

USCDI Activities:

- Submit three clarifying comments on existing USCDI elements.
- Submit new ONDEC proposals for the data elements we list below

The three comments on existing USCDI elements we are proposing are:

Comment for Sex For Clinical Use (SFCU) Data Class

SFCU is a context-dependent clinical sex value and should not be considered a USCDI Data Class unless the class exists only to aggregate the following data elements we suggest be created. We plan to submit a new specific SFCU data element for each of the following data classes:

- Patient Demographics
- Clinical Tests
- Laboratory
- Diagnostic Imaging
- Procedures
- Medications

We understand that SFCU values have not been widely implemented in systems for data classes other than perhaps at the patient level (Patient demographics) because functionality needed for each of these data classes has been shoe-horned into the use of other general sex or gender values, such as sex assigned at birth, or administrative sex with the assumption that a unique value specific to one of these data classes could not occur. The only situation where this has been addressed is in occasions where Ask At Order Entry (AOE) values were collected, as has been discussed with COVID testing. Given that each use can be unique, each data class needs its own SFCU entry.

It should be noted that SFCU is a context-focused summary sex categorization that has as a basis one or more discrete observations. The basis used is usually discrete organ inventory, hormone levels, or other direct physiological measurements that are often the “ideal” for driving clinical decisions, however this data may not be available, and when it is, there can be privacy considerations when exchanging this level of data in some contexts. Our expectation is that contextual SFCU can often achieve similar outcomes to discrete organ inventory and other physiological measurements for many patients, with reduced privacy impact and provider documentation burden.

Recommendation:

- The Gender Harmony project does not suggest and is not supportive of the exchange of context-independent SFCU. We recommend removing SFCU as a data class so that the importance of the context is clear.
- Given that each context can be unique, and will have different levels of adoption in the industry, each existing data class (e.g., Laboratory, Medications) needs its own SFCU data element to clearly define the context of use, and to allow independent advancement as maturity of each contextual SFCU increases.
- Gender Harmony will submit separate ONDEC proposals as described above.

Comment for Recorded Sex or Gender (RSG) Data Class

While there is broad industry implementation of Administrative Gender and Sex assigned at birth (SAAB), there is also wide agreement that the meaning of these data elements is suspect and they can be dangerous if used when the meaning is unclear. But in addition to those prominent recorded sex or gender values, there are many other sex and gender values in clinical and administrative documentation. These other sex and gender values are usually captured within a context, such as a health insurance application or claim, but even then, the meaning may only be known to the individual completing the form and should only be used in the context of that form or data environment. Because of this deep contextual alignment and use, we are concerned that by making a general USCDI data class for RSG, implementers may believe that there is a need to identify and potentially exchange individual RSG values outside of the context they were collected. The Gender Harmony project does not suggest and is not supportive of the exchange of RSG elements. What is useful is to identify sex or gender elements in other USCDI data classes and clearly identify them as a context specific RSG *within the data class*. A new data element of "Recorded Gender for Health Insurance" in the Health Insurance Information would be an example of this.

Recommendation:

- The Gender Harmony project does not suggest and is not supportive of the exchange of generic RSG elements.
- Gender Harmony will submit a separate ONDEC proposal for "Recorded Gender for Health Insurance" in the Health Insurance Information.

Comment on v3 Sex data element (formerly Sex assigned at Birth) in Patient Demographics

While there is broad industry implementation of Administrative Gender and Sex assigned at birth (SAAB), there is also wide agreement that the meaning of these data elements requires conjecture and they can be dangerous if used when the meaning is unclear.

Recommendation:

- Because the meaning around these concepts is unclear, we are supportive of removing 'Sex assigned at Birth' (as was done in USCDIv3).
- We recommend removing 'Sex', and instead consider adding clarification that the concepts of Gender Identity and Sex for Clinical Use are well-defined replacements for 'Sex' and the 'Sex assigned at Birth'.

Links to USCDI ONDEC proposal submissions for new data elements

SFCUs:

Patient Demographic

<https://docs.google.com/document/d/1CaV7nArD8gwcaAx8cLLRAdQIR-c-vaaX/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true>

Clinical Tests

<https://docs.google.com/document/d/1uM21j8ezwJIOAtMU00uJZUv5K3lhwWvs/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true>

Laboratory

<https://docs.google.com/document/d/1aoX7JFqngsT5t3hyr06dNJIJvXmfQr7E/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true>

Diagnostic Imaging

https://docs.google.com/document/d/1z3rzGZhl_OGUi2R0j_EYjdp1UnJxr6n6/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true

Procedures

https://docs.google.com/document/d/10PCZmyOqKYYK6y2tMh-_Srgm-XY1xVdQ/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true

Medications

https://docs.google.com/document/d/11nUwTizHoq0W-_KWY5l4kYlIteyHMRB2/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true

RSG:

Health Insurance Information

https://docs.google.com/document/d/1-U0wORsQWx9H-6-GyxArW8_rpztWMSG/edit?usp=sharing&ouid=100625407754815611779&rtpof=true&sd=true