

# HL7 Gender Harmony project

## Pronouns, Name to Use, and Sex Parameter for Clinical Use (SPCU) in clinical models

Presentation to Interoperability Standards Work Group (IS WG) - HITAC

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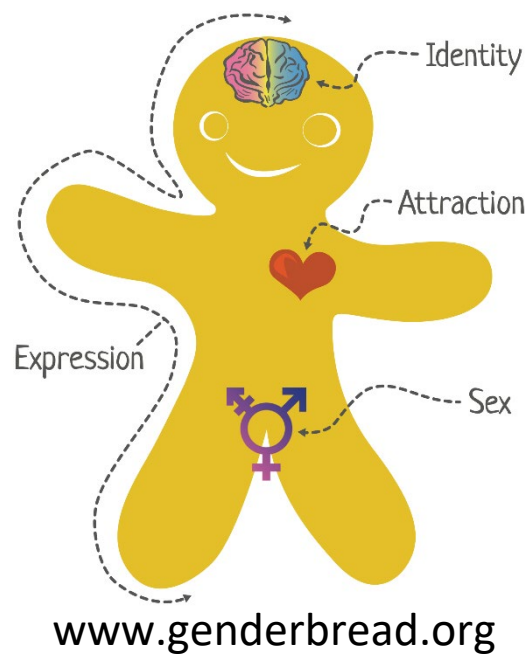
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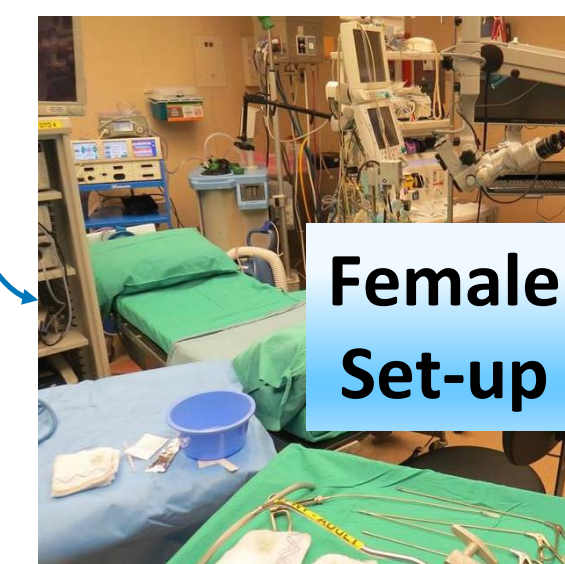
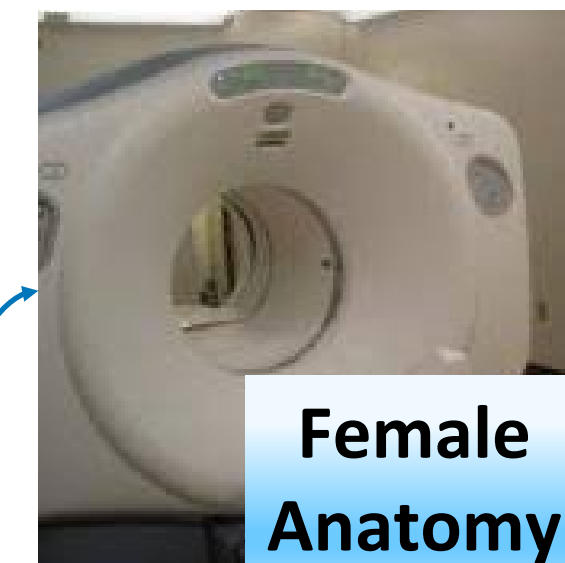
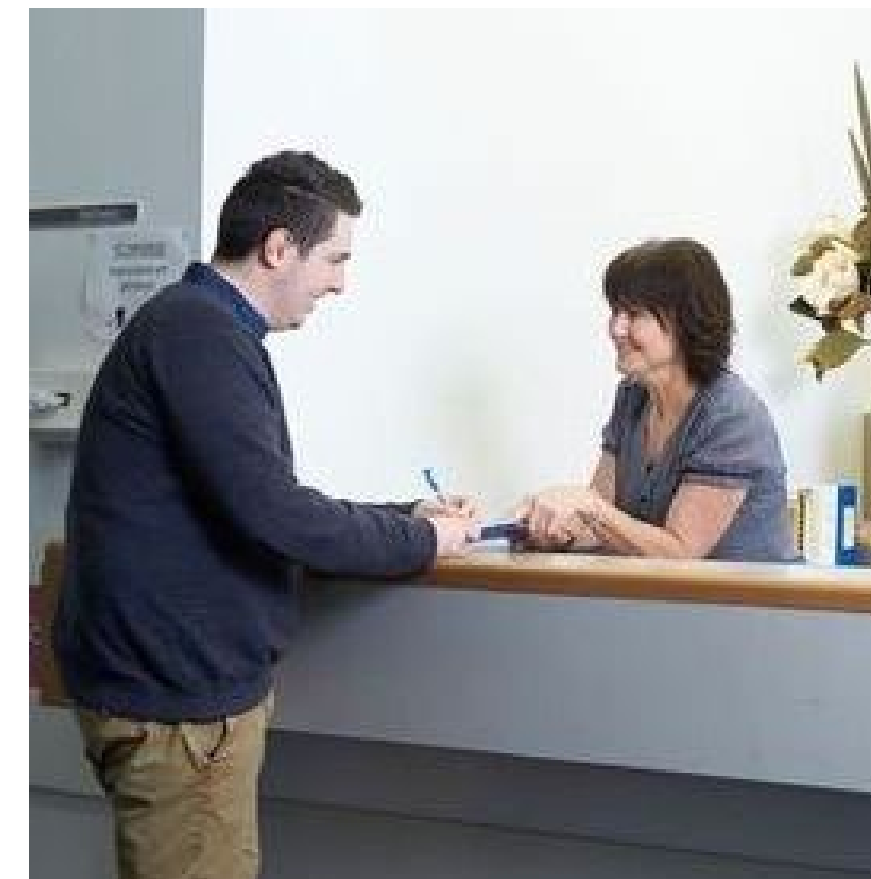
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# Use Case

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

- Gender Identity = Male
- 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

## Use Cases (Cont.)

- 55yo status post bilateral prophylactic mastectomy due to multiple 1<sup>st</sup> deg relatives with breast cancer: Don't assess for mammography
- A person with polycystic ovary syndrome with atypical hormone levels: Properly reported, don't reject as invalid results.

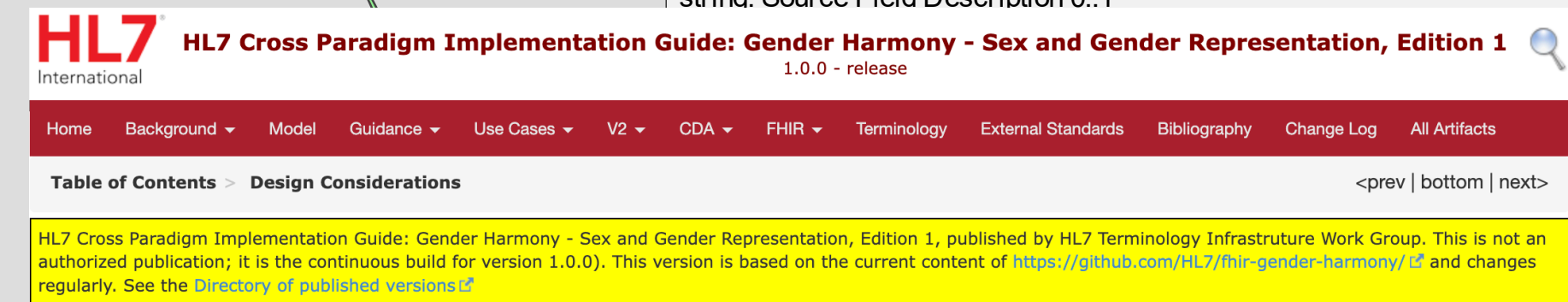
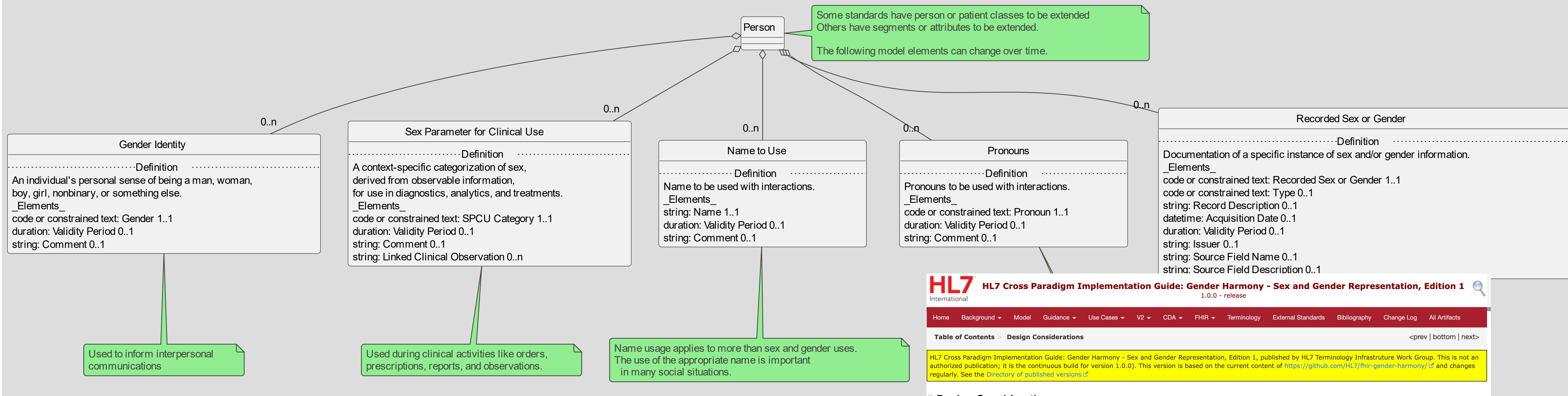
These patients:

- Gender Identity = Female
- Sex for imaging reminders = Read the chart!
- Sex for results reporting = Read the chart!

The data elements are important across ***all patients***, not just transgender

# Gender Harmony Logical Model

Figure 1



## 5 Data Elements

- Gender Identity – [USCDI V2 \(and beyond\)](#)
- Sex Parameter for Clinical Use – [USCDI Draft V5](#)
- Name to Use – [USCDI Draft V5](#)
- Pronoun – [USCDI Draft V5](#)
- Recorded Sex or Gender – [USCDI Level 0](#)

### 5 Design Considerations

The discussion around gender harmony has been on-going for several years. This implementation guide is based on the logical [Gender Harmony initial informative specification](#) published in 2021 and the evolution of the Gender Harmony Project (GHP) team's understanding of how sex and gender information is implemented currently and how it could be more effectively implemented in electronic healthcare systems. Based upon input from the community, the Gender Harmony project has defined (and prefers) implementing a model using extensions so that the added information is "close to user," but it is clear that as an alternative users may choose to implement the information as observations in a manner similar to that found in the Gravity Project, for example [Observation Recorded Sex Gender](#).

The table below lists design requirements considered by GHP for each Gender Harmony Model element and its implementation across the HL7 product families. Both the FHIR and V2 efforts chose to build sex and gender harmony model information into the core model – as FHIR extensions in FHIR and as a new segment in V2 – because the information processing requirements that those standards support benefit from this proximity. CDA does not have this constraint and prioritized ease of use and access to the artifacts, ultimately opting for the use of a clinical statement template as the most feasible approach.

Detailed design considerations for each HL7 product family are included in the appropriate sections in this IG.

#### Gender Identity

Logical Model Requirement	V2	FHIR	CDA
Distinct attribute available in specific places	GSP segment	Extension: <a href="https://hl7.org/fhir/extensions/StructureDefinition-individual-genderIdentity.html">https://hl7.org/fhir/extensions/StructureDefinition-individual-genderIdentity.html</a>	Gender Identity Entry Template
Define where element is available/appropriate for use	As appropriate in the message structure	Patient, Person, RelatedPerson, Practitioner	All Open CDA Templates allow for using any other defined CDA Templates; The context and use of the «inserttemplatename» is driven by the template in which the template is contained.
Support zero to many instances	It is expected, but not required, that there be only one gender identity value for any time period even though the genderIdentity extension/segment can be repeated.	It is expected, but not required, that there be only one gender identity value for any time period even though the genderIdentity extension/segment can be repeated.	It is expected, but not required, that there be only one gender identity value for any time period even though the genderIdentity extension/segment can be repeated.
Value is coded and allows text	SOGI Concept Value (GSP-5), when SOGI Concept (GSP-4) = 76691-5^Gender Identity^LN with datatype Coded with Exceptions (CWE)	Datatype: <a href="http://build.fhir.org/datatypes.html#CodeableConcept">CodeableConcept</a> ( <a href="http://build.fhir.org/datatypes.html#CodeableConcept">http://build.fhir.org/datatypes.html#CodeableConcept</a> )	CD (CONF:4536-48)
Designated value set	<a href="http://terminology.hl7.org/ValueSet/gender-identity">GenderIdentity</a> ( <a href="http://terminology.hl7.org/ValueSet/gender-identity">http://terminology.hl7.org/ValueSet/gender-identity</a> )	<a href="http://terminology.hl7.org/ValueSet/gender-identity">GenderIdentity</a> ( <a href="http://terminology.hl7.org/ValueSet/gender-identity">http://terminology.hl7.org/ValueSet/gender-identity</a> )	<a href="http://terminology.hl7.org/ValueSet/gender-identity">GenderIdentity</a> ( <a href="http://terminology.hl7.org/ValueSet/gender-identity">http://terminology.hl7.org/ValueSet/gender-identity</a> ) (CONF:4536-48)
Support notion of	UNK and asked-declined are in the Gender	UNK and asked-declined are in the Gender Identity value	UNK and asked-declined are in the Gender

# Background

- Terminology Infrastructure Working Group Project begun Spring 2019
  - All success is due to the dedicated work of the committee members
- JAMIA publication - <https://academic.oup.com/jamia/article/29/2/354/6382238>
- Four publications in 2023 from HL7
  - [Cross paradigm informative guide to bind them all – SEP 2023](#)
  - [CDA templates – SEP 2023](#)
  - [FHIR R5](#) contains primary extensions needed to represent new data elements – MAR 2023
  - [V2.9.1](#) contains new segments needed to represent new data elements - Soon
  - [Original Logical Model published AUG 2021 is now superseded and will be retired.]
- Participation from external SDO (DICOM, IEEE, some NCPDP), US (VA!), Canadian & Australian governments, LGBTQIA+, EHR (Epic, Allscripts), AMA, ACP
- ***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>.

# Gender Harmony Model Elements for Discussion

Critical for affirming care for *all* patients

## Name to Use (NTU)

The name that should be used when addressing or referencing the patient.

- Not the legal name.

## Pronouns

Pronoun(s) specified by the patient to use when referring to the patient in speech, in clinical notes, and in written instructions to caregivers

## Sex Parameter for Clinical Use (SPCU)

Provides guidance on how a recipient should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.

- A sex category derived from observable information with context specificity, preferably directly linked to the information this element summarizes (such as a comment or a linked data observation). This element is intended to indicate if observations that align with or vary from female or male are to be considered in the associated clinical activity.

# Gender Harmony is in the House

## Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1)

As stated in the Federal Registry HTI-1 (Department of Health and Human Services, 2024) publication, the addition of Sex Parameter for Clinical Use (§ 170.315(a)(5)(i)(F)), Name to Use in § 170.315(a)(5)(i)(G) and Pronouns in § 170.315(a)(5)(i)(H) as new data elements was finalized.

## National Committee for Quality Assurance – HEDIS measures

Two measures, with relevant clinical evidence bases available and extensive and continued use in the health care system, updated to include ability to report SPCU – effective Measurement Year 2024

## International Implementations

GH project participants from both Canada and Australia have indicated that there are efforts under way to implement the data elements and guidance provides by Gender Harmony.

## Electronic Health Record and Health IT Systems

EPIC, Fenway Health, DICOM standards, Laboratory Information Management Systems

# ONC Advancement Criteria

## Request to focus on Criteria 1, 3 and 4

**Criteria 1: Advances ONC policy goals related to behavioral health, equity, underserved communities, and public health reporting data**

NTU and Pronouns – These have established value

SPCU – Clarifies problematic burdens addressing critical clinical situations unaddressed by ambiguous binary M/F

**Criteria 3: Require only modest standards or implementation guide development burden**

NTU – Simply clarifies how to communicate using existing structures

Pronouns – Support requires typical approach for additional element

SPCU – Once understood, approach is like other attributes of an observation or order

**Criteria 4: Require only modest developmental burden on health IT modules**

NTU – Guidance intuitive and uses existing standards

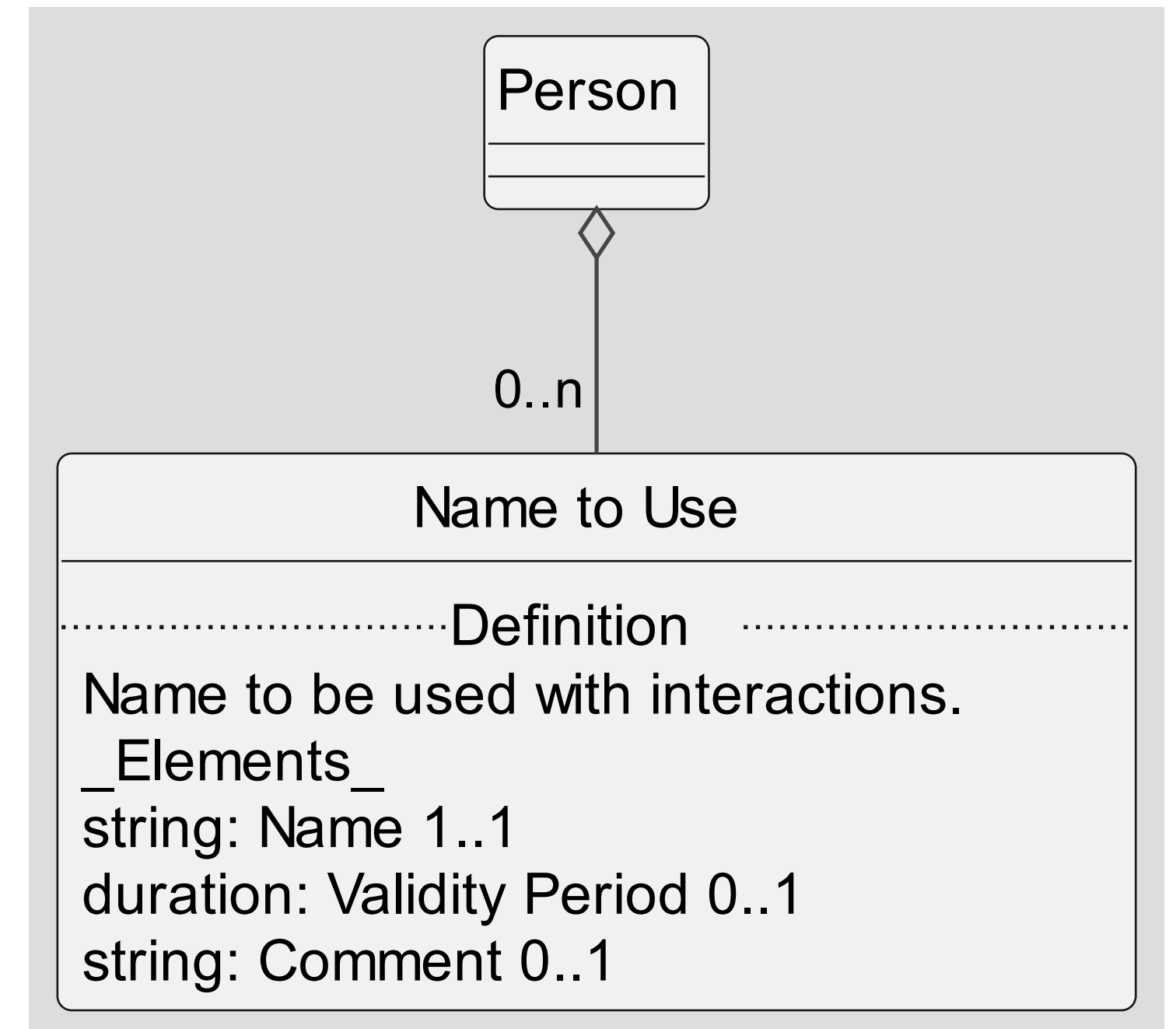
Pronouns – “Standard” addition that many most systems already capture

SPCU – Context-appropriate use of SPCU information can occur using existing tools



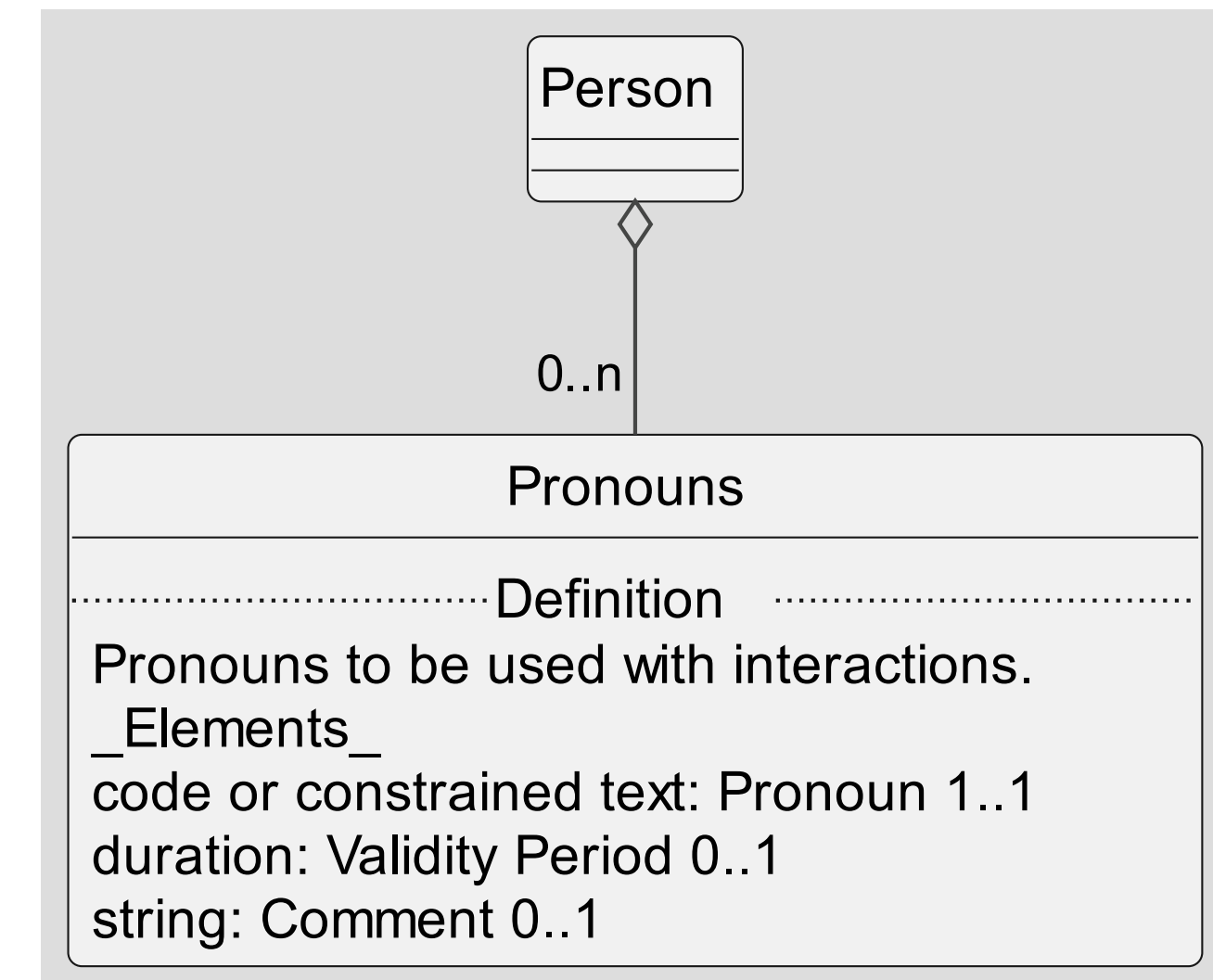
# Name to Use

- 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*
- Standards – Nothing new to include
  - FHIR – HumanName.use = “Usual”
  - C-CDA – Person Name datatype <given qualifier="CL"> (“Call Me”)
  - V2 – Extended Person Name (XPN)



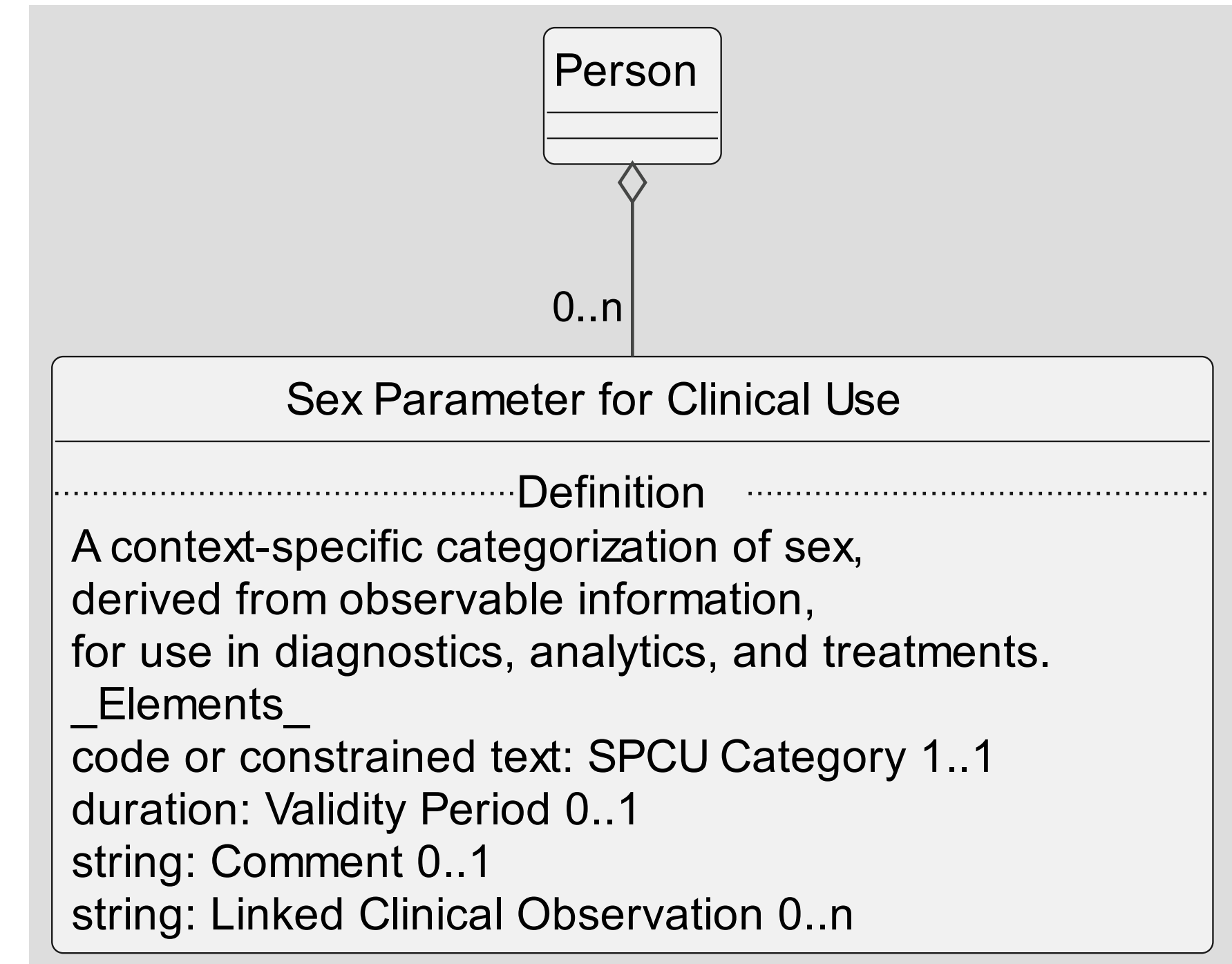
# Pronouns

- Specified by the patient for 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.
- Standards
  - FHIR – R5 Extension
  - C-CDA – a new CDA R2 template
  - V2 – V2.9.1 GSP – Person Gender and Sex Segment (3.4.19)



# Sex Parameter for Clinical Use (SPCU)

- A use-specific sex categorization value that provides guidance on how a recipient should apply settings or reference ranges that are derived from observable information.
  - Ballot name (and USCDI) - SFCU
- Source:
  - Clinical rules system
  - Clinical observations
  - Clinician
- Can be Patient level data, but intended to be specific to a particular context
- LOINC 99501-9
- Use when patient physiology determines appropriate:
  - Tests, drugs, procedures
  - Reference ranges, methods, algorithms, pathways
  - Can be a summary sex classification linked to organ/characteristics inventory
    - Inventory alone can suffice in some instances
- Standards
  - FHIR – R5 Extension
  - C-CDA – a new CDA R2 template
  - V2 – V2.9.1 GSC – Sex Parameter for Clinical Use Segment (3.4.21) as well as vis existing OBX



# Sex Parameter for Clinical Use

**Definition:** The Sex Parameter for Clinical Use is a parameter that provides guidance on how a recipient should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc. This property is intended for use in clinical decision making and indicates that treatment or diagnostic tests should consider best practices associated with the relevant reference population.

**Usage Note(s):** A use-specific sex categorization value derived from and preferably directly linked to the supporting information used to determine the value (such as a comment or a linked data observation). This element is intended to characterize observations that align with or vary from female or male when the observation(s) are intended for use in a clinical activity. In some systems the SPCU value may be automatically determined based on the medical record so that they match the recipient system's needs.

The model supports multiple instances of SPCU to allow, when necessary, more than one concurrent SPCU for a patient. For example, there could be multiple procedure results, each identifying a context specific SPCU determination used to set the normal range used. For example, an SPCU value and linked comment or specific observation could be summarized as "male, based on hormonal measurement."

# Required Value Set

## ***Sex Parameter for Clinical Use (SPCU)***

Use HL7 code system. Bind **REQUIRED**

<b>Code</b>	<b>System</b>	<b>Display</b>	<b>Definition</b>
<a href="#">female-typical</a>	<a href="http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use">http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use</a>	Apply female-typical setting or reference range	Available data indicates that diagnostics, analytics, and treatments should consider best practices associated with female reference populations.
<a href="#">male-typical</a>	<a href="http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use">http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use</a>	Apply male-typical setting or reference range	Available data indicates that diagnostics, analytics, and treatments should consider best practices associated with male reference populations.
<a href="#">specified</a>	<a href="http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use">http://terminology.hl7.org/CodeSystem/sex-parameter-for-clinical-use</a>	Apply specified setting or reference range	Available data indicates that diagnostics, analytics, and treatment best practices may be undefined or not aligned with sex-derived reference populations. Additional information may be available in the form of comments and/or observations.
<a href="#">unknown</a>	<a href="http://terminology.hl7.org/CodeSystem/data-absent-reason">http://terminology.hl7.org/CodeSystem/data-absent-reason</a>	Unknown	The value is expected to exist but is not known.

# Recommended USCDI V5 Draft Changes

## Update the SPCU definition

- Name to Use and Pronouns should be promoted
- The general Sex Parameter for Clinical Use (SPCU) data element is categorized under Observation Class.
  - In 2022, Gender Harmony Project had proposed multiple context-oriented SPCUs.
  - ONC's approach can work based upon incorporation of SPCU in HTI-1 final regulations, but...
  - Recommend that ONC improve the definition to emphasize and clarify this general element will primarily be used in specific contexts.

**Current definition:** Category based upon clinical observations typically associated with the designation of male and female.

**Suggested definition:** A use-specific sex categorization value that provides guidance on how a recipient should apply settings or reference ranges that are derived from observable information such as an organ inventory, recent hormone lab tests, genetic testing, menstrual status, obstetric history, etc.

# An Open ANSI Process

Many thanks to all the contributors, especially the detailed participation by the Canadians. We also would like to thank the US Veterans Association who provided critical resources.

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