Gender Harmony – It Is Within Our Reach!

Robert C. McClure, MD[1], Swapna Abhyankar, MD[2], Robert Horn, BS[3], Sunanda McGarvey, BS[4], Daniel Wise, BS [5]
[1]MD Partners, Inc., Lafayette, CO; [2]Regenstrief Institute, Indianapolis, IN, [3]Fairhaven Technology, Maynard, MA, [4]Northrop Grumman Corporation, Atlanta, GA, [5]Allscripts, Inc. Raleigh, NC

Abstract
Understanding an individual's sex and gender is critical to providing appropriate and compassionate care. Accurately representing sex and gender within clinical systems was once thought to be a simple binary choice of M or F but slowly the broader clinical community has become aware that not only do sex and gender represent different types of information, but that some individuals do not, and have never, aligned with traditional cis-gender system constraints. This has resulted in problematic assumptions based on incomplete or improper representations. This panel made up of modelers, standards organizations, implementors and LGBTQ researchers will present the work of our project to define an improved, yet simple approach to representing sex and gender that will build upon our existing incomplete data and support accurate sex and gender data capture and exchange. Attendees will learn of the methodology taken to gather wide input and the resulting final agreed-upon approach.

Panel Description

Accurately understanding and documenting an individual's sex and gender is critical to providing safe, appropriate, culturally competent, person-centered and compassionate care.[1,2] Diversity in patient sex and gender identities are influenced by a spectrum of factors, including genotype, phenotype, cultural norms and personal preferences. Our historical representation of sex and gender has favored a binary Male/Man and Female/Woman dichotomy. Many clinical systems and standard terminologies have been developed based on this point of view, and as a result have integrated this assumption into our data, creating invisibility in health data for people of sexual and gender diversity. This can result in workflow problems and conditions that can produce clinical mistakes, ultimately hampering the provision of culturally competent care.

The Health Level 7 (HL7) Gender Harmony project[3] was organized during a May 2019 working group meeting and has enjoyed active participation from an international community of Standards Development Organizations (SDOs), the LGBTQ community, laboratory and radiology system developers, EHR vendors, and practicing clinicians and their representative organizations. Preliminary work has been presented and received general support at interoperability conferences and there is interest in adoption of the outcomes across standards.

The project participants believe that good health care for all begins with eHealth equity and therefore has committed to clearly define and more accurately represent a patients' sex and/or gender preferences in clinical systems, resulting in improved clinical processes and care delivery. To that end, over the past year the project committee has settled on three general "sex / gender identity categories" that will support existing data that is often a mélange of meaning, as well as a go-forward approach that will more clearly separate gender identity from sex category observations targeting specific clinical uses. Later this year this proposed domain analysis model will be submitted for international review and comment as a normative HL7 standard. We expect that with approval these resulting standard will be incorporated into current active exchange and messaging standards such as C-CDA, FHIR, DICOM, and others.

This panel brings participants that represent a cross-section of the parties involved to discuss the process of this work, issues that arose and how they were resolved, and plans for adoption, testing, and deployment.

Attendees will gain an understanding of the breadth of input involved, the proposed approach, example use case evidence that the solution is workable, and directions on how to provide input.

Panel member presentations
Robert McClure, MD, FHL7, FAMIA – moderator
Dr. McClure has served as the co-chair for the HL7 Gender Harmony project and has led the project participants in crafting the current proposed solution. He is an expert terminologist and will present the approach taken by the project, the historical issues that led to a demand for improvement, and an initial use case that will demonstrate the issues the proposed model will address.

Swapna Abhyankar, MD – panelist (Standards Development Organization and laboratory system needs)

Regenstrief Institute is committed to improving the health of people and their communities through biomedical informatics innovation. Regenstrief creates and maintains LOINC[4] (Logical observation identifiers Names and Codes), a freely available international standard for tests, measurements, and observations that enables semantic interoperability between systems. Over the years, the LOINC team has worked with a variety of organizations, including HL7, ONC, and others, to create and maintain terminology around sex and gender concepts for a range of use cases. Historically, new LOINC terms were created based on specific requests tied to various standards and regulations, each of which had a normative value set. Over time, this resulted in multiple LOINC terms that represent sex and gender, with six terms representing patient sex, an additional five for fetal sex, and 3 for gender or gender identity as of March 2020. Participating in the Gender Harmony project gives us the opportunity to re-examine our existing content, address inconsistencies, and potentially create new content in order for the LOINC terminology to align with the consensus-driven vocabulary decisions made by this project. During the presentation, we will share our approach for aligning LOINC content with the terminology that is necessary to provide appropriate clinical care, as decided by the Gender Harmony project.

Robert Horn, BS – panelist (Standards Development Organization and imaging system needs)
DICOM[5] (Digital Imaging and Communications in Medicine) is the medical imaging standard that is in use for radiology, pathology, ophthalmology, radiation therapy, and other disciplines. From its introduction in 1993 to the present it has evolved to incorporate new technologies and disciplines but had not revised the description of sex since the original 1993 definitions. In 2018 the DICOM Standards Committee agreed that this was outdated and approved an effort to harmonize with the HL7 and other efforts to capture both gender and sex. DICOM will change to incorporate the separation of gender and sex and utilize the harmonized terminology. We will present how the standards updating process is being coordinated to update the DICOM standard in parallel with the HL7 effort. We will also summarize issues found with incorporating these changes into automated ordering, workflow management, results capture, image analysis and long term archival. Advice is being prepared about transition strategies, both for medical equipment and records archives. Electronic imaging archives are now up to 25 years old and transition strategies for these massive archives are an increasing concern.

Sunanda McGarvey, BS, CBAP, CSM – panelist (Health IT Standards Implementer in the Public Health domain)
The historical representation of a binary Male/Man and Female/Woman dichotomy as represented in many clinical systems and standard terminologies creates a data representation and exchange issue when the standard does not accurately support an individual's clinical sex (such as when they are intersex or transitional). In an effort to address the current recognition of sex and gender diversity in data exchanges, clinical care has encountered scenarios where they cannot adhere to the existing sex/gender standards. This impacts public health, as a recipient of this data. We will present several scenarios of discrepant usages of sex/gender in exchanged data that support the need for gender harmonization from this implementers perspective, review an analysis of the variations in sex/gender representations based on data collected as a part of the gender harmonization project, and finally we will discuss the impact of the gender harmonization work on implementers as the new guidelines are adopted by clinical care.

Daniel Wise, BS – panelist (EHR vendor and implementer)
Allscripts' software is deployed in a variety of clinical environments, both within the ambulatory care and hospital settings. Providers need to be able to apply proper clinical treatment as well as appropriate interpersonal relations (I.E: "bedside manners") to all patients, including those who do not neatly fit into binary "male" vs. "female" designations. While current US federal regulations for certified health IT require the ability to capture concepts such as sexual orientation and gender identity, even these concepts historically have not been well supported in interoperability standards for transferring patient and clinical data between systems. It is imperative that gender-related concepts not only be captured appropriately in a patient registration system, but also exchanged in a reliable and standard way to other clinical systems, labs, public health agencies, etc. We will present some background into some of the current experiences and challenges for providers, as well as how the Gender Harmony project and its more wholistic approach to gender-related concepts and terminology can help reduce the barriers health IT imposes for providers to be able to provide appropriate care to all patients.

Panel questions
1. How will can the proposed approach be implemented and incorporate existing sex/gender data that is not as finely grained?
2. What impact will varied adoption of this new standard have on interoperability?

3. How does the proposed gender harmony model represent patients in gender transition?
4. What happens when the individual does not want to reveal sex or gender information?
5. How does the proposed gender harmony model support patients that are considered intersex?
6. What is the intended impact of the proposed gender harmony model at each point in the information continuum (e.g., point-of-care, information exchange between entities, secondary use [surveillance, research, guidelines])?

Participation statement
Dr. McClure has received commitments from all listed panel participants to take part in this panel.

---

[1] Lunn MR, Lubensky M, Hunt C, et al. A digital health research platform for community engagement, recruitment, and retention of sexual and gender minority adults in a national longitudinal cohort study--The PRIDE Study. Journal of the American Medical Informatics Association. 2019;26(8-9):737-748. doi:10.1093/jamia/ocz082.

[2] Safer JD, Tangpricha V. Care of the Transgender Patient. Ann Intern Med. 2019;171(1):ITC1-ITC16. doi:10.7326/AITC201907020.

[3] https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project. Accessed 2020-03-17.

[4] https://loinc.org/. Accessed 2020-03-17.

[5] https://www.dicomstandard.org. Accessed 2020-03-17.