Supplement 233 Patient Model Gender Enhancements
20 January 2023

- Strategy
  - The gender harmony attributes of a person will be added as optional attributes in the Patient Study Module. The Patient Study Module is included into all SOP instances that refer to a person or pseudo-person (e.g., a phantom).
  - Each of these attributes is a sequence of 1..n instances of the sequences defined in the gender harmony model. Thus a patient can have 1..n SFCU items, each item having the effective dates, coded   value, comments, etc.
    Note, because these are optional attributes the cardinality is 1..n. There is no way to encode the Type 2 conditionality to indicate an attribute that was omitted for cause. ***Note: there is also an open issue in DICOM regarding cardinality for type 2 attributes. The limitation might be removed, in which case the sequences could match the HL7 model cardinality of 0..n.***
    Comment: Consider adding an attribute that controls presence of the sequence.
  - The value types defined in the gender harmony model are mapped to the equivalent data types in DICOM encodings.
    Note that this means the management of value sets is different in detail. This may affect some implementation and translation specific details. For example, an open issue for discussion within DICOM is whether value sets will be "DCID" versus "BCID".
    In a DCID a coded value is not permitted to be replaced by an equivalent code from a different value set. The DCID code must be used. In a BCID, equivalent codes are permitted. This also affects extensions to context groups.
  - The choice of Patient Study Module rather than Patient Module will affect searching and database structuring. Attributes in the Patient Module are required to be the same for all SOP instances for that Patient. (This rule is often a source of QC and database problems in the real world.) Attributes in the Patient Study Module are required to be the same for all SOP instances for that one study or examination. They are permitted to be different for different studies of the same patient.
    For example, a patient's medical record number is put into the Patient Module, while a patient's weight is put into the Patient Study Module.

  - SFCU will probably be renamed and redefined as "Sex related settings and reference ranges". The codes need not changed. It makes the code "Specified" make much more sense. Conditions may be added on the optional comments and observations related to these codes.

- Sections of the standard that are being changed:
  - Part 2 (conformance), changes are expected but not yet specified.
    - This will wait for a stable proposal for all the sex and gender related changes elsewhere.
    - This is also affected by the recent major changes to the structure of Part 2.

- Part 3 (the data model), the bulk of the changes will be in the Patient and Patient Study Module. A search for the Patient's Sex (0010,0040) was done to identify all sections that will need examination. Committee experience may identify other sections.
- Part 4 (services, such as search and store). A search for the Patient's Sex (0010,0040) was done to identify all sections that will need examination. This has revealed some perhaps obsolete services and raised the open issue for discussion of whether these services should be retired.
- Part 6 (Data Dictionary) will need the usual update for the new attributes.
- Part 15 (Security, etc.) will have all the new attributes added to the Attribute Confidentiality profiles. It is expected that the rules for the new attributes will be the same as the current rules for Patient's Sex (0010,0040).
- Part 16 (Coded Terminology, etc.) will have new contexts defined for the new coded attributes. This may include substantive text explaining how coded terminologies are extended and localized in DICOM because local extensions to terminologies such as gender will be needed in many locations. Implementers might need the reminder about how the extension mechanism works.
Note, there are many current open issues regarding details of value set selection, coding, and context groups. Another open question raised is whether old context groups should be revised. There are some old context groups that are used to indicate sex related acquisition contexts within structured reports.
- Part 17 (illustrative examples) will have another annex added. This will cover at least two use cases:
  - A multi-phase examination. (There is some open question how much of this belongs within the DICOM examples and how much belongs as an IHE profile.)
  - A query for patient priors for a complex patient history.
- Part 18 (API) - needs review. The expectation is no changes because most of the API is context independent mapping of attributes.
- Other parts are not expected to be affected.

- Significant current efforts/issues
  - Examine whether the relatively new archive inventory and transfer capabilities reveal issues for the sex and gender, and whether any of the sex and gender changes affect archive inventory or transfer.
  Note, for those not familiar with archive inventory and transfer, it is created to deal with the problem of managing and performing the transfer or merging of large archive datasets. An image archive may have 10,000 terabytes of imaging records for a multi-decade medical record archive. How do you transfer this to a new archive? How do you manage that transfer? How do you manage the many QC issues that are found during such transfers?
  - Prepare the use case text for Part 17
  - Track the HL7 Ballot resolution process and reflect agreed changes into changes to the new DICOM attributes. Until the HL7 Ballot is through its first resolution process it is probably not a good use of time to do more than track changes.
  - (Internal DICOM issue) This is the first reference to FHIR value sets as a source of codes, which introduces some format/structural issues for DICOM.

- Public Access
  - As part of the experiments with technology to replace the current FTP server the work in progress for this supplement is being mirrored on github at https://github.com/rjhorniii/dicom-sup233-wip. This repository has full public access. Only the editors have write access.