sparked Reflection / Action taken
AUCDI005	I believe that this would be more than just the name and specify the substance or drug involved in the adverse event. For example; include the name of the medication, its dosage, and any relevant formulations (e.g., tablet, injection)?	Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG.
AUCDI007	Ensure ability to provide multiple substance to capture a drug interaction.	Comment noted, added to backlog. True drug-drug interaction records are out of scope for this data group and are currently not well recorded in most systems. Further investigation needs to be done. "Drug interaction" has been placed on the backlog for consideration for future use cases.
AUCDI009	Should there be consistent use of "specific substance" vs "specific ingredient". Also consider "AMT provides concepts at various granularities from branded products to specific ingredient" Alias: consider adding "drug", "allergen", "medicine"?	Wording updated to reflect comment. Updated to ensure specific substance has been used consistently. Updated alias list as suggested.
AUCDI014	To allow for groups of medications so that users don't have to put in all the individual substance names. Ie. cephalosporins//opioids	Wording updated to reflect comment. Updated to add an example of class.
AUCDI036	Noted free text entry is available to include novel therapies which may not be included in the Australian Medicines Terminology.	Comment noted. There are occasions when free text entry is necessary, and this is included in the model.
AUCDI045	Pg. 32 "Substance Name" data element should be "Substance" as it is an identifier of the Substance (not its name)	Comment noted.

		The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the substance from other substance-related data elements.
AUCDI048	Noting the need to avoid duplication, in the instance where a person is administered a medication e.g. in a hospital setting, there is some duplication in proposed future elements e.g. route of exposure – this will be recorded when the medication is administered – and will likely be called ‘route of administration’. The medication record will include details such as time of administration, route, quantity etc. Should we therefore be using those terms here? Or have capacity to import that information from the data set relating to the medication administration, thereby eliminating duplication and reducing opportunity for erroneous data entry?	Comment noted, added to backlog. The scope of this data group extends beyond medications; therefore, 'route of exposure' has been used to include 'route of administration'. Smart implementations will be able to auto populate these fields where appropriate. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG.
AUCDI035	As per AMT code if a medicine; need structured codes for other substances	Comment noted. Structured codes for other substances are permitted and examples are in the document.

### 4.3. Manifestation/s

Responder	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI004	Can 'severity of reaction' and 'clinical management description' be included in Candidates for Release 2?	Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog.
AUCDI005	If manifestation is the adverse event itself then this should cover the symptoms, severity, and any relevant context (e.g., timing, duration)?	Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog.
AUCDI009	Alias: consider "sign", "symptom"? Under Considerations section: From my understanding of how drug allergy checking rules are implemented in systems, they don't typically use manifestation data.	Wording updated to reflect comment. Agree, alias list updated. Comment noted. Drug allergy checking rules may be implemented using the substance however manifestation may trigger for other clinical decision support purposes.
AUCDI013	Severity of manifestation is an important indicator of risk to clinicians. In the OpenEhr reference this is termed 'Criticality'. In much software, this is used to sort, colour code to alert busy clinicians to high risk.	Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog.
AUCDI017	I don't think this is done very well. I think a lot of expected adverse reactions and unrelated symptoms are often referred to as allergy (especially with antimicrobials) when they are not.	Comment noted.
AUCDI036	Noted free text entry is permitted. This would enable capture of any new side effects experienced with novel therapies that are not included in SNOMED CT-AU. Noted multiple adverse reactions can be entered.	Comment noted. Agree. There are occasions when free text entry is necessary, and this is included in the model.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this	Comment noted. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where

	<p>mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>It's not clear from the documentation whether the 'Clinical Finding' value set or the 'Clinical manifestation' reference set is being proposed for use for this data element. The 'Clinical Finding' value set seems too broad for manifestation of an adverse reaction. For example, the values 'Already on aspirin' and 'Deserted by mother' don't make sense as a manifestation of an adverse reaction. The value set needs further refinement to ensure that the scope is appropriate for this data element i.e. excluding values that are not relevant in the context of an adverse reaction. Not constraining the value set could impact the data quality by allowing for selection of inappropriate values. The 'Clinical manifestation' reference set seems to have a much more refined scope, with only 739 values compared to 116,784. This appears to be a more appropriate value set for this data element.</p>	<p>they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>The recommended value set is the 'Clinical finding value set' as this is a semantic binding and the maximal nature supports reuse across multiple use cases and supports the breadth of the ecosystem to enable interoperability. This data set may be used in EMRs, patient or clinician apps, etc. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI recommended value set e.g. 'Clinical manifestation value set'.</p>
<p>AUCDI035</p>	<p>Consider severity as this is widely used to record manifestation seriousness in order to make an informed clinical decision to continue or withhold therapy. In the future, care should be given to include whether the source of the adverse reaction risk information is patient provided. <a href="https://www.jacionline.org/article/S0091-6749(22)00007-0/fulltext">https://www.jacionline.org/article/S0091-6749(22)00007-0/fulltext</a> Researchers have worked to address the issue that there is no widely adopted severity grading system for acute allergic reactions, including anaphylactic and nonanaphylactic reactions, thus limiting the ability to optimize and standardize management practices and advance research: <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8273088/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8273088/</a></p> <p>Allergy/Analphylaxis - subset of ARR</p>	<p>Comment noted, added to backlog.</p> <p>Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog.</p> <p>The participant information (e.g. the author and the asserter) should be managed technically and sit in the technical specifications, and is out of scope of the clinical models in AUCDI as this should be done across all patient data consistently.</p>
<p>AUCDI032</p>	<p>Manifestation terminology list should have severity modifiers added. For example "possible", "mild" "severe" are terms that help clinicians understand the nature of an adverse reaction where that</p>	<p>Comment noted, added to backlog.</p> <p>Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data</p>

	<p>information is available. This sort of functionality is discussed for future iterations but it is probably needed from the outset. A drop-down list of typical manifestations could be helpful, plus the option to use free text if it is something different.</p>	<p>group will be proposed, with the scope and details to be agreed by the CDG. Comment noted. Smart implementations will be able to provide easy input for common manifestations. There are occasions when free text entry is necessary, and this is included in the model.</p>
--	---	---

#### 4.4. Adverse Reaction Risk Comment

Responder	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI005	A comment or note on the adr is fine and would be appropriate.	Comment noted.
AUCDI029	Including comments on every data group seems redundant. And if it isn't, why is it limited to a single comment?	Comment noted. A comment is a usual pattern at the end of each data group, to allow a single narrative description for information that is not captured in the other structured fields. The occurrence is limited to a single comment because it is an unlimited free text narrative.
AUCDI036	Useful to have this optional free text field to provide context on the cause of the adverse reaction, in particular if it is related to the treatment.	Comment noted.
AUCDI049	<p>7.1.5. For future consideration - Clinical verification status</p> <p>We may want to get some more clarity on as it sounds like adverse reaction risk may be intended for those adverse events with a higher level of certainty regarding causality.</p> <p>Though we note that this info is included in the openEHR that it would address this issue to some extent in future release (with the verification status planned for release 2):</p> <p>The risk of an adverse reaction event or manifestation must always propose a causative substance or class of substance. If there is a degree of uncertainty that a specific substance is the cause, the level of uncertainty can be recorded using the 'Verification status' data element. If more than one possible substance may have caused a reaction/manifestation, each substance should be recorded using a separate instance of this adverse reaction risk archetype with the 'Verification status' set to an initial state of 'Unconfirmed' so that adverse reaction checking can be activated in clinical systems. If the substance is later proven not to be causal then the 'Verification status' can be modified to 'Refuted' - for example, after allergy testing.</p>	<p>Comment noted, added to backlog.</p> <p>Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been put on the backlog.</p> <p>Comment noted.</p> <p>Medication errors, product complaints etc. are out of scope for this data group, however, may be collected through other data groups in the future.</p>



	<p>7.1.1. Context - Misuse</p> <p>Also note that the 'misuse' does exclude some information, Pharmacovigilance branch at [AUCDI049] routinely collect as ADRs, including medication errors, product complaints etc. However, these could still be reported through other channels.</p>	
AUCDI035	eg only lactose free medication formulations tolerated	Comment noted.

#### 4.5. Adverse Reaction Risk General Feedback

Responder	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI005	<p>To enhance Adverse Drug Reaction (ADR) reporting, consider the following recommendations:</p> <p>1. Substance Name to Substance Details:            - Clearly specify the substance or drug implicated in the adverse event, including its name, dosage, and formulation (e.g., tablet, injection). This level of detail aids in accurately identifying the causative agent of the adverse reaction.            - If this is a coded field proposal then to discuss the elements noted.</p> <p>2. If Manifestation = Event Description then:            - if this includes a comprehensive description of the adverse event, encompassing its symptoms, severity, and pertinent contextual information such as timing and duration. Providing thorough details facilitates better understanding and assessment of the reported reaction.</p>	<p>Comment noted, added to backlog.</p> <p>The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the substance from other substance-related data elements. Other substance details will be represented in separated data elements.</p> <p>In future releases, an extension to this data group to include further substance and event/manifestation details will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog.</p>
AUCDI009	<p>"Misuse" section, first bullet point: agree but it doesn't obviate the need/consideration for creating/ updating an allergy/adverse reaction record. Consider phrasing that indicates a diagnosis of an adverse reaction as the conclusion of a clinical consultation or investigation warrants the use of the Problem/Diagnosis data type but does not obviate the subsequent use of the Adverse reaction risk summary data type for documenting the adverse reaction risk.</p> <p>"Misuse" section, second bullet point: this sentence is confusing to me. Are we trying to say we aren't recording reactions that are not adverse reactions?</p>	<p>Wording updated to reflect comment.</p> <p>The document has been updated with "The finding of an allergy to a specific substance may be recorded in the Problem/Diagnosis data group in addition to the Adverse reaction risk summary data group, for example "Allergy to penicillin". "</p> <p>Comment noted. The second bullet point of Misuse section has been updated for clarity.</p> <p>Comment noted. The clinician's intent is to avoid re-exposure if possible, however recording in this data group implies a relative contraindication.</p>

	<p>Comment re: "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.":                  Use of the term "avoid" when we are not differentiating between allergy and adverse reaction may be problematic. Consider adding a qualifier around use of clinical judgement or softening the "avoid".                  For example, in the context of antimicrobial stewardship (AMS).                  Below is from the Parliamentary Inquiry into allergies and anaphylaxis                  Ref:  <a href="https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Allergiesandanaphylaxis/Report/section?id=committees%2freportrep%2f024422%2f72559">https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Allergiesandanaphylaxis/Report/section?id=committees%2freportrep%2f024422%2f72559</a></p> <p>Para 2.43 "The National Allergy Strategy (NAS) commented 'Up to 25 per cent of patients presenting to hospital report a drug allergy (commonly antibiotics), which has a major impact on antimicrobial stewardship. Many studies have shown that only 10 per cent of those claiming a drug allergy are truly allergic. The importance of a correct diagnosis of a person's drug allergy status is vital as this allows for the use of the most appropriate medications.'"</p>	
	<p>Ref: Drug allergy project  <a href="https://treasury.gov.au/sites/default/files/2019-03/360985-National-Allergy-Strategy.pdf">https://treasury.gov.au/sites/default/files/2019-03/360985-National-Allergy-Strategy.pdf</a>                  Notes a key issue is: "2. Patients are often labelled with a drug allergy when they are not allergic to the drug. If an appropriate health professional determines that the patient is not allergic to the drug, appropriate education, communication and patient record systems need to be in place to ensure the patient is no longer inappropriately and unnecessarily avoiding the drug." ...                  ""Unnecessary avoidance of antibiotics impacts health and antimicrobial stewardship"</p>	<p>Comment noted.                  "Type" is commonly used as a synonym for "Category" (which is an existing data element). Reaction mechanism has been deliberately chosen to be explicit.</p> <p>Wording updated to reflect comment.                  Agree. Updated for clarity.</p>

	<p>Since AUCDI has determined that allergy type (allergy vs intolerance) will be excluded from R1/R2 scope, it may be placing a data element that AMS considers important at a lower priority. Seeking their expert feedback. Acknowledge that it may be more important in inpatient care settings where AMS and high risk drugs are involved to be able to distinguish between an allergy and side-effect/intolerance to a medicine. Interesting too that RACGP noted "To improve the data on allergies and adverse reactions, you should first differentiate between the two when you enter the patient's information in your clinical information system."</p> <p>There are (proposed) initiatives to support drug allergy de-labelling, drug allergy registries, and organisations like the Austin Health launched a National Inpatient Penicillin Allergy Database and smartphone app targeting unconfirmed antibiotic allergies that impact AMS.</p> <p>So we need to be mindful of phrasing that may suggest sweeping statements about avoiding re-exposure due to an adverse reaction risk summary. Inappropriate and unnecessary avoidance of safe and useful drugs in patients who have been incorrectly 'labelled' as being allergic to a drug can impact on patient health and public health.</p> <p>I also think labelling the "type" as "reaction mechanism" in the logical model could lead to some apprehension in data entry.</p> <p>Use cases, and drivers sections: Triggering CDS alerts only mentions prescribing. Dispensing and possibly administering relevant too.</p>	
<p>AUCDI014</p>	<p>Missing "reaction type" data element. This element is clinically important and an attribute of a My Health Record health summary. 'Severity of reaction' is often an important detail and should be prioritised with this sprint or the next one. i.e.. Nausea/vomiting can be mild or it can be catastrophically severe requiring hospital admission</p>	<p>Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog</p>

AUCDI017	<p>I think it is important to have a mechanism to update/remove adverse reactions. Not quite sure though how that would be done. If an adverse reaction is removed from the same system that entered it in the first place then that could potentially send a message to remove it but what if it is considered false by a different system. How would the absence of an adverse effect be sent?</p>	<p>Comment noted. This is out of scope for AUCDI but should be addressed as part of a broader strategy for managing adverse reactions in implementations.</p>
AUCDI021	<p>Please include status and verification elements as they are integral to the Allergy review life cycle. Allergies get recorded and propagated into patient's records forever on often very flimsy evidence. AUCDI v1 represents a chance to more effectively define the 5W's of ADR's. There are significant population health implications for antibiotic prescribing for example</p>	<p>Comment noted, added to backlog. Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. These have been added to the backlog</p>
AUCDI023	<p>The recommended code system is the adverse reaction agent valueset published by the NCTS. This is a very comprehensive set of data, comprising of over 178,000 terms. There is a refset included as part of this valueset called the Adverse Reaction Agent Refset (ARAR), which is a much smaller and potentially more manageable for implementers. If this is to be part of the AUCDI R1, we would ask that the ARAR undergoes a comprehensive review as, whilst it covers common allergies, it also contains terms which are at best unsuitable and at worst could lead to poor clinical outcomes if they are expected to trigger clinical decision support for drug allergies. Some examples below: Concept ID Fully Specified Name 373266007 Anesthetic (substance) 255632006 Anticonvulsant (substance) 372720008 Antidepressant (substance) 372482001 Anti-psychotic agent (substance) 410942007 Drug or medicament (substance) 418165002 Herbal medicine agent (substance) 87708000 Vitamin (substance) 372752008 Central nervous system agent (substance) 418149003 Psychoactive substance (substance)</p>	<p>Comment noted. This data element references an existing NCTS value set. This value set is maximal in nature to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. This data set may be used in EMRs, patient or clinician apps, etc. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI value sets.</p>

	<p>43735007 Sulfur (substance)  111064005 Sulfur compound (substance)  332304007 Product containing sulfur (medicinal product)</p> <p>We first studied this refset approximately five years ago and it has had no significant revision in the time since. All codesets selected for AU core must come with a commitment to ensure they are both fit for purpose and actively maintained.</p>	
AUCDI027	<p>It feels to me like the naming is somewhat off. Adverse reaction risk doesn't quite sound like what these records. This appears closer to a record of adverse reaction events. It just happens that from it you expect the consumer to extrapolate risks.</p>	<p>Comment noted.  This data group documents a clinician's recommendation to avoid future exposure to a particular substance, emphasizing the assessment of exposure risk and its substantiating evidence from each exposure event.</p>
AUCDI029	<p>Need some aspect of whether this is a current adverse reaction risk given that is in problem/diagnosis</p>	<p>Wording updated to reflect comment.  The document has been updated with "The finding of an allergy to a specific substance may be recorded in the Problem/Diagnosis data group in addition to the Adverse reaction risk summary data group, for example "Allergy to penicillin". "</p> <p>Comment noted, added to backlog.  Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. "Status" has been added to backlog.</p>
AUCDI030	<p>* of R2 items +vote for clinical verification status, Onset first and last reaction</p>	<p>Comment noted, added to backlog.  Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>
AUCDI032	<p>Missing data elements that are currently in use:  - Certainty (non-mandatory but useful to clarify how certain if an allergy)  - Date of manifestation if known (again helpful to track back especially if a witnessed allergy eg as an inpatient, also</p>	<p>Comment noted, added to backlog.  Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>

	medicolegally useful to document if known). Also needs to allow entry of just year, or just month and year.	
AUCDI036	<p>Basing standardised entries for substance name on the Australian Medicines Terminology and manifestations (adverse reactions) on SNOWMED CT-AU is appropriate.</p> <p>In section 7.1.1. 'Context' it is stated under 'Misuse' that this data group is not intended to capture adverse reactions related to abnormal use, incorrect dosing or mislabelling. The side effects from these issues are important considerations for health technology assessment and Quality Use of Medicines when evaluating the performance of therapeutic products in practice. It is suggested the users are directed to the 'Encounter – clinical context' section to capture this information.</p> <p>Feedback on genomics provided in Question 10 may be relevant in the next Release.</p> <p>We note that genetic and genomics data has a specific alignment to the AUCD design principles referred to in Table 7 (page 34), namely: Driven by a clinical quality and safety use case supporting person-centred care. A standardised, comprehensive, and shareable record of adverse reaction risks will facilitate consistent use of clinical guidelines and protocol especially pharmacogenomic risk management.</p> <p>7.1.5 For future consideration (page 35) states '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'. Patient's undergoing genomic testing and pharmacogenomic analysis will be part of future risk assessment of medicine-related adverse reactions. We note that Potential candidate data element for Release 2 includes 'Clinical verification status'. This information conceivably could be obtained from pharmacogenomics.</p>	<p>Comment noted, added to backlog.</p> <p>Clinical symptoms that are identified as significant side effects that clinicians deem enough to avoid future prescribing can be recorded using this data model. Identification of true side effects for evaluating the performance of therapeutic products are out of scope for this data group and are currently not well recorded in most systems. Further investigation of secondary use needs to be considered. This has been placed on the backlog for future use cases.</p> <p>Comment noted, added to backlog.</p> <p>Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>
AUCDI033	We recommend removing the line "all adverse reactions are assumed active in the context of a summary	<p>Comment noted, added to backlog.</p> <p>Agree that the scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data</p>

	<p>for exchange” from the Considerations for use row in Table 5 – Adverse reaction risk summary – context. International standards already define status elements and codes, and the consideration in the table could conflict with or restrict existing interoperability implementations.</p>	<p>group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>
<p>AUCDI049</p>	<p>7.1.4 It is great to see adverse drug reporting as an identified case for use/reuse of this data in 7.1.4.</p> <p>To strengthen the potential for this there are a couple of areas that require clarification, particularly whether this is intended to be an expansion of allergy/intolerance fields to include other types of adverse events, or if the primary purpose for this is to collect allergy type information. If not, i.e. if the primary purpose is not only allergy information, then it would be helpful to:</p> <ul style="list-style-type: none"> <li>o be clear about this from the outset, so it isn’t used to collect a mix of allergy and AE info.</li> <li>o Look for opportunities to leverage the fields to make a similar data set specifically for collecting adverse event data</li> </ul> <p>The openEHR set uses ‘adverse reaction risk’ for both immune (i.e. allergy) and non-immune related reactions. We at [AUCDI049] advocate for this – though the misuse advice of ‘not to be used for adverse events...’ may cause confusion regarding the appropriate things to record in this field.</p>	<p>Comment noted, added to backlog.</p> <p>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 and non-immune mediated reactions. Adverse events are out of scope for this data group and has been placed in the backlog for further investigation.</p>
	<p>A. 7.1 – Adverse reaction risk summary, the data group purpose subsection has two scenarios. To record:</p> <ul style="list-style-type: none"> <li>• An assessment of the risk or propensity of a future adverse reaction if exposed, or re-exposed, to an identified substance.</li> <li>• A summary of each exposure event, including details about the reaction experienced, as evidence supporting the risk assessment.</li> </ul> <p>1. Would the second aspect all be captured in the comment field?</p>	<p>A. Comment noted, added to backlog.</p> <p>1. The second aspect has been updated in the document to 'Evidence supporting the risk assessment, such as a summary of each exposure event or genomics test results.' which more accurately reflects the future plan for the data group. At present, manifestation and comment are only two elements currently included for the exposure event. Additional elements will be added in future releases as decided by the CDG.</p>



	<p>2. Is the intention for these two aspects all to be captured in the same record or if different how would a system/person distinguish between records relating to one or the other or both or a relationship between a series of exposure events?</p> <p>3. How would reaction risks relating to the interactions of two or more substances be captured?</p> <p>B. 7.1 - Support the use of terminology sets where possible (AMT, SNOMED etc) as well as the comment field enabling free text to provide additional context – this will be useful for linking to TGA to report AE.</p> <p>C. 7.1.4 It would be useful to clarify whether the adverse reaction risk summary also includes adverse events following immunisations (AEFI). Inclusion of AEFI would be in keeping with the concept description of a ‘harmful or undesirable physiological reaction unique to an individual and associated with exposure to a specific substance’.</p> <p>- In addition to the substance name, manifestation, and comment fields, it would be useful to include information that contributes to the understanding of the association between the substance and the adverse event, such as information relating to de-challenge (the manifestation improved when the substance was ceased) and/or rechallenge (the manifestation recurred when the substance was reintroduced), and time to onset (the time between when the patient took the substance and experienced the manifestation).</p> <p>D. 7.1 - A key point for education would be to clarify that ‘adverse reaction risk’ can be used for suspected adverse reaction (rather than all adverse events) – in the context of a health professional reporting this– and would be further bolstered by release 2 where a reaction could be marked as ‘unconfirmed’ in the verification status.</p>	<p>2. The same record. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG.</p> <p>3. True drug-drug interaction records are out of scope for this data group and are currently not well recorded in most systems. Further investigation needs to be done. This has been placed on the backlog for consideration for future use cases.</p> <p>B. Comment noted. Agreed.</p> <p>C. Comment noted, added to backlog. Agreed. 7.1.1 Considerations for use has been updated for clarity to include vaccination in scope. 7.1.3 Substance name has been updated to include an example of a vaccine. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p> <p>D. Comment noted, added to backlog. Agreed. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>
--	---	---

<p>AUCDI034</p>	<p>A. Include requirements for absence of adverse reaction risk.                      -no known allergy, unknown, or nil known                      -include the date that this phrase was entered</p> <p>B. Page 30 Data group purpose – “An assessment of the risk or propensity of a future adverse reaction if exposed, or re-exposed, to an identified substance.”                      Feedback: We need to ascertain who is performing the risk assessment. Is this for anyone recording adverse reactions?</p> <p>C. Page 30 Consideration for use- “Material derived from plants or animals, or venom from insect stings”                      Feedback: Are these necessary in EHRs? Suggest including in Problem/diagnosis but remove from adverse reaction (for example pollen causing hay fever)</p> <p>D. Page 31 “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.”                      Feedback: Except for exercise-induced anaphylaxis</p> <p>E. Page 31 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                      Feedback: Suggest that EHR should be reserved for serious or significant (non-trivial) adverse reactions, for example exclude pollen causing hay fever, minor food intolerance, local swelling from insect stings etc.</p> <p>E. Page 32 Adverse reaction risk summary                      -Substance name                      -Manifestation                      -Common</p>	<p>A. Comment noted.                      Absence and exclusion statements are managed by the TDG in the FHIR IGs; however, it is intended that the CDG will be involved in discussions where relevant, e.g. wordings of exclusion statements</p> <p>B. Comment noted.                      The participant information (e.g. the author and the asserter) should be managed technically and sit in the technical specifications, and is out of scope of the clinical models in AUCDI as this should be done across all patient data consistently.</p> <p>C. Comment noted.                      The scope of this data group extends beyond medications, and the other examples are useful in a comprehensive health record. The finding of an allergy to a specific substance may be recorded in the Problem/Diagnosis data group in addition to the Adverse reaction risk summary data group, for example “Allergy to penicillin”.</p> <p>D. Wording updated to reflect comment.                      Document updated for clarity; however, exercise is not a substance and should not be recorded using this data model. Exercise-induced anaphylaxis should be recorded using Problem/Diagnosis.</p> <p>E. Comment noted, added to backlog.                      The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p> <p>F. Comment noted.                      "Record one summary instance per substance within a health record." If a person is exposed to two potential substances, this should be recorded as two separate records. Record one summary instance per substance within a health record.</p>
-----------------	---	--

	<p>Feedback: Can we consider including a fourth element where we specify whether the reaction is an allergy, side effect, intolerance, toxicity or idiosyncrasy to ensure that only necessary alerts are fired?</p> <p>F. Page 32 Occurrence- “Mandatory, single occurrence” Feedback: Should we enable multiple occurrence to allow for co-factors i.e. a person experiencing anaphylaxis if exposed to two triggers?</p> <p>G. Page 32: Examples – “AMT provides concepts at various granularities from brand to specific ingredient” Feedback: Excipients should be recorded separately if there is a known excipient allergy</p> <p>H. Page 33 Manifestation – Recommended code system/ value set – “Additionally, the clinical manifestation reference set 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” Feedback: The National Allergy Council are in the process of updating drug allergy terminology. The updated terms need to be incorporated into this standard.</p> <p>I. Page 34 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.” Feedback: Add:</p> <ul style="list-style-type: none"> <li>• Transfer of care summaries, for example, admission and discharge summaries</li> <li>• Medication review</li> </ul>	<p>G. Comment noted. Agree. A known excipient reaction would be recorded as a separate substance.</p> <p>H. Comment noted. Sparked is an open, collaborative community and welcomes the National Allergy Council's feedback around drug allergy terminology.</p> <p>I. Wording updated to reflect comment. Agree. Updated.</p> <p>J. Comment noted. AUCDI will work towards incorporating and harmonising any future standards and peak body recommendations.</p> <p>K. Comment noted, added to backlog. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p> <p>L. Comment noted, added to backlog. De-labelling needs further discussion and has been added to the backlog.</p> <p>M. Comment noted, added to backlog. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p>
--	--	---

	<p>J. Page 35 Aligns and leverages national standards and initiatives –  “Recommended terminology leverages national SNOMED CT-AU and AMT value sets”  Feedback: And in the near future: drug allergy terminology set and National Allergy Council best practice guidelines for the accurate recording, access and transfer of allergy information in electronic health records.</p> <p>K. Page 35 Potential candidate data elements for release 2  Feedback: Add:</p> <ul style="list-style-type: none"> <li>• Severity</li> <li>• timing of reaction/s</li> <li>• dosage (if drug) - including number of doses and number of days on the drug prior to reaction onset</li> <li>• date exposed to substance</li> <li>• patient must avoid statement</li> <li>• adrenaline autoinjector prescribed (yes/no)</li> <li>• Formulation and strength</li> <li>• method of diagnosis (if confirmed)</li> <li>• if delabelled, method of confirmation, and date confirmed</li> </ul> <p>not allergic</p> <p>L. Page 36 “Clinical verification status - for example, unconfirmed/confirmed/refuted”  Feedback: Refuted = De-labelled? If so, de-labelled is a term that more clinicians are familiar with.</p> <p>M. Page 37 Adverse reaction risk summary roadmap  Feedback: Add</p> <ul style="list-style-type: none"> <li>• Formulation and strength (R2)</li> <li>• Dosage (R2)</li> <li>• Severity (R2)</li> <li>• Initial exposure (date) (R2)</li> <li>• Patient must avoid statement (R2)</li> <li>• Adrenaline injector prescription</li> </ul>	
--	--	--

<p>AUCDI050</p>	<p>The data elements 'Substance name' and 'Manifestation' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.</p> <p>Under 'Considerations for use', it says: "In Release 1, all adverse reactions are assumed active in the context of a summary for exchange." This assumption is unlikely to be true and could mean that inaccurate information about adverse reactions is being exchanged. This could have a detrimental impact on patient care e.g. the GP could choose not to prescribe a medication that they believe the patient has an active allergy to when the allergy is actually now inactive due to the patient outgrowing the allergy. To avoid having to make this assumption, it is suggested that 'Active/inactive status' is included in Release 1, noting that it's currently down as a candidate for Release 2.</p> <p>Under 'Misuse', it says: "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." Is there an intention to add an 'Adverse events' data group in later releases, or is this just clarifying that it is and will continue to be out of scope? The AIHW supports the inclusion of an adverse events data group as this is something that could be leveraged for a National Primary Health Care Data Collection.</p>	<p>Comment noted.</p> <p>Comment noted, added to the backlog. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p> <p>Comment noted, added to the backlog. Adverse events, including failures of clinical processes, interventions, or products, are out of scope for this data group, however, may be collected through a new data group in the future and has been placed on the backlog.</p>
<p>AUCDI035</p>	<p>How will null fields be treated, i.e. no known drug allergies versus no documented drug allergies in the accessible medical record. There should be an acknowledgement that data is incomplete.</p> <p>re 7.1.1 Context please include in concept description: the potential for a harmful or undesirable physiological or psychological reaction eg. montelukast (Singulair) has a black box warning related to adverse reaction: potentially serious behavior and mood-related</p>	<p>Comment noted.</p> <p>Null fields will be managed as absence and exclusion statements and these are managed by the TDG in the FHIR IGs, however, it is intended that the CDG will be involved in discussions where relevant, e.g. wordings of exclusion statements</p>

<p>changes. These changes include depression and suicidal thoughts Also consider the ability to record a contraindication due to risk of adverse reaction together with allergy, intolerance, hypersensitivity as part of the data group aliases. Considerations for use- please mention cross reactivity per release 2: Please reconsider as part of release 1 due to the impact incorrect info is having on care now. active and inactive status. the ability to record allergies and adverse medication events as past history- not currently active. Still critical information to have available. This has been difficult to get vendors to accommodate but is really essential for full allergy information eg pencillin delabelling <a href="https://pubmed.ncbi.nlm.nih.gov/32756983/">https://pubmed.ncbi.nlm.nih.gov/32756983/</a></p> <p>I would like to know if 'date' of reaction has been considered to be included here eg childhood reaction or date - or is that captured elsewhere but as part of the ADR reporting it is good to know when it occurred e.g childhood or last year Also the person recording the reaction eg patient reporting, GP, hospital doctor etc. sometime it gives you information on whom to contact for further information eg. if patient reporting</p> <p>Potential consideration for Release 2: Clinical verification status. Consider an option for 'patient reported'. Adverse reactions are often documented as a result of patient-reported information versus direct observation that is verifiable by a clinician.</p>	<p>Comment noted, added to backlog. Physiological reactions to a substance exposure can trigger physical or psychological manifestations, both of which can be recorded in the Manifestation element. A relative contraindication due to risk of adverse reaction can be recorded with this data group however has not been included as an alias. Cross reactivity is not part of a adverse reaction data group, it should be managed through clinical decision support at the point of prescribing/administration. The scope of Adverse Reaction Risk is very tightly constrained for R1. In future releases, an extension to this data group will be proposed, with the scope and details to be agreed by the CDG. Added to backlog.</p> <p>Comment noted, added to backlog. In future releases, an extension to this data group will be proposed for, including reaction event details, with the scope and details to be agreed by the CDG. Added to backlog.</p>
---	--

## 5. AUCDI R1 Section: Problem/Diagnosis Summary

### 5.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
22	11	4	1	10	4

### 5.2. Problem/Diagnosis Name

Responder	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI017	Only generic comment about accuracy with data due to variations in diagnostic processes and stages of diagnosis and also how the feedback loop works to update/refine diagnoses - particularly when that occurs at two different centres - which one is correct?	Comment noted, no change. This is out of scope for AUCDI but should be addressed as part of a broader strategy for managing Problem/Diagnosis lists.
AUCDI019	Use cases should include Decision Support	Wording updated and new content added to reflect comment. Agree. Updated document.
AUCDI032	<p>One of the faults of medical records is the sheer unwieldy extent of information, particularly problem lists. This leads to errors in patient care. Consideration should be given to architecture that can nest problems under an umbrella term. This would require the ability to link a problem/specific diagnosis to an overarching condition. For example: cardiovascular disease umbrella term could have coronary artery occlusion, peripheral vascular disease, stent procedure all linked. My prediction is that machine learning/AI assistance will be able to do as good a job as human clinical coders in tidying up records so long as the architecture is built for this functionality.</p> <p>How are suspected diagnoses going to be handled? Sometimes it is not 100% clear but can be clinically useful to flag some uncertainty "Suspected musculoskeletal chest pain" or "Chest pain suspected to be musculoskeletal in origin".</p>	<p>Comment noted, no change. This is out of scope for AUCDI but should be considered as part of a broader strategy for managing problem lists using the approach outlined by Larry Weed's Problem Oriented Medical Record (POMR) and some of the concepts within the CONTSYS standard (ISO 13940).</p> <p>Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Diagnostic certainty" is a candidate for future extension in AUCDI and has been added to the backlog.</p>

AUCDI034	<p>Page 43 Problem/Diagnosis roadmap Feedback: Add:</p> <ul style="list-style-type: none"> <li>• Practitioner role that confirmed the diagnosis (R2)</li> <li>• Method of diagnosis (R2)</li> </ul>	<p>Comment noted, added to backlog. The scope of Problem/Diagnosis is tightly constrained for R1. "Clinical evidence" is a candidate for future extension in AUCDI which could be used to record this has been added to the backlog. "Practitioner role that confirmed the diagnosis" has also been added to the backlog.</p>
AUCDI036	<p>Noted free text entry is available to include new medical conditions that may not be reflected in SNOWMED CT-AU.</p>	<p>Comment noted. No change. Agree. There are occasions when free text entry is necessary, and this is included in the model.</p>
AUCDI039	<p>Cancer stage at diagnosis is a fundamental gap in Australia's cancer data, as it is critical for clinical decision making and population health reporting. It will enable us to understand the association between stage at diagnosis, treatments and outcomes, and to better understand differences in these aspects for different population groups.</p> <p>In 2022, The American College of Surgeons (ACS) and SNOMED International entered into a licensing agreement, which allowed AJCC staging concepts critical to understanding cancer and treating patients to be captured. These SNOMED codes could be adopted for AUCDI release 1 or 2, subject to AIHW's views</p>	<p>Comment noted, added to backlog. The scope of Problem/Diagnosis is tightly constrained for R1. "Staging/grading" has been added to the backlog.</p>
AUCDI042	<p>As above, please include a cancer-related examples to demonstrate how a cancer diagnosis might be communicated. E.g., Problem diagnosis name examples: 134405005   Suspected breast cancer 254837009   Malignant neoplasm of breast 315004001   Metastasis from malignant tumour of breast</p>	<p>Wording updated and new content added to reflect comment. Document updated with addition of 254837009   Malignant neoplasm of breast   as an example.</p>
AUCDI043	<p>The complexity differentiating between problems and diagnoses is acknowledged in the paper. How would sharing of RFE/chronic condition info/acute problem/diagnoses be handled in practice? This isn't entirely clear from the case study presented on p.19.</p>	<p>Comment noted, no change. There are two different data groups, one for RFE and one for Problem/Diagnosis as the semantics for these groups are different.</p>
AUCDI045	<p>ISO11179 says never use "or" in a data element definition - as you then never really know what concept you are trying to represent.</p>	<p>Comment noted, no change. The name "Problem/Diagnosis" has been given as traditionally, differentiating between problems and diagnoses has been difficult</p>



	<p>- For "Problem / Diagnosis" - choose one of them and consistently stick with it (and the other concept should be an alias/alternative)                  - "Problem / Diagnosis name" data element should be "Problem / Diagnosis" as it is an identifier (not its name)</p>	<p>because they often exist on a continuum, 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.</p> <p>The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the problem/diagnosis from other related data elements.</p>
<p>AUCDI050</p>	<p>Which part of the SNOMED CT-AU value would be captured – the code, the display text or both? Having a clear understanding of the proposed format will assist AIHW to develop standards that align to AUCDI.</p> <p>ICD-10-AM is the national standard for diagnosis classification in Australian hospitals, with investigations underway among relevant agencies of the costs and benefits of a potential move to using ICD-11. For the AUCDI to be able to meet the diagnosis reporting requirements of the current use cases there may need to be a mapping between the SNOMED CT-AU reference sets proposed to be used in AUCDI to the ICD-10-AM codes.</p> <p>In regard to ICD-11, the AIHW would like to work together with the ADHA to help drive collaborative efforts by the World Health Organisation and SNOMED International respectively to harmonise content of and mappings between the two systems. We are not as familiar with the governance and work arrangements of SNOMED, but the area of WHO responsible for the international classifications is poorly resourced and relies heavily on contributions and assistance from member states. Working together to determine how best to focus such efforts will be important to the ongoing interoperability/digital health agenda.</p>	<p>Comment noted, no change.</p> <p>How the SNOMED CT-AU is captured and stored is an implementation consideration which will be represented in technical specifications for the relevant use case. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model.</p> <p>Comment noted.</p> <p>Agree. A mapping may be required for reporting requirements, funding and classification purposes in acute care.</p>

AUCDI035	Assuming SNOMED CT AU used	Comment noted, no change. The recommended value sets are SNOMED CT-AU value sets.
----------	----------------------------	--

### 5.3. Body Site/Laterality

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>The concept representation shows Body site/Laterality, while the table only shows Body site. Please make these consistent.</p> <p>Since Body site can have "multiple occurrences", I would like this to be made more obvious in this table. Perhaps call it "Body sites".</p> <p>Consider making this mandatory. When the Problem does not include or imply the body site, a Doctor may forget to add this information. So it is better to mitigate this form of human error.</p>	<p>Wording updated to reflect comment. Agree. Table updated to say Body site/Laterality.</p> <p>Comment noted, no change. As a policy, each data element is named and defined as a singular attribute, as most use cases will describe a single data item. However, where it is useful to allow more than one response, the occurrences are updated to reflect the cardinality and an accompanying statement will explain that more than one response is allowed.</p> <p>Comment noted. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>
AUCDI010	<p>Body site / laterality in my system is captured as a secondary problem / diagnosis and is not generally entered by the clinicians as it's extra clicks (even if useful). The statement that is required only when the name does not include or imply a specific body site should be adjusted to be recommended. This may become a significant implementation issue down the line due to the lack of clinical entry of the data.</p>	<p>Wording updated to reflect comment. Agree. 7.2.3 has been updated to "Specification of 'Body site/laterality' is recommended when it is required to provide additional clarity about the Problem/Diagnosis and the 'Problem/Diagnosis name' does not include or imply a specific body site.</p>

AUCDI032	Consider using Left / Right /Bilateral / Not applicable (only have one of some organs and some diagnoses may not be organ specific).	Comment noted, no change. Agree with the requirement for both body site and laterality to be specified. The AUCDI is not recommending a solution as the best way to represent this and is still being determined by the TDG and Terminologists.
AUCDI033	The body site/laterality of a condition is typically included as part of the coded representation of the problem (e.g., SNOMED CT-AU Code 112981000119107 Bilateral osteoarthritis of knees), and body site/laterality is not a required element on the referenced standards. We recommend changing the considerations to make the specification of body site/laterality recommended (not required) when the coded problem does not include or imply a body site.	Wording updated to reflect comment. Agree. 7.2.3 has been updated to "Specification of 'Body site/laterality' is recommended when it is required to provide additional clarity about the Problem/Diagnosis and the 'Problem/Diagnosis name' does not include or imply a specific body site.
AUCDI042	Body site example: 110501003   Upper outer quadrant of left breast	Wording updated and new content added to reflect comment. Agree. Document updated with addition of 110501003   Upper outer quadrant of left breast
AUCDI035	Are fields conditional? I.e. systemic diseases don't have a body site or laterality  Allow 'Bilateral' if both sides involved	Comment noted, no change. Implementation considerations such as conditional display of data fields is out of scope for AUCDI.  Comment noted, no change. Agree with the requirement for bilateral to be specified when required. The AUCDI is not recommending a solution as the best way to represent this and is still being determined by the TDG and Terminologists.

## 5.4. Status

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI011	I believe Date/Time clinically recognised is a highly important field and should be considered for R1. Many use cases of problem / diagnosis data need a datetime field separate to the time entered into a clinic system to accurately capture patient clinical history, especially where multiple health services are used or received an initial diagnosis outside this shared system (ie. overseas). In particular, this information is extremely important for the acute and long term treatment of chronic degenerative diseases.	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Date/Time clinically recognised" is a candidate for future extension in AUCDI and has been added to the backlog.
AUCDI013	Verification status (eg. unconfirmed, provisional) may also be important where urgent action needs to be taken, or where a confirmed diagnosis make take an extended time.	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Diagnostic certainty" and "Diagnostic status" are candidates for future extension in AUCDI and have been added to the backlog.
AUCDI016	This field needs to be mandatory, not optional. It's a binary state, and the state will be assumed if not provided (and assumed to be active), it's risky in case that's not the intended state. Better to be explicit.	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.
AUCDI029	It seems arbitrary that there is a status or active/inactive here but not in other data groups.	Wording updated to reflect comment. This was identified as a clinical requirement. The document has been updated that this is a clinical assertion.
AUCDI036	It is noted that the value set for status is still in development (page 40).	Comment noted, no change. Agree.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense

	<p>What is the significance of this data element having the data type 'Coding' rather than 'CodeableConcept'? The term definitions in Appendix A have been reviewed but further detail would be helpful to clearly distinguish between the two data types. Having a clear understanding of the proposed data types will assist AIHW to develop standards that align to AUCDI.</p> <p>The information listed against 'Recommended code system/value set' appears to be contradictory. It says the value set is yet to be determined, but then says it will be limited to active/inactive.</p>	<p>without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>The 'Coding' datatype only allows a simple direct reference to a code defined by a code system, whereas CodeableConcept allows freetext as well as codings.</p> <p>The value set is still to be developed and published, however, the values included will represent active and inactive definitions.</p>
AUCDI032	Status should be optional field as it is contentious. Some doctors do not like having active and inactive problem lists, whereas others do.	Comment noted, no change. Status is optional in AUCDI.

### 5.5. Problem/Diagnosis Summary Comment

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI004	Is that possible to include grade/staging in the Problem/Diagnosis data group? The staging information is quite important to triage immunotherapy now.	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Staging/grading" has been added to the backlog.
AUCDI029	Again not clear that this wouldn't be in every data group.	Comment noted, no change. This instance of 'Comment' was identified as a clinical requirement. It is quite reasonable that a Comment should be considered for all data groups.
AUCDI042	Please include other cancer-related diagnosis information as soon as possible, such as 'stage at diagnosis'. Early-stage disease is obviously treated very differently to late-stage disease, so this is an important set of data elements that should accompany the diagnosis information in a clinical record.	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Staging/grading" has been added to the backlog.
AUCDI035	Resolved vs Ongoing?	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Resolution phase" has been added to the backlog.

## 5.6. Problem/Diagnosis Summary General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>I have some reservations about the semantics of using the same item to describe both Problem and Diagnosis. While a Problem and a Diagnosis may be considered to exist on a spectrum, it appears to me that the rationale to merge them has more to do with the user experience/workflow.</p> <p>I would consider Problem and Diagnosis as distinct data models that are abstracted away at a higher level. The end user might perhaps start entering a Problem; then they may "convert" it into a Diagnosis. Under the hood, we would have 2 different models being used, while keeping the Problem data intact for historical reference.</p> <p>The other reason this might be helpful is the future use of AI analysis. An AI might be asked to cross-reference the patient's historical "problems" with that of their parent's historical undiagnosed "problems" to derive a possible alternative diagnosis.</p> <p>Another feature that could be derived from separating Problem and Diagnosis is auditing Doctor diagnostics performance. This might entail analysing historical Problems of various patients to show that a Doctor is misdiagnosing certain types of diseases.</p>	<p>Comment noted, no change.</p> <p>The name "Problem/Diagnosis" has been given as traditionally, differentiating between problems and diagnoses has been difficult because they often exist on a continuum, 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.</p>
AUCDI013	<p>Severity and Stage (eg. in a cancer diagnosis) are often important considerations.</p> <p>Also for the next iteration: I think Onset Date may be a more important measure than diagnosis date.</p>	<p>Comment noted, added to backlog.</p> <p>Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Staging/grading" and "Date/time of onset" has been added to the backlog.</p>
AUCDI014	<p>Regular surveillance of free text entry required to identify elements that are prevalent but NOT present in the dataset.</p>	<p>Comment noted, no change.</p> <p>Agree. Out of scope for AUCDI, however in practice, commonly used free-text terms can be submitted to the national release</p>

		centre for addition to SNOMED CT-AU and the associated value sets.
AUCDI027	There should be date elements attached. The dates of recording of problems can have impact on medications and the patients current state (particularly for short term conditions). Even of the examples provided "Missed contraceptive pill" may be treated very differently if it was recorded yesterday vs 3 years ago.	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Date/time of onset" and "Date clinically recognised" have been added to the backlog.
AUCDI030	* R2 +vote candidate onset date / date of diagnosis as context	Comment noted, added to backlog. Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Date/time of onset" and "Date clinically recognised" have been added to the backlog.
AUCDI039	Cancer Australia would welcome the opportunity to collaborate with this initiative to advise on cancer related applications. The Core Design Principles that guide the development of AUCDI align with the Framework and present an excellent opportunity to further progress both projects objectives.	Sparked is an open, collaborative community and welcomes Cancer Australia joining the community and contributing.
AUCDI040	<ul style="list-style-type: none"> <li>Consider implications of capturing a single diagnosis/problem and how the dataset can create links to additional diagnoses/problems made related to the primary diagnosis to provide a complete picture of cancer burden. Side effects of cancer and its treatment may be physical or emotional, some clinically diagnosed while others considered problems or issues that are worked through using other interventions such as information or access to supports. While many of these could fall within the proposed Diagnosis/Problem data element group, an opportunity to recognise where one diagnosis has triggered another diagnosis or related problem would enable a greater understanding of the impact of cancer on the person.</li> </ul> <p>Some diagnoses or problems, particularly long-term conditions, could trigger considerations for other aspects of their health and care. For example, a person's disability is not currently captured in many datasets, however, could have implications for health system planning and access to optimal care. The development of</p>	<p>Comment noted, no change.</p> <p>This is out of scope for AUCDI but should be considered as part of a broader strategy for managing problem lists using the approach outlined by Larry Weed's Problem Oriented Medical Record (POMR) and some of the concepts within the CONTSYS standard (ISO 13940).</p> <p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>

	<p>standardised indicators enabling the opportunity to document any physical or mental considerations within data collections could guide better delivery and planning of inclusive health services.</p> <ul style="list-style-type: none"> <li>• Ensure, at a minimum, the following key elements become standard collection items or can be calculated based on available data through AUCDI.</li> </ul> <p>There are currently several important data elements for understanding cancer outcomes that are not captured consistently in cancer-related datasets or individual datasets do not capture the items required to calculate the data element. These data include cancer diagnosis (type), treatment received, stage at diagnosis, incidence, mortality, relative survival, cause specific survival, post treatment mortality, comorbidities, other individual risk factors and self-report health data. Some of which are captured within the proposed release 1 data groups however, including specific cancer examples of how data can be captured would strengthen the AUCDI.</p>	
<p>AUCDI048</p>	<p>Diagnostic certainty – there are three main ways in which a diagnosis can be made with certainty (i) clinical evaluation (ii) pathology test (iii) other diagnostic test (e.g. imaging, endoscopy etc.) – we can probably assume that (ii) and (iii) are consistent in detecting injuries and illness, however (i) relies on the clinical skills of an individual, where there is likely more variability between individuals, as well as variability in an individual’s knowledge/experience in different systems of the body e.g. GP1 is excellent in dealing with MSK injuries, but not as good in detecting skin cancers. GP2 is excellent in detecting skin cancers but isn’t as good in diagnosing MSK injuries/disease.</p> <p>In regard to diagnostic certainty, it seems appropriate to provide links to reports from diagnostic tests that provided a definitive diagnosis. Where a definitive diagnosis could not be made, there is advantage to the clinician recording their perceived diagnostic certainty – perhaps in the future AI will be able to review cases</p>	<p>Comment noted, added to backlog.</p> <p>Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Diagnostic certainty" and "Clinical evidence" have been added to the backlog. Linkage to clinical evidence is largely an implementation related issue, but including 'Clinical evidence' as a data group may be useful.</p>



	with a less than certain diagnosis and provide further options to be explored so a definitive diagnosis can be made. You could also use this data set to determine the diagnostic strengths and weaknesses of clinicians to inform their ongoing training and education.	
AUCDI050	The data elements 'Problem/Diagnosis name' and 'Status' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.	Comment noted, no change.
AUCDI042	Alignment with design principles - comment for consideration: Re. multiple use and re-use - the nature of the cancer disease is that the diagnosis information remains relevant throughout the life of the person with cancer, in the event of residual disease management, progression or recurrence. I hope that our digital health information network will eventually be able to draw on clinical records to compile a summary health record about the person's cancer diagnosis to be contributed to My Health Record, to inform the patient and future clinical consultations and investigations.	Comment noted, no change. Agree. The proposal for the Problem/Diagnosis summary will go a long way to supporting this use case.
AUCDI051	This might be a useful data group for an Aged Care assessment / support plan use case. It would be useful to have some people from IAT / ACAT to look at this to see if their use case is compatible with the definition of this data group.  Status: interested to know why this isn't aligned to condition.clinicalstatus (value set: <a href="https://build.fhir.org/valueset-condition-clinical.html">https://build.fhir.org/valueset-condition-clinical.html</a> ) and have the values active   recurrence   relapse   inactive   remission   resolved   unknown As per the principle "Aligns and leverages international standards", this seems like low hanging fruit.  Evidence: Previous version of AU Core Condition had a non-mandatory "evidence" element to allow for the linking of a diagnosis with the supporting evidence/manifestations/symptoms	Comment noted, added to backlog.  Recurrence, relapse, remission are subtypes of active and there are other ways of qualifying status which have been added to the backlog. Resolved is a subtype of inactive.  Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Clinical evidence" and "Severity" have been added to the backlog.

	<p>that resulted in the diagnosis. Is this not normally captured? I would think its important to prove restrictions have been met to meet the criteria for certain PBS schedules.</p> <p>Severity: From what I can see with reading Aged Care Assessment instruments, most of the problems are captured with a severity rating. i.e. if the problem diagnosis was "129859006   Impaired bed mobility", diagnosis needs to be captured with a severity rating for 1-5 (from "1 - independent/supervision "only to "5 – two or more persons physical assist"). I'm surprised that there isn't a severity element in the AUCDI for Problem/diagnosis</p>	
AUCDI035	Date diagnosed is important as well as date resolved.	<p>Comment noted, added to backlog.</p> <p>Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Date clinically recognised" and "Date/time of resolution" have been added to the backlog.</p>

## 6. AUCDI R1 Section: Procedure Completed

### 6.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
25	12	2	0	9	4

### 6.2. Procedure Name

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI009	<p>In "Groupers that are considered artefacts of the terminology and not useful for clinical records are excluded." - do we mean artefacts of the terminology model?</p> <p>In Considerations, are Procedures codes widely used for triggering decisions support? Perhaps supporting efficient querying and analytics is more relevant.</p>	<p>Wording updated to reflect comment.</p> <p>Agree. This is referring to SNOMED CT-AU non clinical "grouper" concepts. This sentence has been removed from the document to avoid confusion.</p> <p>Comment noted, no change.</p> <p>The terminology is capable of triggering decision support. It could be used to support other business requirements. Section 7.3.4 'Driven by a clinical quality and safety use case supporting person-centered care ' has been updated to "Support efforts to improve clinical safety and analytics"</p>
AUCDI041	<p>Q1. Will this element also be used to communicate procedure history?</p> <p>If so, does it include old-fashioned or alternative procedures that are not currently performed in Australia, but may have been completed earlier in the patient's life or performed overseas?</p> <p>It is important that these can be captured when taking history even if they would never be performed in Australia in the present time.</p> <p>Q2. Will this include anaesthetic procedures?</p> <p>In the AUCDI R1 Draft for Community Comment, it says that: "Use cases include, but are not limited to:</p>	<p>Q1. Comment noted, no change.</p> <p>Yes, this can be used to communicate historical procedures.</p> <p>"Procedure name" allows for both coded values and free text so this will allow for any procedure that needs to be entered.</p> <p>Q2. Comment noted, no change.</p> <p>Each individual anaesthetic-related procedure, such as intubation or insertion of an IV, carried out during a general anaesthetic could be recorded in this model, however, recording an overview of the whole anaesthetic process will be captured in a separate anaesthetic-specific data group.</p>

<p>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..."</p> <p>However the linked OpenEHR site (<a href="https://ckm.openehr.org/ckm/archetypes/1013.1.204">https://ckm.openehr.org/ckm/archetypes/1013.1.204</a>) states under Misuse:          "Not to be used to record details about the anaesthetic - use a separate ACTION archetype for this purpose."</p> <p>Can you clarify whether Procedure Completed should be used for anaesthetic actions such as intubation, insertion of IV/artline/CVC, taking a blood sample etc.? What about anaesthetic-only procedures such as cardioversion, transoesophageal echocardiogram (TOE), epidural blood patch etc.? Some of these follow typical surgical booking processes in EMR systems if they need to secure a procedure room, staff, equipment etc.</p> <p>Q3. How will complex procedures that require multiple codes (but are still a single event) be captured?          The AUCDI R1 Draft says that procedure data group representation can be used to:          "Record one instance per procedure event within a health record"          It is very common in theatre to require multiple MBS Items / SNOMED codes to accurately capture everything that was performed. If only a single instance is allowed, how will we manage complex procedures without it looking like they were performed separately?          Common examples:          Surgical: Hysteroscopy D+C + Insertion of IUD + Laparoscopic excision of endometriosis + Division of adhesions + Excision of endometrioma + Cystoscopy + Insertion of ureteric stent + Insertion of IDC          Anaesthetic: Intubation + Insertion of IVC + Insertion of Art Line + Blood Sample + Insertion of NGT</p> <p>Q4. Will there be consideration for including procedure description?</p>	<p>Cardioversion and epidural blood patch would be captured using this data group. The transesophageal echocardiogram is a mix of procedure and medical imaging, so it may need a combination of data groups to record an interventional radiology procedure.</p> <p>Q3. Comment noted, no change.          This data group is intended to be a clinical record. The billing information can be derived from various parts of the clinical record. This is usually intended to be used as what the clinician records as the name of the operation/procedure.</p> <p>Q4. Comment Noted, added to backlog.          Agree. The scope of Problem/Diagnosis is tightly constrained for R1. "Procedure description" has been added to the backlog.</p>
--	---

	<p>The AUCDI R1 Draft includes Procedure Completed but not Procedure Description. While it would be great if clinicians listed every single intervention performed on a patient, in one EMR system we have seen, they typically select the primary procedure from a category list, and the remaining detail is captured as free-text in the procedure description.</p> <p>For example, looking at the above gynaecology procedure, they are likely to select the major procedure of Operative Laparoscopy, with the rest (hopefully) detailed in the description.</p> <p>Including the Procedure Description free-text field as well would still allow the category list to be used as recommended in the AUCDI R1 Draft:</p> <p>"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."</p> <p>But would provide much greater clarity as to what was actually performed during this event.</p>	
AUCDI042	Please include cancer-related example, e.g. 428923005   Radiotherapy to breast	Comment noted, new content added to reflect comment. Agree. Document updated with addition of 428923005   Radiotherapy to breast
AUCDI045	"Procedure name" data element should be "Procedure" as it is an identifier (not its name)	Comment noted, no change. The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the Procedure from other related data elements.
AUCDI050	<p>Which part of the SNOMED CT-AU value would be captured – the code, the display text or both? Having a clear understanding of the proposed format will assist AIHW to develop standards that align to AUCDI.</p> <p>ACHI is the national standard for intervention classification in Australian hospitals. There may need to be a mapping from the SNOMED CT-AU reference sets to ACHI codes.</p>	<p>Comment noted, no change.</p> <p>How the SNOMED CT-AU is captured and stored is an implementation consideration which will be represented in technical specifications for the relevant use case. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model.</p>

		<p>Comment noted.                  Agree. A mapping may be required for funding and classification purposes in acute care.</p>
<p>AUCDI017</p>	<p>I noticed that blood collection is given as a procedure. I am not sure if minor procedures such as this would necessarily be captured routinely. Even some more significant procedures such as lumbar puncture may be captured in general clinical text field notes. If a procedure drives some sort of ability to bill then it will likely be coded somewhere but it not then may or may not.</p> <p>There may need to be a specific definition of a procedure.</p>	<p>Comment noted, no change.                  This data group can be used to record minor procedures if required. The AUCDI specifications are intentionally kept neutral for any specific use case and does not suggest what is a minor or major procedure.</p>

### 6.3. Body Site/Laterality

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI080	<p>Body site/laterality is in the concept representation however the table lists this only as Body site. Please make these consistent.</p> <p>Consider renaming Body site to Body sites to reflect multiple occurrences.</p>	<p>Wording updated to reflect comment. Agree. Table updated to say Body site/Laterality.</p> <p>Comment noted, no change. As a policy, each data element is named and defined as a singular attribute, as most use cases will describe a single data item. However, where it is useful to allow more than one response, the occurrences are updated to reflect the cardinality and an accompanying statement will explain that more than one response is allowed.</p>
AUCDI010	<p>Body site, laterality is not generally documented in the procedure control which would normally be the summary of any procedures known or performed on the patient regardless of location or facility. A surgery performed in a hospital will have the body site / laterality documented deep within the surgical procedure not but not often as part of the procedure history. Would recommend that the text suggesting that it is required if the procedure name does not imply a site be changed from a required to a recommended as that level of logic is not easily computable (e.g. which procedures are clear enough on their own vs not)</p>	<p>Wording updated to reflect comment. Agree. 7.3.3 has been updated to "Specification of 'Body site/laterality' is recommended when it is required to provide additional clarity about the Procedure name and the 'Procedure name' does not include or imply a specific body site.</p>
AUCDI032	<p>Consider using options Left / Both or bilateral / Right / Not applicable (eg, only have one aorta).</p>	<p>Comment noted, no change. Agree with the requirement for both body site and laterality to be specified. The AUCDI is not recommending a solution as the best way to represent this is still being determined by the TDG and Terminologists.</p>
AUCDI042	<p>Please include cancer-related example, e.g.: 110501003   Upper outer quadrant of left breast</p>	<p>Wording updated and new content added to reflect content. Agree. Document has been updated with example of 110501003   Upper outer quadrant of left breast</p>
AUCDI033	<p>The body site of a completed procedure is typically included as part of the coded representation of the</p>	<p>Wording updated to reflect comment.</p>

	<p>procedure (e.g., SNOMED CT-AU Code 2481000087101 MRI of le<sup>2</sup> knee with contrast) and is not a required element on the referenced standards. We recommend changing the considerations to make the specification of body site recommended when the coded procedure does not include or imply a body site.</p>	<p>Agree. 7.3.3 has been updated to "Specification of 'Body site/laterality' is recommended when it is required to provide additional clarity about the Procedure name and the 'Procedure name' does not include or imply a specific body site.</p>
--	--	---



## 6.4. Clinical Indication

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI010	The clinical indication is not every explicitly set as the reason for a surgery, which is the most common use of the procedure control in hospitals. Bedside procedures (e.g. in the ICU) are not often documented anywhere outside of a progress note. While not required, this could become an implementation issue in the future as it is not common practice to document.	Comment noted, no change. This data element is optional.
AUCDI029	Given this is only historical in nature, why is this in at this stage?	Comment noted, no change. It is a clinical requirement to understand why a procedure was performed e.g. elective mastectomy or for cancer?
AUCDI032	Clinical indication should be optional or able to be linked to problem list to avoid lots of duplicated data. This is often obvious anyway.	Comment noted, no change. This data element is optional.
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>The 'Reason for encounter' value set seems too broad for clinical indication for a procedure. For example, the values 'Tends not to plan ahead' and 'Witness summons received' don't make sense as a clinical indication for a procedure. The same value set is being proposed for clinical indication for a procedure, clinical indication for a medication and reason for encounter. A reason for encounter could be clinical, social or administrative in nature, whereas an indication for a procedure or medication should be clinical in nature. This indicates that there should be tangible differences between the scope of the value sets used for these data elements. The value set may need further refinement to ensure that the scope is appropriate for this data element i.e. excluding values that are not clinical in nature. Not constraining the value set could</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>This value set has been removed, and a new value set is to be developed. This new value set will contain clinical findings, events and procedures. This value set will still be maximal in nature to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. This data set may be used in EMRs, patient or clinician apps, etc. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI value sets.</p>

	<p>impact the data quality by allowing for selection of inappropriate values.</p> <p>Which part of the SNOMED CT-AU value would be captured – the code, the display text or both? Having a clear understanding of the proposed format will assist AIHW to develop standards that align to AUCDI.</p>	<p>How SNOMED CT-AU is captured and stored is an implementation consideration which will be represented in technical specifications for the relevant use case. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model.</p>
<p>AUCDI035</p>	<p>pg. 47 (Considerations) - 'This data element has multiple occurrences to allow the recording of more than one clinical indication per medication'. Information model 7.3.3 pertains to indications for a procedures and not medications so this appears confusing. Presumably, there are terminologies in the Procedure value set that account for procedures required for medication administration, i.e. intravenous, intrathecal, intravesical.</p>	<p>Wording updated to reflect comment. Agree. Sentence has been corrected.</p>

## 6.5. Date Performed

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>This should be mandatory. If a procedure has indeed been completed, then it's date and time must be recorded.</p> <p>Perhaps this also needs to be split into 2 dates. For example, a procedure in an emergency room commencing at 1145pm, ending at 1am (the following day). Also, there might be medical procedures that go longer than 24hrs, so it is important to capture this data.</p> <p>Therefore, I think this field should be split into date commenced and date completed.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>Comment noted, added to backlog.</p> <p>This is not intended as a complete operation report and is a summary record of the procedure. "Total duration" has been added to the backlog.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>It is recommended that DDMMYYYY format is utilised for complete dates e.g. "15032024" rather than "March 15, 2024" (one of the examples listed). DDMMYYYY is the format commonly used within METEOR. It is also recommended that a standardised approach to capturing partial dates is defined that clearly distinguishes partial dates.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>Comment noted, no change.</p> <p>The technical date representation is out of scope for AUCDI, and it would be expected be included in technical standards such as a FHIR IG. Rendering of dateTime is an implementation decision and is also out of scope for AUCDI.</p>
AUCDI032	<p>If entering data retrospectively for previous history, there needs to be an "If known" option, and also needs to allow entry of just year or just month and year.</p>	<p>Comment noted, no change.</p> <p>Partial dates are allowed for this data element and is optional.</p>

## 6.6. Procedure Completed Comment

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI004	Is possible to add 'Purpose/Intent' to the group? The value can be therapeutic, diagnostic, palliative, etc. The 'Reason' doesn't fit in this purpose.	Comment noted, added to backlog. Agree. The scope of Procedure completed is tightly constrained for R1. "Intent" has been added to the backlog.
AUCDI045	When "Description" is added, what difference is there with "Comment"?	Comment noted, no change. Description is a description of the procedure that was done. The comment is defined as additional narrative about the problem or diagnosis not captured in other fields (including the description field).
AUCDI029	Again, this this is redundant in every data group	Comment noted, no change. A comment is a usual pattern at the end of each data group, to allow a single narrative description for information that is not captured in the other structured fields.

## 6.7. Procedure Completed General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>What about partially completed procedures? What about procedures that are commenced and need to be halted/abandoned?</p> <p>Perhaps this group could be called "Procedure". Then, a status can be set to: Completed, Partially Completed, Commenced and halted.</p> <p>Also, is there such a procedure that is overarching other "smaller" procedures. I am not talking about a chain of dependencies necessarily, although that is one way to conceptualize this concept. So perhaps this data group requires a "Dependencies" item which points to other Procedures.</p>	<p>Comment noted, added to backlog. Agree. The scope of Procedure is tightly constrained to "completed" for R1. "Status" has been added to the backlog.</p> <p>Comment noted, no change. For managing complex procedures with multiple sub-procedure that need to be documented, this is out of scope for AUCDI but should be considered as part of a broader strategy for managing documentation.</p>

AUCDI016	Should this object reference the problem/diagnosis object, optionally. It seems that linking the two could be useful, as the latter can be the catalyst for the former.	Comment noted, no change. This may be valid, but implementation is out of scope for AUCDI.
AUCDI027	<p>The current model seems like a good fit for discrete procedures in a world where you don't want any further information about them. It is however a poor fit for cases where you want to track downstream information:</p> <ul style="list-style-type: none"> <li>- E.g. The example list procedures like "taking a blood sample", however, I could not see a way to tie the taking of the rest of the blood sample information (what was done, what were the results, etc). It would be sensible to have id or some kind of linkage information if we wish to record procedures which are steps in a larger process (blood tests, inserting devices that may need to be removed, etc)</li> <li>- It makes it impossible to tie information back to this procedure. E.g. the clinical notes around the procedure, data from the anesthetics machines, etc.</li> </ul>	<p>Comment noted, added to backlog.</p> <p>This data group can be used to record minor procedures if required. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model. Consideration to explore the clinical requirement to be able to link between data groups, where relevant, in a clinical system has been added to the backlog.</p>
AUCDI030	* would like some indication of provenance information - is this a primary record (or copy) of a procedure e.g. performed here, from (discharge) summary OR patient reported as part of a medical history - perhaps this provenance pattern could be applied across all entries	<p>Comment noted, no change.</p> <p>Provenance of data recorded by directly by clinicians should be recorded for every piece of data. When data is moved or transformed into a receiving system, this should be considered by the technical specification. This is currently out of scope for AUCDI.</p>
AUCDI032	<p>Procedure lists could become long and irrelevant if misused to support activity based funding, particularly during a hospital stay. Many procedures will have limited future relevance. Consideration should be given to tagging information occurrences for inclusion in shared clinical records/transfer of care uses.</p> <p>Consideration should be given to a data element where one can write where the procedure was performed (ie, which facility).</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral of implementation strategies and functional workflow and so this is currently out of scope of the data model.</p> <p>Comment noted, added to backlog.</p> <p>Agree. The scope of Procedure completed is tightly constrained for R1. "Location performed" has been added to the backlog.</p>
AUCDI040	<ul style="list-style-type: none"> <li>• Review the placement of information related to supportive care interventions such as exercise and smoking cessation, if they are not to be captured within the 'Procedure completed' data group.</li> </ul>	<p>Comment noted, added to backlog.</p> <p>Information related to supportive care interventions such as exercise and smoking cessation will have their own data group.</p>

	<ul style="list-style-type: none"> <li>Consider how cancer screening data is captured (potentially within the Procedure Completed data element group) Australia has three national population-based cancer screening programs (breast, bowel and cervical), with a fourth targeted program (lung) to be introduced from next year. The purpose of screening an asymptomatic individual is to detect early evidence of an infection or abnormalities (e.g., cervical screening test) or early invasive malignancy (e.g., by mammography) to recommend preventive strategies or treatment that will provide a better health outcome than if the disease were diagnosed at a later stage. Understanding who is participating in these programs and how can inform interventions to increase participation rates and improve outcomes from the programs.</li> <li>Ensure, at a minimum, the following key elements become standard collection items or can be calculated based on available data through AUCDI. There are currently several important data elements for understanding cancer outcomes that are not captured consistently in cancer-related datasets or individual datasets do not capture the items required to calculate the data element. These data include cancer diagnosis (type), treatment received, stage at diagnosis, incidence, mortality, relative survival, cause specific survival, post treatment mortality, comorbidities, other individual risk factors and self-report health data. Some of which are captured within the proposed release 1 data groups however, including specific cancer examples of how data can be captured would strengthen the AUCDI.</li> </ul>	<p>"Cessation" and "Physical activity summary" have been placed on the backlog.</p> <p>Comment noted, added to backlog. Further investigation is required into understanding screening management and how it is recorded. "Screening activity completed" has been placed on the backlog.</p> <p>New content added to reflect comment. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation. Documented updated with specific cancer examples as suggested.</p>
<p>AUCDI041</p>	<p>This feedback has been provided by our team member Rachael who has experience in working with an EMR to develop a master procedure list for surgery across ACT Health. Rachael has not participated in the CDG up to this point. Q5 is a continuation from the Procedure Name section, I couldnt fit it in! Q5. Will it be clear if a surgery was cancelled or abandoned?</p>	<p>Comment noted, added to backlog. Q5. Agree. The scope of Procedure has been tightly constrained to "completed" for R1. "Status" has been added to the backlog.</p>

	<p>In many EMR systems, if a surgery is cancelled the planned procedure, date and time remains, but the case is marked with a status of "cancelled". Similarly, a procedure may commence but for whatever reason (e.g. surgery is more complex than anticipated, patient has an anaphylactic reaction, equipment has failed etc.), the team decides not to proceed and abandons the surgery leaving the case in the EMR but marking it as "abandoned".</p> <p>If there is no "status" field accompanying Procedure Completed, is there a risk that it could appear as though these procedures actually went ahead when looking at the patient's surgical history?</p> <p>General Comment: The challenges of driving functionality such as clinical decision support off Procedure Completed.</p> <p>There are some challenges with the statement in the AUCDI R1 Draft: "It is strongly recommended that 'Procedure name' be coded with a terminology capable of triggering decision support, where possible."</p> <p>As stated in Q4, from experience, typically only the primary/major procedure is captured by clinicians when selecting a procedure from a category list. This means that trying to drive decision support based on all procedures is really challenging.</p> <p>For example, looking at the above gynaecology procedure, if you tried to have a registry/report/decision-support tool looking for "patients that have had a ureteric stent placed in the past 30 days" there is a good chance that you will not capture the above patient as it was coded as "operative laparoscopy".</p> <p>Similarly, procedures that are considered a "given" are typically not documented discretely such as "incision/wound closure" for any invasive procedure, or "placement of indwelling catheter (IDC)" for any caesarean-section patient, so there is also a risk these could be missed. Just something to be aware of!</p>	<p>Comment noted, no change.</p> <p>AUCDI provides the data structure and the terminology value sets, however, there must be other things in place to make it all work e.g., education and training, smart implementations, etc.</p>
--	---	--

AUCDI048	<p>For the Clinical indication data element (not a standalone question in the feedback form), the Considerations section (page 47) states that 'This data element has multiple occurrences to allow the recording of more than one clinical indication per Medication'. It is not clear whether 'medication' is correct as this data element relates to 'Procedure completed'. Also, it's not obvious whether this includes x-rays and other forms of imaging.</p> <p>If the intention is to include all forms of medical imaging, there needs to be a data field for the results/report and ideally critical results could be linked to from the problem/diagnosis summary. If this is used for medical imaging, it would be good to link with the RIS (Radiology Information System) to reduce duplicate examinations, by providing access to the reports of imaging performed at other facilities, and even just flagging that imaging has recently been performed elsewhere.</p> <p>Would it be appropriate to provide a list of potential clinical indications once the procedure type has been selected? AI might be able to assist with this in the future by providing options based on the patient's clinical history.</p> <p>Are there any plans to devise a method of monitoring (within this system) whether a patient has (i) attended for a procedure (ii) if the results of the procedure have been received by the referrer or their substitute (iii) results have been appropriately actioned?</p>	<p>Wording updated to reflect comment. Sentence has been corrected.</p> <p>Comment noted, added to backlog and wording updated to reflect comment. The "Procedure completed" data group does not include x-rays and other forms of imaging. "Imaging completed" has been put on the backlog and the document has been updated for clarity.</p> <p>Comment noted, no change. Results reporting is a detailed and complex domain which may be covered be in future releases of AUCDI.</p> <p>Comment noted, no change. AUCDI will underpin smart implementations such as those described about clinical indications.</p> <p>Comment noted, no change. This is out of scope of AUCDI.</p>
AUCDI045	Date Performed" - is the time of a Procedure relevant?	<p>Wording updated to reflect comment. Agree. Description of Date performed has been updated to 'The date, and optional time, when the procedure was performed.'</p>
AUCDI050	The data elements 'Procedure name', 'Clinical indication' and 'Date performed' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.	Comment noted, no change.
AUCDI034	<p>Page 45 "Recording a procedure completed as part of a Consultation note or Operation note, for example:" Feedback: Add:</p> <ul style="list-style-type: none"> <li>• skin prick test</li> </ul>	<p>New content added to reflect comment. Document updated with example of "skin prick test"</p>



	<ul style="list-style-type: none"> <li>• intradermal test</li> <li>• challenge test (allergy)</li> </ul> <p>Page 45 Concept representation- Procedure completed Practitioner role</p>	<p>Comment noted, no change. The participant information should be managed technically and sit in the technical specifications, and is out of scope of the clinical models in AUCDI as this should be done across all patient data consistently.</p>
--	---	--

## 7. AUCDI R1 Section: Vaccine Name

### 7.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
29	7	3	0	9	4

### 7.2. Vaccine name

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Suggest updating the value set link to point to <a href="https://healthterminologies.gov.au/fhir/ValueSet/australian-vaccine-2">https://healthterminologies.gov.au/fhir/ValueSet/australian-vaccine-2</a> This is a more recent and more specific version.	Wording updated to reflect comment. Agree. This has been updated.
AUCDI031	Unclear whether 'vaccine name' relates to brand name, generic name, or what is being vaccinated against. Brand name and what is being vaccinated against are most important here and need to be 2 separate elements. In addition, to brand name, batch number is a vital recording with any vaccine administered. Batch number is not a 'nice to have' or optional extra, vaccines can't be administered with out batch number being recorded, this section can't be used until in place. In summation, identifiers need to include: 1) What is being vaccinated against 2) Vaccine brand name and paediatric/adult etc 3) Batch number	Comment noted, no change. "Vaccine name" relates to brand name or generic name.  Comment noted, added to backlog. "Target disease" and "Batch number" have been added to the backlog.
AUCDI036	Noted free text entry is available to include novel vaccines which may not be included in the Australian Medicines Terminology or Australian Immunisation Register vaccine codes.	Comment noted, no change. Agree. There are occasions when free text entry is necessary, and this is included in the model.

AUCDI045	Same "Name" issue (see above examples)	Comment noted, no change. The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the vaccine from other related data elements.
AUCDI050	<p>The 'Australian Vaccine' value set seems too broad for vaccine name. The NCTS description says: "The Australian Vaccine value set includes all Australian Medicines Terminology product concepts and Australian Immunisation Register vaccine codes that are available for recording a vaccine product." It doesn't seem necessary to include the Australian Medicines Terminology product concepts in this value set. For example, the value 'Leukoplast (1071) 2.5 cm x 2.5 m tape' doesn't make sense as a vaccine name. The value set may need further refinement to ensure that the scope is appropriate for this data element i.e. excluding all Australian Medicines Terminology product concepts and only including the Australian Immunisation Register vaccine codes. Not constraining the value set could impact the data quality by allowing for selection of inappropriate values. The 'Australian Vaccine' value set is very granular with 151,248 values. In comparison, the 'Vaccine' reference set (<a href="https://www.healthterminologies.gov.au/integration/R4/fhir/ValueSet/sctau-reference-set-1156291000168106">https://www.healthterminologies.gov.au/integration/R4/fhir/ValueSet/sctau-reference-set-1156291000168106</a>) is much less granular, with only 2,131 values. Is there a reason why the 'Vaccine' reference set is not being suggested for use?</p>	<p>Wording updated to reflect comment.          Agree. This has been updated to the specific AMT vaccine value set which is aligned to your suggestion.</p>
AUCDI032	<p>The 7.4.4 detail should reference the Australian Immunisation Handbook, not the RACGP's Guidelines for preventive activities in general practice (Red book).</p> <p>A further use-scenario for vaccine data standards is to support real-time computer decision support in the forms of prompts.</p>	<p>Wording updated to reflect comment. Agree. Updated document to the Australian Immunisation Handbook and for decision support for real-time prompts</p>

### 7.3. Sequence

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>Is this important in any scenario? If so, consider making it mandatory.</p> <p>Examples: First, Second, Third, '2,' or '2 of 3'.            - Recommend forcing consistency here. Better to just have 1 of 1.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>The technical representation is out of scope for AUCDI, and it would be expected be included in technical standards such as a FHIR IG, however there is a need to support text and numeric for this data element and any decisions to enforce representation should not break existing implementations.</p>
AUCDI010	<p>Capturing the sequence number is only required for immunisations which are going to be transmitted to the AIR. Most systems will have a immunisation history function, and that data could be exposed via AUCDI and I would not expect a clinician to enter in a sequence number for an administration that they are documenting historically. I note that the field is optional, but that it could be an implementation issue in the future.</p>	<p>Comment noted, no change.</p> <p>This data element is optional. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element.</p>
AUCDI036	<p>Noted the coding system is in development (p52). Rather than allowing both numeric and text values as per the example, suggest just allow numeric entry for consistency.</p>	<p>Comment noted, no change.</p> <p>The technical representation is out of scope for AUCDI, and it would be expected be included in technical standards such as a FHIR IG, however, there is a need to support text and numeric for this data element and any decisions to enforce representation should not break existing implementations.</p>

AUCDI045	“Sequence” - How are the vaccinations grouped to enable this feature? It will need a “structure” to support the vaccination series	Comment noted, no change. This data group supports the recording of the vaccine administration. Grouping is an implementation issue that is out of scope for AUCDI.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.
AUCDI032	If entering this retrospectively, there should be facility to allow entry if sequence unknown.	Comment noted, no change. Sequence is optional.

#### 7.4. Date of Administration

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI032	If entering retrospectively, needs to allow entry if date unknown and also needs to allow entry of just year or just month and year.	Wording updated to reflect comment. Date of administration is optional and allows partial date. Document has been updated for clarity.
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>It is recommended that DDMMYYYY format is utilised for complete dates e.g. "14012024" rather than "14 January, 2024" (one of the examples listed). DDMMYYYY is the format commonly used within METEOR.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>The technical date representation is out of scope for AUCDI, and it would be expected be included in technical standards such as a FHIR IG. Rendering of dateTime is an implementation decision and is also out of scope for AUCDI.</p>

AUCDI049	<p>7.4. Vaccination administered event                  The date of administration appears to only be a date not a date/time. It would be useful to have this as a date/time element and allow minimum of a date.</p>	<p>Wording updated to reflect comment.                  Agree. This has been updated in the document.</p>
----------	---	---

**7.5. Vaccine Administered Event Comment**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI023	<p>The example 38598009   MMR Vaccination  is a part of the procedure hierarchy and as far as I can see not included within the Australian Vaccine Value set provided by NCTS. Either the valueset or the understanding of its use may need revision</p>	<p>Wording updated to reflect comment.                  Agree. 38598009   MMR Vaccination  is out of scope of the value set and is not a valid example. This has been updated in the document.</p>
AUCDI029	<p>Again, take this as given as we would patient</p>	<p>Comment noted, no change.                  A comment is a usual pattern at the end of each data group, to allow a single narrative description for information that is not captured in the other structured fields.</p>

## 7.6. Vaccine Administered Event General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>Semantically a Vaccination is Procedure. Will there be a "Procedure" that links to a Vaccination? I think there should be.</p> <p>Consider adding a data element to capture complications from taking the vaccine. Unless it is intended to capture that elsewhere, in which case the other item must link back to this Vaccine data.</p>	<p>Comment noted, no change.</p> <p>This is an equivalent data group to a procedure for a common specific purpose. An implementation may link it to a Procedure, but this could be considered duplication.</p> <p>Adverse reactions/complications can be captured in the 'Manifestation' data element - this will become clearer as the 'Adverse reaction risk summary data group' is extended in future releases.</p>
AUCDI014	<p>Body site and route should be prioritised for round 2 to help with things like vaccine reactions.</p>	<p>Comment noted, added to backlog.</p> <p>Agree. "Route" and "Body site" have been added to the backlog.</p>
AUCDI023	<p>General question, the NCTS Australian vaccine valueset contains &gt; 1 code which can be used for the same product (SNOMED code and AIR code). Should the guidance state that it is preferred that both are made available? Or is this out of the scope of the documentation?</p>	<p>Comment noted, no change.</p> <p>This value set is a NCTS value set that contains both AMT and AIR to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. This data set may be where AMT codes are not available and only AIR codes are available and vice versa. It is out of scope of AUCDI to choose a preference however, where the clinical context or use case requires it, a specific IG specification or vendor implementation may specify constrained subsets of the value set to only include AIR codes, or AMT codes for example.</p>
AUCDI031	<p>as per 18 previous:</p> <p>In summation, identifiers need to include:</p> <ol style="list-style-type: none"> <li>1) What is being vaccinated against</li> <li>2) Vaccine brand name and paediatric/adult etc</li> <li>3) Batch number</li> </ol>	<p>Comment noted, added to backlog.</p> <p>"Target disease" and "Batch number" have been added to the backlog.</p>
AUCDI032	<p>Should include missing data element for location of vaccination/body site.</p>	<p>Comment noted, added to backlog.</p> <p>"Body site" has been added to the backlog.</p>

AUCDI049	<p>Future considerations for 7.4.5: Support for inclusion of data elements, such as the vaccine serial ID, that would support future use cases for product traceability through the supply chain. Consideration should also be given to use of international standards (e.g. GS1 GTINs for serialised medicines as outlined in TGA's Standard for serialisation and data matrix codes on medicines) to support this type of use case.</p> <p>7.4.5. For future consideration - Batch number While we note that batch number is a candidate for release 2, can we request consideration for its inclusion in release 1, given that tracking batch numbers can be critical if there is a quality issue. This would also support streamlined sharing with the Australian Immunisation Register.</p>	<p>Comment noted, added to backlog. "Vaccine serial ID" and "Batch number" have been added to the backlog.</p>
AUCDI050	<p>The data elements 'Vaccine name', 'Sequence number' and 'Date of administration' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.</p> <p>The AIHW considers pregnancy status to be an important consideration for vaccinations. Given this is a foundational data element, it is recommended that pregnancy status is included in AUCDI rather than AUeReqDI.</p>	<p>Comment noted, added to backlog. Agree. "Pregnancy status" is in the AUCDI backlog.</p>
AUCDI051	<p>Why does the Australian vaccine value set include both AMT AND AIR vaccine codes? Surely this will cause misunderstandings? Surely its better to use SNOMED/AMT like other medication administrations? "1640431000168105 - Comirnaty Original/Omicron BA.1 Multidose injection, 2.25 mL vial" (SNOMED) seems better than "COMIRN - Pfizer Comirnaty" (Services Australia AIR Vaccine codes)</p> <p>One other problem I've had working with AIR data in the past is Antigen. There doesn't seem to be an elegant way in SNOMED to link a vaccine (AMT trade product) with the antigens (disorders) it</p>	<p>Comment noted, no change. This value set is a NCTS value set that contains both AMT and AIR to support reuse across multiple use cases and support the breadth of the ecosystem to enable interoperability. This data set may be where AMT codes are not available and only AIR codes are available and vice versa. It is out of scope of AUCDI to choose a preference, however, where the clinical context or use case requires it, a specific IG specification or vendor implementation may specify constrained subsets of the value set to only include AIR codes, or AMT codes for example.</p>



	<p>targets. This is important since without an encyclopaedic knowledge of all vaccines, its hard to know that Infanrix hexa targets and protects against the following antigens; Diphtheria, tetanus, pertussis, hep b, poliomyelitis, and hib sched a. FHIR immunization resource supports a protocolApplied.targetDisease field that would be ideal to support this requirement for AIR. This would be good to standardise immunisation reporting regardless of whether it was driven via vaccine-specific, or antigen-specific (like COVID) initiatives.</p>	<p>Comment noted, added to backlog. 'Target disease' has been added to the backlog.</p>
AUCDI035	<p>Agree recording of batch number is a valuable addition to this information.</p> <p>Batch number alone is not enough to help identify the product. The unique identifier of the product as assigned by the manufacturer needs to be considered in this scenario to enable traceability of the product through to the patient.</p>	<p>Comment noted, added to backlog. "Vaccine serial ID" and "Batch number" have been added to the backlog.</p>

## 8. AUCDI R1 Section: Tobacco Smoking Summary

### 8.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
27	5	5	0	11	4

### 8.2. Overall Status

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. Would not be a valid summary without the status. Considerations states "Occasional smoker" is a future consideration, however, it is already included in the recommended value set. If this contradicts the separation of frequency and status a new value set is required.	Comment noted, no change. This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.  Comment noted, added to backlog. Occasional smoker (and regular smoker) refers to "frequency" and not just status. Frequency has been added to the backlog.
AUCDI036	Noted current release includes capture of overall smoking status only with plans for future releases to capture further information on the frequency and amount of tobacco smoked.	Comment noted, added to backlog. Agree. "Frequency" and "Amount of tobacco smoked" have been added to the backlog.
AUCDI039	Cancer Australia notes the inclusion of 'Overall pack years' under the tobacco smoking summary mind map (Figure 20, p. 60) and supports this inclusion. The National Lung Cancer Screening Program (NLCS) will include eligible participants who have a smoking history (30 pack years for current smoker and within 10 years since quitting for former smokers) and are aged between 50-70 years, as recommended by the Medical Services Advisory Committee (MSAC). Pack-years are calculated by multiplying the number of years smoked with the average number of cigarettes smoked per day, based on the National Lung Screening Trial (NLST) criteria.	Comment noted, added to backlog. Agree. "Overall pack years" has been added to the backlog.

	<p>We suggest including pack-years as a value set in the data elements for tobacco smoking. Pack year calculation provides a greater level of understanding of an individual's current behaviour of tobacco smoking and risk for diseases such as lung cancer.</p> <p>As the NLCSF will include pack-years calculator to determine eligibility, it will be beneficial for the AUCDI to also capture this data.</p>	
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p>	<p>Comment noted, no change.</p> <p>This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.</p>
AUCDI035	<p>I believe vaping of tobacco products needs to be captured - there are interacting with medication where tobacco cigarette smoking interacts eg. CLOZAPINE but nicotine vaping does not interact. If we are only capturing cigarette smoking this needs to be defined but then how does one capture nicotine vaping - will it be within the comments section?</p>	<p>Comment noted, added to backlog.</p> <p>Agree. "Vaping summary" will be a new data group and has been added to the backlog.</p>

### 8.3. Tobacco Smoking Summary General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI014	<p>What is the rationale for excluding all other lifestyle risk factors (e.g. alcohol consumption) from AUCDI. More history required to make the 'overall status' clinically significant or the data could be misleading. i.e. an 'Ex Smoker' who quit smoking yesterday is still at higher risk than a 'current smoker' who only smokes 1-2 cigarettes per weekend.</p>	<p>Comment noted, no change.</p> <p>Alcohol and other health risk factors will be addressed in future releases of AUCDI. "Alcohol consumption summary" will be a new data group and has been added to the backlog. We welcome additional health risk factor suggestions.</p> <p>Comment noted, added to backlog.</p> <p>'Frequency' and 'Quit date' have been added to the backlog.</p>
AUCDI027	<p>This seems like a poor choice for making a "special category". It is likely that going forwards in time we would want to capture usage data of any number of "substances of interest". These could be tobacco, alcohol, recreational drugs, risky behaviors, etc. Changing</p>	<p>Comment noted, added to backlog.</p> <p>Tobacco use and Alcohol use have specific data requirements due to their associated unique health risks. Generic "Substance use summary" has been added to the backlog for other substances.</p>

	this from "tobacco use" to "Behavior of interest" and adding a "behavior" field (which would take "tobacco use" as a value to mimic this concept), would make this immediately re-usable for a whole class of data without compromising its utility for tobacco.	
AUCDI029	Why would this not allow for a comment?	Comment noted, added to backlog. When the group is extended, Comment will be a natural extension. "Comment" has been added to the backlog.
AUCDI030	* last date of assessment/confirmation is very important in deciding if this information needs to be checked for decision making	New content added to reflect comment. Agree. Last updated has been added to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.
AUCDI031	Consider how tobacco smoking will be updated once evidence is available for vaping and whether cigarette smoking and electronic device smoking will be conflated into 1 category or distinguished by 2 separate categories. Is there capacity for electronic device smoking to be enabled as a treatment?	Comment noted, added to backlog. Agree. "Vaping summary" will be a new data group and has been added to the backlog.  Comment noted, added to backlog. "Cigarette smoking" has been added to the backlog as an extension to the "Tobacco smoking summary" data group.
AUCDI032	There is a future suggestion to increase level of detail about tobacco smoke exposure for patients. This needs to be done ASAP to support the rollout of lung cancer screening. Lung cancer screening is offered to patients based on risk calculation including an estimate of tobacco smoke exposure rather than just single-point-in-time smoking status. Need to consider inclusion of number of cigarettes (or packs) per day and quit date.	Comment noted, added to backlog. Agree. "Overall pack years" and "Quit date" have been added to the backlog.
AUCDI033	We recommend adding references to HL7 International FHIR standards and the International Patient Summary in section 7.5.4, Table 19 - Aligns and leverages international standards and initiatives. The proposed addition will help align the Tobacco Smoking data concept with international standards.	Wording updated and new content added to reflect comment. Document has been updated with relevant references from US Core and Vital signs IGs.

AUCDI036	<p>This section states “The clinical concept has been limited to an overview of tobacco smoking behaviour to support potential tobacco smoking behaviour change interventions.”</p> <ul style="list-style-type: none"> <li>- Vaping has been identified as a serious public health issue. The Government currently implementing a suite of policy reforms to address the issue, including behaviour change interventions.</li> <li>- Suggestion: Vaping should be added to the R1 scope, either as a standalone data group, or as a component of the “Tobacco smoking summary” data group</li> </ul> <p>Including the potential candidates for future data elements noted on page 59 in Release 2 in relation to collecting details on the amount used, patterns and previous episodes of use and data entry date to assess the currency of the information is supported.</p>	<p>Comment noted, added to backlog. Agree. "Vaping summary" will be a new data group and has been added to the backlog.</p> <p>Comment noted, added to backlog. Agree. "Amount", "Pattern" and "Previous episodes of use" have been added to the backlog.</p>
AUCDI039	<p>Cancer Australia would welcome the opportunity to collaborate with this initiative to advise on cancer related applications related to the National Lung Cancer Screening Program.</p>	<p>Sparked is an open, collaborative community and welcomes Cancer Australia joining the community and contributing.</p>
AUCDI050	<p>The data element ‘Overall status’ aligns to a data element within the AIHW’s data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.</p> <p>The context section says “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.” The AIHW recommends inclusion of a vaping data group in a later release, as the current implementation of this field would result in no tobacco smoking status being recorded for a significant number of clients who use vaping. The National Drug Strategy Household Survey 2022-2023 estimated that more people are using e-cigarettes in Australia. In 2022–2023, 15% of people aged 14 and over reported regularly smoking and/or vaping. Almost one-third of these people reported only vaping (see Table 3.41 of</p>	<p>Comment noted, added to backlog. Agree. "Vaping summary" will be a new data group and has been added to the backlog.</p> <p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p> <p>New content added to reflect content. Last updated has been added to AUCDI R1.</p>

	<p><a href="https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/data">https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/data</a>).</p> <p>Stakeholder feedback on the draft data model for the AIHW's National Primary Health Care Data Collection indicated interest in vaping. Feedback received from PHN stakeholders on the PIPQI national report also highlighted the importance of collecting information on vaping in the future.</p> <p>Based on our learnings from the analysis and reporting of PIPQI data, it will be important to ensure that this field can capture instances where the smoking status is unchanged from the previously recorded smoking status (e.g. where a client that has been a non-smoker at their past two visits). We have learnt from discussions with clinical information software and extraction tool providers that differences in the implementation of this field by individual clinical software providers means that clients with an unchanged smoking status may not be captured if the CIS doesn't have the functionality for a GP to indicate that the smoking status is unchanged from an earlier visit. Where this functionality is available, it requires manual input from GPs to indicate that the status was unchanged, and GPs may not do so for clients with an enduring smoking status.</p> <p>The proposed roadmap for developing the 'Tobacco Smoking Summary' data group suggests including the 'last updated' field for tobacco smoking summary in Release 2. AIHW recommends incorporating this field in Release 1 to improve the context and utilisation of PIPQI data.</p>	
AUCDI051	<p>Interested to know if the recommended NCTS smoking status value set is modern? I've seen SNOMED codes for tobacco chewing, smokeless tobacco, hookah pipe, cigar smoking, pipe smoking etc. also electronic cigarettes, vaping aerosols.</p>	<p>Comment noted, added to backlog.</p> <p>While there are many codes to describe types of smoking, frequency and whether a smoker is a light or heavy smoker, these codes would not be expected to be included in a Smoking status field. It would be expected that this information would go in to</p>

	<p>Also an observation of the US valueset (and LOINC for that matter), they have a lot more codes available to differentiate between heavy and light smokers (past and present). I would think these fields about smoking frequency would have clinical implications. In fact the IG cited in the "Aligns and leverages international standards and initiatives" section (<a href="https://build.xir.org/ig/HL7/xir-ips/StructureDefiniWon-ObservaWon-tobaccouse-uv-ips.html">https://build.xir.org/ig/HL7/xir-ips/StructureDefiniWon-ObservaWon-tobaccouse-uv-ips.html</a>) has a required binding to a more comprehensive value set.</p>	<p>different data elements in this data group such as Smoking "Type", "Pack years", and "Typical use". These have been added to the backlog.</p>
AUCDI052	<p>Data group "Tobacco smoking summary" does not include vaping, but vaping specific data group is not in release 1 or indicated for future release. From a surveillance perspective, this information is often collated and collected at the same time point (e.g. enhanced case questionnaire). We would recommend this as a future consideration/future release given the rapid movement in this space for public health intervention, and the need to consistently measure behaviour and activity.</p>	<p>Comment noted, added to backlog. Agreed. "Vaping summary" will be a new data group and has been added to the backlog.</p>
AUCDI035	<p>Tobacco implies only smoking of tobacco which would preclude vaping, marijuana etc which are all associated with increased cardiovascular or respiratory risk. So elimination of specific reference to tobacco would prompt reference to smoking or inhalation of other substances.</p> <p>Ideally need years of smoking a sa minimum - ie date started (and date stopped if applicable)</p>	<p>Comment noted, added to backlog. "Vaping summary" will be a new data group and has been added to the backlog.</p> <p>Comment noted, added to backlog. "Overall years of smoking", "Regular smoking started", "Daily smoking started" and "Quit date" have been added to the backlog</p>

## 9. AUCDI R1 Section: Measurements and Vital Signs

### 9.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
22	11	5	0	9	5

### 9.2. Blood Pressure: Systolic Pressure

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. A blood pressure measurement would not be a valid without the actual measurement. Unless a blood pressure measurement is valid with either a systolic or a diastolic measure only. If that's the intention it might be helpful to describe this.	Comment noted, no change. This data element is optional. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. A blood pressure could be mean arterial pressure (rather than a systolic/diastolic reading).  In common use cases e.g. FHIR IGs, this will likely be made mandatory, just not for AUCDI.
AUCDI009	incomplete word - consultation?	Typographical error corrected. Thank you. Sentence completed.
AUCDI017	This may have been written somewhere but in an acute hospital setting BP and other observations may be taken many many times a day. I assume this would all still come across and be meaningful.	Comment noted, no change. Agree. The model caters for this.
AUCDI019	Systolic presure description appears to be missing text	Typographical error corrected. Thank you. Sentence completed.
AUCDI032	Consider inclusion of description of position taken (Lying / Seated / Standing).	Comment noted, added to backlog. Agree. "Position" has been added to the backlog.
AUCDI045	Systolic Pressure" - definition is incomplete	Typographical error corrected. Thank you. Sentence completed.



<p>AUCDI050</p>	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p>	<p>Comment noted, no change.                  This data element is optional. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. A blood pressure could be mean arterial pressure (rather than a systolic/diastolic reading).</p> <p>In common use cases e.g. FHIR IGs, this will likely be made mandatory, just not for AUCDI.</p>
<p>AUCDI035</p>	<p>Consider optional rather than mandatory site of reading eg arm, non invasive, invasive These are standard data elements in all EMRs in acute care. Also ensure entry can be systolic only as some systems require both systolic and diastolic to complete entry</p>	<p>Comment noted, no change.                  The data elements in this data group are currently optional. In common use cases e.g. FHIR IGs, systolic measurement will likely be made mandatory, just not for AUCDI</p> <p>Comment noted, added to backlog.                  "Location of measurement" and "Method" have been added to the backlog.</p>

### 9.3. Blood Pressure: Diastolic Pressure

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	<p>Occurrence is optional, suggest it is mandatory. A blood pressure measurement would not be a valid without the actual measurement. Unless a blood pressure measurement is valid with either a systolic or a diastolic measure only. If that's the intention it might be helpful to describe this.</p>	<p>Comment noted, no change. This data element is optional. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. A blood pressure could be mean arterial pressure (rather than a systolic/diastolic reading).  A valid blood pressure may be a systolic measurement only.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p>	<p>Comment noted, no change. This data element is optional. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. A blood pressure could be mean arterial pressure (rather than a systolic/diastolic reading).  In common use cases e.g. FHIR IGs, this will likely be made mandatory, just not for AUCDI.</p>
AUCDI031	<p>In order for blood pressure to have relevance to the Aus CVD Risk calculator, there needs to be 3 other representations:</p> <ol style="list-style-type: none"> <li>1) Ability to record a minimum of 2 readings - a clinically relevant blood pressure reading is usually the average of the 2 most recent readings within the last 6 months</li> <li>2) Ability to record what date readings were taken on - a clinically relevant blood pressure reading is usually the average of the 2 most recent readings within the last 6 months</li> </ol>	<p>Comment noted, no change. The current data model supports collection of multiple readings.  Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p>

	<p>3) Ability to record how blood pressure was measured - seated or ambulatory blood pressures are different and context needs to be provided so clinical judgement can be applied.</p> <p>If the 3 above contexts cannot be provided, then the concept will be irrelevant to the Aus CVD Risk calculator. Either CIS will need to provide a bespoke mapping, or this very much measured variable in the calculator will be a manual input. Either situation undermines the applicability of interoperability.</p> <p>Including these in a later release will be too late for the calculator as it is scheduled to have its implementation guide devised. The burden of unpicking this may be too high a barrier for all involved.</p>	<p>Comment noted, added to backlog. "Position" has been added to the backlog.</p>
--	--	---

#### 9.4. Blood Pressure: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	<p>1. The purpose is stated as recording details of a single recording in addition to associated parameters, which I interpret as data related to the recording such as date and time of the recording. There are no data elements either in R1 or proposed for the future that cover the requirement of specifying the date and time at which the measurement was made.</p> <p>2. There are no data elements to describe the body site - for example, different BP measurements in right and left arms can be a sign of a dissecting aortic aneurysm.</p>	<p>1. Wording updated, and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p> <p>2. Comment noted, added to backlog. "Location of measurement" has been added to the backlog</p>
AUCDI004	Missing measurement date/time	<p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p>
AUCDI009	<p>In section 7.6.1.4, Other standards:</p>	<p>New content added to reflect comment. Thank you. Added to document.</p>

	<p><a href="https://www.safetyandquality.gov.au/our-work/recognising-and-responding-deterioration/recognising-and-responding-acute-physiological-deterioration/national-consensus-statement-essential-elements-recognising-and-responding-acute-physiological-deterioration">https://www.safetyandquality.gov.au/our-work/recognising-and-responding-deterioration/recognising-and-responding-acute-physiological-deterioration/national-consensus-statement-essential-elements-recognising-and-responding-acute-physiological-deterioration</a></p> <p><a href="https://www.safetyandquality.gov.au/publications-and-resources/resource-library/adult-deterioration-detection-system-adds-chart-blood-pressure-table">https://www.safetyandquality.gov.au/publications-and-resources/resource-library/adult-deterioration-detection-system-adds-chart-blood-pressure-table</a></p> <p>Reuse in Observation and Response charts for time series views and Adult Deterioration Detection Systems (ADDs).</p>	
AUCDI014	<p>Site and body position are necessary to accurately interpret and compare BP readings. These attributes should be included in the model. Standing/sitting position provides important context.</p>	<p>Comment noted, added to backlog. Agree. "Location of measurement" and "Position" have been added to the backlog.</p>
AUCDI026	<p>BP is only systolic and diastolic values and does not include data elements for posture or method of measurement, even though these are well developed in OpenEHR</p>	<p>Comment noted, added to backlog. Agree. "Location of measurement" and "Method" have been added to the backlog.</p>
AUCDI027	<p>In general I think having specific elements for vital signs is not a good design decision. There are many vital signs, and they should not be added case by case like this. As for tobacco it would be cleaner to create a vital sign grouping which a field for type of measurement (blood pressure, pulse rate) alongside a recording of the result.</p> <p>Also, fast changing vital signs should have a data. Blood pressure changes over time, and the age of a value is important in decision making. Also, the history of how it evolves can be more important than the actual measurements themselves.</p>	<p>New content added to reflect comment. This has been added to the document for clarity - Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.</p>

		Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI032	The distinction made between pulse rate and something labelled in the notes as 'heartbeat' is unclear. Electrical waveform recordings could certainly give a heart rate that is disassociated with pulse, but this is rare. Revised terminology should be considered, eg "Misuse: recording the rate of electrical activity of the heart instead of pressure waves generated from physical beating of the heart".	Comment noted, no change. The proposed revision is too specific and excludes measurement of heart rate by auscultation and palpation.
AUCDI048	Consider extending 7.6 Measurements and Vital Signs to include Blood Glucose Level and Continuous measures of vital parameters (e.g. oxygen saturation, ECG). At 7.6.1.2 Concept representation – Blood Pressure, consider adding missing values mean arterial pressure (available in Figure 22) and shock index.	Comment noted, added to backlog. Agree. "Blood glucose level", "ECG", "Oxygen saturation" and "Shock index" are new data groups and have been added to the backlog. "Mean arterial pressure" has been added to the backlog.
AUCDI033	Section 7.6.1.3 contains an incomplete description.	Typographical error corrected. Thank you. Sentence completed.

## 9.5. Pulse Information: Rate

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. A measurement would not be a valid without the actual measurement.	Comment noted, no change. This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.
AUCDI035	pg. 65 - 7.6.2.1 Context. Considerations for Use: The measured rate can be recorded using a device. It is unclear why this is a consideration. Pulse if often measured manually (and is considered	Comment noted, added to backlog. pg. 65 - 7.6.2.1 Context. Considerations for Use: The measured rate can be recorded using a device. - This statement allows for where

	<p>best practice). It does not require a device to measure. pg. 65 - 7.6.2.1 Context. Misuse: Not to be used to record information about the heartbeat including heart rate which should only be recorded at the heart. An interesting note. However, it is worth acknowledging that pulse and heart rate are often used interchangeably in clinical practice. Definitions vary. 'Apical pulse' can be considered a heartrate measured at the heart - yet it retains use of the term 'pulse'. 'Peripheral pulse' is perhaps what this document is trying to differentiate. Heartbeat information - It may also be useful to provide further clarifying examples on what this comprises i.e. cardiac rhythm.</p>	<p>devices such as a pulse oximeter are used. It does not preclude manual measurement. "Method" has been added to the backlog.</p> <p>Wording updated to reflect comment.</p> <p>pg. 65 - 7.6.2.1 Context. Misuse: Not to be used to record information about the heartbeat including heart rate which should only be recorded at the heart. - agree distinguishing between heartbeat and pulse is a complex area and used variably in clinical practice. Thank you for your feedback. We have updated the document to take your concerns into account and to add clarity.</p>
--	---	--

### 9.6. Pulse Information: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	There is no data element representing date-time of the measurement. "Any event" should have associated with it the date-time of the event.	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI004	Missing measurement date/time	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI014	Regularity should be prioritised.	Comment noted, added to backlog. "Regularity" has been added to the backlog.
AUCDI026	Rhythm as well as rate for pulse. Rhythm is often more relevant than rate.	Comment noted, added to backlog. "Rhythm" has been added to the backlog.
AUCDI029	It needs a location where the pulse was taken.	Comment noted, added to backlog. "Body site" has been added to the backlog.
AUCDI032	Consider rhythm.	Comment noted, added to backlog. "Rhythm" has been added to the backlog.

<p>AUCDI035</p>	<p>Need rhythm as well</p> <p>The sentence for 'Misuse' doesn't make any sense. It is ridiculous to have such high level information for blood pressure and respiration but separate pulse and heart rate at this point for R1. (cardiothoracic RN here). Pulse is heart rate in most clinical contexts by the majority of those performing vital signs screening and recording vital signs. In critical care environments the distinction becomes relevant. eg I took her pulse and it was 120. Characteristics such as thready, irregular are to be included in r2.</p> <p>There has been a lot of discussion regarding Pulse rate and the differences to Heart rate as the heart can be beating but the Pulse may not be present at a specific site. Clinical folks have made it clear that there is a need for Pulse rate and information. It is also noted that the current FHIR standard and LOINC may not be appropriate for our requirements and if this is the case then submissions should be made to the relevant standards bodies by the Agency to resolve any gaps.</p>	<p>Comment noted, added to backlog. "Rhythm" has been added to the backlog.</p> <p>Comment noted, added to backlog. While pulse and heart rate in some clinical contexts are used interchangeably, there is a distinction as has been noted. "Heart beat" has been added as a new group to the backlog.</p> <p>Comment noted.</p>
-----------------	--	---

**9.7. Body Temperature: Temperature**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI035	Need to be able to confirm body site eg oral, tympanic as there is significant difference in measurement parameters	Comment noted, added to backlog. "Location of measurement" has been added to the backlog.

### 9.8. Body Temperature: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	<p>1. There is no data element representing date-time of the measurement. "Any event" should have associated with it the date-time of the event. This is important for temperature (and any measurement) so the relevance can be assessed, and patterns identified in conjunction with other measurements occurring at different times (e.g. spiking temperature).</p> <p>2. Body Site needs to be included as a data element as body temperature can vary depending on the site.</p>	<p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p> <p>Comment noted, added to backlog. "Location of measurement" has been added to the backlog.</p>
AUCDI011	<p>Comment and/or Location of measurement should be considered for AUCDI Release 2 aligning with the openEHR 'Body temperature' archetype</p>	<p>Comment noted, added to backlog. "Location of measurement" and "Comment" have been added to the backlog.</p>
AUCDI027	<p>As above, it would be nice to unify vital signs and add a datetime. Unifying vital signs in this case would also make it easier to record different types of temperature measurement.</p>	<p>Wording updated and new content added to reflect comment. This has been added to the document for clarity - "Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the "For future consideration" section for each data group."</p> <p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p>



AUCDI029	Hard to see this as providing value without some context of where temp was taken. Should all these require commentary so you could at least recognise that such is needed?	Comment noted, added to backlog. "Location of measurement" and "Comment" have been added to the backlog.
AUCDI032	Consider including detail of method of recording temperature - eg, Tympanic / Temporal artery / Skin / Oral.	Comment noted, added to backlog. "Location of measurement" has been added to the backlog.
AUCDI033	Section 7.6.3.4 contains an incomplete description.	Further clarification required. Unable to find incomplete description.
AUCDI035	Need to be able to confirm body site eg oral, tympanic as there is significant difference in measurement parameters	Comment noted, added to backlog. "Location of measurement" has been added to the backlog.

### 9.9. Respiration Information: Rate

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.
AUCDI006	Occurrence is optional, suggest it is mandatory. A measurement would not be a valid without the actual measurement.	Comment noted, no change. This is currently optional and whether this should become mandatory or not will become clearer as the data group is extended in R2.

**9.10. Respiration Information: General Feedback**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	Requires a date-time of measurement as does "Any Event"	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI027	As above, it would be nice to unify vital signs and add a datetime. It would also be good to add to the future path information on how this is captured. E.g. data coming from a patient on a ventilator is a bit different from that recorded by hand (not in terms of accuracy, but in what the story that is actually happening is)	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary  Comment noted, added to backlog. "Location of measurement" has been added to the backlog.

**9.11. Body Height: Height/Length**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI019	Suggest that this is linked into work of ADHA on Pregnancy and Children's Digital Health Record  Remove the comma in Data Group Alias"	Comment noted, no change. Agree. Sparked is working closely with ADHA as one of its partners  Typographical error corrected. Agree. Comma has been removed.
AUCDI045	"Height /Length" data element - choose one or the other (aka ISO11179 principles)	Comment noted, no change. Both are valid options depending on the context. AUCDI has chosen to provide both.
AUCDI049	7.6.5.3 Height Should specify whether this be a whole number or allow a decimal place?	Comment noted, no change. This is not constrained in AUCDI to allow use cases to constrain to the level of precision needed.

AUCDI035	Length an unclear descriptor and what unit Height should be recorded in i.e. metres versus centimetres	Wording updated and new content added to reflect comment. The document has been updated to "The measured distance from the crown of the head to the sole of the foot."  Centimetres has been specified.
----------	--	--

### 9.12. Body Height: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	Requires a date-time of measurement as does "Any Event"	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI011	Height does not mention "Supports collection of data for Practice Incentives Program Quality Improvement Measures - Proportion of patients with a weight classification". Height is necessary under section 4.3 to calculate BMI. <a href="https://www.health.gov.au/sites/default/files/2022-12/practice-incentives-program-quality-improvement-incentive-quality-improvement-measures-user-guide-for-primary-health-networks_0.pdf">https://www.health.gov.au/sites/default/files/2022-12/practice-incentives-program-quality-improvement-incentive-quality-improvement-measures-user-guide-for-primary-health-networks_0.pdf</a>	Wording updated and new content added to reflect comment. Agree. Document updated.
AUCDI027	As above, it would be nice to unify vital signs and add a datetime. Given the attempt to track birth data, it is clear that this is trying to account for growth over time. However, without a datetime it only covers birth and adulthood (where height is more constant). This does not seem like it will work for pediatrics where height is regularly changing (and may be monitored closely as in some small children).	Wording updated and new content added to reflect comment. This has been added to the document for clarity - Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These

		<p>additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.</p> <p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p>
--	--	---

**9.13. Body Weight: Body Weight**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI014	Suggest to keep is as just 'kg' instead of having the option for 'g' as well. 'kg' with 2 decimal points is useful for newborns and having additional unit may be confusing	Comment noted, no change. This is not constrained in AUCDI to allow use cases to constrain to the unit needed.
AUCDI049	Weight How may decimal places will be supported?	Comment noted, no change. This is not constrained in AUCDI to allow use cases to constrain to the level of precision needed.
AUCDI027	Units should not be part of the weight field. They should be stored as a separate entry. Adding the unit to the field makes it a mixed type (numeric and text) and keeping the weight implicit makes it hard to read the data without the spec sheet.	Comment noted, no change. The AUCDI defines the information model. It does not define the database structure that information is stored in.

### 9.14. Body Weight: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	Requires a date-time of measurement as does "Any Event"	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.
AUCDI020	date needs to be included and we note that this might be covered by the FHIR implementation guide if the data has a timestamp instead of an element here	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.
AUCDI027	As above, it would be nice to unify vital signs and add a datetime. Without weight over time even simple things like growth of children, outcomes from bariatric surgery, or weight control drugs cannot be explored.	<p>Wording updated and new content added to reflect comment. This has been added to the document for clarity - Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.</p> <p>Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p>
AUCDI032	Might also be useful to consider method of weighing, eg Baby scales / Standing scales / Seated scales (as in hospitals).	Comment noted, added to backlog. "Device" has been added to the backlog

AUCDI035	consider criticality of calculated weights for dosing (all ages) but particularly neonates	Comment noted, added to backlog. 'Calculated weight' has been added to the backlog
----------	--	---

### 9.15. Waist Circumference: Waist Circumference

No feedback received on this data group.

### 9.16. Waist Circumference: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	Requires a date-time of measurement as does "Any Event"	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI035	Unit of measurement should be standardised	Comment noted, no change. This is not constrained in AUCDI to allow use cases to constrain to the unit needed.

### 9.17. Measurements and Vital Signs: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	All require a date-time of measurement.	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI004	Need measurement date/time.	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary

AUCDI006	I didn't see a performed date or observation date for these measurements. I think probably all of them are not very useful without a date. Required to consecutively order measurements for trending and to identify the latest. If there is other observation event data specified that is common to all of these it wasn't clear to me.	Wording updated and new comment added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI013	Suggest that the codeable concept for each vital sign be included as a part of the information model (as well as the appropriate quantity measure).	Comment noted, added to backlog. Coding of data groups (including data elements) has been placed in the backlog for consideration.
AUCDI019	Will date and time be considered in the FHIR IG? Any observation field should have a date stamp or some confirmation that is the most current. All dates and time be displayed as: dd-mmm-yy; hh:mm, e.g. 30-Jan-14; 09:21. Need to be able to measure longitudinally for several of the measurements	Wording updated and new comment added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI027	As in the specific cases: - It would be nice to unify vital signs which would allow extras to be added at low cost - Add a datetime so change can be tracked over time - Add explicit units so the data is self describing	Wording updated and new content added to reflect comment. This has been added to the document for clarity - Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.  Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all

		<p>biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p> <p>Units have been included for each measured data element.</p>
AUCDI029	These seem very focussed on primary care needs.	<p>Comment noted, no change.</p> <p>This is the initial scope of AUCDI R1 and will be extended over time.</p>
AUCDI030	* need explicit date of observation to allow decision making wrt currency	<p>Wording updated and new content added to reflect comment.</p> <p>Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p>
AUCDI050	<p>All data elements in this data group align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.</p> <p>The AIHW's draft data model for a national primary health care data collection proposes a different approach to recording measurements. The structure proposed by AIHW includes data elements for measurement type, measurement value and measurement unit. Based on the AIHW environmental scan, this same approach has been used for MedicineInsight, PATRON and POLAR, however this differs from the approach proposed within AUCDI Release 1. Working together on a common approach will be important here.</p> <p>The limitations of the structure proposed by AUCDI are:</p> <p>a) A whole new data element (or even data group) would need to be created to introduce a new measurement type. Using the alternative structure, only the existing value set would need to be updated to introduce a new measurement type.</p> <p>b) Measurement units are embedded assumptions rather than being explicitly captured. This could lead to data quality issues if people use different units and can't capture this decision. Using</p>	<p>Comment noted, no change.</p> <p>Each measurement or vital sign is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the measurement or vital sign, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.</p> <p>In some measurements, a clinician may need to choose units, depending on the use case. Implementations should allow simple user interface to allow clinicians to record what they need depending on the circumstances.</p>



	the alternative structure, measurement units could be specified alongside the value.	
AUCDI051	Apologies if I've missed it, but it would be good to encourage (or mandate) use of the UCUM "code" standard when we use Quantity complex datatypes in FHIR. Allowing free text use of the "unit" string is bad for CDS.	Wording updated to reflect comment. All units are assumed to be represented in UCUM format unless otherwise specified. This has been updated in the document for clarity.
AUCDI033	<p>We recommend adding references to HL7 International FHIR standards and the International Patient Summary to the following tables in section 7.6:</p> <ul style="list-style-type: none"> <li>- Section 7.6.1.4, Table 22 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.2.4, Table 25 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.3.4, Table 28 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.4.4, Table 31 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.5.4, Table 34 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.6.4, Table 37 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.6.7.4, Table 40 – Aligns and leverages international standards and initiatives.</li> </ul> <p>The proposed additions help keep the Measurements and Vital Signs data concepts aligned with international standards.</p>	<p>New content added to reflect comment.</p> <p>Document has been updated with relevant references from US Core and Vital signs IGs</p>

## 10. AUCDI R1 Section: Biomarkers

### 10.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
19	11	7	0	10	5

### 10.2. Lipids: HDL Cholesterol

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI032	<p>There is a question around whether cholesterol is the most important data point. There might be other more important markers – we should not choose investigations and numbers just because they are easy to graph. Exercise, diet, and barriers to these might be more important.</p> <p>It is a good idea to include lipids as this assists with a cardiovascular risk assessment.</p>	<p>Comment noted, no change. Agree. The cardiovascular risk assessment has driven the priorities for R1 and will be extended in future releases.</p> <p>Comment noted, added to backlog. "Physical activity" and "Diet" have been added to the backlog as new data groups.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p>	<p>Comment noted, no change. When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.</p> <p>Mandating specific data groups is use case specific and out of scope for AUCDI.</p>

**10.3. Lipids: LDL Cholesterol**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	<p>Comment noted, no change.</p> <p>When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.</p> <p>Mandating specific data groups is use case specific and out of scope for AUCDI.</p>

**10.4. Lipids: Total Cholesterol**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	<p>Comment noted, no change.</p> <p>When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.</p> <p>Mandating specific data groups is use case specific and out of scope for AUCDI.</p>

**10.5. Lipids: Triglycerides**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	<p>Comment noted, no change.</p> <p>When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.</p>

		Mandating specific data groups is use case specific and out of scope for AUCDI.
--	--	---

## 10.6. Lipids: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	All of the individual data elements are optional. Is this suggesting that the lipid biomarkers group does not require all analysts to be present to be valid? If so, I think some information describing this would be useful. Otherwise, maybe they should be mandatory.	Comment noted, no change. When biomarkers are able to be more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.
AUCDI019	Our understanding is that the primary use case proposed is for CVD risk prediction, therefore we would query why not start with just start with TC and HDLC as the only lipid parameters as they are the only parameters used in the A/NZ calculator The formula used for calculated LDL cholesterol should be stated, as more recent and reliable formulas have emerged and may be adopted by some laboratories In the Australian CVD risk calculator ( <a href="https://www.cvdcheck.org.au/calculator">https://www.cvdcheck.org.au/calculator</a> ), a calculated parameter is the ratio of total cholesterol to HDL cholesterol (which may be reported by pathology laboratories).	Comment noted, added to backlog. Agree. The need for TC and HDLC in the Australian Cardiovascular risk calculator drove the priority for including the lipid profile.  "Formula for LDL" and "Total cholesterol to HDL cholesterol ratio" have been added to the backlog.
AUCDI032	Future measurements should be considered. Lipoprotein may soon become an important lipid measure. Is this list flexible enough to cope with additions in future?	Comment noted, added to backlog. "Lipoprotein measurement" has been added to the backlog

**10.7. Haemoglobin A1c: hbA1c**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. A measurement would not be a valid without the actual measurement.	Comment noted, no change. When biomarkers are able to be more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.
AUCDI036	The proposed accepted units for reporting are mmol/mol or %. There does not appear to be an international consensus on standardisation for reporting HbA1c, e.g. as noted by the "National Glycohemoglobin Standardization Program". HbA1c is also measured as mmol/L or mg/dL and whether these units should also be considered.	Comment noted, no change. The RCPA provides reference ranges for mmol/mol and % only. AUCDI has followed this guideline <a href="https://www.rcpa.edu.au/Manuals/RCPA-Manual/Pathology-Tests/H/HbA1c">https://www.rcpa.edu.au/Manuals/RCPA-Manual/Pathology-Tests/H/HbA1c</a>
AUCDI042	In my mind, this is an observation, although perhaps it is used as a clinical biomarker in this context. Consider if LOINC codes may be useful to define the value set, in addition to SNOMED CT-AU?	Comment noted, added to backlog. When biomarkers are able to be more comprehensively represented as a more formal "Laboratory test result", the question of terminology requirements will be resolved. This has been placed on the backlog.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.  Mandating specific data groups is use case specific and out of scope for AUCDI.
AUCDI011	Under Supports collection of data for Practice .... (PIP QIM) this section should include Proportion of patients the necessary risk factors assessed to enable CVD assessment	Wording updated and content added to reflect comment. Agree. Document has been updated.

**10.8. Haemoglobin A1c: General Feedback**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI019	For HbA1c, it would be important to distinguish between the different units (mmol/mol vs %) as the numerical results are significantly different.	Comment noted, no change. Agree. This would belong in any technical specification representing the AUCDI.

**10.9. Estimated Glomerular Filtration Rate: eGFR**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. A measurement would not be a valid without the actual measurement.	Comment noted, no change. When biomarkers are able to be more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.
AUCDI008	Quantity datatype is listed however the type of quantity is not. It appears to be concentration.	Wording updated to reflect comment. The quantity data type is correct for all of these measurements. UCUM units have been identified and updated.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.  Mandating specific data groups is use case specific and out of scope for AUCDI.
AUCDI035	Creatinine along with eGFR should be used as you are collecting demographic data for age, gender and weight to determine creatinine clearance as there can be vast differences between the two in specific demographics which impacts clinical care	Comment noted, added to backlog. "Creatinine clearance" has been added to the backlog.

**10.10. Estimated Glomerular Filtration Rate: General Feedback**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI014	Worth including creatinine levels as well for a more comprehensive view on kidney function.	Comment noted, added to backlog. "Serum creatinine" has been added to the backlog.
AUCDI019	For eGFR, the upper limit of reporting is typically 90 mL/min/1.73m <sup>2</sup> (i.e. ">90" for values greater than 90).	Comment noted, no change. Specifying valid ranges are not currently in scope for AUCDI.
AUCDI048	It's essential, even in R1, to know the context, because eGFR is not always accurate – for example it cannot be relied upon in the setting of an acute kidney injury. Within medical imaging eGFR is used to assess whether or not it is safe to administer contrast for CT or MRI examinations in the context of Contrast Induced Nephropathy (CIN) in CT, and Nephrogenic Systemic Fibrosis (NSF) in MRI. If there is any reason that eGFR may be unreliable, clinicians need to be aware of this as they cannot rely on eGFR in isolation.	Comment noted, no change. Agree. AUCDI is building towards making a coherent data environment to support best clinical practice.
AUCDI020	date needs to be included and we note that this might be covered by the FHIR implementation guide if the data has a timestamp instead of an element here	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary

**10.11. Urine Albumin Creatinine: uACR**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Occurrence is optional, suggest it is mandatory. A measurement would not be a valid without the actual measurement.	Comment noted, no change. When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.
AUCDI042	Terms should align with RCPA SPIA orders and observation value sets. For example, preferred term for urine albumin creatinine ratio is "Albumin creatinine ratio urine".	Comment noted, no change. Terms used for observables are natural language ordered. These will map directly to RCPA SPIA observation codes, and implementations may use the RCPA Preferred Term (though these can change over time)
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.	Comment noted, no change. When biomarkers are able to be more comprehensively represented as a more formal "Laboratory test result", the question of which data elements in a data group should be made mandatory will be resolved.  Mandating specific data groups is use case specific and out of scope for AUCDI.
AUCDI008	Quantity datatype is listed however the type of quantity is not. It appears to be concentration.	Wording updated and content added to reflect comment. The quantity data type is correct for all of these measurements. UCUM units have been identified and updated.



**10.12. Urine Albumin Creatinine: General Feedback**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI019	Urine ACR is problematic because the diagnosis relies on 2/3 positive results, so the latest result may occasionally be misleading?	Wording updated, new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.

**10.13. Biomarkers: General Feedback**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	Requires a date-time of measurement.	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.
AUCDI004	The biomarkers, e.g. somatic mutations, are becoming important to immunotherapy and other therapies which means more and more key biomarkers are going to be routinely reported. So, this group may be better modelled. For example, consider 'Biomarker' as a whole, and each data contains a value and group identifier. In this case, both HDL and LDL have the same group identifier '365791005   Finding of lipid level (finding)  ', and both BRAF V600K and NRAS have the same group identifier '124975008   Somatic mutation (finding)  '.	Comment noted, no change. This is a temporary representation and will be formalised as Laboratory tests results in the future.
AUCDI006	I didn't see a performed date or observation date for biomarkers. A lot of them are not very useful without a date. Required to consecutively order measurements for trending and to identify the latest. If there is other observation event data specified it wasn't clear to me.	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.

AUCDI007	White blood count would be useful.	Comment noted, added to backlog. "Full blood count" has been added to the backlog.
AUCDI008	Seems thorough, although I am not a medical doctor.	Comment noted, no change.
AUCDI012	Why is AUCDI R1 constrained to biomarkers?	Comment noted, no change. The first release of AUCDI, R1, is the foundation from which will grow more comprehensive information models as standards, policies, technical implementations, and user requirements mature and evolve.
AUCDI017	This is mainly for the chemists - but should you include methodology/assay considering that some assays may have variability in results depending on which platform they are run? I assume this may be included in LOINC coding.  These appear to be very simple results. I would be particularly interested in discussions around reports which are more interpretative and may include a combination of multiple observations and narrative. I can see that this is not yet on the roadmap for part 2 but assume it may come up later down the track.	Comment noted, no change. This is currently out of scope.  It is planned that these biomarkers will be more comprehensively represented as a more formal "Laboratory test result" in the future (in backlog).
AUCDI019	Laboratory test result roadmap appears to have minimal data items identified for future inclusion. This needs further discussion as in out view it will not allow for future work required on reporting interoperability  The Data Group aliases should be aligned to the SPIA Terminology  Preventing duplication of laboratory testing, is linked to decision support, and this should be called out  Throughout "Referrals" are identified; suggest update to also include "Reports"  Will date and time be considered in the FHIR IG?	Comment noted, added to backlog. It is planned that these biomarkers will be more comprehensively represented as a more formal "Laboratory test result" in the future, including the data group aliases and best practice use. "Laboratory test result" is in the backlog. We would welcome RCPA's input.  Wording updated to reflect comment. Agree - "Referrals" has been updated to "Referrals and clinical reports".  Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all

	<p>All test requests and results should incorporate date and time be displayed as: dd-mmm-yy; hh:mm, e.g. 30-Jan-14; 09:21. Any observation field should have a date stamp or some confirmation that is the most current. Need to be able to measure longitudinally for several of the measurements</p>	<p>biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p>
AUCDI021	<p>Suggest inclusion of PEFR as a biomarker in v1. Significant burden of care and would be a useful marker in hospital avoidance initiatives and emerging models of care. Low-cost and can be patient-measured effectively.</p>	<p>Comment noted, added to backlog. "Peak expiratory flow rate" has been added to the backlog.</p>
AUCDI026	<p>Haemoglobin and full blood count (FBC) Incorporating haemoglobin and full blood count (FBC) into the core data set for the FHIR - HL7 standard in Australia is essential for several reasons. FHIR standard aim to facilitate interoperability and efficient data exchange across different healthcare systems, thereby enhancing patient care and clinical outcomes. Haemoglobin and FBC are fundamental tests in clinical practice, offering critical insights into a patient's health. Below are the justifications for including these tests in the core data set, supported by evidence:</p> <ol style="list-style-type: none"> <li>1. Baseline Health Indicators: Haemoglobin and FBC tests are vital baseline health indicators. Haemoglobin levels are crucial for diagnosing anaemia and assessing its severity, which can affect a wide range of patients, including those with chronic illnesses, pregnant women, and individuals with nutritional deficiencies. The FBC provides a comprehensive overview of a patient's blood profile, including white blood cells (WBC), red blood cells (RBC), platelet count, and more, which are essential for diagnosing infections, blood disorders, and immune system issues.</li> <li>2. Chronic Disease Management: These tests are critical in the management of chronic diseases such as diabetes, kidney disease, and heart disease. For instance, anaemia is a common complication</li> </ol>	<p>Comment noted, added to backlog. "Full blood count" (including haemoglobin) has been added to the backlog.</p>

	<p>of chronic kidney disease (CKD) and can significantly affect the patient's quality of life and prognosis. Regular monitoring of haemoglobin and FBC can aid in the timely management of such conditions.</p> <p>3. Preventive Healthcare: Regular screening through FBC and haemoglobin tests can help in the early detection of serious health issues like cancer, hematologic disorders, and autoimmune diseases. Early detection can lead to early intervention, which can significantly improve treatment outcomes and patient survival rates.</p> <p>4. Global Health Standards: The inclusion of these tests aligns with global health standards and practices. Organisations such as the World Health Organization (WHO) and the Center for Disease Control and Prevention (CDC) recognise the importance of these basic diagnostic tests in patient care and public health monitoring.</p> <p>5. Cost-Effectiveness: Implementing these tests as part of the core data set can be highly cost-effective. Early detection and management of diseases through regular monitoring can significantly reduce healthcare costs associated with advanced treatments and hospitalisations.</p> <p>6. Research and Public Health Monitoring: Data on haemoglobin and FBC are invaluable for research purposes and for monitoring public health trends. This data can help identify public health issues, track the effectiveness of health interventions, and support evidence-based policy-making.</p> <p>References:  <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9687310/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9687310/</a>  <a href="https://pubmed.ncbi.nlm.nih.gov/37579529/">https://pubmed.ncbi.nlm.nih.gov/37579529/</a>  <a href="https://www.cncpathlab.com/blogs/FBC-test">https://www.cncpathlab.com/blogs/FBC-test</a></p>	
--	---	--

AUCDI027	As for vital signs, creating individual cases for each lab test is inefficient. There are huge number of different tests done by labs, many of which share a very similar results format. By moving to a model where you record tests generically, with a field for the test type, and result unit, the model is much more reusable, allowing the standard to keep up with lab testing without needing a new release each time a new test comes out.	Comment noted, no change. Each biomarker is designed as a separate data group, with Release 1 deliberately limiting each data group tightly to the minimum recording requirement. In future releases of AUCDI, it is anticipated that each data group will be extended, by including extra attributes that provide additional context such as the state of the patient at the time of measurement and the method of measurement needed for the accurate interpretation. These additional attributes will vary depending on the biomarker, and the range of variation has been represented in the mind map found in the 'For future consideration' section for each data group.
AUCDI029	a decision is needed on the use of commentary as it isn't consistent across data groups	Comment noted, no change. When biomarkers are able to more comprehensively represented as a more formal "Laboratory test result", comment will be included at that time.
AUCDI030	* need collection date (effective date) to assess currency	Wording updated and new content added to reflect comment. Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary
AUCDI033	<p>We recommend adding references to HL7 International FHIR standards and the International Patient Summary to the following tables in section 7.7:</p> <ul style="list-style-type: none"> <li>- Section 7.7.1.4, Table 43 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.7.2.4, Table 46 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.7.3.4, Table 49 – Aligns and leverages international standards and initiatives.</li> <li>- Section 7.7.4.4, Table 52 – Aligns and leverages international standards and initiatives.</li> </ul> <p>The proposed additions help keep the Biomarkers data concepts aligned with international standards.</p>	Comment noted, no change. The proposed biomarkers are temporary. The IPS references laboratory in vitro diagnostic test or panel/study, so are not equivalent information models.

	<p>We recommend adding narrative guidance on expected changes to the Biomarkers group for when the generalized 'Laboratory test result' data group is released in future versions. The guidance will help implementers understand and plan for the proposed future state where AUCDI will focus on the overall laboratory test model instead of modeling individual laboratory measurements. Because the future data group model will encompass all current biomarker groups, recommendations and guidance for specific tests should either move to the AU Core IG or be published by groups such as RACGP.</p>	
<p>AUCDI036</p>	<p>This Biomarkers section focuses on 4 data groups to manage, monitor and drive decision support for patients. We agree with sentiment that the range of the Biomarker collection is expected to expand. (stated on page 82), and note that no potential candidate data elements are proposed for AUCDI Release 2 (page 94). A significant proportion of genetic and genomics test reporting will most likely be reported under the Biomarker data group. The issues raised in Q10 would be applicable to Biomarkers in the future releases of AUCDI.</p>	<p>Comment noted, no change.</p>
<p>AUCDI040</p>	<ul style="list-style-type: none"> <li>• Broadening the proposed Key Biomarkers data group to include other test results. The recommendation in the paper to rename and broaden this data to Laboratory Test Results would be more appropriate and enable the broadening of items which capture genetic, genomic and biomarker information important to predicting cancer risk, identifying cancer early, guiding treatment and care options, and in the monitoring of cancer and treatment progress.</li> </ul>	<p>Comment noted, added to backlog. Agree. "Laboratory test result" has been added to the backlog.</p>
<p>AUCDI042</p>	<p>Overall, the term 'biomarker' has a fairly generic meaning with different interpretation across different care settings. The term is used here to have a more specific meaning. These biomarkers (lipids, HbA1C, eGFR, uACR) all originate from diagnostic observations (laboratory tests), so we suggest giving this section a</p>	<p>Comment noted, no change. Comment noted. It is planned that these biomarkers will be more comprehensively represented as a more formal "Laboratory test result" in the future (in backlog).</p>

	<p>title that is more representative of the content, and also aligns to existing concepts used in interoperability (HL7 v2.x) such as “Key diagnostic observations”. All terms should align with RCPA SPIA orders and observation value sets. For example, preferred term for urine albumin creatinine ratio is "Albumin creatinine ratio urine".  <a href="https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/SPIA-Terminology-Reference">https://www.rcpa.edu.au/Library/Practising-Pathology/PTIS/SPIA-Terminology-Reference</a>  <a href="https://www.healthterminologies.gov.au/access-clinical-terminology/rcpa-pathology-terminology-and-information-models/">https://www.healthterminologies.gov.au/access-clinical-terminology/rcpa-pathology-terminology-and-information-models/</a></p>	
AUCDI046	<p>We note that you have included biomarkers in section 7.7 of this document and agree that laboratory test results need to be included as part of any medical interoperability data standard.</p> <p>In this context, we note that the pathology sector provides a service that is not standardised in the way that pharmaceutical medicines are. Even for seemingly straightforward and commonplace pathology tests, there is no consensus (even across laboratories operated by a single legal entity) on which specific results need to be included, or the best methodology for testing these. Designing a single data standard that is capable of handling the range of clinically valid practices extant in the pathology sector is a formidable challenge that your group will need to address as more use cases are added to the data standard in future.</p> <p>You have included Lipids, HbA1c, eGFR, and uACR as biomarkers in this data standard, which we can see is an attempt by this group to capture some of the proverbial ‘low-hanging fruit’ in this space, likely to have greatest utility to patients with common chronic conditions such as diabetes and cardiovascular disease. As a general observation across all of these biomarkers (as well as for all future biomarkers), the data needs to be able to be accompanied by any notes that may affect the interpretation of the results. These may be technical notes relating to the testing method, or they may</p>	<p>Comment noted, no change.  Agree. "Laboratory test result" has been added to the backlog.</p> <p>Wording updated and content added to reflect comment.  Agree. This sentence has been updated for clarity to "Prevention of unnecessary duplication of laboratory testing".</p> <p>Comment noted, added to backlog.  "Lipoprotein (a)" has been added to the backlog.  The AUCDI community brings together all the stakeholders to support standards development and governance.</p>

	<p>be other relevant clinical or contextual information, particularly clinical information that does not easily reside within other data that is covered by the final standard. For example, a patient's fasting status at the time of testing is a relevant consideration when interpreting many blood test results (and should probably be included in many of these laboratory test result data structures). The data groups will need to be extended to cover this and other more general clinical notes relevant to the pathology tests.</p> <p>In both the Lipids and HbA1c alignment to design principles, we note that you have listed 'preventing duplication of laboratory testing'. In many clinical contexts, repeat testing is actually necessary for the treating clinician to be able to better understand the patient's health. A single lipid reading is of some use, but also of relevance is being able to monitor how a patient's cholesterol and triglyceride values are tracking through time. It is both common and clinically accepted practice for a treating doctor to as a patient to undertake regular tests for precisely this reason. Australian Pathology's members have consistently provided feedback to government that the level of unnecessary pathology testing in Australia is low. Furthermore there is academic evidence to indicate that in some areas we are under-testing. While we can understand the thinking that having improved access to a patient's previous blood test results might see some clinicians simply utilising previous test results, we would caution against any expectations that a functioning digital health record system will result in any sort of dramatic reduction in the volume of pathology testing. In reality, treating clinicians are unlikely to be willing to risk undertaking a course of treatment based on test results that may be outdated for some reason, and it is the treating clinicians who request which pathology tests are undertaken. Specifically, we would object to any plans for any previous test results to automatically exclude re-testing requested by a treating clinician.</p>	
--	--	--



	<p>With regards to lipids biomarkers, we note that many cardiologists are calling for Lp(a) to be included in lipid panel testing in at-risk patient groups. In addition to the specific question this raises with regards to the draft data structure detailed in the document, it also raises a broader question around how the government plans to manage these data standards as clinical practice evolves. In this example, if Lp(a) becomes clinically accepted as a ‘best practice’ inclusion in lipid panel testing, the data standard as drafted would be outdated. The data standard group needs to consider the issues that updating a data standard might cause, and vice versa, the issues that out-dated data standards will cause. Implementing a change affecting the reporting of test results (especially high volume tests, such as lipid panels) across multiple laboratories and test platforms is a costly process which cannot be done quickly and having an understanding of how this would be done in future is an important threshold issue to address to be able to include pathology test results in this kind of data standard.</p>	
AUCDI050	<p>Similar to ‘Measurements and vital signs’, some limitations have been identified with the proposed structure of the ‘Biomarkers’ data group (separating each biomarker analyte out into distinct data groups and elements), however AIHW is comfortable to accept the proposed structure of this data group based on the comment: “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.”</p>	Comment noted, no change.
AUCDI035	<p>Pg. 83 section 7.7 - Arguably, the selected biomarkers do not achieve the goal of a core dataset for interoperability having wide applicability across care settings. Noting the alignment of the selected markers to the Cardiovascular Risk Assessment tool, it is notably applicable for care of some patients in primary care. The rationale for a decision to align with a specific risk assessment tool is not apparent in the document. While the population level burden of cardiovascular disease can be well argued, so too can the disease</p>	<p>Comment noted, added to backlog. The community identified several priority use cases to inform the scope of AUCDI R1. These include:</p> <ul style="list-style-type: none"> <li>• Transfer of care summary (e.g., discharge summary),</li> <li>• Chronic disease management (e.g., care plan),</li> <li>• Decision support (e.g., cardiovascular disease risk), and</li> <li>• Referral.</li> </ul>

	<p>burden of cancer which is not assisted by any of the biomarkers in R1. It is strongly recommended to include the most commonly ordered blood tests that are applicable for multiple clinical indications, specialties and care contexts (e.g. FBC, LFT) at minimum. This is particularly recommended as inclusion of the most commonly ordered biomarkers is not proposed for Release 2.</p>	<p>Comment noted, added to backlog.                  "Full blood count" and "Liver function test" have been added to the backlog.</p>
--	---	---

## 11. AUCDI R1 Section: Medication Use Statement

### 11.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
18	14	2	2	11	5

### 11.2. Medication Name

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI009	Alias: active ingredient?	Comment noted, no change. This data element refers to the name of the medication as a whole, not a specific component such as ingredient.
AUCDI045	Same "Name" issue (see above examples)	Comment noted, no change. The common pattern for naming the index data element is identifying by name, to be explicit and differentiate the name of the medication from other medication-related data elements.
AUCDI050	Which part of the SNOMED CT-AU value would be captured – the code, the display text or both? Having a clear understanding of the proposed format will assist AIHW to develop standards that align to AUCDI.	Comment noted, no change. How the SNOMED CT-AU is captured and stored is an implementation consideration which will be represented in technical specifications for the relevant use case. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model.
AUCDI036	It is noted that free text entry is available to record medicines that are not included in the Australian Medicines Terminology.	Comment noted, no change. Agree. There are occasions when free text entry is necessary, and this is included in the model.

**11.3. Form**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	<p>The recommended value set also contains AMT forms. I suppose technically the description is accurate as AMT is considered part of SNOMED CT-AU. It could be specifically called out.</p> <p>I think more impactful is this value set will be updated to remove them after v4 release.</p> <p>This comment is just a heads up I suppose that the value may need to change.</p>	Comment noted, no change.

**11.4. Strength**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>It seems to me that this should be mandatory. When would it not be required?</p> <p>From a data querying perspective, it is much easier to query data when I know that all of the queried fields have values.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>
AUCDI036	<p>Under 'Considerations' (p99) it is stated that the strength should only be recorded if it is not specified within a coded 'Medication name' value. It is possible that the supplied strength may differ to what is in the 'Medication Form value set'. Suggest changing the 'Considerations' wording to "...Record only if the strength is not available in the Medication Form value set or if it differs to the specified strength for a coded 'Medication value' ...".</p>	<p>Comment noted, no change.</p> <p>This element is referring to strength and name, not the form.</p>

## 11.5. Route of Administration

No feedback received on this data group.

## 11.6. Dose Amount and Timing

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	<p>1. Page 100 - "PRN" is given as an example of Dose Timing, yet the occurrence is listed as Single. Very few medications are taken as needed without an accompanying frequency. Timing modifiers such as PRN should not be included in the same concept as Timing itself. The mindmap that shows the future roadmap, with "As Required" being a separate attribute is correct, however the interim proposal of R1 to include this in a single occurrence of Dose Timing, forcing the user/system to choose between frequency or PRN, will result in insufficient information which could constitute a clinical risk. I would propose including the timing modifier in R1.</p> <p>2. While of not immediate concern, transdermal patches will require consideration in future as there are a number of different methods of describing their administration, including patch-free periods etc.</p>	<p>Comment noted, no change.</p> <p>1. Where a medication is used both PRN and regularly, it would be expected that there would be two separate use statements as they may have different indications/strengths/timings, etc.</p> <p>2. Agree, the Timing datatype is complex. We are using the FHIR datatypes and this will need to be addressed in the near future.</p>
AUCDI008	<p>Quantity: 1-2 is not a quantity. It is a range.</p> <p>Dose timing examples - seems almost like free text. Perhaps they could be made to follow a rule?</p>	<p>Wording updated to reflect comment. Document has been updated to allow quantity and range. Thank you</p> <p>Dose timing examples are common examples used clinically. Please see the Timing data type <a href="https://build.fhir.org/datatypes.html#Timing">https://build.fhir.org/datatypes.html#Timing</a></p>
AUCDI009	Alias: Frequency?	<p>Wording updated to reflect comment. Agree. Document updated</p>
AUCDI049	Dose timing: Consider capturing dose timing in a structured format before the unstructured format?	<p>Comment noted, no change. Please see the Timing data type <a href="https://build.fhir.org/datatypes.html#Timing">https://build.fhir.org/datatypes.html#Timing</a></p>

AUCDI018	Potentially changing dose amount to dosage for consistency with EMRs	Comment noted, no change. Dosage refers to the combination of dose amount and timing, so this would not be an appropriate change.
----------	--	--

## 11.7. Clinical Indication

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	<p>Referring to the previous comment made for Procedure Completed. Ideally the recommended value set would be specific for this context as it's useful to be able to version and manage the life-cycle of a bound value set within its context of use. Currently there is <a href="https://healthterminologies.gov.au/fhir/ValueSet/medication-reason-taken-1">https://healthterminologies.gov.au/fhir/ValueSet/medication-reason-taken-1</a></p> <p>Resolution could be to either use a specific value set for this element or if it is expected that the clinical indication element is going remain the same across other groups over time (e.g. Procedure Completed, Encounter) a common one could be created with a more generic name and description.</p>	<p>Wording updated to reflect comment. Agree. The recommended value set has been updated to <a href="https://healthterminologies.gov.au/fhir/ValueSet/medication-reason-taken-1">https://healthterminologies.gov.au/fhir/ValueSet/medication-reason-taken-1</a> as suggested.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>The 'Reason for encounter' value set seems too broad for clinical indication for a medication. For example, the values 'Tends not to plan ahead' and 'Witness summons received' don't make sense as a clinical indication for a medication. The same value set is being proposed for clinical indication for a procedure, clinical indication for a medication and reason for encounter. A reason for encounter could be clinical, social or administrative in nature, whereas an indication for a procedure or medication should be clinical in</p>	<p>Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>Wording updated to reflect comment. This has been updated to Medication Reason Taken value set. This is still a maximal value set to support reuse across multiple use cases and support the breadth of the ecosystem to enable</p>

	<p>nature. This indicates that there should be tangible differences between the scope of the value sets used for these data elements. The value set may need further refinement to ensure that the scope is appropriate for this data element i.e. excluding values that are not clinical in nature. Not constraining the value set could impact the data quality by allowing for selection of inappropriate values.</p> <p>Which part of the SNOMED CT-AU value would be captured – the code, the display text or both? Having a clear understanding of the proposed format will assist AIHW to develop standards that align to AUCDI.</p>	<p>interoperability. This data set may be used in EMRs, patient or clinician apps, etc. Where the clinical context or use case requires it, specific IG specification or vendor implementations may specify constrained subsets of the AUCDI value sets.</p> <p>Comment noted, no change.</p> <p>How SNOMED CT-AU is captured and stored is an implementation consideration which will be represented in technical specifications for the relevant use case. The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow and so this is currently out of scope of the data model.</p>
--	---	---

**11.8. Last Administration**

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI014	<p>May not be relevant in non-acute settings - ie. outpatient GP/specialist appointments</p>	<p>Content removed as no longer relevant, added to backlog. "Last administration" has been removed from AUCDI R1 and has been added to the backlog.</p>
AUCDI016	<p>Would it be better to wait on "last administration" to see if there's plans or appetite to record all administrations, in which case we shouldn't be just caching the last administration here. We could instead get the last record from administrations.</p> <p>Also it feels out of context with the rest, which are really the prescription of the medication, it's the only field that requires updating later.</p> <p>I just don't think the two concepts should be combined, if administration recording is important (which I believe it to be), we could record it in it's own model.</p>	<p>Content removed as no longer relevant, added to backlog. "Last administration" has been removed from AUCDI R1 and has been added to the backlog.</p>

AUCDI030	would drop this element as unlikely known except when inpatient/reisidential/domicillary and not something to share except in specific transfer cases e.g. aged care to/from hospital perhaps	Content removed as no longer relevant, added to backlog. "Last administration" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>It is recommended that a standardised approach to capturing partial dates is defined.</p> <p>For a medication that is intended to be used indefinitely, would need to be updated during every encounter? Introduction of a data element that requires continual updating may introduce data quality issues if this is not adhered to in practice.</p>	Content removed as no longer relevant, added to backlog. "Last administration" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI035	Only relevant in a hospital or RACF setting when transferring patient or handover. Not essential as part of AUCDI	Content removed as no longer relevant, added to backlog. "Last administration" has been removed from AUCDI R1 and has been added to the backlog.

### 11.9. Endpoint

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI007	Not sure what this means? Does it mean when it was ceased, when it will be ceased, or what the target is?	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI008	The examples are inconsistent. I would hope that the DateTime is cleaned and standardized when storing in the database.	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI009	Consider dropping the words "the sender has just initiated".	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.



AUCDI030	think there should be a seperate regular/once off indicator as end date is not necessarily available and described in instructions	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI032	This terminology is not widely used in clinical settings. Suggest "end date" or "cessation of use".	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI048	Given the description, should this data element be named "end date"? Further, the term 'endpoint' has a well-understood and unambiguous technical meaning in digital health solutions and thus may cause confusion if used for this data element name.	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI050	What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.  Is this the field that would be used to determine the list of current medications? It seems that you could determine whether a medication is "current" by comparing the endpoint to today's date, however that would only tell you if the patient is supposed to be taking it currently, not whether they are actually taking it currently.	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.
AUCDI035	Is this short term vs long term vs PRN use? Or date ceased? If yes, then important.	Content removed as no longer relevant, added to backlog. "Endpoint" has been removed from AUCDI R1 and has been added to the backlog.

### 11.10. Medication Use Statement: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI001	1. It is not clear in this document whether infusions are out of scope, though I believe they are since concepts such as Administration Rate and Administration Duration are omitted in R1. This should be made clearer in the document, since "creative" use of the R1 data elements could result in infusions being represented ambiguously.	Comment noted, added to backlog. 1. It is unclear how to progress with infusions in this context so "Infusion related data" has been added to the backlog.

	<p>2. Missing concepts:</p> <p>a) Preferred brand (often important for patients)</p> <p>b) Medication History concepts - Source, Source flag (primary/secondary), compliance, compliance aids</p> <p>c) Administration Aid - such as requiring the use of a spacer with an asthma inhaler</p> <p>d) It might be necessary to require the use of an episode type or other qualifiers as to the context in which the medication should be taken i.e. as an inpatient only, as an outpatient, only while in Operating Theatre and PACU etc.</p>	<p>Comment noted, added to backlog.</p> <p>2. "Preferred brand", "Medication history", "Administration Aid" and "Episode type" have been placed in the backlog.</p>
AUCDI008	Seems good. Just some minor concerns to address.	Comment noted, thank you.
AUCDI009	<p>Intro para: consider adding patient and/or carer managed medicines list, pharmacist shared medicines list (PSML)  <a href="https://www.digitalhealth.gov.au/initiatives-and-programs/my-health-record/whats-inside/information-healthcare-providers-can-upload/pharmacist-shared-medicines-list-psml">https://www.digitalhealth.gov.au/initiatives-and-programs/my-health-record/whats-inside/information-healthcare-providers-can-upload/pharmacist-shared-medicines-list-psml</a></p> <p>Data group alias: BPMH? <a href="https://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety/cmm/bpmh">https://www.cec.health.nsw.gov.au/keep-patients-safe/medication-safety/cmm/bpmh</a>, current medicines list</p> <p>Obtaining a BPMH assists with continuity of care, reducing errors and informs medication treatment decisions.</p> <p>Other standards and initiatives for consideration:  ACSQHC Medication Safety Standard  National Medication Management Plan  <a href="https://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/national-medication-management-plan">https://www.safetyandquality.gov.au/our-work/medication-safety/medication-reconciliation/national-medication-management-plan</a>  NPS MedicineWise <a href="https://www.nps.org.au/consumers/keeping-a-medicines-list">https://www.nps.org.au/consumers/keeping-a-medicines-list</a></p> <p>In considerations section, mentions alignment wit data groups for med orders and administration but could also include dispensing.</p>	<p>Wording updated and new content added to reflect comment.  Document has been updated to include some of these references and changes.</p>

	<p>Use Cases: discharge medication list / list of medicines at discharge/transfer, reconciled list of medicines</p> <p>General note: in a care setting (residential care facility, inpatient care) the list of medication orders / medication administration record summary is the list of current medicines. i.e. it is a reliable proxy for a list of current medicines for the patient. However, outside of these settings where drug administration may be less controlled, lists of prescriptions or dispensing history is a much less reliable proxy for current list of medicines. This is reflected in clinical practice when clinicians are chasing a BPMH.</p> <p>Reuse:          medication reconciliation and review          care plans          health summaries          patient's own medicines list</p> <p>Drivers: "Improve the precision of clinical decision-making processes" - consider dropping the word "precision".</p>	
<p>AUCDI027</p>	<p>This element seems to merge medication prescription and medication administration. But these are two rather separate concepts.</p> <ul style="list-style-type: none"> <li>- Consider a PRN prescription for a pain killer which may only be given sporadically. We care both about the act of prescribing it, but we may also care about how much was given.</li> <li>- Similarly patient controlled drugs (push button for painkiller) may have no pattern in how it is administered.</li> <li>- Mistakes / delays in medication administration happen in hospitals. It may be important to be able to see a divergence from what was prescribed (e.g. every 4 hours) and what ended up happening (e.g. usually 4-5 hour gaps, but ranging up to 9)</li> </ul>	<p>Comment noted, no change.          This data group is medication use statement. It is not the medication order or administration record.</p> <p>Comment noted, added to backlog.          "Last administration date" has been removed from the AUCDI and added to the backlog.</p> <p>Comment noted, added to backlog.          "Medication order" and "Medication administration record" have been added to the backlog.</p>

	- Take home medications are prescriptions only. We don't actually know anything about their administration, and this should be reflected in the data.	
AUCDI030	* important: regular medication indicator useful to assess potential for substance in persons system * suggest for regular medications 'first prescribed date' is useful to indicate broad history e.g. on statins for 20 years	Comment noted, added to backlog. "Regular medication indicator" and "First prescribed date" have been added to the backlog.
AUCDI032	Needs status for changes, eg New / Unchanged / Increased dose / Decreased dose / Withheld /Ceased. If Ceased, need "Reason why". If Withheld, need "Reason why".	Comment noted, added to backlog. "Status for changes" has been added to the backlog.
AUCDI033	We recommend rejecting this data concept in AUCDI R1 and instead recommend adopting a data concept based on the FHIR R4 Medication Request model. As written now, the AUCDI medication use model represents a snapshot of a medication usage and is only considered up to date at the time of authoring. Subsequent changes to the medication usage outside a clinical context will not be reflected in the model and could lead to the exchange of out-of-date data. Instead, a medication request model is based on a medication a patient is intended to take previously, currently, or in the future. Documenting and exchanging the medication request allows a clinical user to reconcile a patient's current medications during a clinical encounter.	Comment noted, added to backlog. Primarily, the desire is to have a reconciled known medication use at a point in time. This would not prevent systems supplying prescribing/order detail that could be used for a reconciliation (or dispensing, administration based on setting); this would be considered as a prescribing/orders history that is useful in its own right. Only systems that have a curated current medications or reconciled medications list would be in a position to populate medication use meaningfully and would need to be understood in the context of currency of the record (i.e. last updated). This would require the system to be able to assert that a given medication request implies medication use i.e. medication is an ongoing/long term usage or a short-term usage that would expect to be in use based on request date and expected course period.  Comment noted, added to backlog. Medication request has been added to the backlog
AUCDI036	It is noted that the future release will consider capturing details for more complex extemporaneous or compounded preparations.	Comment noted, added to backlog. "Medication details" to allow for complex extemporaneous or compounded medications has been added to the backlog.
AUCDI040	<ul style="list-style-type: none"> <li>Include opportunities within the Medication statement data group to identify medications used in combination. Multiple medicines are often used in combination to treat cancer and are tailored to the individual's disease. The ability to capture</li> </ul>	Comment noted, added to backlog. "Identify medications used in combination/protocols" has been added to the backlog.

	medication use that was used in combination, and not in isolation, in this data element would reflect cancer care practice, creating more complete data.	
AUCDI045	The Mind Map (P105) seems to include some elements that are not documented: Direction Sequence, Timing - Daily, Direction Endpoint	Comment noted, no change. This mindmap is indicating items for further consideration and are not yet included in the model.
AUCDI048	In some contexts (e.g. Diagnostic Imaging Accreditation Scheme—DIAS—accreditation) contrast agents used in diagnostic imaging are considered to be medications. Will this be the case here? In terms of the information gathered and recorded before and after administration of a contrast agent, they can be considered medications. Recommend expansion of ‘medications’ to include contrast agents. This, when tied in with adverse event data would allow national data sets regarding adverse events following administration of contrast agents. Data could also be used to retrospectively evaluate GBCAs (gadolinium based contrast agents, used in MRI) in relation to NSF. To do this, we need to know all the different types of GBCAs administered to a specific patient (throughout their life) as well as dates, times and doses. Having all this data in one place would make it possible to better determine safety profiles of GBCAs in the context of NSF and gadolinium retention, which would allow better decision-making in regards to when it is, or isn’t, safe to administer GBCAs – ultimately we don’t want to misdiagnose a patient because we withheld contrast when we needn’t have – but to reach a higher level of certainty around safety, we need readily accessible data around usage of contrast agents.	Comment noted, added to backlog. This data group is intended to describe ongoing medication use, not a single administration of a medication or contrast agent.  Comment noted, added to backlog. "Medication administration record" has been added to the backlog.
AUCDI049	For future considerations: - It would be beneficial to include data elements to support future medicine traceability, product recalls and possible additional data for adverse event reporting. E.g. batch and serial ID, as above for vaccines.	Comment noted, added to backlog. This data group is intended to describe medication use, not an order or administration. "Medication order", "Medication administration record" and "Medication dispense record" have been added to the backlog. "Batch" and "Serial ID" could be included in those data groups.

	<p>- Due to transition of care element use case for this data concept, consideration should be given to an optional field for medication start date in relation to the patient's current meds.</p> <p>It's unclear whether these data groups will be used for a medication order (mentioned in list at beginning of section, but states 'Not to be used to record a medication order' under misuse). It would be good to clarify the intent, especially for future use cases related to traceability of medicines and management of medicine shortages.</p>	<p>Comment noted, added to backlog. "First prescribed date/Medication start date" have been added to the backlog.</p> <p>Content removed as no longer relevant.</p> <p>Agree. The beginning of the section is not adding clarity and has been removed.</p>
AUCDI050	<p>The data elements 'Medication name', 'Clinical indication', 'Endpoint' and 'Last administration' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.</p>	<p>Comment noted, content removed and added to backlog. Please note "Endpoint" and "Last administration" have been removed from AUCDI R1 and have been added to the backlog.</p>
AUCDI051	<p>Medication use statement might be a useful part of an Aged Care Assessment as clients are interviewed about their medication usage. It might be useful to reach out the ACAT teams to see if they have feedback on this schema.</p> <p>There is another patient record maintained by aged care service providers called the Medication Chart – this would be a useful subdomain of that data group. It would be nice to see if the Electronic National Residential Medication Charts team have any thoughts: <a href="https://www.health.gov.au/topics/aged-care/providing-aged-care-services/delivering-quality-aged-care-services/electronic-national-residential-medication-charts">https://www.health.gov.au/topics/aged-care/providing-aged-care-services/delivering-quality-aged-care-services/electronic-national-residential-medication-charts</a></p>	<p>Comment noted, no change.</p> <p>This data group is intended to describe medication use, and so does not necessarily align to a medication chart. A medication chart would align more closely to "medication order" which is in the backlog.</p>
AUCDI035	<p>In considerations for use "extemporaneous"- please use plain language instead of this. consider specifically identifying herbal or alternative remedies as nutritional product doesn't necessarily cover topical or ingested agents</p>	<p>Comment noted, no change.</p> <p>Extemporaneous is common clinical language and well understood. The list provided is not exhaustive and may include other alternative products.</p>

## 12. AUCDI R1 Section: Encounter – Clinical Context

### 12.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
24	10	4	1	8	5

### 12.2. Reason for Encounter

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI010	The reason for encounter has traditionally been freetext in hospital PAS systems for years so while a codeableconcept supports freetext entry, we need to recognise that the adherence to the proposed value set will be almost nil (in the hospital space). There is no current workflow where any clinician routinely sets a reason for encounter in a codified fashion today so any attempt to do so would be a significant change in workflow in order to implement.	Comment noted, no change. Agree. This data element is optional and supports free text for the reasons you described.
AUCDI014	Agree there needs to be distinction from diagnosis but also can accept crossover.	Comment noted, no change.
AUCDI015	Reason for Encounter Terminology I have commentary related to the recommended code system / value set for Reason for Encounter. The suggested terminology, <a href="https://www.healthterminologies.gov.au/integration/R4/fhir/ValueSet/reason-for-encounter-1">https://www.healthterminologies.gov.au/integration/R4/fhir/ValueSet/reason-for-encounter-1</a> , seems onerous for practitioners to add another piece of information to an Encounter. The terminology in this data set overlaps with, and if not entered or validated correctly may clash with, existing descriptions of the encounter's services that are included for the purposes of claiming for the encounter.	Comment noted, no change. Reason for encounter is not intended to be used for category of encounter. The implementation of reason for encounter is not intended to solve billing issues.  Like the USCDI, the AUCDI's primary purpose is not intended to look at claims/billing specific issues. In the US there is a specific FHIR accelerator called DaVinci which is looking at this problem.

	<p>It would be advantageous if Reason for Encounter could somehow align with existing classifications of the encounter. Some considerations below:</p> <ul style="list-style-type: none"> <li>- Most, if not all, encounters would already align with using an encounter reason to claim for the encounter through known data sets used with ECLIPSE's eligibility or claiming web services. It may be difficult to find consensus between primary, acute and tertiary care but MBS items appear common to all types of Encounter. However there are problems with the wordiness of MBS items.</li> <li>- ECLIPSE's OEC web service has a list of 'presenting illnesses'. While breaching the consideration that this field should not be the 'reason for booking', it does neatly explain 'the reason for initiating a healthcare encounter or contact by an individual, as recorded by the clinician during or after the encounter.' However this is hospital specific for the purposes of health insurance eligibility and therefore not as widely adopted.</li> <li>- Considering the design principle to align with international standards and initiatives (such as International Patient Summary), and that we'd ultimately want to exchange Reason for Encounter information with non-Australian targets, an option that leverages the above considerations may be to use concept maps. Commentary could be included that recommends the development (through AU Sparked) and sharing of concept map(s) using the above examples of existing Australian terminology to the recommended data set. Whilst there are inherent issues in mapping, standardised concept maps would minimise misinterpretation. This approach could be used to encourage the exchange of Reason for Encounter information without imposing additional requirements on practitioners.</li> </ul>	
<p>AUCDI017</p>	<p>This may be a bit more difficult to standardise and have completed correctly than the Diagnoses</p>	<p>Comment noted, no change.</p>
<p>AUCDI050</p>	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this</p>	<p>Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where</p>



	<p>mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>It's not clear whether administrative encounters are considered in or out of scope for R1. Under 'Considerations for use' for the data group, it says: "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 indicates that only clinical encounters are in scope for R1. However, under 'Considerations' for the 'Reason for encounter' data element, it says: "The reason may be for clinical, social, or administrative purposes." Is the proposed value set only scoped to cover clinical encounters, or is this also intended to cover administrative encounters? The AIHW encourages inclusion of administrative encounters in scope for R1.</p>	<p>they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>Administrative reasons for encounter within a clinical context (e.g follow up, review, employment check, annual physical) would be considered in scope. Purely administrative encounters that do not require a clinical consultation would be considered out of scope e.g. notarising a document, generating a medico-legal report</p>
AUCDI025	<p>Scyne Advisory &amp; NSW Health Pathology Forensic Medicine has noted that the clinical field of Forensic Medicine is underrepresented in the FHIR standard. Scyne Advisory &amp; NSW Health Pathology Forensic Medicine would welcome the opportunity to support Sparked in developing this content.</p>	<p>Comment noted. Sparked is an open, collaborative community and welcomes Scyne Advisory &amp; NSW Health Pathology Forensic Medicine joining the community and contributing.</p>

### 12.3. Modality

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	<p>This should be mandatory. It seems to me that this is important information for future data analysis. For example, are some doctors better at video diagnosis than others? Do patients with Problem X tend to consult via Telephone?</p>	<p>Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>
AUCDI015	<p>Encounter Modality vs. Encounter Class</p>	<p>Comment noted, no change.</p>

	<p>It is difficult to envisage, from the examples provided, how Encounter Modality will be distinct from FHIR's Encounter.class for hospital encounters, i.e. where the encounter is classified as IMP (inpatient), AMB (ambulatory / outpatient), EMER (emergency), SS (short stay), etc.</p> <p>Section 7.9.5 (For future consideration) alludes to inclusion of Encounter.class as a potential candidate data element in AUCDI Release 2. How would this information be distinct?</p> <p>I would recommend that Encounter class, as a well supported FHIR resource element, should be used to realise the concept of Encounter Modality. Hence, rather than considering the usage of Encounter class as a separate data element, it should be considered how a single data element may describe both the Encounter's modality and its classification.</p>	<p>Encounter modality is method used to conduct the encounter, not how the encounter is classified by location.</p>
AUCDI025	<p>Scyne Advisory &amp; NSW Health Pathology Forensic Medicine has noted that the clinical field of Forensic Medicine is underrepresented in the FHIR standard. Scyne Advisory &amp; NSW Health Pathology Forensic Medicine would welcome the opportunity to support Sparked in developing this content.</p>	<p>Comment noted.</p> <p>Sparked is an open, collaborative community and welcomes Scyne Advisory &amp; NSW Health Pathology Forensic Medicine joining the community and contributing.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>
AUCDI032	<p>Unclear what "Modality" means in this context. Does it mean Telehealth / Face-to-face or At Clinic / RACF / Home Visit etc? More explanation needed.</p>	<p>Comment noted, no change.</p> <p>Encounter modality is the type of communication or method used to conduct the encounter, not how the encounter is classified by location. The RACF and Home Visit examples are the encounter location and are considered technical attributes and should be recorded by the system.</p>

#### 12.4. Encounter – Clinical Context: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI004	Need date and time	<p>Comment noted, no change.</p> <p>DateTime of recording of an encounter should be recorded for the encounter as a whole, rather than against single data elements. Encounter date is considered 'system information' and is out of scope for AUCDI.</p>
AUCDI008	Seems ok. Make Modality mandatory.	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>
AUCDI016	I don't really see the usefulness of this in its current state, it seems too lacking to be a model of its own. It needs to be expanded upon to have merit. Perhaps it could wait for publication, because the context it gains from expansion would allow it to be considered better.	<p>Comment noted, no change.</p> <p>These two data elements were selected as clinically relevant data elements for inclusion within AUCDI R1. It is anticipated that this data group may be expanded in future releases.</p>
AUCDI021	<p>Not including the Participants greatly undermines the quality of the Encounter concept. Knowing that patient had an encounter for a cough is greatly informed by whether that encounter was with a GP, physician, physiotherapist or oncologist.</p> <p>If the intent is that clinical systems will record Participants anyway, which is what the document seems to indicate, then clear guidance on how to share that information between systems and sectors of care should be included in this release.</p>	<p>Comment noted, no change.</p> <p>System information includes the encounter date, participants, category of encounter, location of encounter, etc. These technical attributes are outside the scope of this data group and would sit in the FHIR IG.</p>
AUCDI025	Scyne Advisory & NSW Health Pathology Forensic Medicine has noted that the clinical field of Forensic Medicine is underrepresented in the FHIR standard. Scyne Advisory & NSW	Comment noted.

	Health Pathology Forensic Medicine would welcome the opportunity to support Sparked in developing this content.	Sparked is an open, collaborative community and welcomes Scyne Advisory & NSW Health Pathology Forensic Medicine joining the community and contributing.
AUCDI027	This really feels like it should have a datetime as when encounters happen matters a lot. Also, it would be good to have some kind of encounter identifier so it can be linked to things like procedures, medications, etc.	Comment noted, no change. DateTime of recording of an encounter should be recorded for the encounter as a whole, rather than against single data elements. Encounter date is considered 'system information' and is out of scope for AUCDI.
AUCDI030	think encounter date for consult/visits and date range should be explicit on exchange as is needed to make use of the information	Comment noted, no change. DateTime of recording of an encounter should be recorded for the encounter as a whole, rather than against single data elements. Encounter date is considered 'system information' and is out of scope for AUCDI.
AUCDI036	Suggest adding a data element to collect a comment. This would be useful to provide further context about the need and outcome of the encounter. e.g. adverse reaction in response to taking a medicine.	Comment noted, added to backlog. "Comment" has been added to the backlog.
AUCDI048	The Encounter data group needs associated date/time stamps as these are relevant for clinical and other use cases. At a minimum, a start date/time stamp needs to be included.	Comment noted, no change. DateTime of recording of an encounter should be recorded for the encounter as a whole, rather than against single data elements. Encounter date is considered 'system information' and is out of scope for AUCDI.
AUCDI050	The data elements 'Reason for encounter' and 'Modality' align to data elements within the AIHW's data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.	Comment noted.
AUCDI051	Would be great to get Aged Care Assessments (IAT an AN-ACC) added to the reason-for-encounter value set so that Aged Care can take advantage of this data group.	Comment noted, no change. System information includes the encounter date, participants, category of encounter, location of encounter, etc. These technical attributes are outside the scope of this data group and would sit in the FHIR IG.
AUCDI052	Encounter – support the requirements to include a location category (e.g. hospital vs home vs aged care). The relevance for us	Comment noted, no change.

	<p>is in the ability to measure severity for our notifiable communicable diseases. Consistency here will lead to better case-based hospitalisations measures. Encounter information is often used by administrative and data integration teams when linking case-based surveillance with inpatient data to measure burden of disease.</p>	<p>System information includes the encounter date, participants, category of encounter, location of encounter, etc. These technical attributes are outside the scope of this data group and would sit in the FHIR IG.</p>
<p>AUCDI033</p>	<p>We recommend adding references to HL7 International FHIR standards and the International Patient Summary in section 7.9.4, Table 58 - Aligns and leverages international standards and initiatives. The proposed additions help keep the Encounter – Clinical Context data concept aligned with international standards.</p>	<p>Wording updated and new content added to reflect comment. Document has been updated to reference the Encounter FHIR profile.</p>

## 13. AUCDI R1 Section: Sex and Gender

### 13.1. Overall Recommendation

Accept	Minor	Major	Reject	Abstain	No vote
25	6	6	0	10	5

### 13.2. Sex assigned at birth

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	Is this meant to be Optional? I thought all birth certificates have this information, so the health record of the birth should as well.	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.
AUCDI012	NZ FHIR IG has "sex-at-birth", bound to the FHIR "AdministrativeGender" value set. Same concept, different solution.	Comment noted, no change. The TDG will be making decisions about how to represent this clinically important concept in the context of current FHIR specs.
AUCDI029	having this without sex for clinical use creates confusion in light of existing sex for administrative use in existing systems	Comment noted, added to backlog. As per discussions in the CDG/TDG, the sex parameter for clinical use has been added to the backlog for future discussions.
AUCDI032	Suggest "Birth sex" used instead in line with current RACGP standards.	New content added to reflect comment. The term 'Sex assigned at birth' has been deliberately chosen to reflect the clinical observation made at birth, especially to try to differentiate the term from the phrasing of 'Birth sex' on official documents.  'Birth Sex' has been added as an alias.

AUCDI048	<p>It is strongly recommended that:</p> <ol style="list-style-type: none"> <li>1. The description of this data element clearly note that Sex assigned at birth is not always clinically reliable because the sex captured at birth is not always correct or can be different to what is required for certain clinical interventions.</li> <li>2. The Considerations section should very clearly clarify what is meant by “stable” in the context for the statement: “Sex assigned at birth is assumed to be stable unless an error is determined by genetic testing at a later date”. Further, what should happen to the Sex Assigned At Birth value if an error is determined?</li> <li>3. The Consideration section should include text describing how and where Sex Assigned At Birth can reliably be collected from? For example, are birth certificates considered reliable or not for obtaining Sex Assigned At Birth?</li> </ol>	<p>Comment noted, no change.</p> <ol style="list-style-type: none"> <li>1. Sex assigned at birth is considered reliable in the majority of situations by clinicians and should be updated if incorrect. If Sex assigned at birth is different to what is required for certain clinical interventions, the clinician should be able to specify what data is required outside of Sex assigned at birth.</li> </ol> <p>Wording updated and new content added to reflect comment.</p> <ol style="list-style-type: none"> <li>2. Document has been updated for clarity to 'Sex assigned at birth' is assumed to be reliable in the majority of births and will not change unless an error is determined at a later date. Any error in 'Sex assigned at birth' should be updated."</li> </ol> <p>Comment noted, no change.</p> <ol style="list-style-type: none"> <li>3. The term 'Sex assigned at birth' reflects the clinical observation made at birth by the clinician recording the birth, and is not necessarily equivalent to 'Birth sex' on official documents. This value is collected in the child's birth record and extracts then used to register a child's birth and feeds into perinatal collections. Birth certificate may not be reliable.</li> </ol>
AUCDI045	<p>“Sex Assigned at Birth” - Sex is not “assigned” - you just have it at birth. Rename to “Sex at Birth”.</p>	<p>Comment noted, no change.</p> <p>The term 'Sex assigned at birth' has been deliberately chosen to reflect the clinical observation made at birth. In that context it is assigned by the clinician recording the birth.</p>
AUCDI049	<p>It was good to note the concept of sex for clinical use was under consideration for future consideration.</p>	<p>Comment noted.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>The proposed value set for ‘Biological Sex’ does not align entirely with the Australian Bureau of Statistics standard for sex. In particular, the proposed Biological Sex value set distinguishes</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p>

<p>between 'Intersex' and 'Indeterminate sex', whereas the ABS standard groups these values together as 'Another term'. It appears the more granular values in the proposed value set could be rolled up to align to the ABS standard. The AIHW currently uses the ABS standard within METEOR and advocates for adoption of or alignment to this standard.</p> <p>We understand there are additional reasons why intersex is captured in a separate item 'Variations of sex characteristics' in the ABS standard, rather than in sex assigned at birth. ABS aligns with intersex human rights perspectives and takes into account data quality issues. For example:</p> <ol style="list-style-type: none"> <li>1. Intersex Human Rights Australia (IHRA) opposes constructions of third categories of sex named 'intersex', as these fail to respect the diversity of sex markers and identities held by people with intersex variations. More information can be found here: <a href="https://ihra.org.au/36785/abs-standard-2021">https://ihra.org.au/36785/abs-standard-2021</a>. The AIHW also recommends direct consultation with IHRA about the collection of the diversity of sex markers and identities that are needed by clinicians that are also sensitive of stigmatisation, discrimination and harm.</li> <li>2. People born with variations in sex characteristics may be male or female.</li> <li>3. Variations in sex characteristics can be identified later in life, not always at birth.</li> </ol> <p>The proposed value set for 'Sex assigned at birth' seems to only include permissible values but no supplementary values (e.g. not stated) that can be used for administrative purposes. This seems to differ from the approach used for the proposed value set for 'Gender identity response', where the value set contains both permissible values and supplementary values. It is suggested that all proposed value sets, including 'Sex assigned at birth', include standardised supplementary values for administrative purposes.</p>	<p>Comment noted, added to backlog. Agree. "Sex characteristics" is important information that should be collected to provide appropriate clinical care and has been placed on the backlog for discussion.</p> <p>Comment noted, no change. The value set proposed is a clinical value set, while the ABS and Meteor is a reporting value set. The values for indeterminate and intersex in the clinical value set can be mapped/rolled up to 'Other'/'Another term' to meet reporting requirements. 'Intersex' is a clinical observation which has clinical implications. Please note: The code value 'Indeterminate' will usually only be recorded at birth or in early infancy as a temporary value until further investigation, including diagnostic testing, enables one of the other three values to be assigned.</p>
---	---



AUCDI035	be able to see timeline information and change history	Comment noted, no change. The AUCDI specifications are intentionally kept neutral of implementation strategies and functional workflow and so this is currently out of scope of the data model.
----------	--	--

### 13.3. Gender Identity

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	Gender identity can change over time and there may be a need to record multiple occurrences (currently only a single occurrence is allowed). If the intention is to only require the most recent, some guidance explaining this could be helpful.	Comment noted, no change. AUCDI states to 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. However, this does not exclude the possibility of accessing a record of previous 'Gender identity' instances through a history of revisions or an audit trail.
AUCDI008	Is there a case to make this mandatory?	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.
AUCDI032	Suggest "Gender" in line with current RACGP standards.	Comment noted, no change. The term 'Gender identity' has been deliberately chosen to reduce confusion from the conflation of sex and gender in use in systems. 'Gender' has been included as an alias to recognise the reality of current implementations.
AUCDI048	It is strongly recommended that: 1. The Occurrence section be updated to change "single occurrence" to "multiple occurrences" given that gender identity is fluid and may change over time and have time stamps associated.	Comment noted, no change. 1. AUCDI states to 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. However, this does not exclude

	<p>2. The Alias of “gender” should be removed as “gender” is very different to “gender identity”.</p>	<p>the possibility of accessing a record of previous 'Gender identity' instances through a history of revisions or an audit trail.</p> <p>2. The term 'Gender identity' has been deliberately chosen to reduce confusion from the conflation of sex and gender in use in systems. 'Gender' has been included as an alias to recognise the reality of current implementations.</p>
AUCDI050	<p>What is the rationale for this data element being optional? It would also be helpful to understand if the intention is to make this mandatory in a later release, or if the intention is to keep this as an optional data item on an ongoing basis and why.</p> <p>The proposed value set for 'Gender Identity Response' does not align entirely with the Australian Bureau of Statistics standard for gender. In particular, the ABS standard includes a permissible value of 'Different term', whereas there is no equivalent value in the proposed Gender Identity Response value set. There would be no way to reverse engineer this value if the proposed value set contains less granularity. The AIHW currently uses the ABS standard within METEOR and strongly advocates for adoption of this standard to make the data element more comprehensive.</p>	<p>Comment noted, no change.</p> <p>The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>The value set proposed is a clinical value set, with non-binary being an umbrella term for gender identities that are not solely male or female. The value set proposed aligns with international HL7 standards.</p>
AUCDI033	<p>The context for the Sex and Gender class implies this data can be used for clinical care, but for adult patients, the sex assigned at birth might be inappropriate for care. To align with the HL7 International Gender Harmony Implementation Guide, you should adopt a patient-level Sex Parameter for Clinical Use to provide the current biological sex categorization. This concept would apply to both newborns and adults, where sex assigned at birth is known to be an accurate biological categorization for newborns. Alternatively, we recommend that you clarify that the Sex and Gender class is not primarily for clinical care and instead is a demographic that can be valuable for patient matching.</p>	<p>Comment noted, added to backlog.</p> <p>As per discussions in the CDG/TDG, the sex parameter for clinical use has been added to the backlog for future discussions.</p> <p>Comment noted, no change.</p> <p>Sex and gender is intended to be used for clinical purposes and should be included in a patient's clinical record for clinical decision support and patient care. Patient matching is out of scope for AUCDI.</p>

### 13.4. Pronouns

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI006	<p>This permits multiple occurrences, but that is to support concurrent pronoun use. If pronoun preferences change over time, how will that be supported? By only recording the latest or adding a date period or a currency indicator? Some informational text on the requirement would be helpful.</p> <p>There is now an NCTS value set - <a href="https://healthterminologies.gov.au/fhir/ValueSet/australian-pronouns-1">https://healthterminologies.gov.au/fhir/ValueSet/australian-pronouns-1</a></p> <p>The examples (xe/xem/xyr, ze/hir/hirs, and ey/em/eir) and alias (Neopronouns) are not covered by the value set. The value set does not include neopronouns. Either the information provided should be updated or recommendation should be made to the TDG to update the value set to include neopronouns. Which neopronouns should be supported could be helpful.</p>	<p>Comment noted, no change.</p> <p>AUCDI states to record multiple instances per data group within a health record; changes or updates over time are captured as a revision rather than a new entry. However, this does not exclude the possibility of accessing a record of previous 'Pronouns' instances through a history of revisions or an audit trail.</p> <p>Free text is permitted and should be used where the value set terms are not appropriate.</p>
AUCDI048	<p>It is strongly recommended that:</p> <ol style="list-style-type: none"> <li>1. The Occurrence section be updated to change “single occurrence” to “multiple occurrences” given that gender identity is fluid and may change over time and have time stamps associated.</li> <li>2. In the Examples section the example of ‘xe/xem/xyr, ze/hir/hirs, and ey/em/eir’ is provided however this value does not appear to be included in the Recommended code system/value set - see <a href="https://terminology.hl7.org/5.5.0/ValueSet-pronouns.html">https://terminology.hl7.org/5.5.0/ValueSet-pronouns.html</a></li> </ol>	<p>Comment noted, no change.</p> <ol style="list-style-type: none"> <li>1. Multiple occurrences are already permitted for 'Pronouns'. In a single implementation, multiple instances of 'Pronouns' may be active at any time e.g. 'She' and 'They'. However, this does not exclude the possibility of accessing a record of previous 'Pronouns' instances through a history of revisions or an audit trail.</li> </ol> <p>Comment noted, no change.</p> <ol style="list-style-type: none"> <li>2. Free text is permitted and should be used where the value set terms are not appropriate.</li> </ol>

AUCDI033	Allowing for multiple pronouns introduces complexity, both for humans and systems. Collecting only a current, single set of pronouns provides significant value, without introducing the complexity of differentiating between which set of pronouns should be used when there are multiple pronouns indicated. We recommend indicating that only a single occurrence of the current pronouns be collected.	Comment noted, no change. In a single implementation, multiple instances of 'Pronouns' may be active at any time e.g. 'She' and 'They'. This could be constrained in a particular use case, technical specification or implementation.
AUCDI035	Would not consider this as medical information	Comment noted, no change. 'Pronouns' is included to intentionally support respectful, person-centred care.

### 13.5. Sex and Gender: General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI008	Seems ok. There is a case for mandatory data elements.	Comment noted, no change. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.
AUCDI040	<ul style="list-style-type: none"> <li>Broaden the sociodemographic data collected.</li> </ul> Gender is the only demographic data element currently captured. Broader sociodemographic data is required to understand experiences of different people and socioeconomic factors on cancer outcomes. Some communities in Australia have significantly poorer cancer outcomes, including people living in socioeconomically disadvantaged areas, rural and remote locations, and Aboriginal and Torres Strait Islander peoples, have significantly poorer cancer outcomes than the general population . Understanding why these inequities occur is the first step to	Comment noted, added to backlog. Agree. Social determinants of health and social emotional wellbeing items are on the backlog and are candidates for AUCDI R2.

	<p>identifying solutions enabling Australia’s world’s best cancer outcomes to be experienced by all. Currently not all cancer-related datasets capture comprehensive area and individual level characteristics, as shown in the table on page 13 of the Developing a Data Strategy: A report for discussion (provided alongside this submission). There is variation in which items are captured, creating gaps in the data and knowledge about the experiences of these groups.</p>	
<p>AUCDI048</p>	<p>In the Context section, under use cases:</p> <ol style="list-style-type: none"> <li>1. In relation to the following bullet point: “As a foundation for personalised medical treatment, supporting both biological- and gender- specific health needs, and improving assessment of disease risk and outcomes,” - this statement needs to clarify what is meant by ‘foundation’ and the content needs to recognise that neither the data elements in this data group (i.e. Gender Identity and the Sex Assigned At Birth) are not completely reliable for all kinds of medical treatment and that further work is required in this area.</li> <li>2. In the Aligns and leverages international standards and initiatives section (pages 112 and 113): the link to the HL7 Cross Paradigm Implementation Guide: Gender Harmony – Sex and Gender Representation, Edition 1 reference, the link is to the Continuous Improvement / CI publication, and not the actual publication. The correct link is: <a href="https://hl7.org/xprod/ig/uv/gender-harmony/">https://hl7.org/xprod/ig/uv/gender-harmony/</a></li> <li>3. In the 'For Future consideration' section: In relation to the following statement: “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.” It is strongly recommend that this statement be removed for the following reasons: <ul style="list-style-type: none"> <li>• It is not only the HL7 FHIR community that has recommended the use of SPCU, it is all the stakeholders who participated in the development of the Gender Harmony implementation guides</li> </ul> </li> </ol>	<p>Comment noted, added to backlog.</p> <ol style="list-style-type: none"> <li>1. Gender Identity and Sex assigned at birth are both required to support appropriate clinical care decisions. As per discussions in the CDG/TDG, the Sex Parameter for Clinical Use (SPCU) has been added to the backlog for future discussions.</li> </ol> <p>Typographical error corrected.</p> <ol style="list-style-type: none"> <li>2. This has been updated in the document.</li> </ol> <p>Wording updated to reflect comment.</p> <ol style="list-style-type: none"> <li>3. SPCU from the Gender Harmony project has been considered for AUCDI due to suggestions from members of the HL7 AU FHIR community. This has been updated in the document for clarity.</li> </ol> <p>Comment noted, added to backlog.</p> <p>AUCDI is currently undergoing a review process to ensure each core concept has clinical utility and is clinically safe. It is appropriate that those same considerations about clinical utility and safety are undertaken prior to the proposal of a novel clinical concept such as SPCU.</p> <p>Comment noted, added to backlog.</p> <p>SPCU has been added to the backlog</p>

	<p>including clinical peak bodies, standards developers, standards development organisations and members of the LGBTQ+ community.</p> <ul style="list-style-type: none"> <li>• In relation to the statement about clinical utility and safety implication, it is expected that this applies to all data elements in the AUCDI and thus SPCU should be no different. - The statement does not clarify what is meant by “broader national evaluation” and who is responsible for this work.</li> <li>• In relation to Figure 44 (Proposed roadmap for developing the ‘Sex and Gender’ data group, [AUCDI048] has a strong need for a Sex Parameter for Clinical Use data element and would like to see this data element added to the roadmap for the next version of AUCDI.</li> </ul>	
AUCDI050	The data elements ‘Sex assigned at birth’ and ‘Gender identity’ align to data elements within the AIHW’s data model for a National Primary Health Care Data Collection and could be leveraged for this purpose.	Comment noted, no change. Agree.
AUCDI051	Based on the confluence page, it looks like 8 different substantive changes are being suggested to navigate the modernisation of sex and gender concepts in FHIR. Based on attending some of the TDG’s, this looks to be a controversial topic, is orthogonal from the standards suggested by ABS, AS4590 and the NMDS and is burning a lot of the finite time and energy of the program to come to a consensus. Although it is an important topic, given the huge roadmap of work, it might be worthwhile triaging the remaining changes with the rest of the work to do. Things like changing references to “indigenous” to “first nations people” are equally important to create an Australian culturally sensitive core.	Comment noted, added to backlog. As per discussions in the CDG/TDG, the Sex Parameter for Clinical Use (SPCU) has been added to the backlog for future discussions.
AUCDI052	For data group sex and gender – strongly support the ‘last updated’ data element for AUCDI release 2. For population health including contact tracing purposes (e.g. syphilis and HIV), the timeliness factor of gender identity is important to support the purpose to promote the cultural psychological safety of individuals, as well as our understanding of risk factors.	Comment noted. Last updated has been added to this data group for AUCDI R1.

<p>AUCDI026</p>	<p>Demographics                      Indigenous status is an important inclusion and the future road map should includes ethnicity and place of birth - both highly relevant in the big data/personalised medicine space.</p>	<p>Comment noted, added to backlog.                      "Indigenous status", "Ethnicity" and "Place of birth" have been added to the backlog</p>
-----------------	---	---

## 14. General Feedback

### 14.1. General Feedback

ID	Community Comment Feedback	Sparked Reflection / Recommendation
AUCDI047	<p>AHPA is in strong agreeance with the data groups currently being considered for AUCDI Release 2.</p> <p>AHPA would welcome a meeting with you to gain a deeper understanding of how we can best provide you with use cases which will assist in demonstrating why such data groups should be prioritised and to apply this knowledge to three areas we strongly recommend are also considered for prioritisation: functional tatus, plan of care, medical devices and equipment.</p> <p>Many different allied health professions generate clinical information of importance in these data groups as we understand them. The sharing of this information is critical for consumers and other health professionals as it can lead to: 1) More readily identifying long standing vs new conditions to help understand a level of deterioration and/or urgency related to a new care scenario; 2) Ensuring intended outcomes are achieved where consumers need assistance from their support network to implement a care plan; 3) Ensuring other health professionals assess an individual’s capacity and capability with any relevant devices and equipment in place, e.g., if an individual presents without their usual mobility devices, their independence may be assessed differently as compared to arriving with this in place; or if they present without their hearing aid, their ability to communicate may be misinterpreted.</p>	<p>Comment noted. Sparked will be in contact with AHPA.</p>



	<p>During the 2021/22 financial year, AHPA worked with practicing professionals from the 12 different allied health professions most prevalent among Aged Care service delivery to determine the most</p> <p>critical pieces of clinical information generated which should be shared. Whilst this document requires expansion beyond an Aged Care focus, we don't envisage the content requirements at the data group level would change substantially from what we found during this work if expanded. Therefore, we consider this document, which highlights the need for the 3 data groups noted, the basis for our reasoning.</p> <p>This piece of work was funded by the Australian Digital Health Agency (ADHA), therefore we have sought permission from the ADHA to share this document with you. We believe sharing this document and utilising our learnings from this work will provide a starting point for liaising with you regarding development of case studies relevant to future priority data groups. We await the ADHA to approve sharing of the document and will then provide you with the document to supplement this response as soon as possible.</p>	
AUCDI003	I am hoping that the Clinical Synopsis will be considered for R2 noting that the challenge will be a change to the vendor's clinical user interface and clinical business processes and will require collaboration and codesign with vendors. I am sure that CSIRO are up to this challenge.	Comment noted, add to backlog. "Clinical synopsis" has been added to the backlog.
AUCDI004	Is there a special reason that alcohol consumption is not included in the AUCDI? It can be as simple as the current Tobacco smoking summary group. Heavy alcohol consumption	Comment noted, added to backlog. "Alcohol consumption" has been added to the backlog and has been proposed for R2.

	does impact the decision on clinical and mental health intervention.	
AUCDI013	The absence of Date of Birth is a significant missing data group. In the webinar it was stated that this was not clinically relevant, but in the AUCDI document there are multiple use case references that require knowledge of age, and normal ranges for vitals and other measures are age dependent...	Comment noted, no change. Date of Birth has been addressed in the AU Core IG.
AUCDI016	Overall you've done a great job! I think this is on track to be very useful.	Thank you for your support.
AUCDI022	RANZCO commends the combined efforts of CSIRO, HL7 Australia, ADHA and DoHA in forming the Sparked initiative. We would like to remain part of this conversation, collaborate and promote the adoption of FHIR standards throughout the clinical community in Australia (within and beyond eyes), in keeping with the recently published National Digital Health Strategy 2023-2028 and the Interoperability Roadmap.	Thank you for your support.
AUCDI026	<p>Location MMM classification of home address or something similar should be in the road map particularly for advanced decision support and AI solutions. Also understanding socio/cultural/geographic issues will be crucial in future releases and can be underpinned by this information.</p> <p>We recognise that release one is a very pared down version of what's required for the Australian core data set and that this process has unintentionally excluded information relevant to this early release. For example, BP is only systolic and diastolic values and does not include data elements for posture or method of measurement, even though these are well developed in OpenEHR.</p> <p>We appreciate there is some benefit in starting simple and keeping to simple use cases such as existing CQI measures, to getting the technical working group started on the FHIR</p>	<p>Comment noted, added to backlog. Social determinants of health and Social emotional wellbeing items are on the backlog and are candidates for AUCDI R2. Additional elements for blood pressure have also been added to the backlog.</p> <p>This backlog is published on the Sparked website.</p> <p>Thank you for your support.</p>

	<p>specification and a path to viable early implementation. The scope section 4.4 discusses this but has not outlined a timetable of future release. There would be benefit to the community if future planning was made more visible.</p> <p>The College is comfortable with what's proposed in release one partly because it is so limited and references to existing well developed models, however we have also recommended some additions below.</p> <p>We would encourage further engagement with the College's Digital Health Committee, who are keen to be involved and understand the project workplan and process for delivery. This is a good start and important for testing the collaboration process as well as informing the 'core of the core' data.</p>	
AUCDI029	This feedback sheets hides feedback opportunities unless you explicitly answer yes to providing feedback on every element.	<p>Comment noted.</p> <p>We were trying to balance usability and functionality. Thank you for your support.</p>
AUCDI032	<p>Aboriginal and Torres Strait Islander status should be part of this standardised minimum data set.</p> <p>Future data points to consider patient self-rated wellbeing and outcome of consult. Need to move away from testing and tablets to proper preventative/public health evidence-based data. Ensure data can look at complexity; ie, problem lists and consultation issues eg NESB, expressed emotion.</p>	<p>Comment noted, added to backlog.</p> <p>"Indigenous status" and "Ethnicity" have been added to the backlog</p> <p>Comment noted, added to backlog.</p> <p>Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) have been added to the backlog for further discussion.</p>
AUCDI034	<p>Page 41 Inactive – a health condition that has resolved, is in remission, or no longer requires active treatment or management.</p> <p>Feedback: Is "inactive" appropriate for de-labelled drug allergy/ resolved allergy?</p> <p>Page 42 Potential candidate data elements for Release 2</p> <p>Feedback: Method of diagnosis</p>	<p>Comment noted, added to backlog.</p> <p>"Clinical status" and "Clinical verification" for Adverse reaction risk have been added to the backlog. Further discussion is required to ensure appropriate management of de-labelled drug allergies.</p> <p>Comment noted, added to backlog.</p> <p>"Method of diagnosis/Clinical evidence" has been added to the backlog.</p>

	<p>Please note that as an allergy organisation, we have reviewed all content with allergy in mind and our submission is limited to this perspective.</p> <p>Thank you for the opportunity to provide feedback.</p>	Thank you for your support.
AUCDI037	<p>Thanks for the opportunity to review the AUCDI release 1. We are happy with the content and have no comments. Please keep us in the loop as this piece of work is evolving.</p>	Thank you for your support
AUCDI041	<p>The Department of Health and Aged Care - Digital Health Branch is generally supportive of the AUCDI. We have abstained from endorsing each data element as we don't have the clinical expertise to do this.</p>	Thank you for your support
AUCDI042	<p>Section 7.7.5, page 93, Diagnostic Report.</p> <p>Feedback: The observation names, observation identifiers, result values, data types and units of measure will need to align with the Standard for Pathology Informatics (SPIA) and the Cancer Protocols published by Royal College of Pathologists of Australasia (RCPA), and of course the eRequesting worked being done under the Sparked project. The observations should be considered individually but also as part of the group that is the eRequesting concept.</p> <p>Section 11.1 (Appendix D), page 123 National and International initiatives.</p> <p>Feedback: this section should include reference to:</p> <ul style="list-style-type: none"> <li>• The Australian Cancer Plan and the National Cancer Data Framework</li> <li>• RCPA Pathology Terminology and Information Standardisation Projects,</li> <li>• RCPA Structured Reporting of Cancer projects, and</li> <li>• RANZCR developments in Structured Reporting.</li> </ul>	<p>New content added to reflect comment. Comment noted.</p> <p>The national initiatives have been added to the appendix.</p>

	The International section could refer to the International Collaboration on Cancer Reporting (ICCR).	
AUCDI002	Will the medical devices/implant information be included in the problem/diagnosis summary data?	Comment noted, added to backlog. Medical devices/implants will be a separate data group and has been added to the backlog. Implanted medical device summary has been started and included in the AUReqDI R1.
AUCDI004	The date format in this document is not consistent and does not follow the Australian date format. For example: 'March 15, 2024' on page 47; '0830, March, 2024' on page 102.	Wording has been updated to reflect comment. Document has been updated.
AUCDI008	<p>Please note that while I am giving feedback, I am, of course, limited in my exposure to these data models. Any input may hence be taken as food for thought without any ill intent. I am not a medical expert, however I have software engineering and data experience.</p> <p>When querying data involving DateTime having it stored internally as UTC makes it much easier. Australia (including its territories) has 6 timezones, with variations during the daylight saving period. When storing DateTime, perhaps you also need to store the timezone of where it was recorded.</p> <p>5.1.1.1 - I have comments regarding the naming under "Clinical description". Each item is prefixed with "Data group", which seems unnecessary. Is it better to rename these to Purpose, Representation, etc?</p> <p>"Alias" is described as "A list of synonyms...". Since the intention is to allow multiple synonyms, the plural "Aliases" would be more appropriate.</p> <p>7.1.x "Concept description" - Since all descriptions are summaries, would it be better to name this "Concept summary"?</p>	<p>Thank you for your support.</p> <p>Comment noted, no change. How the DateTime is stored should be represented in the technical specifications implementing the AUCDI.</p> <p>Content removed as no longer relevant. Document has been updated to remove redundancy in Data group table</p> <p>Wording updated and new content added to reflect comment. Document has been updated to reflect your suggestions.</p> <p>Comment noted, no change. The concept descriptions are not necessarily summaries of the concept, but rather a description of the clinical concept that is being modelled.</p>

AUCDI009	<p>Thorough and well-structured. Very long document. The "Reduce duplication, single entry..." and "Driven by clinical quality..." sections could be candidates for tightening the document as they outline general alignment to design principles which are often repeated for each data group.</p> <p>In future, perhaps a model-based systems engineering approach could be considered where the logical data model sits alongside, and is linked to business architecture like drivers, business capabilities, value streams etc. and technology architecture elements like servers, NCTS, etc., all represented as elements that are re-usable and traceable. The model views provide different levels of abstraction and detail which can be used to communicate with different stakeholder groups.</p> <p>Figure 6, Page 22: are the arrows for "builds on" and "feeds into" meant to be flipped? Figure 7, Page 23: is the arrow for "enables" meant to be flipped?</p>	<p>Comment noted. Figures have been updated.</p>
AUCDI011	<p>Currently there is no section which records information concerning alcohol consumption or use. While its addition has been noted for future releases, I believe this is a key minimum piece of information to collect, similar to smoking status. This data supports the collection of data for Practice Incentives Program Quality Improvement Measures, specifically necessary for the calculation of proportion of patients with an alcohol consumption status. Additionally a record of alcohol consumption can be used to support other initiatives such as cardiovascular disease risk and is commonly used for clinical decision making.</p>	<p>Comment noted, added to backlog. "Alcohol consumption" has been added to the backlog.</p>
AUCDI012	<p>AUCDI R1 appears to exclude service requests and diagnostic results (p.p. 18, 29). Case study 1 (p.19) references "pathology request" and case study 2 references "pathology results". Laboratory test results inform the biomarkers.</p>	<p>Comment noted, no change. These were included for completeness and are the focus of eRequesting which is currently in development.</p>

AUCDI014	<p>There are no data components to represent "provider" and "health service". No data components representing patient demographics (with exception of gender). Exclusion statements are unspecified (e.g. none recorded, non known). Require clarification whether optional attributes are optional for implementation in software systems. How does this relate to and support the work on e-requesting? These issues must be addressed/clarified for the final draft.</p>	<p>Comment noted, no change.  Provider and patient are supported by the AU Core IG. Modelling of absence of concepts (including exclusion statements) is a TDG responsibility. The CDG will be involved included in discussions in how to represent these concepts.</p> <p>Comment noted, no change.  The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements are only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation.</p> <p>AUeReqDI defines the Data for Interoperability requirements for eRequesting and incorporates the relevant data groups from AUCDI and contains additional data groups that are required to facilitate the exchange of a request.</p>
AUCDI016	<p>I think "created at" and "last updated" fields would be useful on most models. They would be mandatory.</p>	<p>Wording updated to reflect comment.  Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary</p>
AUCDI017	<p>I think the challenges will be (i) getting updated data following an initial notification and (ii) having the data correctly entered at the point of contact.</p> <p>The updated data is discussed at various points - so looks like this has been considered. There are several scenarios - coded incorrectly in the first place; was initially suspected but then disproven or is no longer an active problem. If people have multiple contacts of care and one contact enters a diagnosis which is subsequently found to be incorrect at another contact</p>	<p>Comment noted.  The backlog for AUCDI is now available on the Sparked website and will assist with the scoping of R2. It will be updated as work progresses.</p>

	<p>of care - how would that be recognised and updated? I frequently receive referrals where the medication list is not current because it has not been reviewed and updated; there may also be a long list of diagnoses (including anything from medical problems to dates in which vaccination was provided) but they are not necessarily all current problems.</p> <p>We have recently converted from paper to electronic medical records system. It contains lots of boxes for data to be entered but there still lacks consistency in what is added when and where. The more specific the data you are after, I suspect the less complete and accurate it will be.</p>	
<p>AUCDI018</p>	<p>Further releases of AUCDI could closely mirror USCDI data elements for uniform data exchange across continents.</p> <p>The following data elements should be considered:</p> <ul style="list-style-type: none"> <li>• Patient Demographics - Data used to categorize individuals for identification, records matching, and other purposes. <ul style="list-style-type: none"> <li>o First Name</li> <li>o Last Name</li> <li>o Middle Name</li> <li>o Suffix</li> <li>o Previous Name</li> <li>o Race Ethnicity</li> <li>o Preferred Language</li> <li>o Current Address</li> <li>o Previous Address</li> <li>o Phone Number</li> <li>o Phone Number Type</li> <li>o Email Address</li> </ul> </li> <li>• Clinical Notes - Narrative patient data relevant to the context identified by note types. <ul style="list-style-type: none"> <li>o Consultation Notes</li> <li>o Discharge Summary Notes</li> </ul> </li> </ul>	<p>Comment noted, no change.  AUCDI references the USCDI and aligns as much as possible given the different priorities.</p> <p>Thank you for your suggestions. The backlog for AUCDI is now available on the Sparked website and will assist with the scoping of R2. It will be updated as work progresses.</p>



	<ul style="list-style-type: none"> <li>o History &amp; Physical</li> <li>o Procedure Notes</li> <li>o Imaging Narrative</li> <li>o Laboratory Report Narrative</li> <li>o Pathology Report Narrative</li> <li>• Care Team Members - Information on a person who participates or is expected to participate in the care of a patient.</li> <li>o Care Team Member</li> <li>• Assessment and Plan of Treatment - Health professional's conclusions and working assumptions that will guide treatment of the patient.</li> <li>• Laboratory - Analysis of clinical specimens to obtain information about the health of a patient.</li> <li>o Lab Tests</li> <li>o Lab Results/Values outside of the available Biomarkers</li> </ul>	
<p>AUCDI021</p>	<p>* I would welcome a position on the inclusion of Provenance resource in the initial release. If adoption proceeds as we would hope, then there will be a wealth of Resources saved, updated and deleted and often done so by machine processes rather than humans, and patient-collected rather than clinician. The degree of quality or trustworthiness of data in large repositories will not be equal and metadata on who, what, when, where and why collected from the outset in a standardised manner will provide clarity and trust across the CRUD lifecycle. Provenance can be directly visible for for clinical usage in circumstances that Audit Logs may not be appropriate to show. I think that it will be harder to retrofit Provenance in a later release, particularly for already collected data.</p> <p>* I would welcome a position on the inclusion of CareTeam resource in the initial release. Australia is extremely fragmented in it's care coordination across primary, aged, acute and allied sectors with all of the negative consequences in quality and efficiency evident. Including CareTeam will provide the industry</p>	<p>Comment noted, no change. Provenance is a TDG responsibility. The CDG will be involved included in discussions in how to represent these concepts.</p> <p>Comment noted, added to backlog. Care team has been added to the backlog.</p> <p>Content updated to reflect comment. Thank you for the feedback. The tables have been updated to hopefully be more readable.</p>

	<p>with clear direction on how to model multidisciplinary, multisector care. It will put the patient at the centre and assist them with understanding who is who in their zoo. Large and complex care teams such as in cancer management are an example. It will help inform emerging models of care with greater clarity if the eHealth industry players can all contribute in a common manner to the assembly and maintenance of CareTeams and provide valuable insight into what works and what doesn't. eg "do patient cohorts with Type 2 Diabetes complications have better outcomes with a designated dietician and podiatrist on their care team?".</p> <p>* Orange is a very FHIRy colour but is a bit hard on the eyes when used in big colour blocks (eg pages 27-34). Can the document be reviewed by a graphic designer with expertise in colour theory to optimise readability and cognitive burden and reduce eye strain.</p>	
<p>AUCDI022</p>	<p>RANZCO endorses this initiative and collaboration. Ocular health is not only about optimising vision and preventing blindness, the eye is also a window into and manifestation of disease states affecting the whole body. These include some of the highest sources of morbidity and mortality in Australia, including diabetes, blood pressure and other cardiovascular risk factors, as well as neurodegenerative diseases, such as Alzheimer's dementia. Hence, there is collaboration within eyecare (optometry and ophthalmology), as well as with other physicians and allied health professionals throughout the course of chronic disease.</p> <p>At present in Australia, access to eye healthcare is not equitable. Aboriginal and Torres Strait Islander people, ethnic minorities and other vulnerable groups, regional Australian residents, and those Australians with lower incomes have reduced access to eye healthcare. In addition to the problem of inequity, the need</p>	<p>Thank you for your feedback. The Sparked team look forward to your contributions in eye related content.</p>

	<p>for eye healthcare services is increasing across all patient groups. This is due to our growing and ageing population, with eye disease more prevalent in older Australians, increased obesity and thus diabetic retinopathy, and the advent of new treatments and technologies, which improve outcomes but require increased servicing and costs to deliver.</p> <p>Therefore, there are many reasons for the eye care professional community to participate in and advocate for standards based interoperability. The 'Sparked' initiative, based on HL7-FHIR technology is a step forward for healthcare technology in Australia that holds great potential to save costs, track outcomes and deliver higher quality care more effectively and efficiently.</p> <p>As a high volume multimodal imaging specialty, ophthalmology would certainly take full advantage of the native FHIR-DICOM interface. Additionally, recent advancements in artificial intelligence (AI) in medicine have presented (predominantly) image-based algorithms that can assist with tools for population-based screening and prognostication. AI's new frontier will be able to cater for more personalised prediction model development when imaging and clinical data can be combined. This is only feasible with FHIR's real-time underpinning technology.</p> <p>Developing AUCDI is a necessary step to ensure semantic interoperability that is based on a single lexicon that is suitable for Australians. This is similar to the USCDI, which emerged from the 21st Century Cures Act final rule in the United States. However, one key learning was the lack of specialty-specific extensions and/or implementation guides. For instance, there was no universal way of digitally representing visual acuity within the base standard of USCDI (likely the most basic and fundamental piece of clinical information captured and</p>	
--	--	--

	<p>communicated) until the American Academy of Ophthalmology published a paper and underwent a very rigorous submission process to include this single clinical parameter (Ref: Baxter, S. L. et al. Ocular Health and National Data Standards: A Case for Including Visual Acuity in the United States Core Data for Interoperability (USCDI). Ophthalmol Sci 2, 100210 (2022)).</p> <p>Given the multitude of use cases for FHIR it is absolutely essential to have a clinically informed ophthalmic-specific (in the case of eyes) implementation guide to enable homogenous implementation and adoption nation-wide. This is where the real gains to all healthcare stakeholders can be realised.</p> <p>RANZCO has supported and its members been involved with leading the development of the “Eyes on FHIR” project, which intends to address this precise issue. However, this initiative (housed within the Patient Care Working Group of HL7), lacks regional specification for Australia, and would also benefit from broadening its scope through ongoing use-case driven standards development work and additional development of FHIR Resources (Profiling) to expand its utility.</p>	
<p>AUCDI023</p>	<p>In general we support the program and can see it is following best practice and utilising existing resources wherever possible. A broad question would be around the maintenance of the valuesets specified. Is there a commitment to regular review and if so, what is the proposed schedule and who will undertake the reviews for each valueset?</p> <p>Secondly we would recommend that alternative codes be supported in the model - in addition to the recommended codes system. E.g. MIMS has over 3000 terms in our database which are not available in AMT. Of those terms, over 500 are ARTG registered products. When there is no AMT available, the ability to send a code, together with an identifier for the origin of said</p>	<p>Comment noted, no change.</p> <p>The value sets that have been specified are broad value sets maintained by the National Clinical Terminology Service. As content is added to SNOMED CT and AMT, the value sets are updated.</p> <p>The recommended value sets in the AUCDI (and the recommended bindings in the AU Core IG) do not prohibit the use of other codesystems outside the value sets specified. This means that other codes (and their associated code systems) could still be exchanged.</p>

	code, will provide more robust coverage. Note, MIMS codes have previously been referenced in HL7 FHIR spec v2 <a href="https://build.fhir.org/ig/hl7au/au-fhir-base/CodeSystem-mims-external.html">https://build.fhir.org/ig/hl7au/au-fhir-base/CodeSystem-mims-external.html</a>	
AUCDI025	Scyne Advisory & NSW Health Pathology Forensic Medicine has noted that the clinical field of Forensic Medicine is underrepresented in the FHIR standard. Scyne Advisory & NSW Health Pathology Forensic Medicine would welcome the opportunity to support Sparked in developing this content.	Comment noted. Thank you for your support.
AUCDI026	<p>We recognise that release one is a very pared down version of what's required for the Australian core data set and that this process has unintentionally excluded information relevant to this early release. For example, BP is only systolic and diastolic values and does not include data elements for posture or method of measurement, even though these are well developed in OpenEHR.</p> <p>We appreciate there is some benefit in starting simple and keeping to simple use cases such as existing CQI measures, to getting the technical working group started on the FHIR specification and a path to viable early implementation. The scope section 4.4 discusses this but has not outlined a timetable of future release. There would be benefit to the community if future planning was made more visible.</p> <p>The College is comfortable with what's proposed in release one partly because it is so limited and references to existing well developed models, however we have also recommended some additions below.</p> <p>We would encourage further engagement with the College's Digital Health Committee, who are keen to be involved and understand the project workplan and process for delivery.</p>	<p>Comment noted. Thank you for your support.</p> <p>The backlog has been published on the Sparked website and will assist with the scoping of R2.</p>

	This is a good start and important for testing the collaboration process as well as informing the 'core of the core' data.	
AUCDI027	<p>It would be nice to address the clinical coding issue in more detail. Clinical coding systems rarely have a unique way of specifying a data point (particularly when you consider existence of both more general and more specific terms). Systems like SNOMED can have synonyms with different values. Just saying use clinical codes, even specifying SNOMED is possibly still too general without consideration for how to make them understood on the other side.</p> <p>Consistency with the future is stated as an important goal. However, the roadmap shows significant changes and increase in structure going forwards (adverse risk is a good example of this). While I understand that these structures aren't useful given the limited information that is aimed for release 1, keeping the structure the same, even where it is excessive seems logical since it means that R1 can continue running even with R2 released. Having to handle many different versions and structures (that we can already foresee) seems like it would limit adoption and create avoidable fractures within the community as versions changed. This is particularly problematic if there is to be more than one potential receiver of this data.</p>	<p>Comment noted, no change. The AUCDI specifications are not technical implementation guides and intentionally kept neutral of implementation strategies and functional workflow and so this is currently out of scope of the data model.</p> <p>Comment noted, agree. The roadmap has been included to give guidance towards extensions that will be backwardly compatible.</p>
AUCDI028	<p>Currently I am convening a consumer reference group to help guide WA's foundational work on an Electronic Medical Record on behalf of the Health Consumers' Council of Western Australia (HCC). This follows on from the co-design of a Consumer Charter for an EMR, based on the Queensland Consumer Digital Charter. This AUCDI R1 initiative came to my attention and I wanted to provide some overarching comments as a consumer consultant, on behalf of HCC.</p> <p>From a consumer perspective, it is of concern that there hasn't been a consumer voice embedded in this project from the start, and at all levels of governance. For example, the choice of</p>	<p>Comment noted. Sparked appreciates all voices and agree that consumer input is critical. One of the CDG co-leads is a consumer advocate. The CDG membership also includes consumer advocates and public health consumer organisations. We welcome your participation.</p>

	<p>clinical information models for R1 has been made in the absence of a consumer voice.</p> <p>While there are challenges in having a well-informed, well-resourced group of digitally literate consumers, this is surely a challenge this project needs to tackle.</p> <p>Essentially we would like to know in relation to the clinical information models outlined in this version "If this is the way it operates, will it assist consumers in their health journey?" This is not something that we can provide for this round of feedback. However we wanted this feedback noted for future planning.</p> <p>Our work over the last several years has highlighted that interoperability is at the absolute top of the list for digital health consumers. The siloes of our health system lead to fragmented care and digital solutions may potentially assist in alleviating the challenges which impact the consumer and their families first and foremost. We need to be at the table.</p>	
<p>AUCDI029</p>	<p>Figure 3: Unclear how and why International Patient Summary is included in the AUCDI scope. This needs description/justification.</p> <p>4.4.3: Can the community identification process be referenced? Reads like we made it up after a few beers :-). There is also some confusion on the purpose of the chosen use cases as previously it was stated that AUCDI isn't aimed at a single use case but that could imply it aimed only at the chosen 4 use cases only.</p> <p>4.5: This implies that AUCDI is expecting to design and govern data entry. I do not believe that AUCDI should be making rules around the UI experience that covers data entry.</p> <p>4.5: there is a mention of co-design but it isn't clear who the co-design is with, only the AU Core TDG is mentioned. won't the TDG just design it?</p> <p>Figure 6: what does builds on mean in reality?</p> <p>4.6 Why is IPS included when other FHIR work is not?</p> <p>Table 1: not clear on why or how person-centred is related to good clinical care and cds?</p>	<p>Comment noted, no change.</p> <p>The IPS has been included to ensure we are aligning with international standardisation efforts and was also chosen as a way to help focus and prioritise efforts for R1.</p> <p>4.4.3 While AUCDI is not for a specific use case, but to provide a foundation for multiple use cases, a series of workshops were undertaken with the community to identify and prioritise the use cases that should inform the scope and backlog prioritisation for AUCDI. Patient Summaries, including International Patient Summary, provided a good scope driver, this also recognises the significant international community process which identified the core elements of the International Patient Summary.</p> <p>4.5 AUCDI does not make rules around the UI experience, however its focus is creating data that is suitable for reuse - the principle of design but not how it is actually implemented.</p>

	<p>Table 1: primary clinical data use is a principal aimed at R1 and not a general principal for AUCDI.</p> <p>Table 1: the support now principle and alignment does not make sense, especially the bit about additional data elements. Stating they are inconsistent seems an arbitrary comment.</p> <p>Table 1: alignment with initiatives contradicts with the implementation independence stated earlier.</p> <p>Table 1: Why is IPS an alignment principle? Is there any reference for where these principles came from? It just says they were developed.</p> <p>4.7: Wouldn't someone implement the AU Core rather than implement AUCDI? If it is to be implemented then it should include implementation guidance.</p>	<p>Wording updated to reflect comment.</p> <p>4.5 This has been updated.</p> <p>Figure updated to reflect comment.</p> <p>Figure 6 - figure has been updated.</p> <p>Wording updated to reflect comment.</p> <p>4.6 This has been updated.</p> <p>Wording and table updated to reflect comment.</p> <p>Table 1 "There is good evidence that person-centred care can lead to improvements in safety, quality and cost-effectiveness of health care, as well as improvements in patient and staff satisfaction" (<a href="https://www.safetyandquality.gov.au/our-work/partnering-consumers/person-centred-care">https://www.safetyandquality.gov.au/our-work/partnering-consumers/person-centred-care</a>) .</p> <p>Primary clinical data use was referring to primary/clinical data use - Primary has been removed to avoid confusion.</p> <p>Table has been updated</p> <p>It is intended that the AUCDI is an independent foundation, with efforts made to align where possible.</p> <p>This was proposed and discussed in the CDG meetings and agreed.</p> <p>4.7 This has been updated for clarity</p>
AUCDI030	* consider including effective dates generally to allow currency assessment in decision making	<p>Wording updated to reflect comment.</p> <p>Agree. Last updated has been to all "summary" data groups and Date of measurement or Date of observation has been added to all biomarkers, vital signs and measurements. Date of assertion has been added to Medication use summary.</p>
AUCDI031	For future releases need to consider all elements of Aus CVD Risk calculator. Tools, particularly this tool, needs to be comprehensively covered, otherwise if there is too much requirement for tailoring, then concepts may be bypassed and just bespoke mapping and definitions done when integrating.	<p>Comment noted, added to backlog.</p> <p>"Ethnicity", "Family history", "Pregnancy record" and "Severity" for Problem/Diagnosis have been added to the backlog</p> <p>Comment noted.</p> <p>Agree.</p>



	<p>Items to consider for future releases include:</p> <ul style="list-style-type: none"> <li>-Ethnicity - this has impact on risk of cardiovascular disease and is listed in the Aus CVD Risk calculator.</li> <li>-Family history - this has impact on risk of cardiovascular disease and is listed in the Aus CVD Risk calculator.</li> <li>-Historical pregnancy complications - from a data perspective, these need to be handled differently to how they are currently considered. There is emerging evidence that what was once considered an historical pregnancy event, now has implications for present and future clinical condition risk. This is a crucial emerging area.</li> <li>-Ability to classify severity - eg severe mental illness. This has impact on risk of cardiovascular disease and is listed in the Aus CVD Risk calculator.</li> </ul> <p>Insight and support will need to be provided to software vendors on SNOMED mapping, this has been variable in the past and the risk is that variability will be repeated.</p>	
<p>AUCDI032</p>	<p>The RACGP wishes to provide the following general feedback from member respondents:</p> <p>Secondary use of data should not be an afterthought but purposely designed into the system. Secondary use of data supports important opportunities including:</p> <ol style="list-style-type: none"> <li>1. Research - particularly primary care research to establish evidence-based best practice.</li> <li>2. Population healthcare approaches - where healthcare design is adjusted to meet and continuously improve patient outcomes. Healthcare design can be at the microsystem (small coalface teams such as GP clinics), meso-system (regional such as PHNs), and macrosystem (eg national policy such as PBS and MBS).</li> </ol>	<p>Comment noted, no change.</p> <p>Agree. While secondary use is not the primary driving use case, it is not an afterthought. Much of R1 will be reusable in the secondary use space and part of the design process will be to optimise secondary use directly. There will be specific data groups that will be required for secondary use purposes as well, for example groupings and classifications data that is not used in direct patient care.</p> <p>Blank data groups will be not a feature of AUCDI as it is a specific roadmap for data.</p> <p>The AUCDI specifications are intentionally kept neutral for implementation strategies and functional workflow such as reconciliation and so this is currently out of scope of the data model.</p>

<p>3. Computer decision support - to directly improve implementation of best-practice care in an ever more complicated and rapidly changing environment.</p> <p>Design features of AUCDI should include blank spare data-groups to allow faster and easier iterations.</p> <p>Clinicians are aware that patient records held in different systems contain multiple inconsistencies. Design principles should support systems for reconciliation of information. The more automated information upload becomes, the higher the risk of errors being replicated. For example, removing an allergy or a diagnosis becomes increasingly impossible when the information is replicated across healthcare settings and information repositories.</p> <p>Additional fields of data that should be considered include PRESCRIPTIONS. When first script, when last script, name, quantity etc, number of repeats. In other words the sort of information currently exchanged with prescription monitoring services and with My Health Record. Patient safety in handovers of care requires this information to be available, so FIHR standards will be important.</p> <p>Another data area that should become available is past prescription list including "reason for cessation". It is important in clinical practice to know what has been used in the past. Some medicines have lifetime cumulative impact (eg, clomifene). Some past prescribing influences current medication choice (eg, recent antibiotic use influencing choice of subsequent antibiotic).</p> <p>Alcohol status has been postponed to later iterations. It has direct clinical applicability for safety of sedating medications and should be prioritised.</p>	<p>Comment noted, added to backlog. "Medication order", "Medication summary" has been added to the backlog.</p> <p>"Alcohol consumption" has been added to the backlog.</p>
--	---

<p>AUCDI033</p>	<p>AUCDI R1 establishes an initial set of core data elements for interoperability in Australia and, importantly, seeks alignment to international standards. As AUCDI grows into R2 and future releases, it will be important to continue fostering alignment with international standards, such as HL7 FHIR and the International Patient Summary. This alignment will accelerate the implementation of Australian interoperability using FHIR Implementation Guides, such as AU Core. It will also allow Australia to learn from worldwide experience and avoid pitfalls, reduce cost, increase speed to market, and expand the market for Australian digital health products. Benefits will be maximised if localisation unique to Australia is minimised to only the deviations necessary.</p> <p>Operationalizing Interoperability in Australia</p> <p>As a data model for enabling interoperability, AUCDI should focus on the data models necessary for information exchange without dictating the collection or use of health data. As written, it is unclear if the goal of AUCDI is for interoperability of health data or enforcing data collection and modeling on clinical systems and practices. AUCDI proposes to define the “clinical requirements of the clinical information ... for data entry, data use, and sharing” (section 4.5). While interoperability specifications can define a technology’s capability of exchanging a data element, interoperability technology itself is incapable of (and unrelated to) ensuring data use or collection in clinical workflow. We recommend AUCDI focus on the data modeling necessary for interoperability, and that data entry and use for clinical practices be addressed separately through other policies with appropriate clinical and vendor engagement.</p> <p>Currently, you plan to develop distinct information models per interoperability use-case (e.g., AUCDI,</p>	<p>The goal of AUCDI is for interoperability of health data, however, to achieve semantic interoperability there must be focus on both the technology to exchange the data and the quality of data being exchanged.</p> <p>Wording updated to reflect comment. The 4.2 in the document has been updated for clarity to "The AUCDI is changing the approach to health data and is set to become a national asset focused on establishing an independent base of reusable, standardised information models and related artefacts. As clinical systems converge their internal data structures towards AUCDI, this common, consensus-based data foundation will reduce the need for data transformations and mappings, supporting safer and simpler interoperability."</p> <p>Comment noted, no change. A singular AUCDI is being considered.</p> <p>Comment noted, no change. Agree. The CDG has been tasked with developing agnostic logical models and the TDG will transform this into technical specifications (IGs) for particular use cases.</p> <p>Comment noted, no change. AUCDI has a clinically focussed approach, and the roadmap reflects clinical requirements. A maturity scoring is being considered. The AUCDI specifications are intentionally kept neutral for any specific use case. Data elements will only made mandatory where they are ubiquitous and considered necessary in every possible use case, or when the remainder of the data group makes no sense without a mandatory index data element. Any optional data element in this data group can be mandated in a particular use case, technical specification or implementation, but not necessarily in AUCDI.</p>
-----------------	--	---

	<p>followed by eRequesting-DI, etc.). Instead, we recommend that AUCDI be maintained as the single formal information model for healthcare interoperability in Australia. To avoid fragmentation of processes, owners, and models, separate data sets should not be created for individual use cases. The AUCDI model should form the basis for all interoperability use cases in Australia, and FHIR implementation guides should be used to detail use case solutions, such as the AU Core FHIR IG, the AU eRequesting IG, and future use cases.</p> <p>The division of responsibilities between the Clinical Design Group (CDG) and Technical Design Group (TDG) should be clearly defined to enable the CDG to focus on the clinical data concepts necessary for interoperability and the TDG to determine functional requirements, including specific HL7 FHIR data types, terminology bindings, and cardinality.</p> <p>The emphasis on current system support (or minimal effort) in the AUCDI design principles is an important consideration for containing the financial cost of mandating the collection and exchange of new data elements on a recurring basis. In the same way that other principles are applied to each data element, each proposed data element should document a maturity score of how well that element is “understood, commonly used, and well supported by existing clinical systems,” as described in section 4.4.</p>	
<p>AUCDI034</p>	<p>Data group purpose – “An assessment of the risk or propensity of a future adverse reaction if exposed, or re-exposed, to an identified substance.” (first dot point, second row table 5). The concept of the adverse reaction risk summary is agreed but it is important to note that this is an output, an inference or a</p>	<p>Wording updated to reflect comment. Agree. The data group purpose in table 5 has been updated to include the recording of 'Evidence supporting the risk assessment, such as a summary of each exposure event or genomics test results.'</p>

<p>dependent variable. It must be distinguished from the input which is the reason or information giving rise to the risk assessment.</p> <p>The reason might be a previous adverse reaction event or events, a clinical assessment based on allergy testing, or a genetic susceptibility determined either by pharmacogenetics or immunogenetics (e.g. HLA type predicting risk of severe cutaneous adverse reaction from specific drug exposure). Hence second dot point, second row table 5 is incomplete.</p> <p>The risk assessment may change depending on new information, including patient-independent information about, for example, cross-reactivity between drugs- concepts of drug cross-reactivity risk have altered in recent years. Or future discovery of modifying genes, etc.</p> <p>Hence there is some confusion between table 5 and table 6 which must be clarified. Current EMRs (including My Health Record) do not allow for the distinction between prior events and risk assessment, usually these are entered synonymously. Risk assessment (based on reason information entered in the EMR) is a clinical judgement, the validity of which is likely to be higher when made by specialist, could be used for CDS and would be amenable to AI interpretation.</p> <p>Although the data group purpose is explained (table 5), basic concepts of risk, namely likelihood of event and severity of event are not incorporated into subsequent data tables or the “mind map”. The recording of manifestation might provide some implication of reaction severity. However the list of substances tends to confer an implication of absolute avoidance, which becomes a problem if trivial or mild reactions are included. It is suggested that concepts of absolute and relative contraindication/avoidance need to be incorporated. For example, re-exposure may be allowable if reaction likelihood is</p>	<p>Diagram updated to reflect comment. Mindmap has been updated to reflect the distinction between clinical evidence (including prior events and genetic testing) and propensity of risk.</p> <p>Comment noted, added to backlog. Dates relating to reaction have been added to the backlog.</p>
---	--

	<p>very low or reaction severity very mild, this might require tiered alerts in prescribing systems.</p> <p>Date of reaction (or approximate date, year) is critical information in enabling risk assessment, for certain reaction types risk will change depending on time since index reaction and age of reaction.</p> <p>It is important to distinguish whether reaction event is entered into the EMR contemporaneously or historically- impacts considerably on level of detail available, veracity of reaction details and substance (for example, the common scenario of a patient recalling reaction that occurred many years previously in the absence of clinical records).</p>	
<p>AUCDI034</p>	<p>Page 41 Inactive – a health condition that has resolved, is in remission, or no longer requires active treatment or management.</p> <p>Feedback: Is "inactive" appropriate for de-labelled drug allergy/ resolved allergy?</p> <p>Page 42 Potential candidate data elements for Release 2</p> <p>Feedback: Method of diagnosis</p> <p>Please note that as an allergy organisation, we have reviewed all content with allergy in mind and our submission is limited to this perspective.</p> <p>Thank you for the opportunity to provide feedback.</p>	<p>Comment noted, no change.</p> <p>AUCDI will continue to incorporate existing standards and ongoing work from national and international programs and initiatives.</p>
<p>AUCDI036</p>	<p>For health technology assessment and the evaluation of quality use of medicines, it is important to capture where patients experience side effects that are directly related to a medicine. This includes if the medicine is not taken appropriately. The AUCDI does not have specific data elements to record these events. The “Adverse reaction risk” data group states that the misuse a medicine and resulting adverse effects should not be recorded in this data group. Please consider how this information could be incorporated into the AUCDI. Please see</p>	<p>Comment noted, added to backlog.</p> <p>"Adverse event" has been added to the backlog</p> <p>"Ethnicity" and "Indigenous status" have been added to the backlog</p> <p>"Genetic/genomic test results" has been added to the backlog.</p> <p>Comment noted, no change.</p>

<p>comments provided for Question 15 and whether users could be directed to the “Encounter – clinical context” data group to record adverse events from the misuse of medicines.</p> <p>Data on ethnicity would be valuable as it is relevant to disease risk, appropriate drug treatments and adverse drug reactions.</p> <p>Data on Aboriginal or Torres Strait Islander status would be valuable for ‘Closing the Gap’ reporting.</p> <p>- Suggestion: Data on ethnicity and Aboriginal or Torres Strait Islander status should be added as standalone data groups within the R1 scope</p> <p>The AUCDI should consider the expected increasing use of genetic and genomic testing in Australia. Genetic and genomic testing generates large (terabyte range) and complex data sets, that have a potentially powerful impact on the identification and management of patient conditions when the data is linked to other patient outcome data.</p> <p>The intended outcomes and design principles of FHIR AU program and AUCDI has the potential to support implementation of genomic medicine into the Australian health care system, by assisting with standardised data sets and data interoperability between different data custodians, consistency through standardised reporting and communication amongst healthcare professionals, the reuse and reanalysis of data, and systems/standards to obtain patient consent.</p> <p>Patient data could be a single gene or the whole genome sequence. Genetic and genomic testing is presently funded via the Medicare Benefits Schedule, public hospitals, and private health care.</p> <p>Researchers at the Zero Childhood Cancer Program recently indicated that a terabyte of data is generated from in depth genomic analysis. This type of sampling and data generation may become standard practice in the future.</p>	<p>Data security and data storage requirements are technical and security standards and are out of scope AUCDI.</p>
---	---

	<p>Platforms for genomics are being developed in the international standard and initiatives referenced in this AUCDI R1.</p> <ul style="list-style-type: none"> <li>• HL7 international at <a href="https://www.hl7.org/fhir/R4/genomics.html">https://www.hl7.org/fhir/R4/genomics.html</a></li> <li>• openEHR International at <a href="https://ckm.openehr.org/ckm/projects/1013.30.50">https://ckm.openehr.org/ckm/projects/1013.30.50</a></li> </ul> <p>An international example of what happens to patient genomic data is outlined in the following articles from the UK</p> <ul style="list-style-type: none"> <li>• <a href="https://www.ukbiobank.ac.uk/explore-your-participation/understanding-genetics/why-have-we-sequenced-half-a-million-genomes">https://www.ukbiobank.ac.uk/explore-your-participation/understanding-genetics/why-have-we-sequenced-half-a-million-genomes</a></li> <li>• <a href="https://www.nature.com/articles/s41431-021-00976-w">https://www.nature.com/articles/s41431-021-00976-w</a></li> <li>• <a href="https://www.genomicsengland.co.uk/patients-participants/data">https://www.genomicsengland.co.uk/patients-participants/data</a></li> <li>• <a href="https://ourfuturehealth.org.uk/our-research-mission/how-our-future-health-works/">https://ourfuturehealth.org.uk/our-research-mission/how-our-future-health-works/</a></li> </ul> <p>Indigenous Data Sovereignty must be a consideration for all data. Particularly in the field of genomic medicine, engagement with First Nations peoples is vital.</p> <p>Data security and data storage requirements should be considered as part of the early AUCDI releases. The centralised collection of large amounts of health data, particularly patient genetic and genomic data, has the potential to be interest to third parties to access and misuse. National security risks have been recognised internationally:</p> <ul style="list-style-type: none"> <li>• <a href="https://www.nbcnews.com/politics/national-security/congress-wants-ban-china-genomics-firm-bgi-from-us-rcna135698">https://www.nbcnews.com/politics/national-security/congress-wants-ban-china-genomics-firm-bgi-from-us-rcna135698</a></li> <li>• <a href="https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/NCSC_China_Genomics_Fact_Sheet_2021revision20210203.pdf">https://www.dni.gov/files/NCSC/documents/SafeguardingOurFuture/NCSC_China_Genomics_Fact_Sheet_2021revision20210203.pdf</a></li> </ul>	
--	---	--



	<ul style="list-style-type: none"> <li>• <a href="https://www.axios.com/2024/02/03/biotech-us-china-tech-competition-bgi">https://www.axios.com/2024/02/03/biotech-us-china-tech-competition-bgi</a></li> <li>• <a href="https://www.washingtonpost.com/world/interactive/2023/china-dna-sequencing-bgi-covid/">https://www.washingtonpost.com/world/interactive/2023/china-dna-sequencing-bgi-covid/</a></li> </ul>	
<p>AUCDI038</p>	<p>Overall comments</p> <ul style="list-style-type: none"> <li>• MHR is one component of the digital health environment but will remain an important avenue for consumers to access their key health information.</li> <li>• Future expansion of data relating to pathology and diagnostic imaging needs to be undertaken in context of the Improved sharing of health information to MHR agenda. This includes ensuring that systems are constructed in a way that enables the ease of management of information. For example in circumstances where consumers request not to have their health information uploaded to MHR that this can be easily identified and managed appropriately including when utilising the information in the creation of other summary documents.</li> </ul> <p>Section 7. AUCDI Release 1 Draft for Comment Library</p> <ul style="list-style-type: none"> <li>• In this section, there is frequent mention of MHR in the context of data capture under specific alignment to AUCDI design principles. The way that health information is presented should consider the need for the consumer to be in the inner circle of design and participate in discussing the questions posed so that consumers can understand the information and get the best utility out of it. How this information is presented to the consumer is a key element of delivering person-centred care particularly as we progressively grow information in MHR with sharing by default. The presentation of health information in a manner that supports consumer understanding and engagement with their health has been raised through the public consultation submissions and the Clinical Reference Group. Having this in focus will be important as the AU Core is expanded upon.</li> <li>• As MHR also contains health information entered by the consumer such as for allergies will these design principles apply</li> </ul>	<p>Comment noted, no change.</p> <p>The AUCDI will continue to incorporate existing standards and ongoing work from national and international programs and initiatives. MHR is acknowledged as a key stakeholder through the document. AUCDI is intended to support standardisation of data and interoperability that will support MHR.</p> <p>AUCDI is agnostic of implementation and author. These same information models could be used to underpin data entry by consumers, supported appropriate consumer-centred user experience design.</p>

	<p>for data entered by consumers as well as healthcare providers and where would this data entry fit within the reuse approach to data?</p>	
<p>AUCDI039</p>	<p>In November 2024, the Australian Government released the Australian Cancer Plan (the Plan). Developed by Cancer Australia, the ten-year Plan is designed to improve cancer outcomes and experience, particularly for those groups whose health outcomes are poorer.</p> <p>Improving the availability and timely access to data is key to delivering on the ambitions of the Plan with a 10-year ambition of having a modern, fit for purpose cancer control infrastructure, advanced by the innovative application of technology, research and data to improve Australia’s cancer outcomes.</p> <p>Cancer Australia is undertaking a number of activities to implemented Plan pertinent to the AUCDI including developing a National Cancer Data Framework and an optimal Care Pathways Framework to embed optimal cancer care into the health system.</p> <ul style="list-style-type: none"> <li>• Cancer Australia, in partnership with the Australian Institute of Health and Welfare and Cancer Council Australia, is leading the development of a National Cancer Data Framework (Data Framework) and a minimum dataset for the collection and reporting of comprehensive cancer data across the cancer control continuum. The Framework seeks to utilise data to inform patient-centred care and health system improvements and planning across the cancer continuum through the better collection, linkage and sharing of data, including filling key data gaps. There are a number of common elements across the Framework and AUCDI project and we welcome working together to ensure common goals are met (A copy of the National Cancer Data Framework discussion paper will be provided separately). The move towards standardisation of</li> </ul>	<p>Comment noted. Thank you for your support.</p> <p>Comment noted, added to backlog.</p> <p>An extension of "Smoking summary" has been added to the backlog including "Pack years", "Previous episodes of use" etc.</p> <p>"Care pathways" has been added to the backlog.</p>

	<p>health record documentation for data harnessing and integration is a common goal shared with the Framework.</p> <ul style="list-style-type: none"> <li>• The national collection of cancer stage at diagnosis and recurrence (stage data), which is a fundamental gap in Australia’s cancer data. Stage data is critical for a cancer diagnosis and subsequent clinical decision making, and for population health reporting. Capturing stage data as part of the AUCDI release should be explored.</li> <li>• The National Lung Cancer Screening Program (NLCSPP) will be introduced in July 2025 and those eligible will be people aged 50-70yrs with a 30 pack year smoking history, and if a former smoker, those who have quit within 10yrs. Capturing smoking history, including a calculation of pack years, as part of the AUCDI release should be explored.</li> <li>• The standardisation of data outputs from pathology and imaging reporting, through structured reporting, to advance readily available data to support the development and evaluation of health policies and drive equitable outcomes.</li> <li>• The Optimal Care Pathways (OCPs) are a framework for the delivery of consistent, safe, high-quality, and evidence-based care for people with cancer. Embedding the OCPs into health service delivery, and capturing data to evaluate system performance should be explored as part of the AUCDI release to support best practice cancer care.</li> <li>• Data across the cancer control continuum are captured differently across cancer services, primary care services including Aboriginal Community Controlled Health Services, the National Cancer Screening Register, Australian Cancer Database, jurisdictional registries, and administrative databases. As part of the Data Framework development we plan on developing a cancer minimum dataset that can be linked to the design of the AUCDI.</li> </ul>	
--	--	--

	<ul style="list-style-type: none"> <li>The establishment of a data linkage environment and national approach to enduring integrated datasets – collect once and use many times.</li> </ul>	
AUCDI040	<p>Cancer Council’s submission focuses on the opportunities of the Australian Core Data Interoperability (AUCDI) initiative and the interaction with cancer-related data. In October 2023 Cancer Council published Developing a Data Strategy: A report for discussion (<a href="https://www.cancer.org.au/assets/pdf/developing-national-data-strategy-for-cancer">https://www.cancer.org.au/assets/pdf/developing-national-data-strategy-for-cancer</a>) to generate discussion on a strategy for improving the collection, reporting and use of cancer data in Australia for health system performance monitoring. This report captures work conducted by Cancer Council to define a vision for cancer data in Australia, an assessment of existing cancer-related datasets to identify inequities in cancer outcomes and the development of a data maturity model to achieve the vision for cancer data in Australia. Cancer Council welcomes further discussion with the Department of Health and Aged Care and partners about the content in this report. The establishment of the AUCDI can support the objective of the National Cancer Data Framework (action 4.2.1 of the Australian Cancer Plan) which is to support optimal cancer care and a high performing cancer care system. Cancer Australia is leading the development of the National Cancer Data Framework and a minimum dataset, in partnership with Cancer Council Australia and the Australian Institute of Health and Welfare, for the collection and reporting of comprehensive cancer data across the cancer control continuum. Australia’s current health data system is fragmented, limiting our understanding of people’s experiences and outcomes from their interactions with the health system. Standardising the capture, structure, usage and exchange of health data across all data collections is necessary progress towards a complete and comprehensive health data system. Australia currently has no standardised or mandatory performance measurement and reporting system for health</p>	Comment noted. Thank you for your support.

	<p>services. Therefore, we are missing information needed to benchmark performance across the health system and to systematically identify opportunities for improvement. It is up to individual health services, networks, or jurisdictions to adopt reporting mechanisms and then to make this publicly available. Collections are often varied in the data elements captured, how they are defined and whether this data can be linked with other datasets to provide more comprehensive insights into experiences. Combined, these variations impede our collective ability to maximise use of existing data and to create new insights that will assist in improving cancer outcomes and managing health service costs.</p> <p>Critical to the success of the AUCDI is understanding the collection methods by other data sets and identifying meaningful ways to standardise collections. Currently health related data is collected in many ways, by many different agencies. The AUCDI should be the foundation from which all health-related datasets build on. It must define the essential items to be shared by all relevant health related datasets. This requires integration with other initiatives including from a cancer perspective, the development of the National Cancer Data Framework, an initiative of the Australian Cancer Plan.</p> <p>The core-design principles align with those identified by stakeholders who informed Cancer Council’s vision for cancer data in Australia. The principles reflect a commitment to establishing data systems which collect and use data efficiently and to support person-centred care and best practice care. A purposeful, safe and respectful approach to data collection could overcome existing cultural and structural barriers to the use of data to inform health system improvements based on quality information.</p>	
--	--	--

	<p>The following opportunities to expand the proposed data element groups would improve the collection of cancer-related health information to understand interactions with the health system and cancer outcomes, and the experiences of different people across the population.</p>	
<p>AUCDI041</p>	<p>Use of OpenEHR and archetypes:                  While OpenEHR is getting quite a lot of traction in Europe we need to be very conscious of any implications that going down the ‘openEHR and archetype’ path have on data re-use longer term. We are not aware that going down the OpenEHR path as a data model of choice is a decision that has been consciously made, or received consensus on.</p> <p>We are comfortable with referencing OpenEHR as a data model however have concerns that the document is underpinned by it. It may be fine to head down that route, but we need to keep our eyes open about technical and architectural implications. The intent of OpenEHR is to be technology agnostic, to support the building of EHR and associated solutions without the need to know about the clinical data it will process, clinical models for these are built separately. From a CDS perspective and adopting associated tools, this can have advantages. We just need to be aware of longer term implications and any implied or explicit choice made on behalf of the national healthcare system.</p> <p>**note, since compiling this feedback we have had further conversations with Kate and Kylynn and are comfortable with the approach to referencing openEHR, with some clarity added to the document as per discussions,. We have still included the feedback as its important its noted.</p> <p>4.3.1 Clinical Information Models:</p>	<p>Comment noted, no change.                  OpenEHR provides a valuable consensus driven data source, along with USCDI, UK PRSB, International Patient Summary and existing Australian Specifications to inform AUCDI. This enables us to build on the years of experience in data modelling and fast track the development of AUCDI. A number of countries globally are taking this approach, which further supports the goal of International Alignment and provides opportunity to take advantage of any advancements in tooling, which will help ensure sustainability. We also welcome the recent announcements of OpenEHR and HL7, with the agreement to collaborate.</p> <p>Comments noted. Thank you for your support.</p>

	<p>It's great that the definition for the clinical data models are generic and are intended for re-use across multiple use cases.</p> <p>4.4.4 Case study: The case study is a great inclusion and puts a lot of the data and associated documents into perspective.</p> <p>The explanation to support the scope is clear and helps with the understanding of what is being covered.</p>	
AUCDI042	<p>In 2023, cancer was the highest contributor to Australia's burden of disease (17%). Cancer Australia recently launched the Australian Cancer Plan with a strong focus on cancer control. It is important to include the Australian Cancer data network on the journey to improve clinical record keeping for legislated registration of cancer information. Please ensure the clinical and cancer control workforce can understand and contribute to the work being done in the Sparked program. I ask that we (1) include at least one example in each information model, of a cancer-related concept (where applicable) so that the layperson can see how it applies to their use cases, and (2) provide easy access for the layperson to see and search the complete value sets, to check that they are suitable for their use cases. <a href="https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2023/contents/about">https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2023/contents/about</a> <a href="https://www.australiancancerplan.gov.au/welcome">https://www.australiancancerplan.gov.au/welcome</a></p>	<p>Comment noted, wording updated to reflect comment.</p> <p>(1) The document has been updated with cancer-related examples where relevant.</p> <p>(2) Agree, this has been noted.</p>
AUCDI043	<p>Standardising data for the purpose of, and at the point of, clinical care is a positive step for any subsequent use of that data. We are supportive of this work and keen to keep in touch about opportunities for the CDC to make use of the resulting technical capacity for standardised data sharing. For example, sharing of problem/diagnosis and vaccination information in a consistent and timely way within and beyond the health system would be useful for the CDC's intended functions.</p>	<p>Comment noted, thank you for your support.</p> <p>AUCDI is agnostic of any particular project, implementation or health sector. There are many vendors and jurisdictions involved in this program and any of them could reference AUCDI and implement resulting FHIR IGs.</p>

	A question that came up for us is: Which parts of the health system do you expect this to be implemented in first? (e.g. primary health care, hospitals etc..)	
AUCDI045	<p>All of the “Comment” data elements are defined like “Additional narrative about the XXXX not captured in other fields”. This is very much harking back to the “CDA document” times and is no longer necessary in today’s data environments. The definitions should be more simple: “Additional narrative about XXXX”.</p> <p>Note: all of the “XXX Name” data element should be “XXX” as it is an identifier of the XXX (not its name) is important as different language contexts need to be supported.</p> <p>There is one glaring omission from AUCDI R1 - the Patient !!!</p>	<p>Comment noted, no change.</p> <p>The definition has been intentionally worded this way to distinguish it from other narrative data fields (e.g. Description).</p> <p>The index data element has been intentionally worded to identify the concept by name, to be explicit and differentiate the name of the data element from other related data elements.</p> <p>Patient has been defined by the AU Core FHIR IG and is out of scope for AUCDI R1.</p>
AUCDI046	<p>Australian Pathology represents the majority of private pathology providers in Australia. Our members perform the testing relating to approximately 90 per cent of the Medicare claims arising from the pathology services table.</p> <p>Finally, we note your plans for future development of the ‘Laboratory test result’ data group and would suggest that our members are key stakeholders in this work.</p>	Comment noted. Thank you for your support.
AUCDI047	<p>AHPA and our member organisations have no concerns with the document released in terms of detail at the level presented, our feedback relates to the data items and their prioritisation in the AUCDI roadmap as this great work continues. Therefore we have not completed the detailed feedback form, however, have included points for consideration and collaboration into the future within the attached document.</p> <p>AHPA congratulate the Sparked Group for their collaborative working method which has produced such a high-quality product.</p>	Comment noted. Thank you for your support.



	<p>AHPA have liaised with our member associations regarding the document and this response and have no suggestions for improvement in the data groups or elements. However, we do note that we have not reviewed the content to the extent of checking each code system and/or value set for each clinical word which may be required. This level of review has not occurred for two key reasons; time and limited availability of people with both the clinical and technical skills required to do this task.</p> <p>We look forward to the addition of data elements included in the backlog and have not identified any missing aspects at this level of detail.</p>	
AUCDI048	[AUCDI048] recommends the changes provided as well as clinical review	Comment noted, no change. AUCDI has been a clinically driven initiative. Thank you for your involvement.
AUCDI049	<p>Considerations for the AUCDI release 1:</p> <ul style="list-style-type: none"> <li>- It is noted that Aboriginal and Torres Strait Islander status is not included in release 1. [AUCDI049] recommends that Aboriginal and Torres Strait Islander status is considered for priority inclusion within the AUCDI. Indigenous status is a key data field required for interoperability across healthcare settings and would align with the objectives and priorities of the National Agreement on Closing the Gap and the Department of Health and Aged Care Reconciliation Action Plan 2021-2023. As the AUCDI will establish the foundations for connected, real-time health information sharing across Australia's healthcare system, it should include and address the collection and sharing of Aboriginal and Torres Strait Islander status information as a priority area.</li> <li>- Ethnicity, ancestry, and cultural identity are also notable exclusions from the AUCDI release 1. Early inclusion within the AUCDI will allow for consistent reporting of these data fields and provide significant benefits to the healthcare sector and CALD</li> </ul>	Comment noted, added to backlog. "Ethnic identity"(which involves ancestry and cultural identity) and "Indigenous status" have been added to the backlog.

	<p>communities through ensuring reliable collection and transfer of data.</p>	
<p>AUCDI050</p>	<p>AUCDI can provide a strong basis for an interoperable health system</p> <p>Thank you for the opportunity to comment on the Australian Core Data for Interoperability (AUCDI) Release 1. The AIHW is a strong supporter of the Sparked initiative, and the development of the AUCDI, as they promise to provide a strong basis for an interoperable health system that can best support those providing care to patients with the information they need to make sure that care is high quality and evidence-based. Digital standards that support the exchange of structured and accurate information across the sector are vital at the point of care.</p> <p>Those same features of accurate and structured information to support the point of care can also underpin the creation of data that supports and encourages:</p> <ul style="list-style-type: none"> <li>better operational management, coordination and planning of the system</li> <li>better resource allocation and prioritisation of effort across the system</li> <li>better and more evidence-based health policy making</li> <li>better support for research on the effectiveness of existing and potential new models of care and health interventions.</li> </ul> <p>To meet this aspiration and support the development of a learning health system based on the seamless and efficient exchange of health information for both its primary and</p>	<p>Comment noted. Thank you for your support.</p>

	<p>secondary purposes, it will be important for the AUCDI to do four things:</p> <p>Ensure engagement between the AU Core (and the other outputs of Sparked) with existing data systems.</p> <p>The aim of that engagement should be to ensure interoperability between the AU Core data exchange standards and the data standards that underpin existing systems. We need to test that the important operational, program and policy work that those data systems support can continue once AUCDI is implemented. There has been substantial work over decades at all levels of the system to develop and test agreed indicators/measures, definitions, standards, metadata and other information 'infrastructure' that supports the uses of the information by governments and other parties that make an important contribution to the quality of care in our health system.</p> <p>We think the following general principles should guide the implementation of the AUCDI for interoperability across all parts of the health sector:</p> <p>Drawing on the substantial development work that has already been done by using existing data standards within AUCDI wherever possible (e.g. AIHW METEOR, Australian Bureau of Statistics (ABS), ISO and other existing national and international health standards). Considering these existing standards early in the development will reduce the overall development work, create alignment across the system and smooth the implementation process for the AUCDI. See the feedback provided on the "Sex and gender" data group and the example below of where the current AUCDI will not meet the requirements for dementia.</p>	
--	---	--

	<p>Where more granular information is required at the point of care than would be provided by the adoption of existing data standards, early consideration on how the AUCDI can be mapped to existing data standards will ensure that the work supported by those standards can continue through implementation of the AUCDI. It will also ensure consistency with existing activities across the health system, including the sharing of information across primary care and hospitals and the linkage of data across sectors. See the feedback provided on the "Sex and gender" data group and the example below on the need to map to diagnosis classifications used in Australian hospitals (ICD-10-AM).</p> <p>Where there is no existing classification, or the existing classification is not suitable for use at the point of care, engaging with the relevant stakeholders to determine whether the proposed data group in AUCDI would be suitable as a future standard that could be applied more broadly.</p> <p>The feedback we have provided below on the individual data elements has been informed by this broad set of decision-making principles (though we cannot claim to have done this comprehensively at this stage). The process should also involve other agencies that have roles in the health information ecosystem that rely on data, including for example, the Independent Hospital and Aged Care Pricing Authority, the ABS, the Australian Commission on Safety and Quality in Health Care, the Therapeutic Goods Administration, and the interim Australian Centre for Disease Control.</p> <p>Establish governance arrangements to ensure alignment over time between the AU Core and health data standards.</p>	
--	--	--

	<p>Naturally, clear data governance will need to be established for collection, receipt, secondary use of information created by AUCDI based systems—although in many cases that already exists. A key issue will be that the AUCDI will continue to develop to reflect changing models of care and clinical needs as well as other factors. So too will data standards used for the monitoring, management, planning, coordination, and policy making for the health system. We will need to work out a way of managing these changes over time to maintain alignment between the digital and data standards. Preferably this would not simply be the combination of their respective governance systems (nor their pursuit in sequence) and we are happy to work with CSIRO, the Department of Health and Aged Care and others on a sensible arrangement for this.</p> <p>Embed the use of consistent health care identifiers in the AUCDI</p> <p>The development of a truly interoperable AUCDI with national linkage systems will also create a comprehensive and robust evidence-base to develop health policy and effective modes of care. For example, it could support de-identified linking of data across datasets that use consistent identifiers and data elements and in doing so provide a more comprehensive understanding of the factors that affect health and health care, such as education, employment, financial support, and family and support systems. Embedding consistent identifiers within the AUCDI at the outset would facilitate potential future secondary use of the data. The research undertaken on this comprehensive data will in turn inform individual health management in clinical settings. The use of IHIs, HPI-Is and HPI-Os are recommended as unique identifiers. The AIHW notes that identifiers have been flagged as being within the remit of the Technical Design Group.</p>	
--	--	--

	<p>Engagement with other initiatives in the system to maximise alignment across the sector and minimise duplication</p> <p>There are other initiatives under development across the system that have potential overlaps with Sparked and present opportunities for alignment. For example, in 2024 the government funded the development of a proposal for a national linked general practice and acute care dataset, led by NSW Department of Health. It builds on linkage that has already been done in NSW as part of the Lumos project (Lumos (nsw.gov.au)). The national dataset would also potentially create a 'core' dataset to inform policy and models of care, highlight priorities for the AUCDI, and potentially set expectations on the information available from GPs. Further, the AIHW is developing a National Health Data Hub, where the AUCDI will have significant value to draw together data about primary health care with other data. See examples below on the Practice Incentives Program Quality Improvement (PIPQI) and AIHW Primary Health Care Data Collection.</p> <p>To achieve these outcomes the AIHW recommends further early consultation with data providers across all levels of government and across the public/private divide on what already exists. We should take account of the range of existing data standards/collections, the broad range of health priorities the AUCDI can enable, and the time/cost implications of rolling out these new standards in determining an approach to implementation that avoids duplication as far as possible.</p> <p>We have reviewed the AUCDI data elements and provided detailed comments in the attachment as well as some brief examples of potential issues where data flows to important uses</p>	
--	--	--

	<p>in the system could potentially be disrupted if we do not ensure alignment between AUCDI and existing data standards.</p> <p>EXAMPLE – Monitoring and treatment of dementia</p> <p>Dementia is not a single, specific disease. There are many types of dementia with symptoms in common, and these are caused by a range of conditions affecting brain function. It is also common for people to have multiple types of dementia at once. Identifying the type of dementia is important to ensure people receive appropriate treatment and services. For example, dementia-medications on the PBS are also only available to people diagnosed with Alzheimer’s disease. The different types of dementia also have varied rates of progressive decline. However, there is a lack of reliable information on dementia type in health and aged care data collections, and those that do collect information on dementia type use different classification systems, which is an interoperability issue that can lead to inconsistencies in how dementia data are recorded and reported.</p> <p>AUCDI proposes the use of SNOMED CT-AU codes to capture problems and diagnoses. There are substantial limitations with using SNOMED CT-AU to identify dementia type. Many of the codes used to identify dementia within SNOMED CT-AU are broad (e.g. ‘52448006 Dementia’ and ‘12348006 Presenile dementia’) and cannot be mapped directly to a specific dementia type.</p> <p>By comparison, national statistics on hospital admissions due to dementia using ICD-10-AM provide information on:</p>	
--	---	--

	<p>6 specific dementia types (Alzheimer’s disease, vascular dementia, Lewy body dementia, fronto-temporal dementia, dementia in Parkinson’s disease, dementia due to effect of substances) a collective group of ‘other’ dementias (comprising dementia in Creutzfeldt Jakob disease, Huntington’s disease, HIV or rarer causes) unspecified dementia.</p> <p>The Dementia National Best Practice Data Set (NBPDS) provides best practice recommendations for collecting and recording dementia data, including dementia type. The Dementia NBPDS recommends the collection of dementia type for 14 specific types and 3 broad categories. If more than one dementia type is diagnosed it also recommends to record all types.</p> <p>This is an example of where it is important that the AUCDI is tested for compatibility against existing standards for data collections to ensure continuity of information and data provided for use cases throughout the system, such as costing/payments, research, planning and coordination, and policy making.</p> <p>EXAMPLE – Alignment of diagnosis classifications used in Australian hospitals</p> <p>ICD-10-AM is the national standard for diagnosis classification in Australian hospitals, with investigations underway among relevant agencies of the costs and benefits of a potential move to using ICD-11. For the AUCDI to be able to meet the diagnosis reporting requirements of the current use cases there may need to be a mapping between the SNOMED CT-AU reference sets proposed to be used in AUCDI to the ICD-10-AM codes.</p> <p>In regard to ICD-11, the AIHW would like to work together with the ADHA to help drive collaborative efforts by the World Health</p>	
--	--	--



	<p>Organisation and SNOMED International respectively to harmonise content of and mappings between the two systems. We are not as familiar with the governance and work arrangements of SNOMED, but the area of WHO responsible for the international classifications is poorly resourced and relies heavily on contributions and assistance from member states. Working together to determine how best to focus such efforts will be important to the ongoing interoperability/digital health agenda.</p> <p>On a question of detail on the use of SNOMED term sets in the AUCDI, we have frequently commented on the data elements in the attachment that it should be specified which part of the relevant SNOMED CT-AU values will be captured – the code, the display text or both. This must be clear to assist the AIHW to develop data standards that align to AUCDI.</p> <p>EXAMPLE – Monitoring areas of health policy priority</p> <p>Several AUCDI Release 1 data items will support the reporting of key health priority areas identified in the Practice Incentives Program Quality Improvement (PIPQI). However the core AUCDI does not cover all measures that are collated at the local level by the Primary Health Networks to assist in supporting improvement and understanding population health needs, and included in measures that are submitted to the Department of Health.</p> <p>The areas, that GPs report on as part of PIPQI, that are not included in the scope of the Release 1 are:</p> <p>alcohol consumption status (this has been identified as a potential extension to capture a larger group of models for lifestyle risk factors)</p>	
--	--	--

	<p>cervical screening tests.</p> <p>There is currently a PIP review that may look at the indicators that are collected under that arrangement. Even if these change though, information on matters such as alcohol consumption and cervical screening drawn from general practices sources will remain important.</p> <p>Likewise, will information on smoking remain important (and information on vaping become important). Based on our experience over 4 years of analysis and reporting of PIPQI data, it will also be important to ensure that this field can capture instances where the smoking status is unchanged from the previously recorded smoking status.</p> <p>Additionally, while the importance of incorporating information on vaping has been recognised for future releases, the current implementation of this field in AUCDI would result in no tobacco smoking status being recorded for a significant number of clients who use vaping.</p> <p>The National Drug Strategy Household Survey 2022-2023 estimated that more people are using e-cigarettes in Australia. In 2022–2023, 15% of people 14 and over reported regularly smoking and/or vaping. Almost one-third of these people reported only vaping (see Table 3.41 National Drug Strategy Household Survey 2022–2023, Data - Australian Institute of Health and Welfare (aihw.gov.au)). It will be important for the AUCDI and data standards to remain alive to these changes in health behaviours.</p> <p>EXAMPLE – AIHW Primary Health Care Data Collection</p>	
--	--	--

	<p>The AIHW has mapped the data elements in AUCDI Release 1 to the draft data model that has been developed for AIHW's National Primary Health Care Data Collection (NPHCDC). Based on this mapping, about 34 of the AUCDI Release 1 data elements could be used for the NPHCDC.</p> <p>There are some key differences between the data elements in AUCDI Release 1 and the data elements that have been proposed for AIHW's NPHCDC. For example, AIHW's draft data model proposes that measurements are recorded using data elements for measurement type, measurement value and measurement unit. This same approach has been used for MedicineInsight, PATRON and POLAR, however this differs from the approach proposed within AUCDI Release 1. Working together on a common approach will be important here.</p> <p>AUCDI – structural improvements</p> <p>A suggested improvement to the AUCDI is adding in a reason for inclusion against each data element. Including a rationale for each data element will support engagement in these matters by a broader audience and support understanding of the prioritisation approach to the inclusion of each item. An example of where this has been done elsewhere is the 'Selected considerations for performance measurement and reporting in primary care' column included against each data element in CIHI's Pan-Canadian Primary Health Care EMR Minimum Data Set for Performance Measurement: Pan-Canadian Primary Health Care EMR Minimum Data Set, Version 1.1 (2022) (cihi.ca).</p> <p>It would also be helpful to have clear definitions for the terms "optional" and "mandatory" in the context of AUCDI. At present, it is difficult to ascertain whether these terms refer to data capture or data exchange, and what conditions might apply e.g.</p>	
--	--	--

	<p>a data element is only mandatory if an instance of the data group exists. It would also be helpful to understand how the AUCDI terms of “mandatory” and “optional” relate to terms such as “must support” that are used in the Technical Design Group for the development of the AU Core FHIR IG.</p> <p>Document issues</p> <p>This comment is just flagging a minor issue with the document itself. There are some weird things going on when you copy and paste the content or search the content. For example, all instances of ‘ti’ show up as ‘W’ when you copy and paste the content, meaning the word ‘optional’ shows up as ‘opWonal’. Similarly, you have to search the document for the word ‘opWonal’ to find all instances of ‘optional’. This does make it challenging to interrogate the document fully.</p>	
<p>AUCDI035</p>	<ul style="list-style-type: none"> <li>On the roadmap at the very least, should be the ICNP reference set following extensive work seeing the nursing terminology mapped to SNOMED, to increase nursing visibility, ensure safety and enhance quality. <a href="https://www.icn.ch/news/new-icnp-snomed-ct-nursing-practice-refset-first-product-recent-agreement-increase-nursing">https://www.icn.ch/news/new-icnp-snomed-ct-nursing-practice-refset-first-product-recent-agreement-increase-nursing</a></li> <li>In Section 4 (4.7) it states that the AUCDI does not need to be implemented as a whole single product and that certain sections can be implemented for specific use cases, there may be a few potential risks with this:             <ol style="list-style-type: none"> <li>Fragmentation: Implementing only sections of the AUCDI may lead to fragmentation of data standards and terminology usage across different systems and use cases, hindering interoperability and data exchange.</li> <li>Inconsistency: Different implementations of the AUCDI across various projects may result in inconsistencies in data models and</li> </ol> </li> </ul>	<p>Comment noted, no change. ICNP has been noted for investigation.</p> <p>Comment noted. The AUCDI cannot directly influence how it is implemented, however, CDG and TDG are working together to ensure that the AUCDI is faithfully represented in the AU Core FHIR IG as a national technical standard.</p> <p>Wording updated to reflect comment. This sentence has been updated for clarity to "The AUCDI does not need to be read or consumed as a whole single product. Sections can be used as required for specific use cases. This is true for both the data model and the recommended terminology value sets."</p> <p>Comment noted, no change.</p>

	<p>terminology usage, leading to confusion and errors in data interpretation and exchange.</p> <p>3. Compatibility Issues: As the AUCDI evolves over time, there is a risk that new versions or updates may introduce compatibility issues with existing implementations, requiring additional effort for integration and migration.</p> <p>4. Complexity: Managing and maintaining multiple implementations of the AUCDI for different use cases may increase complexity and administrative overhead, potentially resulting in inefficiencies and resource constraints.</p> <p>5. Adoption Challenges: The selective implementation approach may pose challenges in promoting widespread adoption of the AUCDI, as stakeholders may have differing interpretations of which sections are necessary for their specific use cases, leading to delays or resistance in implementation efforts.</p> <p>A few additional comments include:</p> <ul style="list-style-type: none"> <li>o Legislation: the My Health Records system and the collection, storage and use of health data is governed by legislation that needs to be factored into the design. There are major legislative reforms of the My Health Records, Privacy, and Healthcare Identifiers legislation due to come into effect over the next 12 months that also needs to be considered.</li> <li>o Policy: the associated policy settings, based on the relevant legislation, also require consideration in the design, management, and use of the data sets. For example, discussions about removing the policy to delay consumer access to pathology or diagnostic imaging results for seven days.</li> <li>o Access Controls: the My Health Records system has an existing range of user access controls that may be applied to restrict access to specific health information. These controls are granular allowing the consumer to manage a record, within a record. For example, a consumer can apply a restriction (to one or more providers) or delete a specific item that has been</li> </ul>	<p>AUCDI will continue to incorporate existing standards and ongoing work from national and international programs and initiatives.</p>
--	--	---

	<p>uploaded to their record. Noting, this data may become available in the future Health Information Exchange (HIE) these are still important factors in the design of the data set from My Health Record or HIE purposes.</p> <ul style="list-style-type: none"> <li>o Share by Default: this mandate will commence at the end of 2024, starting with pathology and diagnostic imaging reports and expanding to other types of health information. This potentially supports the transition of health data between systems and requires consideration as currently these are PDF reports and images are not stored.</li> </ul>	
AUCDI052	<p>Is there more information available on the person information/demographics scope of AUCDI? These data are included in Figure 3 (also noted to be in scope for the E-Request/service request work). There is potential for feedback from us on settings of residence (e.g. aged care, disability homes).</p>	<p>Comment noted, no change. Patient and Organisation has been defined by the AU Core FHIR IG and is out of scope for AUCDI R1.</p> <p>Comment noted, added to backlog. "Housing" and "Living arrangements" as part of a focus on Social Determinants of Health has been added to the backlog.</p>
AUCDI051	<p>Page 14 re developing data sets for secondary use rather than primary: I'm not sure these sentences are in lockstep with some of our Portfolio initiatives. Aggregated secondary use data is vital to designing an economically-sustainable healthcare system and ensuring quality of care and outcomes is measurable across health care services. For more information on how secondary use can be used to strengthen the effectiveness of clinical decision support systems and the overall quality of health care (rather than compromise it), please see: <a href="https://www.aihw.gov.au/getmedia/57ed4b65-5919-43ce-bb21-933ea9a8b012/aihw-aus-221-chapter-2-5.pdf.aspx">https://www.aihw.gov.au/getmedia/57ed4b65-5919-43ce-bb21-933ea9a8b012/aihw-aus-221-chapter-2-5.pdf.aspx</a> Likewise check out MHR's policy on secondary use here: <a href="https://www.health.gov.au/topics/health-technologies-and-digital-health/what-we-do/use-of-my-health-record-data#secondary-use-framework">https://www.health.gov.au/topics/health-technologies-and-digital-health/what-we-do/use-of-my-health-record-data#secondary-use-framework</a> Page 15 re existing standards:</p>	<p>Comment noted, no change. While secondary use is not the primary driving use case, it is not an afterthought. Much of R1 will be reusable in the secondary use space and part of the design process will be to optimise secondary use directly. There will be specific data groups that will be required for secondary use purposes as well, for example groupings and classifications data that is not used in direct patient care.</p> <p>AUCDI references standards that have been used. The list of proposed standards are technical in nature and will be relevant for any technical specifications that get produced.</p> <p>Comment noted, added to backlog. The scope of AUCDI will become broader as work is done. "Care plan", "Medication order", "Medication administration" and "Consent" have been added to the backlog.</p>

<p>Given the various healthcare-related government agencies that are involved in this all have standards sections, it would be good to ensure all the existing standards are spelled out. There are a few national standards that I've noticed are absent from considerations; AS4590, AS4846, AS5017, SACC, NMDS, ISO12967, ISO13940 etc.</p> <p>Page 17 re scope: It would be great to get some Aged Care use cases included in future scopes: "Support Plan", "Medication Chart", "Assessment", "Consent" etc.</p> <p>Page 22 re other local and international initiatives: There are several notable differences between some of the schematic changes proposed to AUCDI and the current version of AIHW's Aged Care National Minimum Data Set. This would also be an opportunity to call out a principle to align to standards designed by Standards Australia such as AS4590 and standards developed by the ABS (SACC, ANZSIC, ASCL, Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientations, Country of Birth, Year of Arrival etc.</p> <p>Page 24 re design principle driven by primary clinical data use not secondary data use needs: Once again – not aligned with AIHW minimum data sets – also think the statement in Scope drivers is at odds to this principle: ".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)."</p> <p>Page 24 re design principle alignment with national health data standards and initiatives: Consider adding AS4846 – Health Care Provider Identification, AS5017 – Health Care Client Identification to list of recognised national health data standards to list of recognised standards.</p>	<p>Sparked is working closely with AIHW to facilitate alignment.</p>
---	--

