

HL7 Gender Harmony project

Representing sex and gender identity in clinical models

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Project Lead

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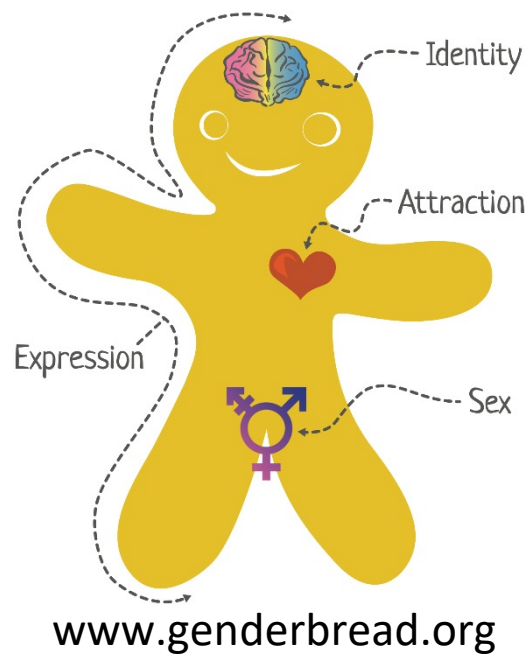
Carol Macumber (she, her)

Co-lead

EVP, Client Services, Clinical Architecture



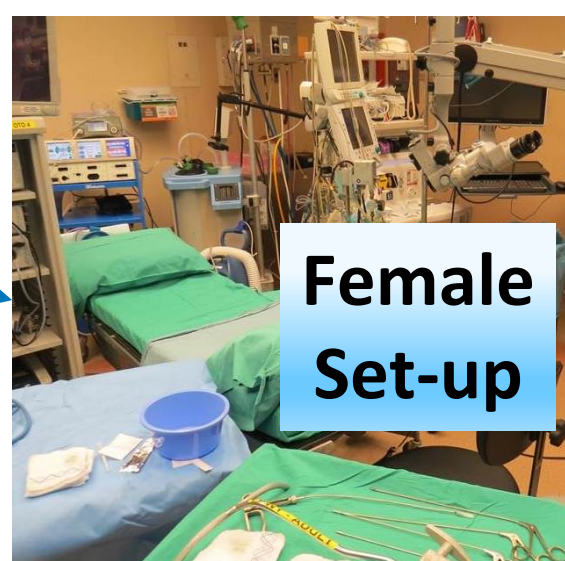
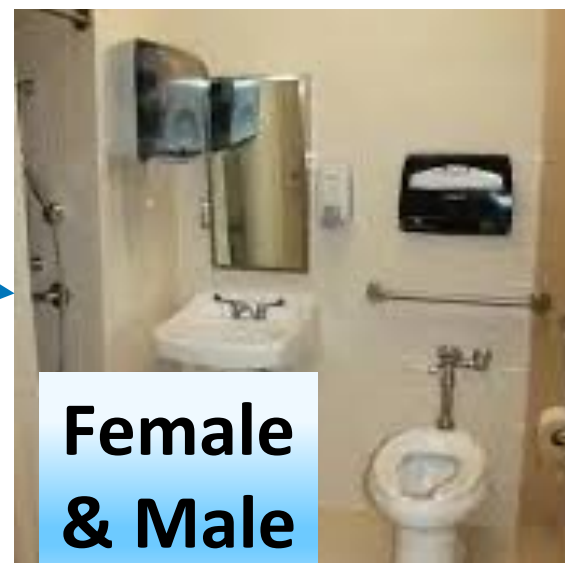
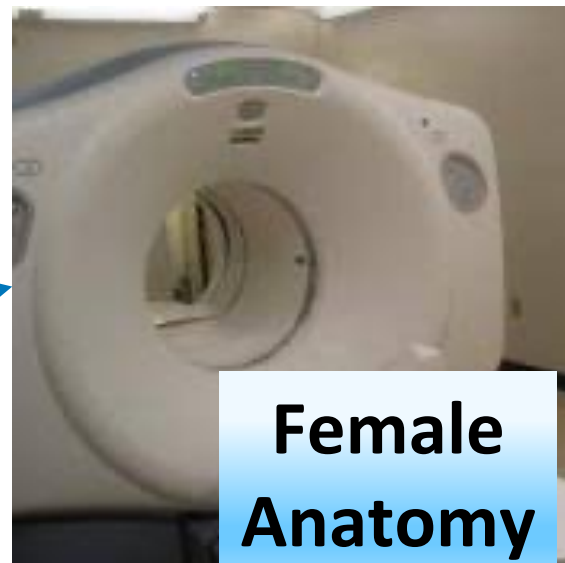
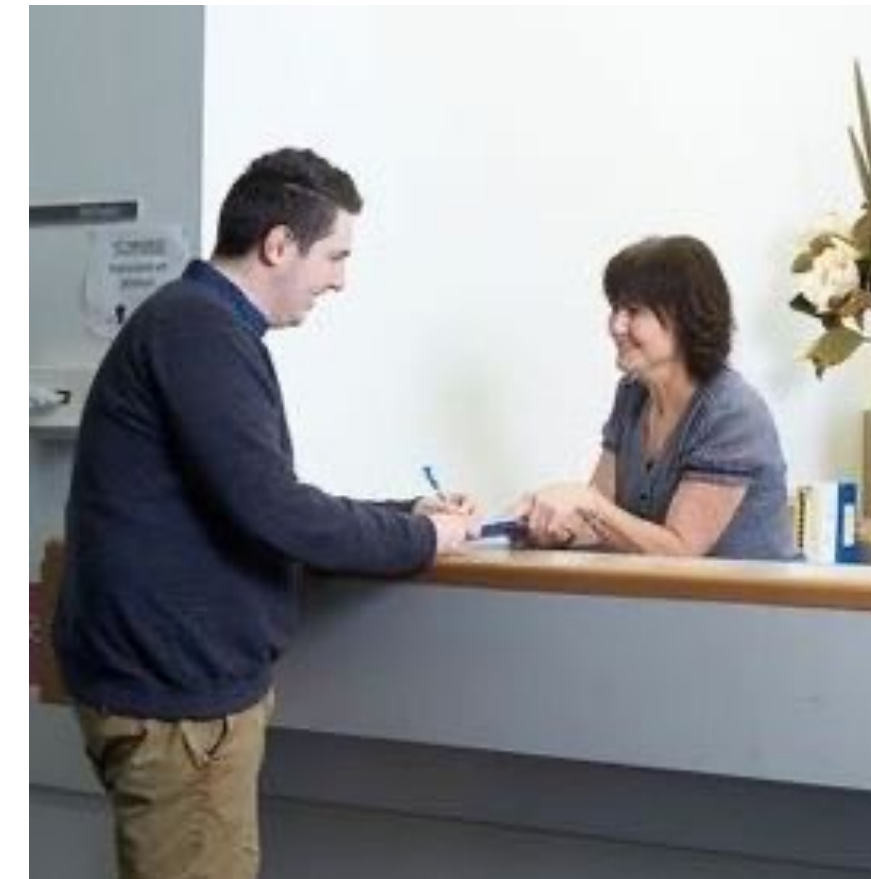
June 2022



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
 - All success is due to the dedicated work of the committee members
- Informative HL7 Specification (Jan 2021) Ballot, Published Aug 2021
- Describes logical model for sex and gender 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
- JAMIA publication - <https://academic.oup.com/jamia/article/29/2/354/6382238>
- ***The time has come!***
 - USPSTF Approach to Addressing Sex and Gender When Making Recommendations for Clinical Preventive Services. *JAMA*. Oct 25, 2021. doi:10.1001/jama.2021.15731
 - National Academies of Sciences, Engineering, and Medicine 2022. Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26424>.

Informative HL7 Specification

- Balloted in Jan 2021, Published Aug 2021
- Describes logical model for sex and gender data representation
- Background
- Current State overview
- Impact on clinical care
- Sex and Gender in:
 - Quality measurement
 - Reporting in Payment for Care
 - Data Analysis
- Implementation Guidance
- Appendices

HL7_GENDER_R1_INFORM_2021AUG



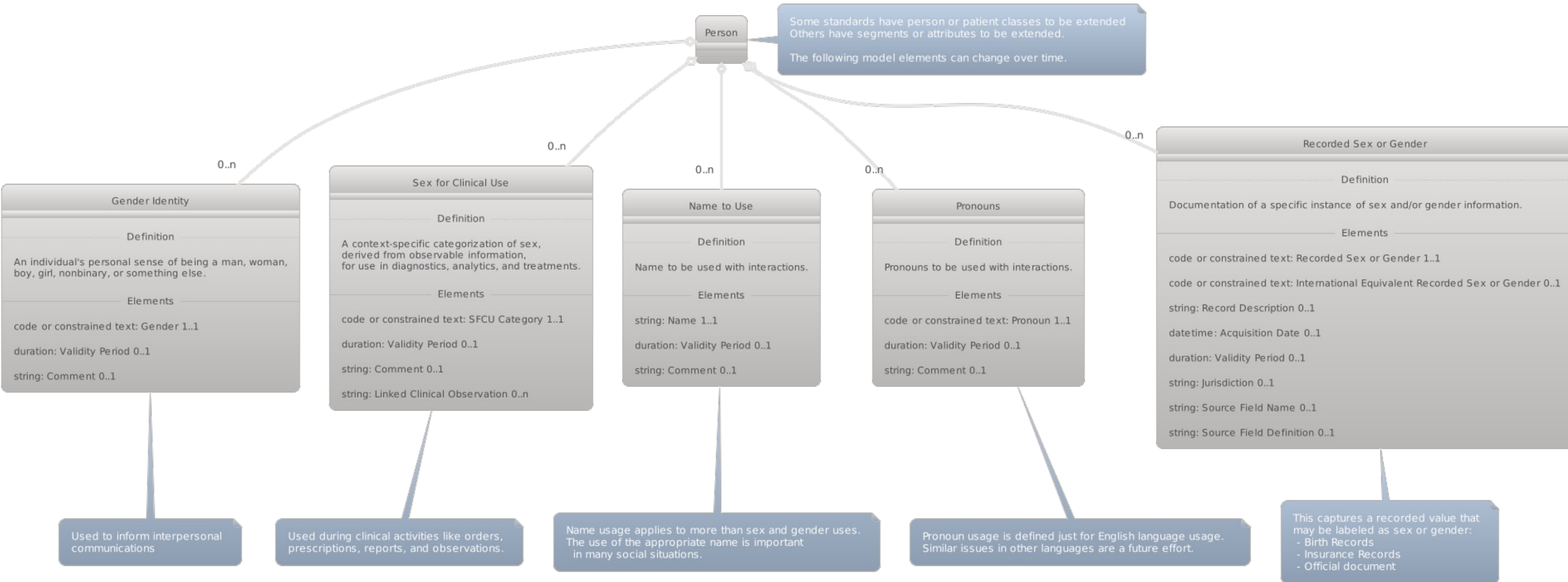
HL7 Informative Document:
Gender Harmony -
Modeling Sex and Gender Representation,
Release 1

August 2021

Sponsored by:
HL7 Vocabulary Work Group

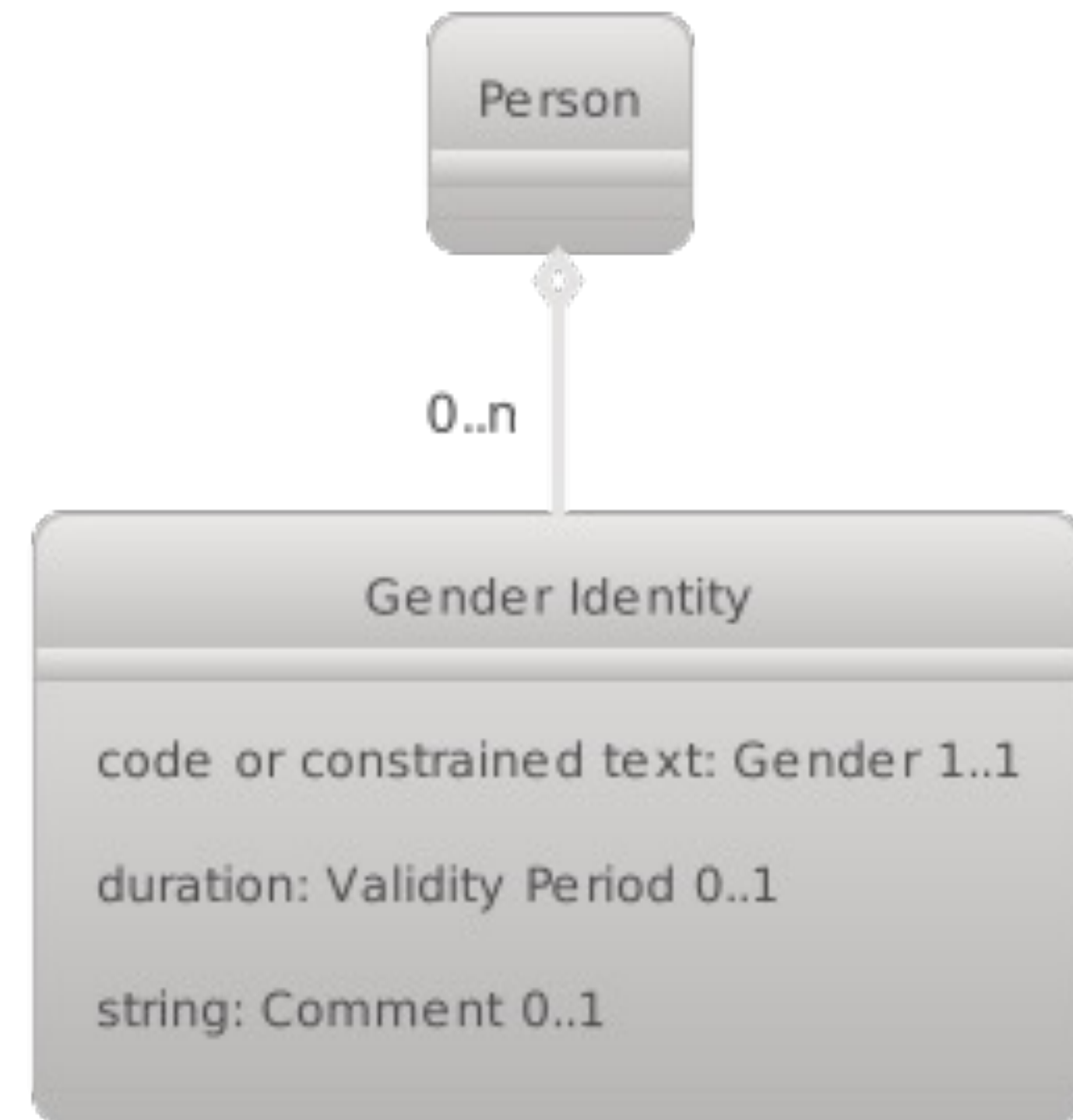
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Gender Harmony Logical Model



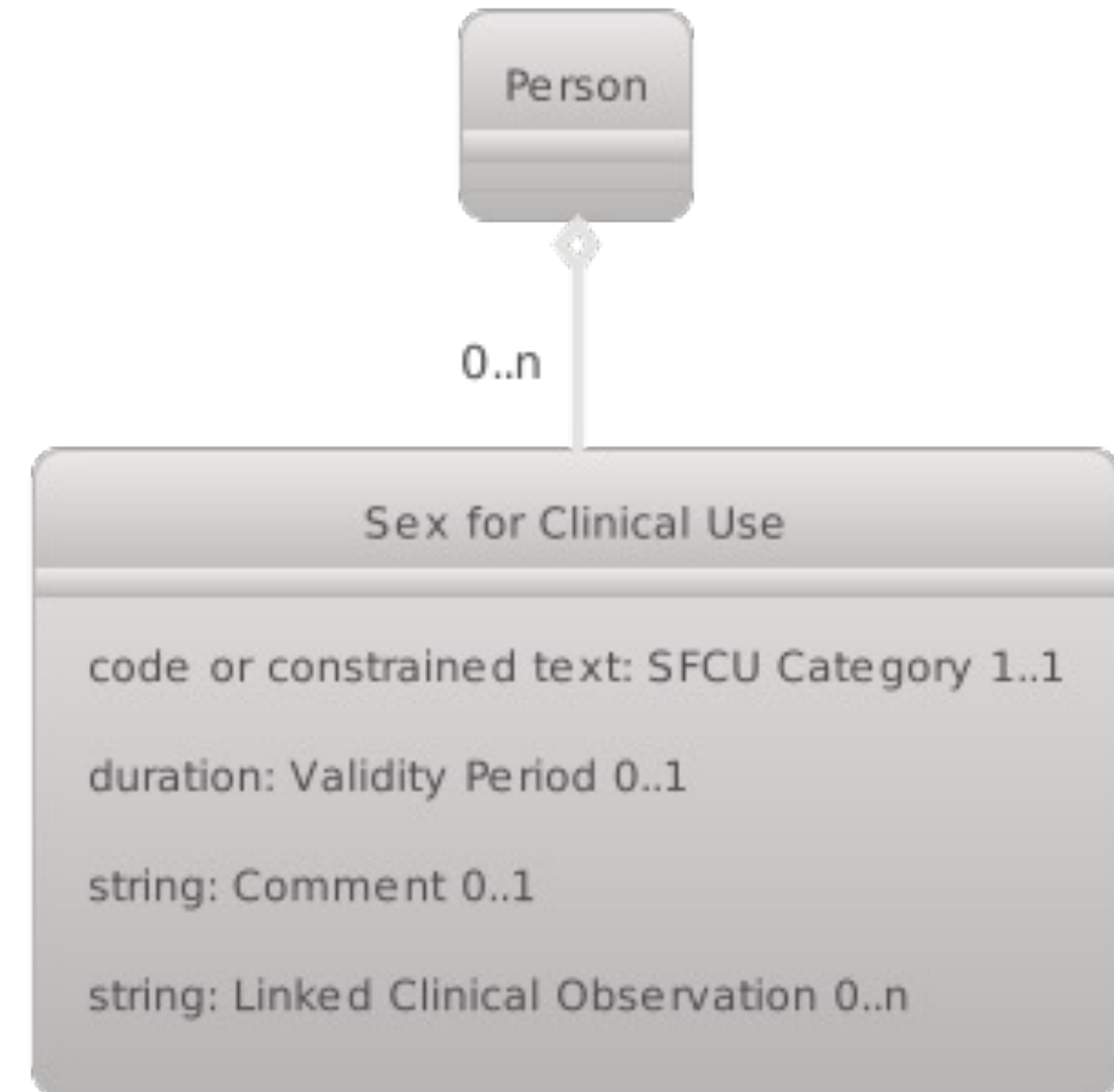
Gender Identity

- An individual's personal sense of being a man, woman, boy, girl, nonbinary, or something else.
- Source:
 - Patient *only*
- Always Patient level datum
- LOINC 76691-5
- 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

- Context-specific categorization of sex, derived from observable information, for use in diagnostics, analytics, and treatments.
- Source:
 - Clinician
 - Clinical rules system
 - Clinical observations
- Can be Patient level data, but often specific to a particular context
- LOINC 99501-9
- 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



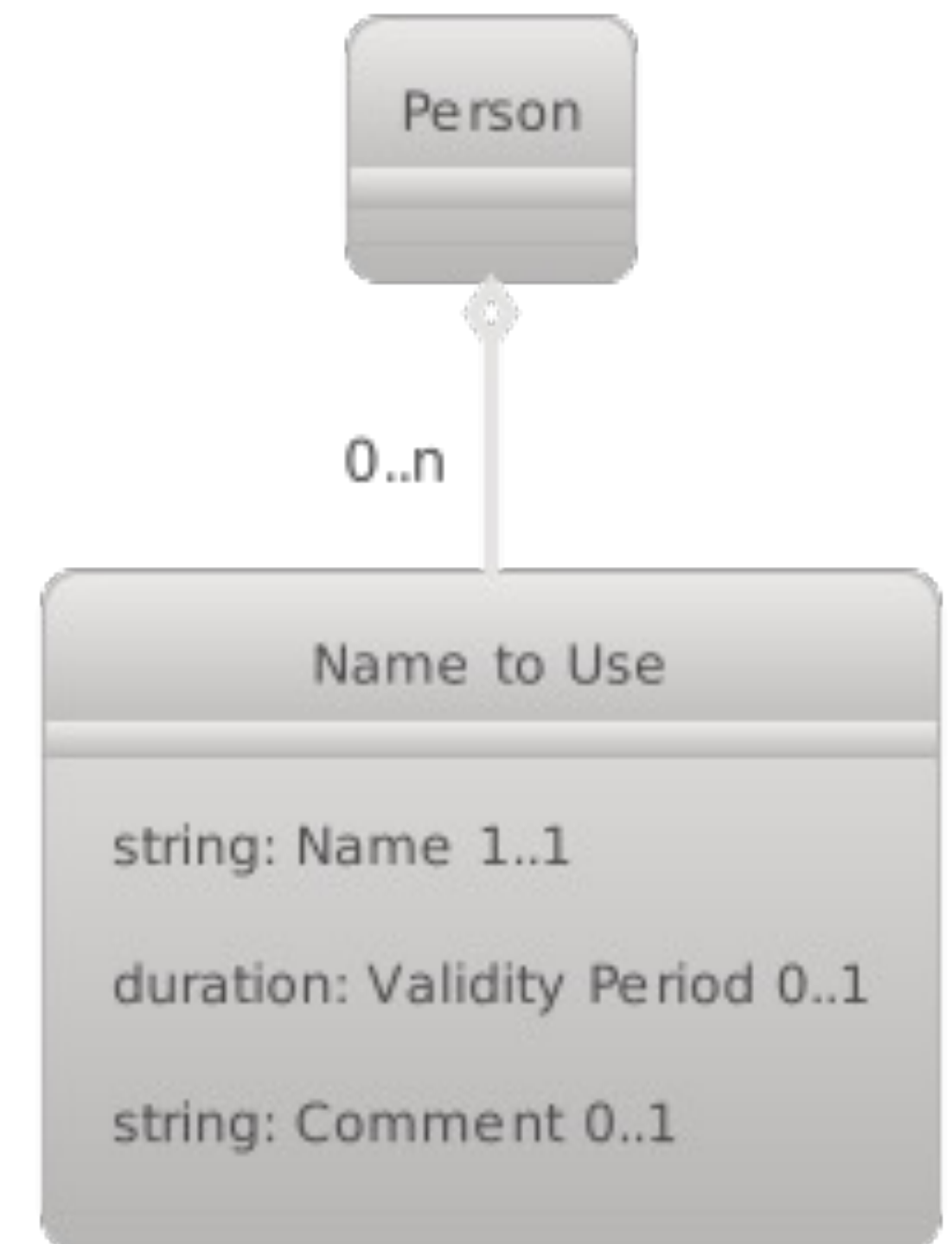
Recorded Sex or Gender

- Documentation of a specific instance of sex and/or gender information
- Sources:
 - Medical Records
 - Identity documents (e.g., passport)
 - Insurance and other administrative documents
 - Other relevant sources
- Patient level data
- Essentially tagging as not Gender Identity or Sex for Clinical Use
- 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



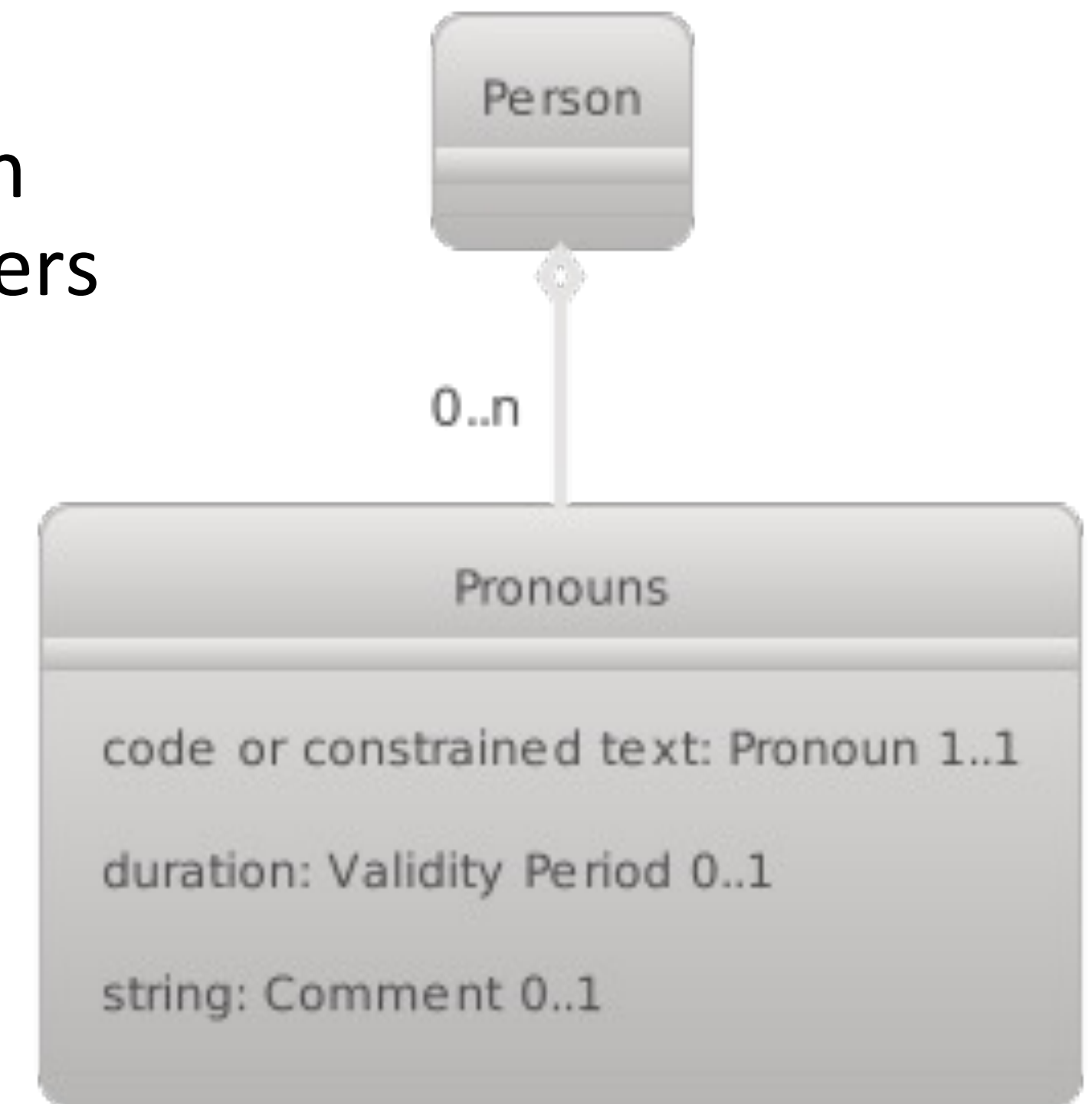
Name to Use

- Text attribute that provides the name that should be used when addressing or referencing the patient
- Source:
 - Patient
- 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

- Specified by the patient to use when referring to the patient in speech, in clinical notes, and in written instructions to caregivers
- Source:
 - Patient
- Always Patient level datum
- LOINC 90778-2
- Use:
 - Where appropriate in clinical interactions
 - Establish therapeutic relationship
 - Use in reports, instructions, guidance, etc.



Proposed Minimum Value Sets

Gender Identity

Use SNOMED CT. Bind Extensible

Term	Definition
Identifies as female gender	A person's self-identification as a woman, as female, or as a girl.
Identifies as male gender	A person's self-identification as a man, as male, or as a boy.
Identifies as non-binary gender	Fluctuating between male and female, or identifying as either having a gender that is in-between or beyond the two categories or as having no gender, either permanently or some of the time.
Unknown	The person's gender identity is not known at this time, for any of a variety of reasons.

Many additional phrases are appropriate for gender identity and each phrase/concept should be considered independent and non-overlapping.

Do not “roll-up” to the minimum set.

Sex for Clinical Use (SFCU)

Use HL7 code system. Bind REQUIRED

Term	Definition
Female sex for clinical use	Available data indicates that diagnostics, analytics, and treatments should consider best practices associated with female reference populations.
Male sex for clinical use	Available data indicates that diagnostics, analytics, and treatments should consider best practices associated with male reference populations.
Specified sex for clinical use	Available data indicates that diagnostics, analytics, and treatment best practices may be undefined or not aligned with sex-derived reference populations. Additional information (usually, but not always, in the form of comments and/or observations) is available but does not align with male sex for clinical use or female sex for clinical use. <i>Usage note:</i> <i>Individuals or systems providing care should either use default behavior that is safe for both male and female populations, individually review treatment options with the patient, or carefully inspect comments and relevant observations before proceeding with treatment. Systems that are unable to review additional information that may be associated with an SFCU value may manage a SPECIFIED and an UNKNOWN value in the same way.</i>
Unknown	No information can be provided at this time.

Proposed Minimum Value Sets

International Recorded Sex or Gender

Use HL7 code system. Bind REQUIRED

Term	Definition
<i>F</i>	<i>A value which corresponds to female ('F') has been recorded in some context.</i>
<i>M</i>	<i>A value which corresponds to male ('M') has been recorded in some context.</i>
<i>X</i>	<i>A value which corresponds to 'X' (any non-M or non-F value.) has been recorded or the value is unspecified. Code for this is "<"</i>

Only used when providing additional international exchange representation of recorded value intended to align with travel documents.

Based upon ICAO Doc 9303: Machine Readable Travel Documents, Eighth Edition (2021), Part 7: Machine Readable Visas

Pronouns

Use LOINC code system. Bind Extensible

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.

Many additional phrases are appropriate for use as pronouns and each phrase (set)/concept should be considered independent and non-overlapping.

Do not “roll-up” to the minimum set.

USCDI Alignment

USCDI Orgnaizational Class (Level)	Gender Harmony Element
Patient Demographics (Level 2)	Name to Use
Patient Demographics (Level 2)	Pronoun
Patient Demographics (Draft V3)	Gender Identity
Sex for Clinical Use (Level 2)	Sex for Clinical Use
Recorded Sex or Gender (Level 2)	Recorded Sex or Gender

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

Why Not Use “Sex Assigned at Birth?”

Birth Sex / Sex assigned at birth:

- Does not represent a sex categorization that:
 - Is proper for all clinical use situations
 - Is correct for all time periods
- Can be changed in every USA state/territory
(<https://transgenderlawcenter.org/resources/id/state-by-state-overview-changing-gender-markers-on-birth-certificates>)
- Sex recorded on birth certificate is based upon infant external genitalia
 - Likely not useful in situations where SFCU distinctions are critical

Phase 2 – Implement Changes in Standards

- Normative track HL7 Cross-paradigm Gender Harmony Implementation Guide (IG) using FHIR publishing
 - September Target
 - Likely alignment by **DICOM, ISO, NCPDP, USCDI**
- IG focus
 - Describe the overall solution and approaches taken by each HL7 Product Family
 - Provide Examples based upon key use cases
 - Patients in and post transition, and other lived experiences
 - Patient interactions
 - Proper SFCU use in ordering and approvals
 - Show alignment across V2, CDA, FHIR
 - Provide value sets
- V2 and CDA will require family-specific separate IGs to properly document changes
- FHIR changes will be in R5, with additional guidance in Gender Harmony IG

V2 approach for GH content

- **Short-term** (Immediate) – SOGI
- New Jersey [passed legislation earlier this year](#)
- Requires “The gender identity, sexual orientation, and racial and ethnic information of a patient shall be included in laboratory orders generated by electronic medical record systems.”
- HL7 Work Group Collaboration
 - Short term solution around lab message reporting of SOGI information [here](#)
 - Does not address the sending of either Recorded Sex or Gender values or Sex for Clinical Use.

Long-term (September 2022 Ballot) – include Sex For Clinical Use

New Segment for “Sex and Gender”

Two Segment Fields

- One for Gender Identity , Sexual Orientation, Pronouns
- One for Sex For Clinical Use
- Sex For Clinical Use will also include context (e.g., OBR) and Evidence (e.g., ORX)

FHIR GH enhancements

- All required elements will exist in FHIR [R5](#)
- Alternatives: Changes to specific *close to use* resources versus a profiled Observation
 - Patient.gender = administrative gender can only be used when B2B clarify use
 - **NOT a standard for Gender Identity or Sex For Clinical Use**
- **GH change summary**
 - Gender Identity – [Extension](#) on [Patient](#), Related Person, Person and Practitioner
 - Sex for Clinical Use – [In-line \(general\) extension](#) with solicitation of feedback in comparison to Gravity implementation (Constraint via Observation Profile)
 - Recorded Sex or Gender – [extension](#) on selected resources such as Patient
 - Pronouns – [extension](#) on selected resources such as Patient
 - Name to Use – Use existing HumanName.use = “usual”
- Notes on the evolution, including pros/cons of the recommended FHIR implementation of GH elements are located [here](#)

CDA GH enhancements

- Examples focused on C-CDA
- Plan is to align. Observation-based approach may be a part of any solution.

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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