

Research and Applications

Will clinical standards not be part of the choir? Harmonization between the HL7 gender harmony project model and the NASEM measuring sex, gender identity, and sexual orientation report in the United States

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ABSTRACT

Objectives: To propose an approach for semantic and functional data harmonization related to sex and gender constructs in electronic health records (EHRs) and other clinical systems for implementors, as outlined in the National Academies of Sciences, Engineering, and Medicine (NASEM) report *Measuring Sex, Gender Identity, and Sexual Orientation* and the Health Level 7 (HL7) Gender Harmony Project (GHP) product brief “Gender Harmony—Modeling Sex and Gender Representation, Release 1.”

Materials and Methods: Authors from both publications contributed to a plan for data harmonization based upon fundamental principles in informatics, including privacy, openness, access, legitimate infringement, least intrusive alternatives, and accountability.

Results: We propose construct entities and value sets that best align with both publications to allow the implementation of EHR data elements on gender identity, recorded sex or gender, and sex for clinical use in the United States. We include usability- and interoperability-focused reasoning for each of these decisions, as well as suggestions for cross-tabulation for populations.

Discussion and Conclusion: Both publications agree on core approaches to conceptualization and measurement of sex- and gender-related constructs. However, some clarifications could improve our ability to assess gender modality, alignment (or lack thereof) between gender identity and assigned gender at birth, and address both individual-level and population-level health inequities. By bridging the GHP and NASEM recommendations, we provide a path forward for implementation of sex- and gender-related EHR elements. Suggestions for implementation of gender identity, recorded sex or gender, and sex for clinical use are provided, along with semantic and functional justifications.

Key words: gender identity, sex, health information interoperability, Health Level Seven, National Academies of Science, Engineering, and Medicine

INTRODUCTION

Sex and gender are complex, interrelated constructs.^{1–11} Over the past century, there has been an increasing interest in understanding sex- and gender-related differences in a number of scientific fields.^{11–13} Increasing visibility of nongeneralized conceptualizations and cultural components of sex and gender have informed the need to address those concepts differently than outdated conventions and approaches that are currently utilized.^{14–20}

Collection of sex- and gender-related data in healthcare settings is considered a particular priority, given how these constructs function as proxy mechanisms for numerous aspects of health and well-being.^{6,21–23} Both individual- and population-level health are affected by enhancement of collection of such constructs in healthcare settings. Individuals who are marginalized due to gender- and/or sex-related characteristics, and those who care for them, often face difficulties within a binaristic healthcare environment.^{6,24} On a population level, quality assessment requires data able to identify such populations without sacrificing individual privacy and well-being.²⁵

Populations which face a disproportionate amount of marginalization on the basis of sex and gender include transgender and intersex persons, who make up approximately 2.1% (6.96 million people) of the US population.^{26–28} However, these population values can vary greatly depending on the mechanism of measurement.²⁹ More reproducible characterization and measurement of these marginalized populations could provide an essential foundation for evidence-based policy and practice initiatives.⁶

Several initiatives related to capture of sex- and/or gender-related constructs have been put forward over the past decade in the United States. In 2011 and 2013, the Institute of Medicine (now the National Academy of Medicine) recommended that sexual orientation and gender identity (SOGI) data be collected in the electronic health record (EHR).^{30,31} In 2015, regulations from the Office of the National Coordinator for Health Information Technology (ONC)³² and the Centers for Medicare & Medicaid Services (CMS)³³ at the US Department of Health and Human Services (HHS) established the 2015 Edition Certified EHR Technology (CEHRT) requirement that EHR systems certified under Stage 3 of the federal Meaningful Use of Electronic Health Records incentive program be capable of collecting structured SOGI data³⁴ using the Systematized Nomenclature of Medicine (SNOMED) code sets. In 2021, SOGI demographic fields were included in Version 2 of the US Core Data for Interoperability (USCDI).³⁵ Further refinement and codification of these fields in Version 3 of the USCDI were made apparent in mid-2022.

Despite these initiatives and policy advances, a number of barriers to implementation and standardization of sex- and/or gender-related constructs have presented themselves. The United States has pursued a highly heterogeneous and fragmented approach in relationship to EHR implementation, with multiple federal and state government entities simultaneously seeking to use and regulate EHR systems or clinical data collected therein. Some federal-level examples include the Department of Veterans Affairs, which has developed the oldest EHR system in the United States, as well as HHS divisions such as ONC, CMS, the National Institutes of Health (NIH), and the Centers for Disease Control and Prevention (CDC).

Multiple competing EHR vendors and a number of distinct standards bodies are also part of the landscape, resulting in varied and often conflicting standards for clinical use and data collection.

Two recent publications have provided recommendations for the implementation and standardization of sex- and gender-related data collection in the EHR: the Health Level 7 (HL7) Gender Harmony Project (GHP) product brief “Gender Harmony—Modeling Sex and Gender Representation, Release 1”³⁶ and the National Academies of Sciences, Engineering, and Medicine (NASEM) report *Measuring Sex, Gender Identity, and Sexual Orientation*.³⁷ While both have similar goals for application in relationship to sex- and/or gender-related constructs, they depart in that the GHP’s approach specifically focuses on worldwide operational representation of those constructs in EHR systems built around clinical use cases, while the NASEM report is more focused on practices for collecting data on those constructs, as well as the construct of sexual orientation, across 3 domains, including general population surveys of adults, administrative settings, and clinical and health settings. This perspective piece discusses aspects of both publications directly related to sex- and/or gender-related constructs and elucidates areas of alignment between the 2 proposals to serve as a preliminary reference for implementors and policymakers.

Both GHP specification contributors (CAK, CG) and NASEM consensus committee members (KEB, DC) participated in drafting this perspective. Our perspectives do not necessarily represent the views of HL7, the National Academies, or of any other contributors to either set of recommendations. Additionally, for this piece, we considered the following out of scope: (1) the GHP model’s constructs for “Name to Use” and “Third-Person Pronoun,” (2) the NASEM report’s discussion of sexual orientation, (3) sex- and/or gender-related constructs utilized outside of explicitly clinical settings and systems, (4) standards outside of the US context, except when necessary in relationship to immigration and tourism, and (5) content issues not specifically addressed in both publications, such as question order. While these are out of scope for the purposes of this piece, we would like to emphasize that they are fundamental to creating an environment for safe, respectful, inclusive, and affirming care.

MEASURING SEX, GENDER IDENTITY, AND SEXUAL ORIENTATION (NASEM REPORT)

The National Academies of Sciences, Engineering, and Medicine are private, nonprofit entities chartered by Congress to provide independent, expert, and authoritative advice to the nation to solve complex problems and inform public policy. The National Academies also encourage education and research, recognize outstanding contributions to knowledge, and increase public understanding of topics in science, engineering, and medicine.

History

In 2020, the National Academies released a consensus study report, *Understanding the Well-Being of LGBTQI+ Populations*,³⁸ which provided a comprehensive review of what is currently known about sexual and gender minority populations over the life course. The report detailed the remarkable progress that has been made in

Table 1. Constructs of sex and gender, as defined in the NASEM report

Construct	Definition	Relevant subconcept	Values
Sex	“...a multidimensional construct based on a cluster of anatomical and physiological traits that include external genitalia, secondary sex characteristics, gonads, chromosomes, and hormones.” (pages 1–3)	Sex Assigned At Birth on Original Birth Certificate	[Binding: required?] Female; Male; Don’t know; Prefer not to answer
Gender	“...a multidimensional construct that links <i>gender identity</i> , which is a core element of a person’s individual identity; <i>gender expression</i> , which is how a person signals their gender to others through their behavior and appearance; and cultural expectations about social status, characteristics, and behavior that are associated with sex traits.” (pages 1–3)	Current Gender/Current Gender Identity/Gender Identity	[Binding: required?] Female; Male; Transgender; [If respondent is American Indian/Alaska Native (AIAN)] Two-Spirit; I use a different term; Don’t know; Prefer not to answer

Note: Each of these constructs is broken down further in [Supplementary Table S1](#) of the report.

research about these populations, but it also highlighted glaring knowledge gaps caused by a lack of data on sexual orientation, gender identity, and variations in sex characteristics. The 2020 report made 5 recommendations for improving the measurement of these variables, and in 2021 NIH responded to these recommendations by commissioning the National Academies to develop a report on the measurement of sex, gender identity, and sexual orientation.

Philosophy

The National Academies operate as independent, neutral forums for the free exchange of expertise and ideas. Major reports from the National Academies are authored by consensus study committees composed of leading experts in various disciplines, all of whom serve in an uncompensated volunteer capacity. Committee deliberations are closed to the public to foster open discussion, but public meetings may also be held to invite external experts to brief committees on points of particular salience to their projects. National Academies reports are intended to be authoritative summaries and statements of the best available scientific knowledge that can serve as a foundation for evidence-based policymaking.

Process

Nineteen offices, centers, and institutes across NIH, coordinated by the NIH Sexual and Gender Minority Research Office (SGMRO), contributed funding towards the development of the NASEM report ([Supplementary Table S2](#)). In response to the statement of task ([Supplementary Statement S2](#)) provided by NIH, the National Academies convened a consensus study committee for the project in May 2021. The committee had 9 members ([Supplementary Table S3](#)) and was co-chaired by Nancy Bates (she/her), MS, a retired senior statistician from the US Census Bureau, and Marshall Chin (he/him), MD, MPH, the Richard Parrillo Family Professor of Healthcare Ethics at the University of Chicago. Members of the committee brought both professional expertise and personal experience with intersex, transgender, nonbinary, Two-Spirit, and sexual minority identities and were diverse in terms of race, ethnicity, age, geography, and primary areas of work in relation to SOGI data collection. Following the charter and NASEM standards for the evidentiary basis of consensus study reports, the committee’s recommendations were limited to measures of identity that had been tested and used with the general population and for which standard evaluation

information was available in the extant methodological literature, which largely focuses on survey research. During May 2021 through January 2022, the committee met 7 times for extended virtual sessions to review the literature, develop the approach to outlining the report, and discuss progress in drafting. In summer 2021, the National Academies hosted 2 public meetings with invited speakers who briefed the committee on topics such as Two-Spirit communities, privacy concerns, and emerging SOGI data collection best practices in various contexts; insights from these briefings were incorporated into the report. The entire report was drafted collaboratively, reviewed, and approved by the full committee and was also comprehensively reviewed in a multistage process by 14 independent reviewers ([Supplementary Table S5](#)) whose identities were blinded to the committee.

Takeaways

The report was released in March 2022 and provides an overview and recommendations for the measurement of sex and gender across 3 domains: general adult population surveys; administrative settings; and clinical and health settings, including EHRs, public health surveillance, and clinical trials. It articulates several foundational principles to guide the collection of these data: inclusiveness, precision, autonomy, parsimony, and privacy. The report also defines the constructs of sex and gender for the purposes of the report ([Table 1](#)).

These definitions underpin the report’s conceptualization of the terms *transgender* and *cisgender*. Transgender refers to a person whose gender identity is different from the sex they were assigned at birth, while cisgender refers to a person whose gender identity corresponds to the sex they were assigned at birth.^{6,39} This definition of transgender encompasses a wide range of populations, such as those with nonbinary identities and some people with intersex traits.⁶ Not all individuals who are classified as transgender under this definition, however, identify as transgender.^{6,40,41} For this reason, the NASEM report makes a distinction between *transgender experience*—when someone currently identifies with a gender identity that is different from their sex assigned at birth—and *transgender identity*—when someone currently identifies oneself using the adjective “transgender.”

The research that the committee reviewed strongly supported the use of a 2-step acquisition of gender data in survey settings to enumerate both persons who identify using the term “transgender” and

Q1 (NASEM-SAAB): What sex were you assigned at birth, on your original birth certificate?

- ☐ Female
- ☐ Male

Q2 (NASEM-CG): What is your current gender? [Mark only one]

- ☐ Female
- ☐ Male
- ☐ Transgender
- ☐ [If respondent is American Indian or Alaska Native:] Two-Spirit
- ☐ I use a different term: [free text]

Figure 1. Outline of 2-step provided in the NASEM report.

those who have transgender experience but do not describe themselves as transgender. Based on that evidence, the report recommended the version of a 2-step question presented in [Figure 1](#).

While the committee recognized that there is a variety of example practices from healthcare organizations across the country, no evidence was found that this question design does not function as well in clinical settings as it does in survey settings. As such, the report recommended this 2-step design also serve as the basis for the collection of gender data in the EHR. The report also recommends that data on current gender be collected and reported by default, and that data on any component of sex alone should never be collected without also collecting data on current gender. Moreover, the report emphasizes that collection of data on sex outside of the specific reference to sex assigned at birth in the 2-step question design be limited to circumstances where information about sex traits is relevant, as in the provision of clinical preventive screenings or for research investigating specific genetic, anatomical, or physiological processes and their connections to patterns of health and disease. This second part refers to processes which may be termed as anatomic inventories and/or karyotyping in other pieces.

In relation to intersex populations, the committee reviewed the literature and determined that there is not yet a sufficient methodological consensus on how best to collect demographic data on people with intersex traits. Instead, the report outlines 3 promising measures of intersex status and calls for additional research to comparatively evaluate the 3 measures.

THE HL7 GENDER HARMONY PROJECT (GHP) MODEL

HL7 is a set of international standards specified by HL7 International for transfer of clinical and administrative data by software applications, focusing on the application layer itself (“layer 7”) of the Open Systems Interconnection (OSI) model. HL7 has been adopted by other standards bodies, such as the American National Standards Institute (ANSI) and the International Organization for Standardization (ISO). HL7 is additionally supported by more than 1600 members from over 50 countries, representing healthcare providers, government stakeholders, pharmaceutical companies, vendors and suppliers, and consulting firms. Some of the HL7 standards include the Version 2.x Messaging Standard, the Version 3 Messaging Standard, Clinical Document Architecture (CDA), Continuity of Care Document (CCD), Structured Product Labeling (SPL), and Fast Healthcare Interoperability Resources (FHIR).

History

The HL7 GHP was founded in January 2019, with its stated purpose and goals being consistent capture and exchange of gender- and sex-

related variables by taking into account user needs and end-user community requirements worldwide, thereby producing a set of use-contexts for each variable and suggested guidance in relationship to clinical practice and administrative data contexts. The full purposes and goals statement is presented in Supplementary Statement S1.

The first meeting of the HL7 GHP took place on 20 May 2019. Its current co-chairs are Robert McClure (he/him), MD, FHL7, FAMILIA, and Carol Macumber (she/her), MS, PMP, FAMILIA. Dr McClure is president and owner of MD Partners, Inc., in addition to HL7 work. Macumber is the executive vice president of Clinical Architecture, also in addition to work with HL7. Members from multiple stakeholder organizations, including Allscripts, Epic, ONC, and Fenway Health, also attended meetings and provided feedback throughout the project ([Supplementary Table S1](#)).

HL7 balloting is a formal process, in accordance with the ANSI-Accredited Standards Developer’s (ASD) procedure, used to obtain feedback on proposed standards or informational documents in an effort to ensure that affected stakeholders agree with the proposal. GHP passed its first ballot in January 2021. Individuals voting on the ballot could provide comments that were addressed during ballot reconciliation: 214 comments were provided, and each was addressed (individuals who made these comments are listed in [Supplementary Table S4](#)). Votes were either negative (against the ballot), affirmative (for the ballot), or abstained. In total, the ballot passed with 201 affirmative votes, 29 negative votes, and 9 abstained votes. Once all comments were addressed, the updated ballot was published as a product brief entitled “Gender Harmony—Modeling Sex and Gender Representation, Release 1” in August 2021.

The GHP model was also published in *JAMIA* in October 2021 under the title “Gender harmony: improved standards to support affirmative care of gender-marginalized people through inclusive gender and sex representation.”⁴² The GHP’s next ballot, in September 2022, will incorporate implementation feedback from other standards systems, such as HL7 v2 and Consolidated CDA (C-CDA). The GHP has also sought alignment from other standards systems, such as SNOMED, USCDI, and ISO.

Philosophy

The HL7 GHP, like many of the project groups in HL7, operates on principles of operationalization, implementation, utilization, and harmonization. Use cases are constructed via requirement elicitation and model-based analysis. Requirement analysis is performed regarding use cases, which include both edge cases and nonedge cases. Additionally, HL7 considered and summarized previous and ongoing work within other biomedical standards communities such as USCDI,³⁵ Interoperability Standards Advisory (ISA), FHIR, Digital Imaging and Communications in Medicine (DICOM), HL7 v2 and v3, C-CDA, National Council for Prescription Drug Programs (NCPDP), and X12.

While much of HL7 GHP’s core membership represents the Anglosphere, the GHP needed to consider all jurisdictions that currently implement HL7 and those which may implement HL7 in the future. Thus, while the US perspective influenced the GHP, it was not the only consideration when constructing the GHP model. Individual jurisdictions had a wide variety of use cases specific to those areas, meaning that many constructs had to be considered, and those constructs often needed substantial flexibility. As such, HL7 does not specify what questions could or should be asked to elicit data in clinical settings; rather, HL7 identifies only the names of the data

Table 2. Outline of the HL7 GHP constructs

Name	Attributes	Values	Example use case	Usage notes
Gender Identity (HL7-GI)	- GI value; - Validity period; - Comment	(Attribute: GI value) [Binding: extensible] - Female; Male; - Nonbinary; - Another gender identity not listed, please specify; - Unknown	A female patient indicates that she wants to be treated socially as such (eg, using appropriate pronouns, appropriate titles, bed placement)	If a fetus, infant, or uncommuni- cative new patient cannot express GI, then it should be recorded as unknown. Individ- uals may identify using differ- ent terms at different times for various reasons, or use multiple gender identities simultane- ously.
Recorded Sex or Gender (HL7-RSG)	- RSG value; - Identity type; - Acquisition date; - Validity period; - Jurisdiction; - Source field name; - Source field descrip- tion	(Attribute: International equivalent RSG) [Binding: extensible] - F[emale]; - M[ale]; - X; - Unknown	A person has a gender marker registered with their health insurance that is different from their gender identity	RSG is to be used when a sex/gen- der element's intent or meaning is not known to be a represen- tation of gender identity or sex for clinical use, and for instan- ces in which an individual has identity documents which record sex or gender.
Sex for Clinical Use (HL7-SFCU)	- Sex category; - Validity period; - Comment; - Linked clinical observation	(Attribute: Sex category) [Binding: required] - Female; - Male; - Otherwise specified (see comment or observation); - Unknown	Early in a transgender person's use of gender-affirming hor- mone therapy (GAHT), an endocrinologist may want both "male" and "female" reference ranges, which can be indicated using "Otherwise specified (see comment or observation)"	SFCU is not meant to be applied to an individual, but rather, in most cases, to a clinical use (eg, procedure, clinical test, diag- nostic imaging, laboratory, medications). SFCU is derived from an observable (eg, a clini- cal observation, radiology report, laboratory report, genetic testing).

elements and their minimum value sets. These minimum value sets, when provided by HL7, are required to be used by EHR vendors.

Process

The HL7 GHP currently meets for 1.5 h on Mondays, other than international federal holidays, per the countries represented within the core GHP team. All meeting agendas and notes are available via Confluence from 20 May 2019 to present (around 90 meetings to date, representing over 135 h of deliberation). Meetings are open to the public; however, ballot commenting and voting are restricted to HL7 membership and individuals that pay to participate in a specific ballot cycle. Agendas are set in previous meetings and are usually split between reporting on worldwide developments by other organizations and their impact on the HL7 GHP model, individual member task updates regarding implementation and guidance, and presentations from external organizations.

Use case analyses were the primary mechanism by which the GHP model was created. The HL7 GHP model focuses on how to operationalize those use cases in clinical systems in a collaborative manner in order to create more usable and useful sex/gender stand-
ards.

Takeaways

The HL7 GHP model is built around needs expressed by the informatics community, the clinical community, and the LGBTQIA+ (lesbian, gay, bisexual, transgender, queer/questioning, intersex, asexual/aromantic/agender, and persons of other identities who are marginalized due to gender, sex, and/or sexuality) community, and is both flexible and durable.

The GHP model includes 3 constructs: Gender Identity (HL7-GI), Recorded Sex or Gender (HL7-RSG), and Sex for Clinical Use (HL7-SFCU) (Table 2). Each was determined through rigorous stakeholder feedback, use-case analysis, and considerations related to usability, understandability, translatability, and durability. Minimizing the number of elements and connecting each element to specific use cases in clinical care was a central design component related to the concepts of least intrusive alternatives. Further, openness of GHP meetings, open documentation of all meetings, and inclusion of reasoning for each structure were meant to foster general openness as to how the concepts differ and how they could be utilized, while also supporting a philosophy of general accountability.

HARMONIZATION BETWEEN THE NASEM REPORT AND THE GHP MODEL

Principles of alignment

The NASEM report's focus is on obtaining reliable and comparative information at a population level across multiple domains. It primarily relies on the survey literature, where most methodological testing of how to design question/answer sets to measure sex and gender has been done for population-level measurement. In contrast, the GHP focuses specifically on data in clinical environments and patient care, including laboratory testing, clinical intake, patient matching algorithms, and other use cases. This difference is reflected in how each report approaches its specific recommendations: the NASEM report reviews and synthesizes the existing methodological literature to develop recommended questions based on the best available scientific evidence, while the GHP model identifies critical

gaps in existing documentation of clinical practice and provides innovative solutions to close those gaps based upon both the biomedical literature and clinical needs. These 2 approaches draw from similar rationales and complement each other in numerous ways. They lead to the same primary conclusions about sex- and gender-related data: (1) these data are essential for the provision of high-quality care and services, (2) they are not currently adequately collected in clinical settings, and (3) they need to be consistently and routinely collected and used throughout clinical systems to improve patient- and population-level experiences and outcomes.

Both the GHP and the NASEM report agree sex and gender are complex, multidimensional, and both temporally and contextually fluid, meaning that unidimensional and static measures of sex and gender are inadequate and reductive. Based on the evidence available in the survey literature, the NASEM report recommends utilizing 2 questions for gender/sex, as part of a 2-step formulation. This process involves collecting both current gender and sex assigned at birth as it appears on an original birth certificate (NASEM-CG and NASEM-SAAB, respectively). To address specific needs in clinical settings and patient care regarding gender/sex, the GHP model expands on this multicomponent approach and recommends gender identity, recorded sex or gender, and sex for clinical use (HL7-GI, HL7-RSG, HL7-SFCU, respectively). Both of these approaches reflect the NASEM report and GHP conclusions—independently formulated but shared—that data collection should clearly specify what component(s) of sex or gender are being collected and that these constructs should not be used as proxies for each other.

Harmonization of technical constructs

We will review harmonization on 2 levels: (1) semantically, in terms of the constructs the NASEM report and the GHP model intend to capture for use and exchange, and (2) functionally, in terms of how the constructs align on a technical level in practice. Generally, if constructs do not have equivalents, there is no need for harmonization, because they refer to distinct entities that can be captured as stated without interfering with one another.

Ethical principles for harmonization were derived from each individual piece, as well as from those outlined in the Yogyakarta Principles, the Belmont Report, and the Declaration of Helsinki. These principles include, but are not limited to, privacy, highest attainable standard of health, accountability, preservation of cultural diversity, respect for persons, and beneficence.

Semantic harmonization

The construct that is the closest conceptual match is HL7-GI ~ NASEM-CG. NASEM-SAAB could be read as HL7-RSGOBC (Recorded Sex or Gender on Original Birth Certificate). The flexible hypernymic element in the GHP model—“Recorded Sex or Gender” (HL7-RSG)—can be used to template sex assigned at birth as HL7-RSGOBC if necessary, as was stated in the HL7 ballot document itself and restated in the HL7 GHP’s official comments regarding USCDI draft v3.⁴³

HL7-SFCU has no direct match in the NASEM report. This construct has utility for all populations (including transgender, intersex, and other gender- and sex-diverse populations), where laboratory reference ranges, growth charts, dosage curves, radiation exposure monitoring, and other clinical uses may require a level of information not encoded in either gender identity (HL7-GI/NASEM-CG) or recorded sex or gender (HL7-RSG/NASEM-SAAB).^{44–49} The GHP

model thus offers an additional level of detail that is necessary for clinical function and interoperability.

Notably, the GHP does not include any modeling in relationship to intersex status. Instead, it recommends current state for specific intersex conditions and, if necessary, usage of “Otherwise specified (see comment or observation)” (mapping to “Specified”) for HL7-SFCU, because the term “intersex” can be translated and treated differently in different regions. In the US context, evidence suggests that collection of intersex status as a demographic variable is useful.³⁷ Therefore, because there is no equivalent in the GHP, the intersex status measures outlined in the NASEM report can be developed and used without causing interoperability issues between the 2 recommended approaches.

Table 3 outlines the above semantic harmonization between the GHP and NASEM constructs.

Functional harmonization

Notably, NASEM and GHP constructs that may be close matches differ in their cardinality. For instance, both NASEM-CG and NASEM-SAAB are intended as “Mark only one,” giving them a cardinality of (assumedly) either 0..1 or 1..1. However, HL7-GI and HL7-RSG (and therefore HL7-RSGOBC) have a cardinality from 0..n, both at a single time instance and across multiple time instances. Additionally, the NASEM report does not address multiple time instances of values for NASEM-CG or NASEM-SAAB.

Other jurisdictions outside the United States implementing the GHP model may allow multiple values to be selected for HL7-GI and HL7-RSG; sending those multiple values to the United States would require 1 of 2 solutions: (1) display nothing and output the multiple values using the HL7 nullFlavor INV (“invalid”), or (2) display the first value selected only. Both of these approaches could cause significant data quality and fidelity issues, meaning EHR systems that use cardinality 0..n, per the GHP recommendations, would be better positioned to ensure interoperability.

Additionally, the cardinality 0..n recognizes individuals who may identify with multiple gender identities simultaneously (eg, bigender people who identify as male and female or nonbinary women who identify as nonbinary and female), individuals who identify with different gender identities in different circumstances (such as transgender people who have not disclosed their transgender status to certain healthcare providers), and individuals whose gender identities may vary temporally (eg, individuals who are genderfluid or genderflux). On the 2021 Gender Census, 92.3% of the 44 581 participants selected 2 or more identity terms.⁵⁰ The 2015 United States Transgender Survey likewise included 13 353 participants (48.2% of all 27 715 participants) who indicated that they identified as no gender or as more than 1 gender.⁴¹

Functional harmonization between the GHP and NASEM constructs is shown below in Table 4.

Harmonization of value sets

The GHP includes minimum required value sets which are extensible for both HL7-GI and HL7-RSG. These value sets can include jurisdictional or organizational codes in addition to the required minimum value sets as long as the required minimum value sets are still present.

For this reason, “Two-Spirit” (within NASEM-CG) can be added as an extension to the HL7-GI value set without issue (see also Supplementary Figure S3). However, “Nonbinary” is not represented in the NASEM-CG options and must be an allowed gender

Table 3. Semantic harmonization between GHP and NASEM constructs

HL7 GHP construct and definitions	NASEM report construct and definition	Relation
Gender Identity (HL7-GI): “An individual’s personal sense of being a man, woman, boy, girl, nonbinary, or something else. This datum represents an individual’s identity, ascertained by asking them what that identity is.”	Current Gender (NASEM-CG): “A core element of a person’s individual sense of self. . . Gender is often conceptualized in Western cultures as man/male and woman/female, although it also includes categories that lie outside this binary. . . ”	Approximately equivalent; however, HL7-GI can only be ascertained by asking an individual, whereas the provenance of NASEM-CG is not indicated.
Recorded Sex or Gender (HL7-RSG): “Documentation of a specific instance of sex and/or gender information.”	Sex Assigned At Birth on Original Birth Certificate (NASEM-SAAB): “Usually assigned as female or male. . . Most often defined at birth based on visual inspection of external genitalia. . . [appears] on your original birth certificate. . . ”	NASEM-SAAB is a subconstruct of HL7-RSG, based on its definition relating specific to a birth certificate. However, NASEM-SAAB cannot cover instances wherein a birth certificate is not present, or cases wherein a birth certificate is not “male” or “female.”
Sex for Clinical Use (HL7-SFCU): “A category that is based upon clinical observations typically associated with the designation of male and female.”	N/A	No observed equivalency.

Note: The NASEM Report recommendation uses “current gender” in the question but refers to the construct as gender identity in the recommendation itself. The definition here is therefore the definition listed for gender identity on [Supplementary Page S2](#) under “Dimensions” as well as additional context from Pages 1–3. Sex Assigned At Birth is never explicitly defined in the NASEM report, so the definition here includes material from [Supplementary Table S1](#) and Recommendation 4 to approximate the construct definition.

Table 4. Functional harmonization between GHP and NASEM constructs

HL7 GHP construct	NASEM report construct	Relation
Gender Identity (HL7-GI)	Current Gender (NASEM-CG)	HL7-GI is close match to NASEM-CG, except in relationship to cardinality
Recorded Sex or Gender (HL7-RSG) • Recorded Sex or Gender on Original Birth Certificate [HL7-RSGOBC] can be templated using HL7-RSG attributes (see Supplementary Figure S1)	Sex Assigned At Birth on Original Birth Certificate (NASEM-SAAB)	HL7-RSG has no direct equivalent in NASEM HL7-RSGOBC, which can be templated as a HL7-RSG, is a close match to NASEM-SAAB, but also lacks alignment regarding cardinality
Sex for Clinical Use (HL7-SFCU)	N/A	HL7-SFCU has no direct equivalent in NASEM

identity value for HL7 compatibility. Additionally, “Transgender” should not be an option for gender identity in clinical settings for its lack of alignment^{36,42} and its potential for confusion.⁶ This reasoning is similar to the HL7 GHP’s reasoning for not including “MTF,” “FTM,” “trans male,” “trans female,” and other variants that position “male” and “female” as unqualified terms presumed to refer to cisgender people and position transgender people as deviant and othered.⁶ Further, at least one recent study indicated 70% of trans respondents indicated their gender identity as “male” or “female” when presented with a “transgender” option or some other variant of transgender.⁵¹ Both of these result in severe difficulties in estimating population size and for charting clinical workflows. However, for those who use “transgender” or a variant thereof as an identity term, they can indicate as such using the HL7-GI option “Another gender identity not listed, please specify,” which aligns with the free-text response option for NASEM-CG.

The NASEM-CG option “Don’t know” has a direct mapping in HL7’s nullFlavor, using ASKU, but nullFlavor ASKU is currently used to encode “Choose not to disclose” and “Prefer not to answer” in USCDI v2 and v3, among other systems. A future version of the HL7 nullFlavor should address this distinction, as it has multiple use cases, including but not limited to: (1) a patient does not understand the question because of the wording, (2) a patient does not know the value (eg, they have never seen their birth certificate), or (3) a patient does not understand the language in which the question is

presented. These use cases are separate from use cases that would prompt a respondent to select “Choose not to disclose” or “Prefer not to answer.”

Harmonization of these value sets is shown in [Table 5](#).

“X” is needed in clinical settings for interoperability purposes and alignment for international equivalency within HL7-RSG based upon ICAO (International Civil Aviation Organization) standards. Inclusion of “X” as a value for HL7-RSG is further necessary in the United States specifically because of its increasing use on birth certificates; some US states and territories have recently added such an option for original and/or amended birth certificates (see [Supplementary Table S6](#)), which the NASEM report also flagged as a key area for future research. Inclusion of a free-text option for HL7-RSG and NASEM-SAAB is also needed because of the possibility of nonstandard options on birth certificates in different US states and internationally. Some options which have been seen in the United States include: blank (meaning nothing is recorded at all), “–,” “Not determined,” “Not yet determined,” “Not yet determined/Unknown,” “U,” “Undetermined,” and “Unknown” (see [Supplementary Table S6](#)).

International equivalency was based off the ICAO standards presented in *Doc 9303: Machine Readable Travel Documents, Seventh Edition (2015), Part 7: Machine Readable Visas*, because this was the only known international publication regarding recorded sex/gender information in the context of identity documents.^{36,52} This

Table 5. Harmonization between GHP minimum required values (*italics*) and suggested values (*nonitalics*) alongside NASEM response options for HL7-GI and NASEM-CG, respectively

HL7 value set (HL7-GI)	HL7 code equivalent	NASEM response options (NASEM-CG)
<i>Female</i>	F	Female
<i>Male</i>	M	Male
<i>Nonbinary</i>	X	...
...	...	Transgender
Two-Spirit*	...	Two-Spirit
Exploring or questioning gender identity*	...	...
Another gender identity not listed, please specify: [free text]*	nullFlavor OTH	I use a different term: [free text]
...	nullFlavor ASKU†	Don't know
Choose not to disclose*	nullFlavor ASKU†	Prefer not to answer
<i>Unknown</i>	nullFlavor UNK	...

Note: Minimum required values from GHP are pulled from the most recent ballot. Suggested values from GHP are per the GHP's official comment regarding the USCDI v3 draft. Note that the GHP allows additional values specific to a given jurisdiction alongside the minimum required values (indicated by *). Also note the issue in relationship to the dual mapping of nullFlavor ASKU (indicated by †). Not included is indicated by "...". Different usages of the terms "nonbinary" and "transgender" are provided in [Supplementary Addendum A1](#); the NASEM report, while not providing nonbinary as an option in its recommendation, did suggest future research in this area. Further, in relationship to usage of "female" and "male" instead of "woman," "girl," "man," and "boy" or "woman/girl" and "man/boy," please refer to [Supplementary Addendum A2](#).

standard was reaffirmed in the subsequent 2021 eighth edition.⁵³ In these documents "X" is defined as anything other than male or female, including unspecified. When templating, these are the minimum requirements for the attribute "International Equivalent Recorded Sex or Gender"; the GHP recommends that "Source Recorded Sex or Gender" be left more open, so that it can record exactly what was on a source document, regardless of language or character set, which is necessary for the purposes of international interoperability.³⁶

Harmonization of these value sets is shown in [Table 6](#).

CONCLUSIONS

Both the HL7 GHP and the NASEM report agree on several fundamental principles: sex and gender are complex, multidimensional constructs that are essential for improving health at both the individual and population levels. In particular, these constructs can help provide better care for transgender and cisgender patients and populations, and they can serve as a bridge between public health and healthcare settings, allowing for disparities and inequities to be identified at the broader population level and addressed at the individual patient level.

Providing comprehensive, individualized care

Each entity provided by the HL7 GHP is based upon use case requirements that impact individual health status. The GHP model elements ensure that patient gender is expressed in an interlingual manner (HL7-GI), that patient matching algorithms can function in relationship to patient identification or insurance matching (HL7-RSG), and that personalized care can be provided with the most correct reference intervals and other sex-specific designations (HL7-SFCU). Both the GHP and the NASEM report outline possible additions to these values to support the highest standard of care, including the potential for inclusion of hormone panels, anatomic inventories, comprehensive and interlinked surgical histories, and karyotyping. Additionally, both works make clear the importance of strong privacy protections for sex/gender-related data in the EHR.

Identification of transgender and cisgender populations in health settings

Although "transgender" and "cisgender" have been understood to reflect a construct different than gender identity for several decades, the construct itself did not receive a definitive name until 2019, when bioethicist Florence Ashley coined the term "gender modality" to describe correspondence (or lack thereof) between assigned gender at birth (AGAB, often also referred to as *assigned sex at birth* or *sex assigned at birth*) and gender identity.⁵⁴ Previous work has indicated how the gender modality construct can reproducibly define transgender and cisgender populations by avoiding the drift in definition the term "transgender" has experienced over the past 6 decades.⁶ Examples of cross-tabulation using HL7-GI and HL7-RSGOBC to define gender modality are shown in [Supplementary Table S7](#). Gender modality can theoretically be used at the patient level as a proxy for some individual patient medical needs (although hormone panels, organ inventories, and karyotyping are more likely to be directly useful in these contexts)⁶ and at the population level to stratify quality and outcome measures and to identify and track health disparities. However, any kind of identification mechanism must include robust privacy protections and keep patient autonomy in mind.⁶

Interoperability promotes public health: bridging patient and population health

Interoperability between sex/gender data elements in EHRs (as defined by GHP) and those collected through government, academia, or industry for public health surveillance or research (as defined by the NASEM report) could ultimately promote the use of preventive services, improve public health surveillance, and support research to improve population health. For instance, this healthcare data interoperability can facilitate public health surveillance and research to improve population health when EHR data are exchanged between clinical entities and state, tribal, local, and territorial public health departments. As of 2019, 72.3% of office-based physicians were using an EHR system that met meaningful use criteria (certified EHR system),⁵⁵ meaning sex/gender data element interoperability could rapidly improve the efficiency of sex/gender data use at both the individual and population levels. Nationally, sex/

Table 6. Harmonization between GHP minimum required values (*italics*) and suggested values (*nonitalics*) alongside NASEM suggested options for HL7-RSG [HL7-RSGOBC] and NASEM-SAAB, respectively

HL7 suggested international equivalency value set (HL7-RSG)	HL7 code equivalent	NASEM response options (NASEM-SAAB)
<i>F[emale]</i>	F	Female
<i>M[ale]</i>	M	Male
X	X	...
Additional gender marker not listed, please specify: [free text]*	nullFlavor OTH <i>or</i> X	...
...	nullFlavor ASKU† <i>or</i> X	Don't know
Choose not to disclose*	nullFlavor ASKU† <i>or</i> X	Prefer not to answer
<i>Unknown</i>	nullFlavor UNK <i>or</i> X	...

Note: Minimum required values from GHP are pulled from the most recent ballot. Suggested values from GHP are per their official comment regarding the USCDI v3 draft. Note that the GHP allows additional values specific to a given jurisdiction alongside the minimum required values (indicated by *). Note the issue in relationship to the dual mapping of nullFlavor ASKU (indicated by †). Not included is indicated by "...". Additionally, if aligning fully with the ICAO guidelines, organizations would map everything that is not "F" or "M" to "X."

gender data are collected piecemeal and inconsistently between systems. Improved practices around sex/gender data collection in electronic case reporting, syndromic surveillance, and public health registries can help identify trends and disparities by sex/gender among all recorded health outcomes, instead of only select health outcomes such as HIV⁵⁶ and other sexually transmitted diseases (STDs).^{57,58} In the future, USCDI+ may play a pivotal role in defining the accessibility and usefulness of clinical data for population-level health uses, which further highlights the importance of semantic and functional harmonization between GHP and the NASEM report recommendations.⁵⁹ This harmonization can also enhance the usability of data reported by Federally Qualified Health Centers (FQHCs) and other Health Resources and Services Administration (HRSA) grantees through the Uniform Data System (UDS).

Considerations regarding further sex/gender diversity

Both the HL7 GHP and the NASEM report grapple with significant unknowns in the sex/gender data collection space. Each approaches the current state by acknowledging its usage of proxies for other data.

For instance, HL7-SFCU may be a proxy for organ size in one situation, a proxy for hormone levels in another, or a general proxy for an unknown or as-yet uncharacterized entity. The NASEM report does not address these circumstances directly but does note that "[i]t is important not to use any one [sex/gender-related datum] as a proxy for any other one." Thorough reexamination of unknown or as-yet uncharacterized entities in relationship to sex-specific reference values and moving away from using proxies could promote the highest standard of care.

Further, the HL7-GI notes that jurisdictions may add additional options relevant to their specific sociocultural context, naming Two-Spirit, Māhū, and Palao'ana specifically. However, it is unknown how appropriate such data collection is or how accurate it would be in a given jurisdiction. For example, there are a number of gender-related terms used by various groups of Indigenous Americans which may make sense as separate options in one region, but not in another (such as nádleeh, wík'ovat, etc.). Additionally, certain terms may be conceptually broader than gender identity, such as Two-Spirit, which may make having a separate question to ascertain identity status more feasible.

Importantly, while HL7-GI and HL7-RSG allow for values in addition to the minimum required value set, the process by which to add or implement such additional values has not been clarified, and

issues remain in relationship to how jurisdictions would communicate such information. The upcoming HL7 implementation guide will hopefully address this issue, as well as the issues with nullFlavor.

Moving forward with sex/gender standards

Following the minimum required value sets for the HL7 GHP concepts, being HL7-GI, HL7-RSG, and HL7-SFCU, provides the most flexibility and durability in sex/gender data collection as these concepts continue to evolve. If individual jurisdictions want to use NASEM-SAAB, they could template it as a form of HL7-RSG (namely, HL7-RSGOBC) for interoperability purposes. Broader cardinalities (0..*n*) for values could be followed in order to facilitate system compatibility and to prevent potential system failure or miscommunication. Clarification from the GHP in relationship to the usage of the nullFlavor for clarifying options like "Don't know" from "Prefer not to answer," and the like would be useful for implementation purposes. Additionally, the HL7 GHP does not address intersex status directly, so if wishing to capture intersex status as a demographic variable, an organization could use the measures present in the NASEM report, but the NASEM report does state that more research is needed regarding intersex data collection measures.

AUTHOR CONTRIBUTIONS

All authors contributed equally to the manuscript. CAK and KEB conceived the research idea. KEB and DC provided background regarding the NASEM report. CAK and CG provided background regarding the HL7 GHP model. EDF provided contributions to public health. All authors contributed critical revisions and provided significant feedback regarding all portions of the piece, in all sections. Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

SUPPLEMENTARY MATERIAL

[Supplementary material](#) is available at *Journal of the American Medical Informatics Association* online.

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CONFLICT OF INTEREST STATEMENT

Both CAK and CG participated in the production of the GHP model, while both KEB and DC participated in the production of the NASEM report. EDF acted as a neutral party. There are no other conflicts of interest to declare.

DATA AVAILABILITY

No new data were generated or analyzed in support of this piece. The NASEM report is publicly available here (<https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation>). The HL7 GHP informative ballot is available here (https://www.hl7.org/implement/standards/product_brief.cfm?product_id=564) and the HL7 GHP Confluence page, which includes minutes and use cases discussed, is available here (<https://confluence.hl7.org/display/VOC/The+Gender+Harmony+Project>).

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