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Data Element Information

Data Class	<b>New Data Class:</b> Sex For Clinical Use Class
Data Element Name	Sex For Clinical Use (SFCU)
Description	A category that is based upon clinical observations typically associated with the designation of male and female.
Rationale for Separate Consideration	While we strongly suggest this is incorrect, many systems dangerously operate assuming that the category known as "Sex Assigned At Birth" can be assumed to be a sex categorization for the patient in all situations.
Current Status	Submitted
Overall Classification Level	N/A

Use Case Description(s)

Use Case Description	<p>The Sex For Clinical Use categorization is intended to communicate the sex category (Male or Female) that would best align with the expected observations based upon the identified observation context used to determine the value. When male or female is not a proper categorization, then "Specified" is to be used as a flag to indicate that the SFCU value for the intended use must be based upon the specific clinical observations that pertain.</p> <p>In short, the SFCU is a sex category, specific to an intended use, with a value based upon specified observations. When no observations are specified then the user must assume that the sender has properly determined the SFCU for the intended use.</p> <p>Per the HL7 Gender Harmony specification :                  SFCU is a sex categorization that can provide context specificity, derived from observable information (e.g., Clinical Observation, Radiology report, Lab report, genetic testing) that is preferably directly linked to the information this data element summarizes (such as a comment or a linked data observation) in order to clarify the context and resulting value. 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. Examples of clinical observation that may be used to determine a value are: karyotype, phenotype, sex from imaging, hormonal values, organ inventory, certain surgical procedures, genetic observations, external genital</p>
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	<p>morphology and internal organ morphology. In some systems the SFCU value may be automatically determined based on the medical record so that they match the recipient system's needs.</p> <p>The Gender Harmony specification identifies a set of intended data attributes to best clarify the SFCU use. Additional information is also found in the JAMIA article discussing the project .</p> <p>International H. HL7® Informative Document: Gender Harmony - Modeling Sex and Gender Representation, Release 1.                  2021.<a href="http://www.hl7.org/implement/standards/product_brief.cfproduct_id=564">http://www.hl7.org/implement/standards/product_brief.cfproduct_id=564</a> (accessed 21 Nov 2021).                  McClure RC, Macumber CL, Kronk C, et al. Gender harmony: improved standards to support affirmative care of gender-marginalized people through inclusive gender and sex representation. J Am Med Inform Assn 2022;29:354-63. doi:10.1093/jamia/ocab196</p>
<p>Estimated number of stakeholders capturing, accessing using or exchanging</p>	<p>This data element has not been widely implemented but is central to many use cases in clinical care and is expected to be necessary in any system that requires information on the clinical sex characteristics of a patient.</p>
<p>Link to use case project page</p>	<p><a href="https://confluence.hl7.org/display/VOC/Cross+Paradigm+Use+C">https://confluence.hl7.org/display/VOC/Cross+Paradigm+Use+C</a></p>
<p>Use Case Description</p>	<ol style="list-style-type: none"> <li>1. We recommend that a form of "Sex For Clinical Use" (SFCU) be included within "Clinical Tests". It could be called "Sex for Clinical Test" and is recommended for Level 1. Please see B2, below.</li> <li>2. We recommend that a form of "Sex For Clinical Use" (SFCU) be included within "Diagnostic Imaging". It could be called "Sex for Diagnostic Imaging" and is recommended for Level 1. Please see B3, below.</li> <li>3. We recommend that a form of "Sex For Clinical Use" (SFCU) be included within "Laboratory". It could be called "Sex for Laboratory Use" and is recommended for Level 1. Please see B4, below.</li> <li>4. We recommend that a form of "Sex For Clinical Use" (SFCU) be included within "Procedures". It could be called "Sex for Procedure" and is recommended for Level 1. Please see B5, below.</li> </ol> <p>The "See below" items are included in the attached pdf.</p>
<p>Estimated number of stakeholders capturing, accessing using or exchanging</p>	<p>We expect most clinical systems doing tests or procedures on patients will need to use this element. In addition most clinical care systems may need to be able to represent SfcU</p>

Supporting Attachments	<a href="#">SFCU use case examples.pdf</a>
Healthcare Aims	<ul style="list-style-type: none"> <li>▪ Improving patient experience of care (quality and/or satisfaction)</li> <li>▪ Improving the health of populations</li> <li>▪ Improving provider experience of care</li> </ul>
<b>Maturity of Use and Technical Specifications for Data Element</b>	
Applicable Standard(s)	LOINC “Sex for clinical use” 99501-9 <a href="https://loinc.org/99501-9/">https://loinc.org/99501-9/</a>
Additional Specifications	HL7 Gender Harmony informative publication <a href="http://www.hl7.org/implement/standards/product_brief.cfm?product_id=564">http://www.hl7.org/implement/standards/product_brief.cfm?product_id=564</a>
Current Use	In limited use in production environments
Supporting Artifacts	There are systems, such as Epic, and other locally configured systems, such as at the Fenway Institute in Boston, that support an approach similar to SFCU.
Number of organizations/individuals with which this data element has been electronically exchanged	N/A
<b>Potential Challenges</b>	
Restrictions on Standardization (e.g. proprietary code)	No restrictions other than changing the perceived approach to this common element.
Restrictions on Use (e.g. licensing, user fees)	None
Privacy and Security Concerns	Some SFCU data items may represent PHI
Estimate of Overall Burden	Most systems will require updates to implement the SFCU element, differentiating it by context and previously recorded Sex information.
Other Implementation Challenges	None