

SHIELD - IVD Semantic Interoperability Working Group

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Getting Started

Our presentation of SOLOR at 2nd HSPC meeting in August 2018 raised public interest in our work and our **vision for semantic** interoperability.

Our goal during this presentation is to:

- Introduce you to SOLOR
- Show how we can help SHIELD
- Receive your feedback on how we can improve our tooling to meet your needs

Semantic Interoperability

A Common Mission

To develop, harmonize and implement <u>semantic</u> <u>interoperability</u> standards in order to protect and promote public health by:

- Improving support for clinical decisions
- Reducing burdens to the healthcare ecosystem
- Promoting the development of innovative solutions to public health challenges

SOLOR achieves semantic interoperability by integrating disparate health standards into a common model.

Types of Interoperability

Foundational

Data exchange from one system to another

Structural

The syntax of the data exchange at the data format/field level

Semantic

 The exchange of information in a way that the receiving system can interpret the data

Where We Are Today

Today's Challenges

- Mapping is always out of date
- Internal curation of local terminology is not scalable
- Potential information loss at each transformation
- Unnecessary complexity
- Patient safety is compromised

Administrative Data Standards

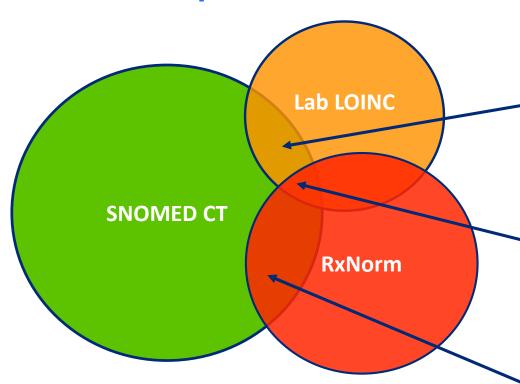
- Content is not driven by implementation needs
- Insufficient detail for a clinical care

Clinical Data Standards

- Lack coherence
- Submission process does not meet operational needs

Every System is Different!

Overlap in Content



SNOMED CT

LOINC

LOINC: Gentamicin is a component of laboratory tests

SNOMED: Gentamicin is a component of laboratory tests

SNOMED CT

LOINC

RxNorm

LOINC: Gentamicin is a component

SNOMED: Gentamicin is a substance

RxNorm: Gentamicin is an ingredient

SNOMED CT

RxNorm

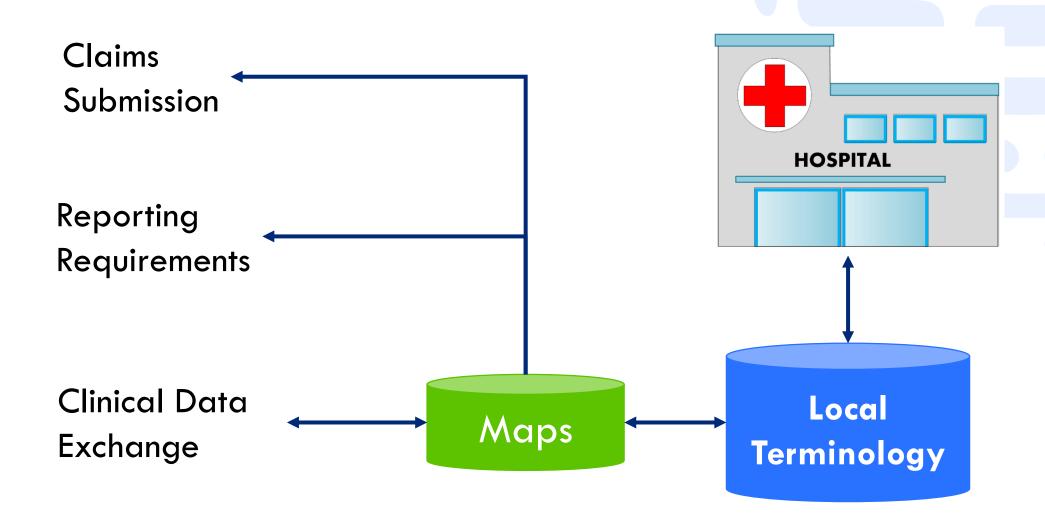
SNOMED: Gentamicin is a PRODUCT

SNOMED: Gentamicin 0.3% preservative-free eye drops

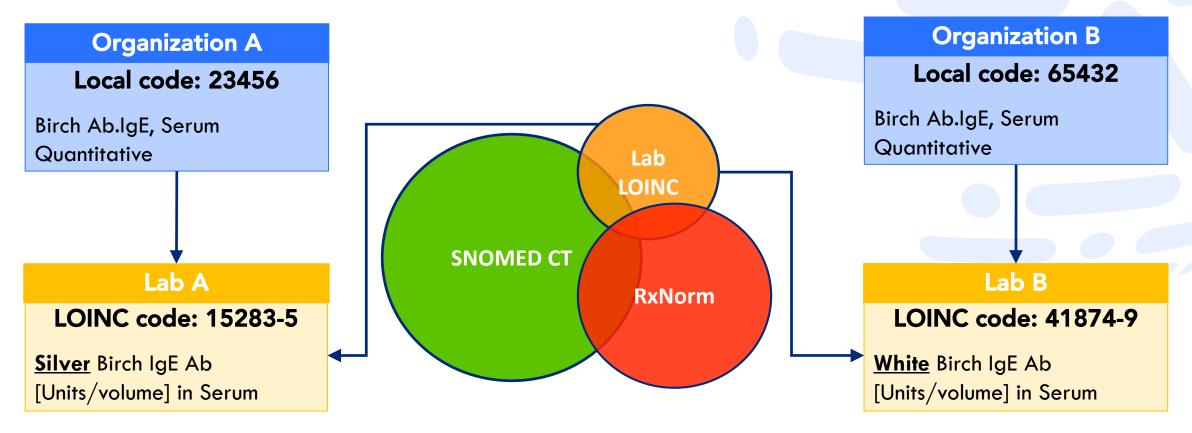
RxNorm: Gentamicin sulfate 0.3% Ophthalmic Solution

RxNorm: Gentamicin is a PRODUCT

Mapping-based Implementation



LOINC Mapping Example



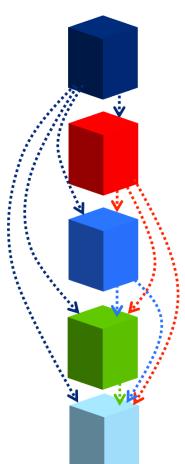
Mapping can add false information

Enabling Semantic Interoperability

- Standardize the Standards
 - Standardize the encoded data model
 - Standardize the extension model
- Meet Operational Needs
 - Enable sharing of extensions
 - Open-extensions
 - Proprietary-extensions
- Evolve Existing Systems
 - SNOMED, LOINC, RxNorm and other terminologies

Introduction to SOLOR

Architectural Layers for Separation of Concerns



Procedural Knowledge

Assertional Knowledge

Statement Model

Definitional Knowledge

Language

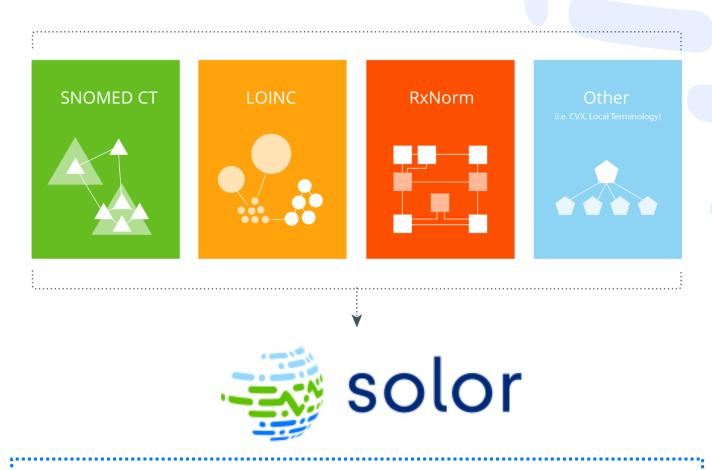
HL7 FHIR CIMI CIF CIMI ANF...

Define how to record a measurement (Numerical and Subject of Information)

SOLOR

Define what can be measured (Description Logic and Language)

What is the System Of LOgical Representation (SOLOR)?



Integration of terminology in a common model

Architectural Separation of Concerns



Measurement is a concern of the statement model

- Quantitative measurement
- Existential measurement



Defining what is measured is a concern for SOLOR

- Dot-blot hemorrhage of the retina
- Pressure ulcer on the left olecranon process
- Type 1 diabetes



Measurement of absence needs to be removed from SOLOR sources to allow layers to address separate concerns

An Example of a SOLOR Extension

Hospital A Creates SOLOR Extension

Localization of clinical data representation is very common

Hospital A

Local code: 12345

Infiltrating ductal carcinoma of lower inner quadrant of breast

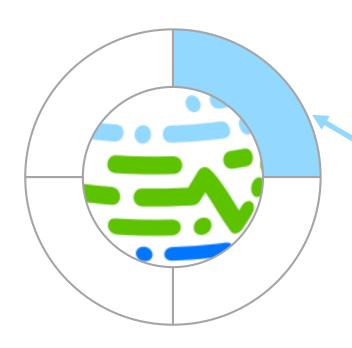
Hospital A

Local code: 67890

• • •



Medical Practice Creates SOLOR Extension



Each localization of clinical data representation is different

Medical Practice

Local code: 54321

Infiltrating ductal carcinoma of lower inner quadrant of breast

Shared SOLOR Extension

SOLOR allows local and native representations of clinical data to co-exist in a common model

Hospital A

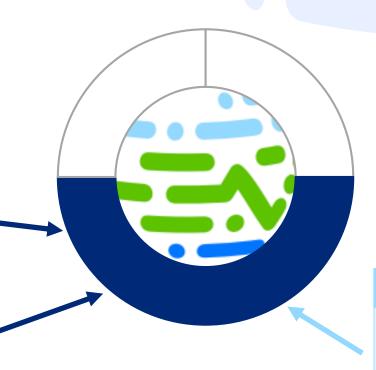
Local code: 12345

Infiltrating ductal carcinoma of lower inner quadrant of breast

Hospital A

Local code: 67854

. . .



Searches for concept in shared SOLOR extension

Medical Practice

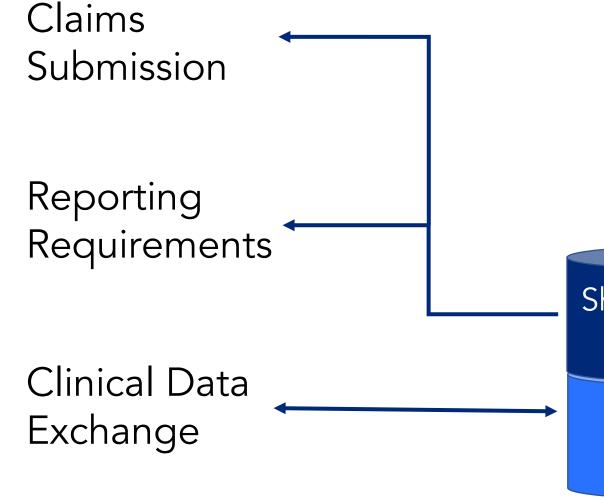
Infiltrating ductal carcinoma of lower inner quadrant of breast

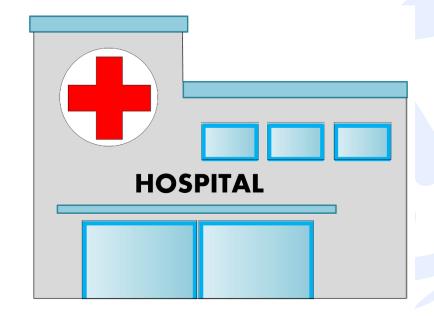
Content Contributed to the Standard



New concepts in extensions can be contributed back

SOLOR Implementation





Shared SOLOR Local Enhancement

SOLORized Standards

SOLOR is a Way to Transition

"Interoperability of Today"



Interoperability of the Future

- Big bang switch won't work
- Need to support current systems while evolving to native interoperability

Simplifies Systems

By simplifying content management, SOLOR makes:

- Implementation easier for business owners and safer for patients
- Management of change easier for business owners and safer for patients

SOLOR & SHIELD

LOINC to IVD (LIVD)

- In vitro diagnostics (IVDs) products are intended for use in diagnosis of disease or other conditions
- Fundamentally, IVDs ask a 'question' of a specimen taken from a human body (e.g. LOINC)
- The result that follows is the 'answer' to that question (e.g. SNOMED CT, UCUM)
- Each individual device is 'who's asking' (e.g. Unique Device Identifiers)

LIVD Example

- A particular IVD may measure the Minimum Inhibitory Concentration (MIC) of Ampicillin that will inhibit the growth of a microorganism after incubation. The unit of measure for MIC is microgram/milliliter.
- The MIC test result and the units of measure are mapped to LIVD:

"The Question"

LOINC Code 28-1

Ampicillin [Susceptibility] by Minimum inhibitory concentration (MIC)

"The Answer" (UCUM)

UCUM Code

C64572 Microgram per milliliter

"The Answer" (SNOMED)

SNOMED CT Codes

258796002 Milligram per liter

258801007 Microgram per milliliter

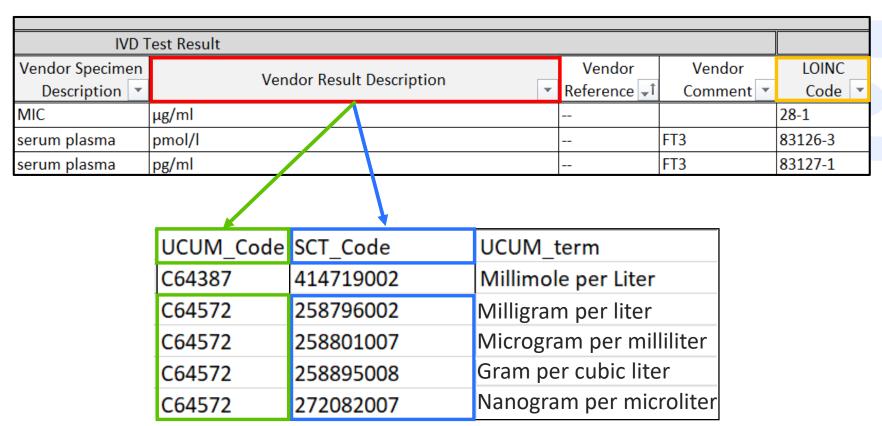
258895008 Gram per cubic liter

272082007 Nanogram per microliter

Managing LIVD Today

Example of LIVD Mapping

LIVD Table Format: IVD Test Transmission Codes



Managing LIVD with SOLOR

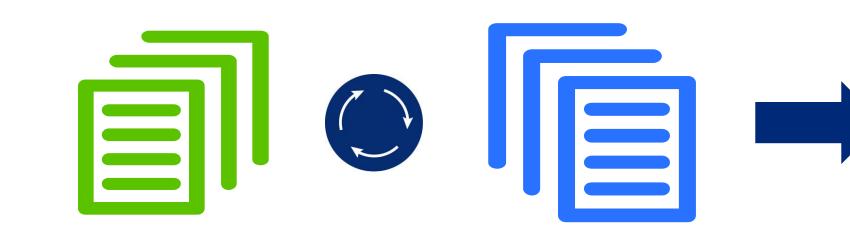
SOLOR & SNOMED CT Taxonomy

- ▼ SOLOR concept
 - Metadata
- ▼ SNOMED CT Concept
 - Body structure
 - Clinical finding
 - ▶ Environment or geographical location
 - Event
 - Observable entity
 - Organism

Proposed LIVD Integration

- SOLOR concept
 - Metadata
 - SNOMED CT Concept
 - > LIVD
 - > LOINC (28-1)
 - UCUM value (C64572)
 - SNOMED CT value (258796002)
 - SNOMED CT value (258801007)
 - > SNOMED CT value (258895008)
 - SNOMED CT value (272082007)

Integration into a Common Model



SHIELD

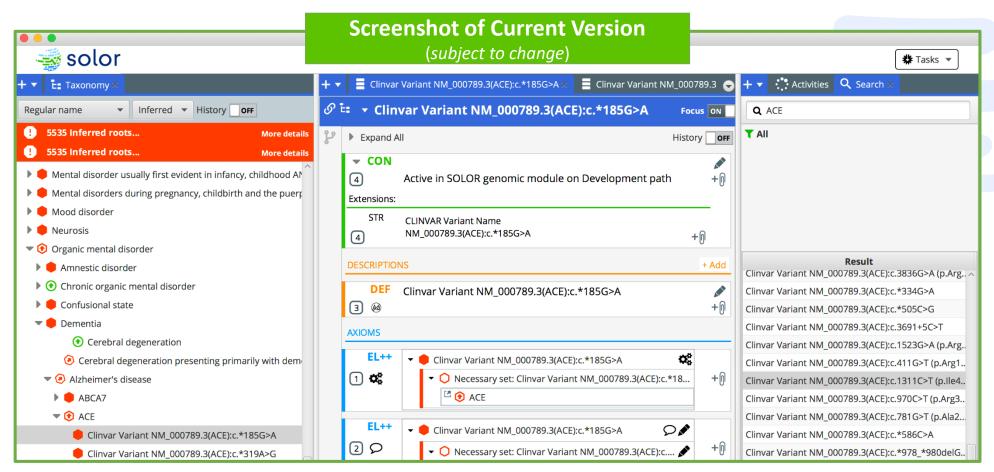
LIVD Specifications

LIVD SOLOR Extension

SOLOR Ecosystem

Knowledge Management Environment

 We are currently developing a knowledge management environment that could potentially be used to integrate LIVD specifications



Continued Collaboration

We are looking for your feedback on the following topics:

- How we can work together going forward
- Understand your requirements and any pain points you have experienced
- Define a process of transforming LIVD data into SOLOR's common model
- Manage data within a common model
- Provide SOLOR/Knowledge Management Environment documentation

Discussion with SHIELD Working Group

Appendix

LOINC Improvements



Better integration through improved description logic



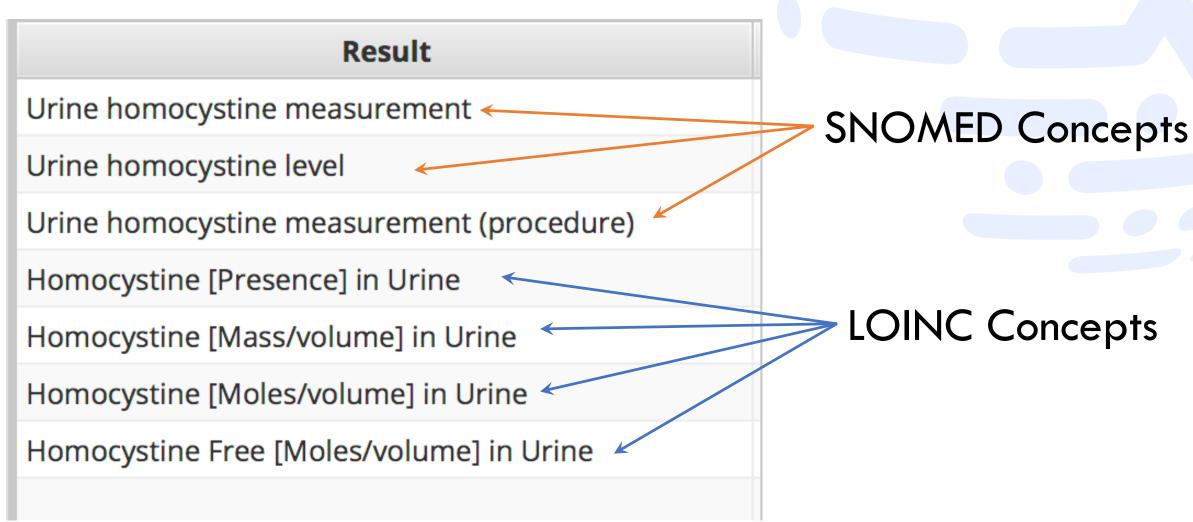
OWL EL++ with concrete domains

- Multiple sufficient sets
- Support for numeric values and ranges

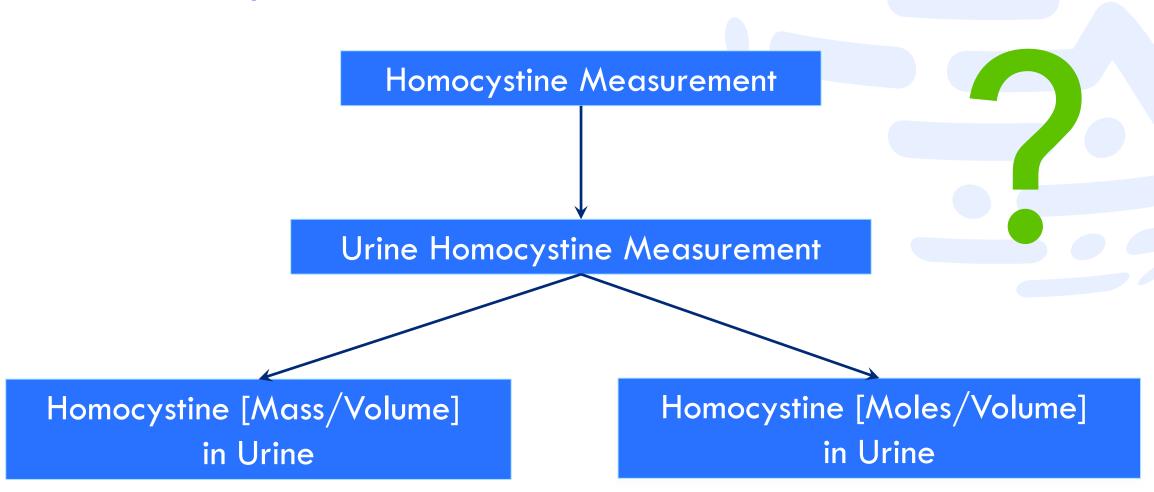


Compatible with SNOMED's stated future direction

+urine +homocystine

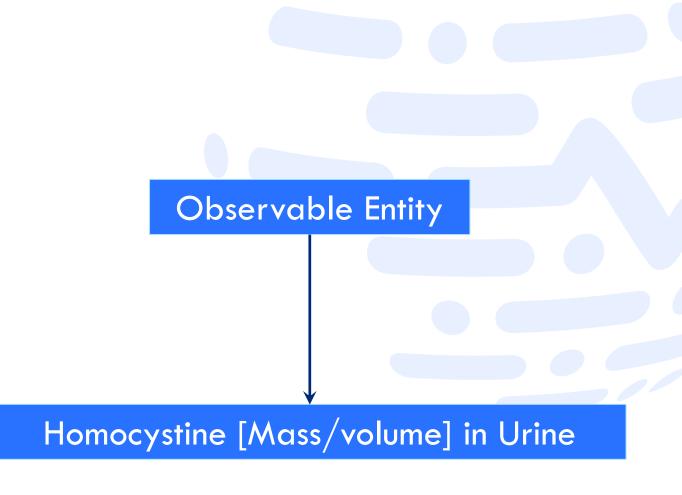


Taxonomy

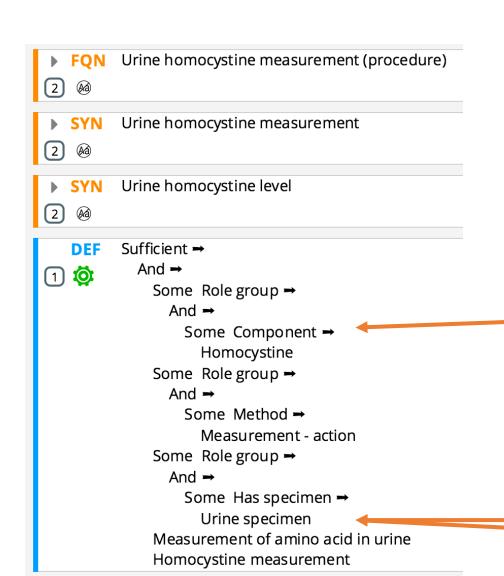


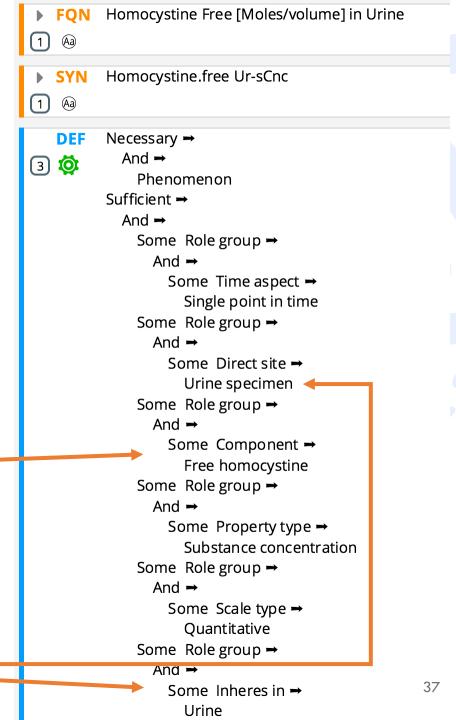
... Not Quite

- ▼ Homocystine measurement
 - Plasma homocystine measurement
 - Serum homocystine measurement
 - Procedure
 - Procedure by method
 - Evaluation procedure
 - Measurement
 - Measurement of substance
 - Measurement of substance in specimen
 - Measurement of amino acid
 - Evaluation of urine specimen
 - Measurement of amino acid in urine
 - Urine homocystine measurement



SNOMED → LOINC





Minor Model Differences

Observation Model

- - ▶ ∃ (Direct site)→[Urine specimen]

Procedure Model

- ▼ \(\begin{align*} \equiv \left\ \quad \text{\quad \quad \q
 - ▶ ☐ ∃ (Has specimen)→[Urine specimen]
- ▼ **≔** [Measurement action]
 - ▶ ∃ (Method)→[Measurement action]

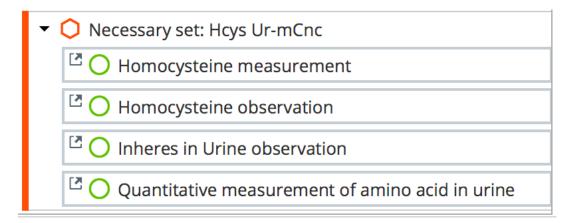
Multiple Sufficient Sets

- Sufficient set: Hcys Ur-mCnc Observation ► ☐ [Mass concentration] != [Urine specimen]
- Sufficient set: Hcys Ur-mCnc Procedure

Organizing Concepts, Classification

Necessary set: Hcys Ur-mCnc Homocysteine measurement Homocysteine observation Inheres in Urine observation Quantitative measurement of amino acid in urine

New Taxonomy



- Inheres in Urine observation (OP)
 - **(SOLOR)**
 - Substance observation (OP)
 - Amino acid observation (OP)
- Homocysteine observation (OP)
 - Procedure (SOLOR)
 - Procedure by method (procedure)
 - Evaluation procedure (procedure)
 - Measurement procedure (procedure)
 - Measurement of substance (procedure)
 - Measurement of amino acid (procedure)
- Homocysteine measurement (procedure)
- Homocysteine [Mass/volume] in Urine

Why Does this Matter?



The ability to find all equivalent concepts is:

- Necessary for decision support
- A patient safety issue



If not done properly in the defining taxonomy:

- Each decision support rule must take into account all the different ways to represent the same thing
- It results in a redundant effort at best
- There is a greater opportunity for omissions, which may result in patient harm