

HL7 Gender Harmony project

Representing sex and gender identity in clinical models

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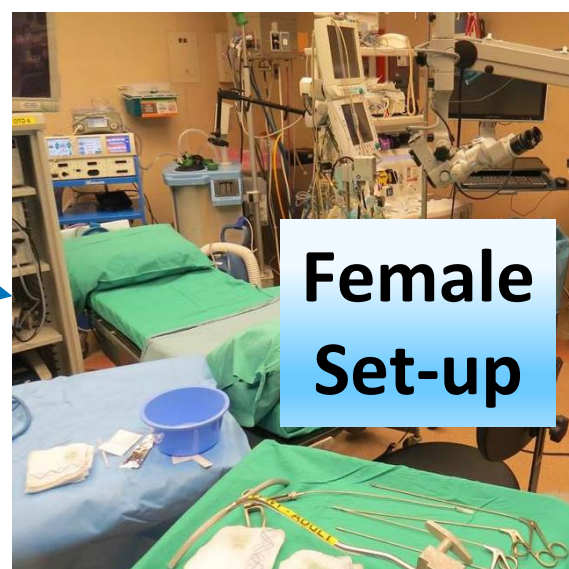
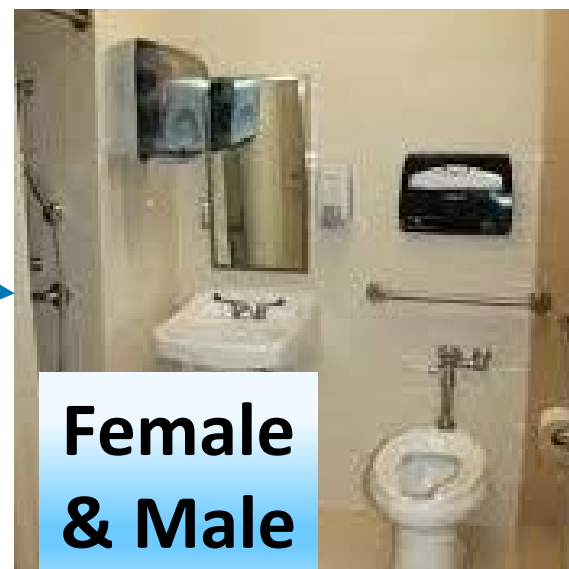
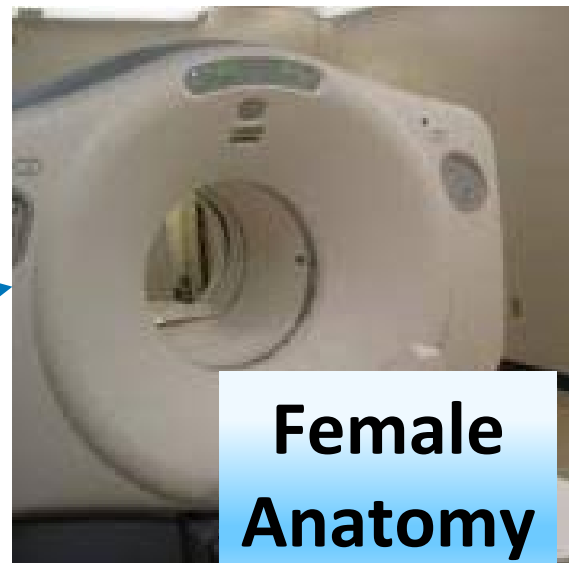
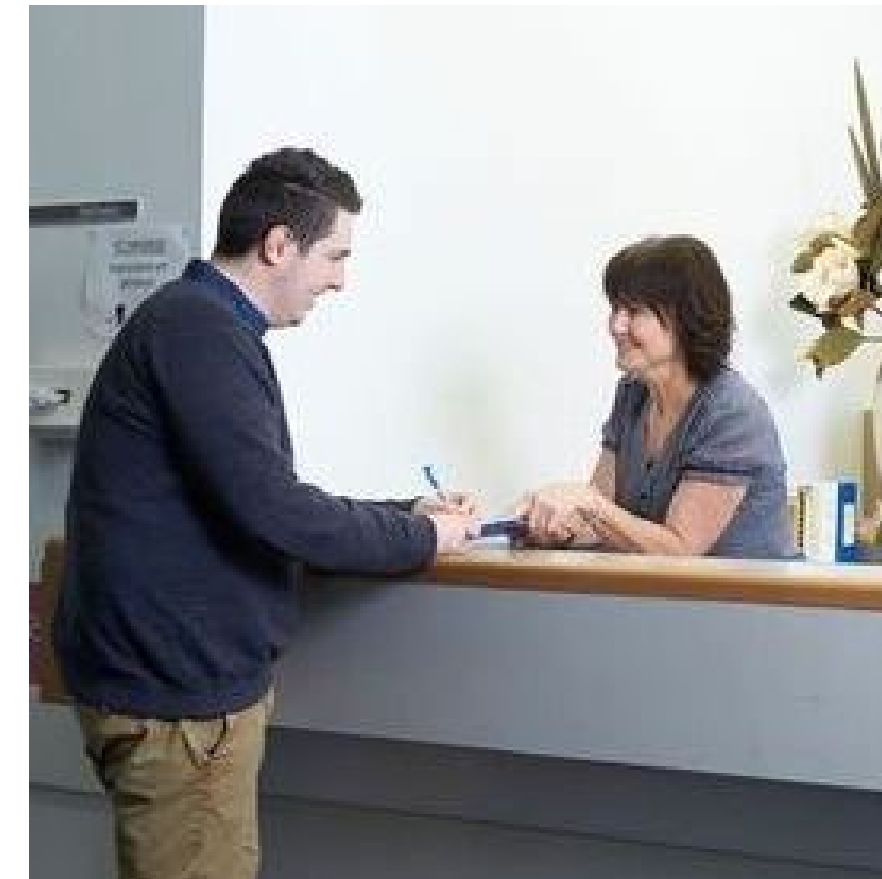


February 2022

Use Case

F->M transgender patient presents for imaging and admit.
Anatomic Female but undergoing hormone transition.

- Gender Identity = M
- Sex for Imaging Use = F
- Sex for Lab = M or more complicated
- Sex for clinical devices (for OR set-up) = F



Birth Sex, Administrative Sex, Sex, Gender Identity
are not consistently used or understood

Background

- Vocabulary Working Group Project begun Spring 2019
- Informative HL7 Specification (Jan 2021) Ballot, Published Aug 2021
- Describes logical model for sex and gender identity data representation
- Weekly (Monday 4p ET) web calls and HL7 Confluence content site (<http://hl7.me/GHP>)
- Participation from external SDO (DICOM, IEEE, some NCPDP), US, Canadian & Australian governments, LGBTQIA+, EHR (Epic, Allscripts), AMA, ACP, ACLA etc.
 - Use cases [here](#)
- JAMIA publication - <https://academic.oup.com/jamia/article/29/2/354/6382238>
- ***The time has come!*** (EG: USPSTF Approach to Addressing Sex and Gender When Making Recommendations for Clinical Preventive Services. *JAMA*. Oct 25, 2021. doi:10.1001/jama.2021.15731

Contents

- Background
- Current State overview
- Impact on clinical care
- Sex and Gender in:
 - Quality measurement
 - Reporting in Payment for Care
 - Data Analysis
- Model
- Implementation Guidance
- Appendices

HL7_GENDER_R1_INFORM_2021AUG



HL7 Informative Document:
Gender Harmony -
Modeling Sex and Gender Representation,
Release 1

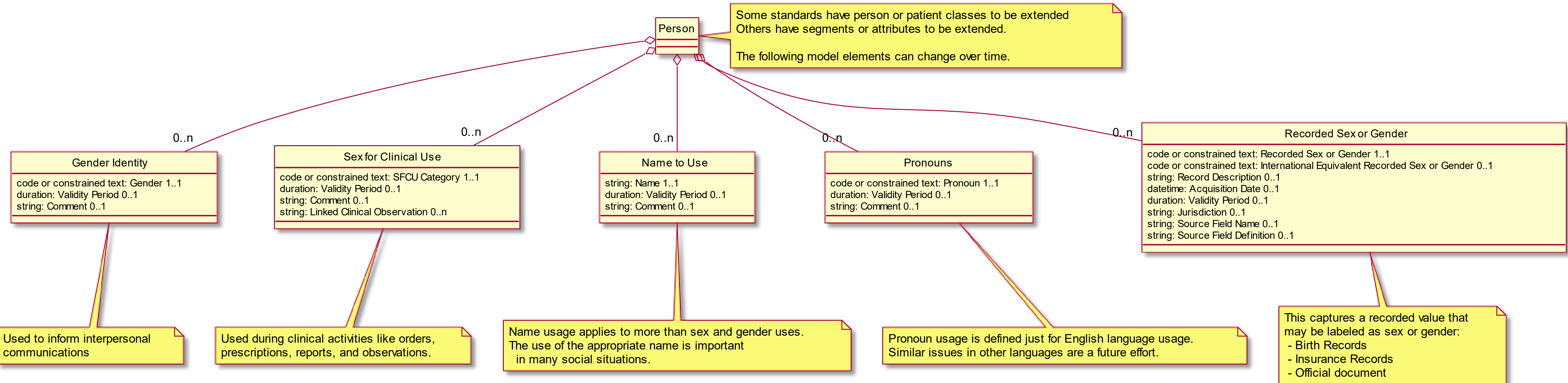
August 2021

Sponsored by:
HL7 Vocabulary Work Group

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Gender Harmony Logical Model

This is an abstract class model that each standard will need to map into the specific concrete classes used



GH Element Specifics

Gender Identity (GI)

- Source:
 - Patient *only*
- Is *always* Patient level datum
- Use:
 - Appropriate clinical interactions
- Not intended for clinical assessments or payment functions
- May, or may not, be aligned with the proper value for a clinical, administrative or legal based decision
 - IE: this is not administrative, legal, or clinical

Sex For Clinical Use (SFCU)

- Source:
 - Clinician
 - Clinical rules system
 - Clinical observations
- Can be “Patient level datum” but often specific to a particular use
- Use when patient physiology determines appropriate:
 - Tests, drugs, procedures
 - Reference ranges, methods, algorithms, pathways
 - Analysis and diagnostic methods
 - selecting and describing subjects for clinical trial and other research activities

GH Element Specifics-2

Recorded Sex or Gender (RSG)

- Sources:
 - Medical Records
 - Identity documents (e.g., passport)
 - Insurance and other administrative documents
 - Other relevant sources
- Are Patient level data
- Essentially tagging as not GI or SFCU
- LOINC 99502-7
- Uses:
 - Administrative Processes like ordering and billing
 - Understanding patient history
 - Legal and regulatory requirements (e.g., insurance cards)
 - Patient identity determination (e.g., passport information)
 - *Sex assigned at birth* is an RSG

GH Element Specifics-3

Name to Use (NtU)

- Source:
 - Patient
- Is *always* Patient level datum
- Use:
 - All clinical interactions
 - Establish therapeutic relationship
 - Use in reports, instructions, guidance, etc.
 - If “legal” name needed, send NtU *in addition*

Pronouns

- Source:
 - Patient
- Is *always* Patient level datum
- Use:
 - Where appropriate in clinical interactions
 - Establish therapeutic relationship
 - Use in reports, instructions, guidance, etc.

Proposed Minimum Value Sets

Gender Identity

Term	Definition
Female	A person's self-identification as a woman, as female, or as a girl.
Male	A person's self-identification as a man, as male, or as a boy.
Nonbinary	Having a specific identity which is nonbinary (not within a binary construct of male or female) or having an identity which falls under the nonbinary umbrella (i.e., any or all gender identities which are not female or male).
Unknown	The person's gender identity is not known at this time, for any of a variety of reasons. (e.g., "was not able to ask" or "person does not want to answer".)

- Gender Identity should allow many other phrases but these are the minimum required that any other could be mapped to

Sex for Clinical Use (SFCU)

Term	Definition
Female SFCU	The "female" values apply to this patient, in the case of a given procedure or process in a given context, for instance for a procedure, algorithm, hormone level, organ inventory, etc.
Male SFCU	The "male" values apply to this patient, in the case of a given procedure or process in a given context, for instance for a procedure, algorithm, hormone level, organ inventory, etc.
Specified SFCU	This patient has specific documented characteristics that do not fully match either male or female in a given context, for instance for a procedure, algorithm, hormone level, organ inventory, etc.
Unknown SFCU	The SFCU can not be determined because there are no observations or the observations are not sufficient to determine a value. For example, an emergency trauma case may require treatment before SFCU can be established.

- SFCU should be Required binding. This is intended to be a categorization of the linked observations

Proposed Minimum Value Sets

Recorded Sex or Gender

Term	Definition
F	A value which corresponds to female ('F') has been recorded in some context.
M	A value which corresponds to male ('M') has been recorded in some context.
X	A value which corresponds to 'X' (nonbinary, intersex, etc.) has been recorded or the value is unspecified.
<	A value has not been recorded or a value cannot be ascertained for any reason.

- This value set is intended to be an “International Equivalent,” that is based on the set noted in Doc 9303: Machine Readable Travel Documents, Seventh Edition (2015), Part 7: Machine Readable Visas published by the International Civil Aviation Organization (ICAO)

Pronouns

Term	Definition
He, Him, His, Himself	English personal pronouns, typically associated with masculinity, that are requested by a person to be used by them.
She, Her, Hers, Herself	English personal pronouns, typically associated with femininity, that are requested by a person to be used by them.
They, Them, Their, Theirs, Themselves	English personal pronouns, typically not associated with masculinity or femininity, that are requested by a person to be used by them.
Uses Other Pronouns	Person indicates that they use other pronouns than he/him, she/her, or they/them pronouns.
Unknown Pronouns	Unknown; used in situations wherein no pronouns can be asked for (young children, infants, neonates, etc.).

- Based on LOINC answer list for [Personal Pronouns - Reported, LL5144-2 Personal pronouns / Answers: 10; Scale: Nom; Code: -; Score: -.](#)

FHIR, V2.?, CDA/C-CDA Enhancements

Changes need to be aligned

- We are currently working on **Phase 2** of this project
- Crafting specific changes in each HL7 product to clarify how to represent the 5 elements
- Also working with DICOM, ISO, NCPDP
- Plan to publish a “cross-paradigm” FHIR IG ballot (please review!) in May 2022 that identifies changes for each product.
- **V2 DRAFT** example:
 - PID-8 (Administrative Sex) will be unchanged but is not any of these elements
 - GI – either:
 - New PID field
 - Guidance on use of OBX
 - Entirely new segment for all GH (and SO?)
 - SFCU
 - Patient level same as GI?
 - OBX for others

Alignment with USCDI v3

GH Element	USCDI Element(s)
Name to Use	
Pronoun	
Gender Identity	Gender Identity
Sex for Clinical Use	
Recorded Sex or Gender	Sex (Assigned at Birth)*

*Sex (Assigned at Birth) is one type of *Recorded Sex or Gender*, qualified by the available properties including Record Description, Jurisdiction, Validity Period etc.

Gender Identity

US Jurisdiction Extension

- USCDI, HL7 GH minimum, ISA →
- The GH minimum can be extended to meet jurisdictional needs. USCore plans to align with ISA.
- GH set likely is unbounded, but jurisdictional “must send if known” is expected to be larger than min.
- Strongly suggest also adding indigenous codes (IE: two-spirit.)
- Caution about rolling up more distinct codes into a general code. Get input!
 - Use-based classification into buckets is better than requiring everyone to pick one of the chosen few.
- This *is already evolving...*

Gender Identity

A person's internal sense of being a man, woman, both, or neither.

Applicable Vocabulary Standard(s)

Gender Identify must be coded in accordance with SNOMED CT® and HL7 Version 3 Standard, Value Sets for AdministrativeGender and NullFlavor, attributed as follows:

Male. 446151000124109

Female. 446141000124107

Female-to-Male (FTM)/Transgender Male/Trans Man. 407377005

Male-to-Female (MTF)/Transgender Female/Trans Woman. 407376001

Genderqueer, neither exclusively male nor female. 446131000124102

Additional gender category or other, please specify. nullFlavor OTH

Choose not to disclose. nullFlavor ASKU

Term	Definition
Female	A person's self-identification as a woman, as female, or as a girl.
Male	A person's self-identification as a man, as male, or as a boy.
Nonbinary	Having a specific identity which is nonbinary (not within a binary construct of male or female) or having an identity which falls under the nonbinary umbrella (i.e., any or all gender identities which are not female or male).
Unknown	The person's gender identity is not known at this time, for any of a variety of reasons. (e.g., “was not able to ask” or “person does not want to answer”.)

- Gender identity. LOINC® code: 76691-5
- Male. SNOMED CT® code 446151000124109
- Female. SNOMED CT® code 446141000124107
- Female-to-Male (FTM)/Transgender Male/Trans Man. SNOMED CT® code: 407377005
- Male-to-Female (MTF)/Transgender Female/Trans Woman. SNOMED CT® code: 407376001
- Identifies as non-conforming gender (SNOMED CT (US) synonyms include: Genderqueer; Identifies as neither exclusively male nor female, Non-binary gender) SNOMED CT® code: 446131000124102
- Additional gender category or other, please specify. HL7 Version 3 code: OTH
- Choose not to disclose. HL7 Version 3 code: ASKU

Gender Identity

NEW SNOMED CONCEPTS

- Requested as part of Canada Health Infoway's (Canadian national release center for SNOMED) Sex and Gender Work Group, in collaboration with HL7 Gender Harmony Project
- Improves the specificity of concepts related to Gender Identity



Canada Health Infoway

Logical Definition of GI Concepts

- 302147001|demographic history detail (observable entity)
- *Reclassification request: FSN |Gender (observable entity) or New concept Gender of subject
- *New concept request: | FSN: Gender identity (observable entity)
- * New concept request: | FSN: Gender identity of patient (observable entity)

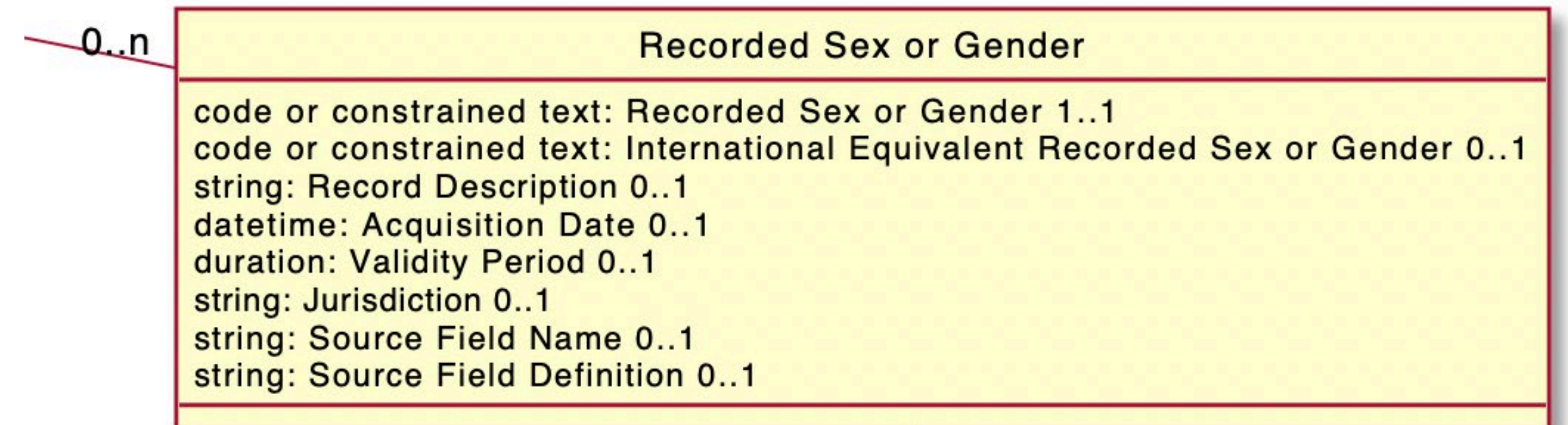
Refers to:

- 365449009|Demographic history finding (finding)|
- *New concept request: | FSN: Gender identity (finding)
- *New concept request: | FSN: Male gender identity (finding)
- *New concept request: | FSN: Female gender identity (finding)
- *New concept request: | FSN: Nonbinary gender identity (finding)
- *New concept request: | FSN: Indigenous gender identity (finding)
- *New concept request: | FSN: Two-Spirit gender identity (finding) – CA only

Sex (Assigned At Birth)

This is a type of Recorded Sex or Gender

- RSG exists essentially to provide a way to identify important context-defined sex or gender classification values **that are not GI or SFCU**.
- SAAB has been overloaded in meaning and varies by jurisdiction.
- Even if SAAB could stabilize to be an unchanging observation at birth, this is **not useful** as a *clinical sex characterization observation*
- GH understands this will need to be in records.
- We recommend adding SFCU as the way to communicate sex characteristic observations.



English language usage.
are a future effort.

This captures a recorded value that may be labeled as sex or gender:

- Birth Records
- Insurance Records
- Official document

Example

- Recorded Sex or Gender: "Male"
- Record Description: "Patient EHR Record"
- Acquisition Date: 2022-02-08
- Validity Period: "February 3, 1957"
- Jurisdiction: (hospital)*EHR_managing_entity*
- Source field name: LOINC 76689-9 "Sex assigned at birth"
- Source Field definition: null

Validity period usually will be the date on record
Provenance of information often important

An Open Process

- Join us <http://hl7.me/GHP> Mondays 4-5:30p ET
- VA is providing person-power to create the IG
- Seeking use cases to demonstrate common use across all standards protocols

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