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Health informatics — Sex and gender in electronic health records

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Often, considerations related to sex- and/or gender-related data in electronic health record (EHR) systems are thought of as purely a "how does an individual identify?" issue, greatly misrepresenting the extent of the systems involved. Currently, many systems rely on a single value which dictates most (if not all) of the internal logic of the EHR. It is used for everything from how to address patients, gendered expectations of patient appearance, patient bed placement, checking demographic fields for matches before surgery, patient matching algorithms, laboratory work, reference intervals and values, diagnostic algorithms, imaging algorithms, matching with health insurance documentation, matching with various identity documents, quality assurance with diagnostics and procedures, limitations of diagnostics, limitations of procedures, alerts for particular medications and screenings, growth charts, pharmaceutical dosages and contraindications, cohort analysis in research, clinical trials recruitment, and much more.

Any successful approach moving forward needs to carefully consider all of these use cases and whether they require distinct data elements and value sets, alongside the specific cultural and jurisdictional contexts in which they occur. In addition to that, the approach needs to centre some form of interoperability between those specific contexts while simultaneously preventing loss of information.

The current inability of EHRs, and the standards and ontologies which underpin them, to distinguish between these use cases has led to issues for persons marginalized due to gender and/or sex characteristics (MGSC). Over the past decade, there has been a significant rise in interest regarding and visibility of diversification and sex- and gender-related data in EHR systems, beginning with the 2011 United States' Institute of Medicine Report on the Health of Lesbian, Gay, Bisexual, and Transgender (LGBT) Individuals.[1]

Since the publication of that report, a number of jurisdictions have separately begun constructing their own recommendations for standards regarding sex- and gender-related data collection, such as:

— Australia Standard for Sex, Gender, Variations of Sex Characteristics and Sexual Orientation Variables 2021[2];

— Canada is the first country to provide census data on transgender and non-binary people in 2022 and Proposed Action Plan to Modernize Gender, Sex and Sexual Orientation Information Practices in Canadian Electronic Health Record Systems[56];

— Nepal introduced "others" gender category in latest census 2021[57];

— New Zealand, Sex and gender identity statistical standards: Consultation 2020[3], Pakistan; and

— the United States Committee on Measuring Sex, Gender Identity, and Sexual Orientation, Committee on National Statistics, Division of Behavioral and Social Sciences and Education, National Academies of Sciences, Engineering, and Medicine 2022[4].

A patchwork of differing recommendations, if they exist at all, has led to a confusing and contradictory EHR standards landscape, even within single jurisdictions. While there have been calls for changes in many international standards and systems, change has been slow, although one substantial effort has been put together by the Health Level 7®[1)] (HL7) Gender Harmony Project (GHP).[55] It is within this context that this document provides an overview of the current state and international approaches to sex- and/or gender-related data as well as challenges and opportunities in the space. This document provides expected benefits for standardization regarding such data.

While sexual orientation is also an important, and often interrelated, entity to sex and gender, through common acronyms such as SOGI (sexual orientation and gender identity), it is substantially different from sex and gender constructs and presents unique challenges and opportunities of its own. Therefore, this document will not consider sexual orientation specifically. See information related to sexual orientation in the Challenges and Opportunities sections.

1) HL7 is the registered trademark of Health Level Seven International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

Background

Collection of gender- and/or sex-related data has been routine in health care for much of the 20th century Therefore, it is no surprise that it is collected as demographic information across almost all electronic health record (EHR) systems. However, despite the longevity of this data collection, the underlying constructs are many times poorly understood and not well characterized, leading to systemic inconsistencies. These inconsistencies are most apparent in relationship to populations marginalized due to gender and/or sex characteristics.

Marginalization due to one's gender and/or sex characteristics (MGSC) permeates most, if not all, countries worldwide.

Considering the following MGSC populations, which are the most likely to be affected by systemic changes, can help the purposes of EHR standards development and help appreciate the impact of the current gaps. The table below provides an approximation of the impacted population.

Name	Estimated population size worldwide
Cisgender women and girls (CWG)	Approximately 3,8 billion people[58]
Transgender people, including nonbinary people (TGNB)	Approximately 31 million people[59]
Gender-diverse and gender-nonconforming people (GDGN)	Unknown, highly dependent upon one's analytical lens[60]
Intersex people (I)	Approximately 130 million people[61]

Importantly, these groups are not mutually exclusive—some transgender people are also intersex, for instance. Some cisgender women are intersex; many gender-diverse people are transgender.

Experiences in the health care system, even when present and available, are often worse among MGSC than among cisgender, heterosexual men. Looking at medical standards and ontology systems, which electronic health records were built around, these systems often treat normal differences between MGSC persons and cisgender, heterosexual men as pathologies.

There are cases where transgender persons are forced into a pathological, binary system of male/female, whether that system is called "transsexualism", "gender dysphoria syndrome", "gender identity disorder", "transgenderism", etc. While newer terminology systems, such as the International Classification of Diseases, 11th Edition (ICD-11), have indicated a path for depathologization, the pathologization of trans persons is still deeply embedded in EHR systems. Likewise, Systematized Nomenclature of Medicine (SNOMED CT®[2)]) includes content that is inaccurate or out-of-date. For example, "472981000 |Fetishistic transvestism (disorder)|" is based on a label, not a true disorder. Better, more accurate EHR standards are necessary to better characterize individual- and population-level cisgender women's health, which can be used to direct efforts where most needed.

In the case of GDGN people, it is very difficult to describe their health outcomes, and how they are represented, because they simply are not represented at all. Very rarely, when represented, such gender nonconformity is immediately pathologized, just as it is for transgender people and cisgender women. Better, more comprehensive, and culturally focused EHR standards would help to grasp at the extent of the problems that GDGN people face.

Generally, the systems and EHR standards discussed are often slow to change, and do not often take in diverse inputs and lived experiences across stakeholder groups most affected by changes.

Considering those groups in relation to the political realities in which they reside is also important. A transgender person in one country will have a very different relationship to health care, and therefore to EHR systems, than one in another country. Language and cultural differences also lead to potential for miscommunication and exploitation within EHR systems.

Since many efforts have been undertaken to address the gaps in the past and before any effort is undertaken in the future to enhance sex- and gender-related standards, an in-depth understanding of lived experiences is necessary.

2) SNOMED CT is a trademark of SNOMED International. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO if the product named.

Health informatics — Sex and gender in electronic health records

1 Scope

The purpose of this document is to:

— describe the current challenges with documenting and sharing sex and gender information in electronic health records.

— identify the current state of international standards and specifications that include sex and gender.

— summarize the findings and identify opportunities to improve clarity and consistency in the use of sex and gender in electronic health records.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1.1
sex
biological category based on reproductive, anatomical and genetic characteristics

Note 1 to entry: Includes the broad categories of male, female and intersex

Note 2 to entry: Typically, within health care settings the only officially recognized and assigned at birth categories are female and male categories, which becomes part of someone's official government record and societally assumed gender.

3.1.2
gender
composite of socially constructed roles, behaviours, activities and/or attributes that a given society considers appropriate for members of a given sex

3.1.3
cisgender women and girls
CWG
women who were assigned female at birth and/or were reared or raised as female, in relationship to their culture

[SOURCE: Reference 58]

3.1.4
transgender people, including nonbinary people
TGNB
persons whose gender identity is incongruent (either partially or fully) with their assigned gender at birth and/or the gender they were reared or raised as

Note 1 to entry: Annex A contains a noncomprehensive list of identities often considered as falling under the nonbinary umbrella.

Note 2 to entry: Other definitions for transgender and nonbinary exist.

3.1.5
gender-diverse and gender-nonconforming people
GDGN
persons who are considered to not conform to any of various aspects of gender roles in a given culture and/or people who are considered to be beyond a Eurocentric binarist gender framework

Note 1 to entry: 'Eurocentric' means focused on European culture and history and its emigration via routes of colonialism and imperialism, to the exclusion of viewpoints outside of the Eurosphere, being those cultures and regions directly affected by such emigration.

Note 2 to entry: A binarist gender framework is an artificially constructed gender system supposedly consisting of two distinct and non-overlapping cultural categories, usually labeled as "female" and "male". Such a framework is a relatively recent invention.

Note 3 to entry: Annex B contains a non-comprehensive list of identities which can be considered to be gender-diverse.

3.1.6
intersex people
I
persons who, from birth, express biological characteristics, or have the propensity to develop biological characteristics, which are not strictly sexually dimorphic

Note 1 to entry: A list of conditions often considered to be intersex is included in Annex C.

3.1.7
grammatical gender
gender category ascribed to a class of nouns

Note 1 to entry: For instance, many Romance languages have a masculine and a feminine grammatical gender, while many Germanic languages have masculine, feminine, and "neuter" grammatical genders. For example, in German, "Buch" (book) is neutral, while in French "livre" (book) is masculine.

3.2 Abbreviated terms

AFAB	Assigned female (gender) at birth
AMAB	Assigned male (gender) at birth
EHR	Electronic health record
GHP	Gender Harmony Project
LGBT	Lesbian, Gay, Bisexual, and Transgender
LGBTQIA+	Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, Intersex, Asexual/Aromantic/Agender, and other sexually- and gender-marginalized groups not explicitly named ("+")
MGSC	Marginalization due to one's gender and/or sex characteristics

PMDS	Persistent Müllerian duct syndrome
SOGI	Sexual orientation and gender identity

4 Background

In 2011, the U.S. Institute of Medicine report The Health of Lesbian, Gay, Bisexual and Transgender People[1] provided, as its third recommendation, that data related to sexual orientation and gender identity (SOGI) are "included in the required set of demographic data" and that "the collection of such data will need to be performed with adequate privacy and security protections".

In the United States in October 2015, the Centers for Medicare and Medicaid Services and Office of the National Coordinator for health information technology require EHR vendors to include sex and gender data fields as part of the EHR software certification, Inclusion of Sexual Orientation and Gender Identity in Stage 3 Meaningful Use Guidelines: A Huge Step Forward for LGBT Health,[5] but healthcare providers are currently not required to collect this information.

In August of 2021, the Health Level 7 (HL7) Gender Harmony Project (GHP) released a product brief entitled "Gender Harmony – Modeling Sex and Gender Representation, Release 1" as the result of two years of deliberation and a successful ballot within the organization. The GHP's approach was unique in evaluating use cases in clinical settings, and recommending several distinct entities, namely: Gender Identity, Recorded Sex or Gender [RSG], Sex for Clinical Use [SFCU], Name to Use, and Third-Person Pronoun. This work is ongoing within HL7.

5 Current state

Standards development organizations (SDOs) play a role in providing standards and specifications that provide the capability for systems to distinguish, capture, and share gender and sex information. ISO/TC 215 Health informatics standards define how to represent the data elements needed for identifying the subject of care, HL7 standards such as Fast Healthcare Interoperability Resources (FHIR®[3]) define how information can be shared in a consistent manner. Standard clinical terminologies such as SNOMED CT® are often used to encode data via coded concepts.

Currently, most international standards provide a single data element to document gender and/or sex. These international standards include inadequate data element names and descriptions, lack of use case guidance or intent of use results in the need for organizations to refine the content or leave it up to implementers to figure out, which in turn leads to inaccurate and inconsistent use of the standards. And in some cases, leads to causing harm to MGSC persons.

Organizations often further refine international standards by adding or modifying data elements from international standards such as the case with the datum "assigned gender at birth".

The complex multi-level challenge to document and share sex and gender continues to contribute to implementation barriers. The multi-level challenges with international standards and local specifications consists of a lack of adequate specification of the following:

— data element names and unambiguous definitions

  — Gender and Sex are often represented in a single data element and that inconsistency in data capture and implementation leads to downstream issues for quality measurement instruments and outcomes.

3) FHIR is a trademark of HL7®. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named.

  - The terms gender and sex are often used interchangeably within a standard.
- context for how the data element is expected to be used such as:
  - Person identity and/or patient matching.
  - Clinical use that can include the use in algorithms to suggest tests or workflows based on sex or the presence of specific organs.
- code systems that provide the concepts to be used in value sets.
  - Concepts are sometimes created without adequate understanding of the requirements.
- general guidance within the standard that can include how a data element is not intended to be used.
- data element relationships between other attributes that provide information related to the gender of an individual, due to modern thinking of gender as well as new knowledge of psychological, biological and social manifestations of gender.
- use of observations to specify sex and gender is another way that standards have been developed for some specific use cases or as a work around when there were limitations in the intent of the use of the data element.

The following SDOs published material related to sex and gender summarized in Annex D.

- ISO/TC 215
- HL7V2, V3, and FHIR
- DICOM
- OpenEHR including the Gender Archetype

6 Challenges

6.1 Overview

Several types of challenges are covered in this document. Challenges are defined as issues related to the current state or barriers which could impact any future state and could therefore be considered as well. They include challenges impacting electronic health records, challenges impacting persons on an individual or group level, and challenges related to cultural and linguistic differences.

- Electronic Health Record (EHR)-Related Challenges
- Person-Level Challenges
- Cultural and Linguistic Challenges

6.2 Electronic health record-related challenges

1. There is inconsistency in the data element names, descriptions, code systems, concepts and value sets used to represent sex and gender concepts across EHRs. The appropriateness and adequacy of some value set options are questioned as the societal understanding of sexual health continues to evolve. Outdated value set options raise concerns about current EHRs supporting the provision of culturally competent, safe, and affirmative health care. The limited options available also perpetuate the inequities faced by the TGNB populations.
   - It is also fundamentally impossible to list all possible values for instances of certain data, such as gender identity (see Annexes A and B); a system would need to expect unexpected values,

which can be in the form of free text. New standards would need to be clear with guidance about how to handle situations with new variables from a technical standpoint.

2. One data element is not enough to serve the business requirements and meet non-binary person health care needs.

   — Existing data element descriptions lack clarity, are inaccurate and lack guidance on how to use them within different use cases and contexts, thus making them difficult to implement consistently, non inclusive and harmful to non-binary persons.

   — Healthcare organizations struggle with how to incorporate gender identity and assigned gender at birth information into EHRs when only one demographic data field is available in the EHR to indicate assigned gender at birth, with no field for gender identity. A healthcare provider could enter gender identity information into a progress note, but this addition might not be noticed by other healthcare providers.

3. Limited value options available for selection perpetuate inequities faced by MGSC populations by making them invisible in health data sets. At the same time, expanded definitions from leading organizations and international standards communities such as transgender, gender nonconforming, and nonbinary gender have raised implementation challenges in how one could migrate these definitions into existing EHR systems.

4. Current system cannot provide effective, comprehensive disaggregated information.

   — This leads to issues in cohort construction for retrospective EHR research, as well as issues with effectively assessing healthcare quality indicators.

   — Patient matching algorithms, where implemented, depend on accurate, contiguous data.

   — Clinical trials recruitment and research also require such disaggregated data.

   — It is unclear how translational research regarding non-human species and application to humans can be treated in terms of sex-related development; comprehensive guidelines in this area would contribute to producing the most effective treatments.

5. Medical providers continue to add being transgender or being intersex to problem lists and as diagnoses in multiple jurisdictions, under labels such as “gender identity disorder”. As well, the lack of inclusion of data provenance and fidelity in demographics generally means that providers can change patient answers without their consent.

6. Some EHR systems have already begun to suggest tests or workflows based on sex or gender data which is often inaccurate in describing the needs of transgender, gender-diverse, and intersex persons. For instance, a patient can need to switch their insurance “sex” for a procedure to avoid denial of coverage or to even be offered a procedure or test in the first place. Pharmacies can also have to administratively change “sex” for approvals for particular medications and then switch the “sex” back to avoid denial of coverage.

7. Clinicians can miss proper risk assessments based on whether the “correct” sex field is provided. For instance, a transgender woman who is marked as “male” can miss crucial breast cancer screenings, but a transgender woman who is marked as “female” can miss prostate cancer screenings.

8. Pronoun sets create difficulties when considering standardization of rule-based grammatical systems, meaning that each language which includes pronouns in their systems will need to have specific rules related to their various forms and how they are parsed.

9. In languages that do not utilize pronouns, other signifiers will likely need to be coded in some form, specifically in relationship to honorifics.

10. Any effort or standard to improve the data elements to address sex and gender in EHRs might not be supported and might not be implemented based on the political realities in some regions where non-binary and transgender people are not accepted and harshly treated.

11. While sex/gender data are more firmly entrenched in EHRs as they currently stand, sexual orientation (and related data elements) have similar issues in relationship to how collection is done, and misunderstandings in relationship to the data element, its usage when inappropriate, and its opportunities for discriminatory usage.

6.3 Person-level challenges in EHR

1. MGSC individuals face significant barriers to adequate and culturally responsive healthcare, leading to numerous health disparities; these barriers are further exacerbated by inadequate digital health documentation.

2. Relying on assigned gender at birth or gender identity alone within an EHR for all medical decisions creates potential hazards to quality and safety when used as a marker even with other variables—such as current anatomy, height, and weight—for health screenings, medication dosing, and other medical decisions.

   — Likewise, assigned gender at birth is currently usually said to be equivalent to the gender marker present on a birth certificate or other birth record.

   — Oftentimes, assumptions based on assigned gender at birth can cause issues in unexpected cases. For instance, a transgender woman assigned male at birth (AMAB) became pregnant, learning that she had PMDS in the late 2010s.[6] The assumption that she could not get pregnant because she was AMAB was inaccurate.

3. Medical mistreatment and/or malpractice, as well as violence against MGSC persons is well documented to varying extremes, meaning that EHR standards can exacerbate such inequities. Security is therefore of the utmost importance.

   — For instance, some countries have created "LGBT" registries and others have suggested and put in place mandatory testing for migrant workers to determine if they are gay or transgender, by requiring submission of medical records.[7] It is also not uncommon in many jurisdictions for medical providers to call for the arrest of LGBTQIA+ patients. Given that many countries do not have patient privacy protections codified, it is possible that providing values can open the door for further mistreatment.

   — Some situations, while less deadly, can have disastrous effects for individuals' lives and relationships, such as TGNB youth being outed to their parents via billing codes or open access to all of the child or adolescent's EHR, depending on jurisdiction. While many parents are supportive, many are not, and this could cause significant psychiatric issues, or even lead to suicide. In other situations, a TGNB adult cannot be out to all providers, or to some individuals but not others. This accidental outing can result in anxiety, depression, strained relationships, or increased suicidality.

   — While some countries have limited protections available for intersex persons, most do not. Whether intersex individuals can be discriminated against in these jurisdictions in relationship to health insurance, life insurance, etc. is often open to legal debate, rather than strictly codified.

   — Similarly, many cisgender women and TGNB people risk losing access to health insurance, life insurance, or other forms of relief based upon BRCA mutations, dependent on jurisdiction[8].

4. Oftentimes, gender diversity is inaccurately mapped to being transgender; for instance, healthcare providers in literature have often inaccurately referred to hijra or kathoey as having "transsexualism".

5. It is unclear how clinicians will react and agree to capture more specific sex, gender related data on their patients. Also unclear how comfortable patients in various jurisdictions will be with being asked routinely about aspects such as sexual orientation, gender identity, etc.

6. If provided with gender identity questions in order to populate "Gender Identity" data elements, patients can be uncertain of the definition of some of the terms. For example, "trans" could refer to

individuals who had socially or medically transitioned, or neither, or who had a gender identity that differed from the gender they were assigned at birth.

6.4 Cultural and linguistic challenges in EHR

1. Culturally-specific gender diversity presents a number of categories which (1) have not been fully characterized or researched in clinical populations, (2) do not fit well into Eurocentric categorizations such as gender identity, sexual orientation, etc., and/or (3) face additional marginalization within a culturally-specific context. While such terms might not be understood by a provider outside of that context, the terms themselves cannot be inappropriately translated.

2. Grammatical gender exists in many languages to varying degrees; approximately 40 % of the world's languages include explicit categorization of word classes by grammatical gender, and approximately 75 % of those define their grammatical gender using terms such as "feminine", "masculine" or "neuter"[9],[10].

   — However, the number of grammatical genders observed in a language is by no means set at two: some languages observe three, four, five, or more grammatical gender classes[9].

   — Further, classification of an individual's gender grammatically often does not align with their perceived or actual gender identity, even for cisgender people, and systems which include "masculine", "feminine", etc. are often biased toward the masculine. For instance, the Lak language classifies girls as non-male and non-female animate grammatically; German does the same, with "Mädchen" (girl) being neuter gender grammatically. Additionally, in French, the feminine third person pronoun "elles" is used to refer to a group of women. If only one man were to join said group, the masculine third person pronoun "ils" would be used. Therefore, assumption of one's actual and/or perceived gender cannot necessarily be determined from grammatical gender alone.

   — Even languages without explicit grammatical gender often include terms which have associated gendered connotations. For example, English includes terms such as "king", "actress", "man", "executrix", etc. While many of these terms have fallen out of favour in the English language over the past century, in favour of gender-neutral or gender-inclusive language, many of them still exist and are used frequently, such as in the cases of pronouns and honorifics. Thus, just because a language is grammatically genderless does not mean it is necessarily a gender-neutral or gender-expansive language.

3. Pronouns, broadly, are a class of terms used to replace nouns or noun phrases in particular contexts. It is estimated that around 43 % of the world's languages include gendered pronouns in some form.[11] Languages which do not include pronouns can be known as pro-drop (or pronoun-dropping) languages. However, even many of these languages include some gendered languages in other forms, such as pro-drop Japanese include gendered honorific suffixes such as -chan and -kun.

   — Because gender-neutral and/or gender-expansive pronouns can have language-specific connotations, translation from one to another is a challenge.

4. Similarly to pronouns, honorifics are common across many of the world's languages and often reflect some aspect of gender. This can be seen in English with the conceptualization of "Miss", "Ms.", and "Mrs." and the more recent development of the gender neutral "Mx". Additionally, they can display roles within academic, military, religious, or royal settings which can or cannot be gendered. Some can be formal, informal, or lie somewhere between the two. Depending on the relationship that medical providers have to the society within which they practice, the types of honorifics they use can be entirely different, even for the same patient.

   — Similarly to pronouns, honorifics can thus not be assumed to translate from one system to another outside of a given cultural context. In regions with many spoken languages, such as in India, even intra-jurisdictional communication of honorifics can be complex.

5. Simply defining "sex" and "gender" without qualifiers is likely to be unhelpful, as many languages do not have a sex/gender distinction. This means that translations including "gender" would be

prepared to be translated as “sex”, and then, if translated back, would reappear in the original language as “sex”. Additional language-specific information would determine how prevalent such an issue can be, and what the best way to solve it can be as well.

7 Opportunities

7.1 Overview

Opportunities in this context refers to those modifications needed for the benefits to be realized.

Robust data elements related to sex and gender that are based on sound recommendations and guidance for use will help understand health disparities, assess health care quality, and build more inclusive and diverse clinical research studies. Specifically identifying base-level relationships to health will provide a better and more accurate foundation for all patients, regarding entities which have classically been boiled down to a single sex or gender variable. This will lead to better understanding of health pathways, better research, and better care.

The effort to create sex- and gender-related data elements can include a diverse stakeholder input using an inclusive approach so that the standard will have the best chance of addressing the complexity. Creating precise terminologies and standards that go beyond data elements for sex and gender and utilizing data elements such as sexual orientation is essential for electronic health records and for streamlining education and training, as well as opening pathways for cross-cultural care practices. Inclusion of MGSC populations worldwide in their own health research and practice is a huge opportunity for advancement, and funding of survey and clinical studies will help better position evolving terminologies and standards.

Since this topic touches all SDOs, there is an opportunity for collaboration and a deeper sharing of knowledge and of the impact to existing EHR standards to facilitate consistent adoption.

However, standardized terminology in the form of data elements and value sets for sex and gender alone will not affect the paradigm of health worldwide as it applies to MGSC persons. Indeed, it is just one step in that process and needs to be flexible regarding the human rights situations experienced by MGSC persons.

7.2 Benefits

Benefits in this context refers to those positive effects brought about by addressing current challenges and present opportunities.

The more accurate and complete collection and use of sex- and gender-related information can contribute to the creation of a trusting care environment resulting in which patients feel comfortable and safe. Additionally, this collection provides care providers information to guide clinical care pathways. Important benefits of standardized data collection regarding sex and gender include:

1. Provision of a more complete and long-term picture of the health of MGSC populations, through more consistent data collection and aggregation procedures.

2. Helping to create more inclusive environment with culturally-competent staff and enabling EHR systems to work more effectively for MGSC persons.

3. Integration of sex- and gender-related data with national and international data can help reduce disparities, address determinants of health inequities, and improve care experiences for MGSC individuals.

4. Usage of EHR data-driven analytics and quality improvement approaches that draw on GSSO (gender, sex, and sexual orientation) data will enable organizations to profile who is being served, stratify health service utilization and outcome data and inform clinical care to ensure that all populations receive timely and high-quality care.

5. Provision of comparable and actionable information (on MGSC populations) across different geographic, organizational and/or administrative boundaries can track progress over time. Satisfies increasing interest in inclusive EHR systems, particularly in relationship to personalized health care.

6. Empowerment of MGSC persons in managing their own healthcare.

7. Usage of multiple fields related to sex and gender, such as in relationship to the two-step question, has been shown to contribute to a higher response rate than asking a single question that is "sex" or "gender" in certain jurisdictional contexts.

8. Reduction of provider burden in relationship to changing the single administrative sex value to match particular diagnostics, procedures, etc., or having to deal with automated demals based on a singular "sex" value.

Annex A
(informative)

Identities which can be considered as falling under the nonbinary umbrella

This is a non-comprehensive list of gender identities which are typically thought of as falling under the nonbinary umbrella. The identities shown are based on the results of the Gender Census (run from 2013-2021, including 44,583 usable responses in 2021)[12], the Gender Wiki (which lists over 300 gender identities)[13], the Nonbinary Wiki (which lists over 100 more common gender identities underneath the nonbinary umbrella),[14] and the MOGAI Gender Wiki (which lists over 200 gender identities).[15] While many of these terms originated in the Anglosphere, many have effectively become globalized identity terms and are used worldwide.

Name	Description	Percentage of Respondents in 2021 Gender Census (Raw #)
agender	Considered by most to be a lack of gender identity, or synonymous with genderless, non-gendered, or ungendered.	22,3 % (9,942)
androgyne	Used to describe gender nonconforming and intersex persons for centuries. Came to refer to gay men who were considered to be feminine by the late 19th and early 20th century. By the 1980s, some transgender persons began using the term as a gender identity which has both feminine and masculine components. Today, the term is seen as falling under the nonbinary umbrella, being simultaneously masculine and feminine, male and female.	10,5 % (4,696)
bigender	Used in the 1980s to describe persons who were "dual-gendered", both male and female. Although many bigender people today still identify as both male and female, many use various other gender identities: for instance, a person could be both female and nonbinary, or demigender and neutrois, and still be bigender.	4,1 % (1,836)
demigender	Any of various gender identities which are said to be partially overlapping with another gender identity. For instance, demigirl is thought of as partially overlapping with female.	5,9 % (2,649)
genderfluid	The concept of fluidity in one's gender has been written about for decades, and has often be intermingled with the histories of other terms like bigender, genderqueer, and cross-dresser. By the mid-1990s, the term had become a marker of transcendence beyond gender itself. However, by the early 200s, it became a gender identity noted for flowing to and from various other gender identities. For instance, a genderfluid person can feel and present as male in some circumstances, and then as female in others.	22,6 % (10,068)
intergender	In the late 1990s, intergender was thought of as falling between male and female, or as being a mix between the two. It was also described as an umbrella term in a manner not too dissimilar to nonbinary today. However, by the 2010s, it became an identity meant to solely describe the unique gender experiences of some intersex persons.	0,08 % (35)
multigender	An umbrella term for individuals having multiple gender identities, usually at the same time; usually thought of as including terms like bigender, polygender, and trigender.	0,16 % (70)
neutral	A gender identity considered to be neutral, usually somewhere between masculine and feminine.	14,4 % (6,406)
neutrois	A gender identity often described as neutral, coined in the mid-1990s. In contrast to terms like androgyne, neutrois usually refers to being nongendered or ungendered rather than between genders.	2,6 % (1,150)

Name	Description	Percentage of Respondents in 2021 Gender Census (Raw #)
nonbinary	Both an umbrella term and a specific identity which is neither male nor female. While identities beyond the Eurocentric conceptualizations of 'male' and 'female' have existed for millennia, the specific identity term nonbinary began to come into use in the late 1990s or early 2000s.	68,2 % (30,406)
pangender	A gender identity which is said to encompass all other identities, either in whole or in part, in some fashion.	0,24 % (108)
polygender	Having multiple gender identities, usually at the same time.	0,14 % (61)
trigender	Having three gender identities, usually at the same time.	0,09 % (40)

Annex B
(informative)

Identities which can be considered to be gender-diverse

This annex only includes identities that can be considered to be gender-diverse which have been attested in the last 50 years. EHR systems could be prepared for identities outside of member countries, in relation to immigration, tourism, asylum, and other forms of voluntary or involuntary travel. Many of these terms have non-standardized spellings, and many of these terms can be considered offensive or pejorative in various contexts. This list is not comprehensive or authoritative. Additionally, many of these identities do not fit into Eurocentric frameworks of gender identity, gender expression, gender roles, sexual role, and/or sexual identity.

Of the more than 70 terms below, 26 originate from Southern Asia, 13 from Southeastern Asia, 12 from Northern America, 5 from Australia and New Zealand, 4 from Central America, 3 from Middle Africa, 2 from Eastern Africa, 2 from Melanesia, and 1 from each of the following: Eastern Asia, Southern Africa, Southern Europe, and Western Asia.

Transliterated Value Name	Name in Original Language(s)	M49 Region	Country or State	Ethnic or Cultural Group(s)
agule		Middle Africa	Congo, Democratic Republic of; Uganda (West Nile)	Lugbara
aravani	أرافاني (Arabic); अरावनी (Marathi); அரவாணி (Tamil)	Southern Asia	India (Tamil Nadu)	Tamilar
asegi		Northern America	United States (North Carolina, Tennessee, South Carolina, Georgia, Alabama)	Cherokee
āshitimē	አሽትሜ (Maale)	Eastern Africa	Ethiopia (Southern Nations, Nationalities, and Peoples' Region)	Maale
baklâ		Southeastern Asia	Philippines	Filipino
banci		Southeastern Asia	Indonesia	Indonesians
basaja		Southeastern Asia	Indonesia (South Sulawesi)	Torajans
basir		Southeastern Asia	Indonesia (Central Kalimantan)	Ngaju
bencong		Southeastern Asia	Indonesia	Indonesians
bissu		Southeastern Asia	Indonesia (South Peninsula, Sulawesi)	Makassar
biza'ah		Central America	Mexico (Oaxaca)	Zapotec
brotherboy		Australia and New Zealand	Australia	Indigenous Australians and Torres Strait Islanders
calabai		Southeastern Asia	Indonesia (South Sulawesi)	Bugis
calalai		Southeastern Asia	Indonesia (South Sulawesi)	Bugis
dhuranji		Southern Asia	Nepal	Nepalis
fa'afāfine		Northern America	United States (American Samoa)	Samoans
fa'atama		Northern America	United States (American Samoa)	Samoans
femminiello		Southern Europe	Italy (Naples)	Neapolitans
fulumulu		Southern Asia	Nepal	Nepalis

Transliterated Value Name	Name in Original Language(s)	M49 Region	Country or State	Ethnic or Cultural Group(s)
hatukholba		Northern America	United States (Mississippi, Alabama, Tennessee)	Chicasaw; Choctaw
Hijra	هجرة (Arabic); হিজড়া (Bengali); हिजड़ा (Hindi); हिजडा (Marathi); ਹਿਜੜਾ (Punjabi); හිජ්රා (Sinhala); హిజ్రా (Telugu); ہجڑا (Urdu)	Southern Asia	India; Pakistan	Indians; Pakistanis
isángoma		Southern Africa	Botswana; Eswatini; Lesotho; Malawi; Mozambique; South Africa; Zimbabwe	Zulu
jogappa	जोगप्पा (Hindi)	Southern Asia	India	Indians
jogata	जोगतास (Hindi)	Southern Asia	India	Indians
jogti		Southern Asia	India	Indians
kathoey	ກະເທີຍ (Lao); กะเทย (Thai)		Lao People's Democratic Republic; Thailand	Laotians; Thais
khanith	خنيث (Arabic)	Western Asia	Oman	Omani
khasua	खसुआ (Hindi)	Southern Asia	India	Indians
khusara	खुसरा (Hindi)	Southern Asia	India (Punjab)	Indians
khusra	خوسرا (Arabic); ਖੁਸਰਾ (Punjabi)	Southern Asia	India; Pakistan	Indians; Pakistanis
khwaja sira	خواجه سرا (Urdu)	Southern Asia	Bangladesh; Pakistan	Bengalis; Indians
kinnar	किन्नर (Hindi)	Southern Asia	India	Indians
kothi	कोथी (Hindi)	Southern Asia	India; Nepal; Pakistan	Indians; Nepalis; Pakistanis
māhū		Northern America	United States (Hawaii)	Hawaiians (Kanaka Maoli)
māhū kāne		Northern America	United States (Hawaii)	Hawaiians (Kanaka Maoli)
māhūwahine		Northern America	United States (Hawaii)	Hawaiians (Kanaka Maoli)
maitya		Southern Asia	India	Indians
mak nyah		Southeastern Asia	Singapore	Singaporeans
manang bali		Southeastern Asia	Brunei; Indonesia (West Kalimantan); Malaysia (Sarawak)	Iban
mangaiko		Middle Africa	Congo, Democratic Republic of (Mambasa Territory)	Mbo
mangalmukhi		Southern Asia	India	Indians
maruni		Southern Asia	Nepal	Nepalis
maugiya		Southern Asia	Nepal	Nepalis
meti		Southern Asia	Nepal	Nepalis
mogha		Southern Asia	India	Indians
morat		Southern Asia	Pakistan	Pakistanis
muxe		Central America	Mexico (Oaxaca)	Zapotec
nádleeh		Northern America	United States (Arizona, New Mexico, Utah)	Diné (Navajo)
natuwa		Southern Asia	Nepal	Nepalis

Transliterated Value Name	Name in Original Language(s)	M49 Region	Country or State	Ethnic or Cultural Group(s)
nechani		Southern Asia	Nepal	Nepalis
okule		Middle Africa	Congo, Democratic Republic of; Uganda (West Nile)	Lugbara
omegiid		Central America	Colombia; Panama	Guna
palao'ana		Northern America	United States (Guam, Northern Mariana Islands)	Chamorro
palopa		Melanesia	Papua New Guinea	Papuan New Guineans
sekrata		Eastern Africa	Madagascar	Sakalava
shivashakti		Southern Asia	India	Indians
singaru		Southern Asia	Nepal	Nepalis
sistergirl		Australia and New Zealand	Australia	Indigenous Australians and Torres Strait Islanders
thirunangai	திருநங்கை (Tamil)	Southern Asia; Southeastern Asia	India (Tamil Nadu); Malaysia	Tamilar
tida wena		South America	Guyana	Warao
travesti		South America	Argentina; Brazil; Peru	Argentines; Brazilians; Peruvians
Two-Spirit	niizh manidoowag (Ojibwe)	Northern America	Canada; United States	First Nations; Native Americans
Two-Spirit		Australia and New Zealand	Australia; New Zealand	Indigenous Australians and Torres Strait Islanders; Māori
vaka sa lewa lewa		Melanesia	Fiji	Fijians
wadam		Southeastern Asia	Indonesia	Indonesians
wakatane		Australia and New Zealand	New Zealand	Māori
waria		Southeastern Asia	Indonesia	Indonesians
whakawāhine		Australia and New Zealand	New Zealand	Māori
wik'ovat		Northern America; Central America	United States (Arizona); Mexico (Sonora)	Tohono O'odham; Pima
winkte		Northern America	United States (North Dakota, South Dakota)	Lakota
X-gender	Xじぇんだー (Japanese)	Eastern Asia	Japan	Japanese
zanan		Southern Asia	Pakistan	Pakistanis

Annex C
(informative)

Conditions which can be considered to be intersex

This is a non-comprehensive list of conditions and features which can be considered intersex in some cases. What is and is not an intersex condition is not widely agreed upon.

Name	Description
5α-reductase deficiency (5ARD) — 5α-reductase deficiency, type 1 (5ARD-1) — 5α-reductase deficiency, type 2 (5ARD-2)	An autosomal recessive condition occurring in individuals with a 46,XY karyotype. Such individuals are often assigned female at birth (AFAB), and can have testicles (but not a penis or scrotum). Because of a genetic difference, the testosterone produced by the testes cannot be converted into dihydrotestosterone, which leads to the development of clitoral and vaginal genital structures. Often, during puberty, the testicles descend and the penis enlarges. 5ARD is more common in some communities around the world, such as in one community in the Dominican Republic, where AFAB children "become" male at puberty are known as guevedoces. 5ARD is simply one reminder of how permanent legal gender assignment can be non-constructive.
17β-hydroxysteroid dehydrogenase deficiency	A rare autosomal recessive condition occurring in individuals with a 46,XY karyotype. Such individuals are often assigned female at birth (AFAB) and can have testes. Individuals with such a condition often do not produce much testosterone, meaning that clitoral and vaginal genital structures develop. In some cases the genital structures are referred to as ambiguous and in others the genital structures can coincide with other conditions such as micropenis or hypospadias. During puberty, individuals can experience a deepening of the voice, significantly increased facial and body hair, and the development of breasts.
Androgen insensitivity syndrome (AIS) — Complete androgen insensitivity syndrome (CAIS) — Partial androgen insensitivity syndrome (PAIS) — Mild androgen insensitivity syndrome (MAIS)	An umbrella term referring to individuals with whose cells are mildly, partially, or completely unable to recognize androgens, such as testosterone. Because this condition is usually not recognized in individuals who are 46,XX, it is almost always diagnosed in individuals who are 46,XY. Phenotypes of the condition can vary wildly, but are usually differentiated based on the appearance of external genitalia. Women with CAIS can not be aware of their status as 46,XY status well into adulthood.
Anorchia	A general term referring to the lack of testes at birth for an individual who is 46,XY.
Aphallia	A general term referring to the lack of a phallus (usually in reference to the penile phallus, but sometimes also used to refer to the clitoral phallus) at birth.
Bladder exstrophy	A complex condition in which the bladder develops outside of the foetus during gestation; bladder exstrophy can cause differences in development of the bony pelvis, pelvic floor, and genitalia, among other structures.
Clitoromegaly	A general term referring to a clitoris perceived as being larger than normally expected; other than societal intersex phobia, there are usually not issues associated with having a larger clitoris.

Name	Description
Congenital adrenal hyperplasia (CAH) — Classic CAH — Salt-wasting CAH — Simple-virilizing CAH — Nonclassic CAH	Any of a group of autosomal recessive conditions characterized by differences in cortisol synthesis, which can cause excessive or deficiency production of hormones, and can therefore cause differences in development of sex characteristics.
Cryptorchidism	A general term referring to the absence of one or both testes from the scrotum, which can happen for various reasons.
De la Chapelle syndrome	An autosomal dominant condition in which an individual with a 46,XX karyotype develops a penis and testes to some degree. Many (but not all) cases are caused by the SRY gene crossing over from the Y chromosome to the X chromosome during meiosis. Thus, most individuals are said to be SRY positive.
Epispadias	A general term referring to any condition in which the urethra ends in an opening on the upper part of the penis or when the urethra develops further anteriorly.
Fraser syndrome	An autosomal recessive condition usually marked by any of several differences of development, such as cryptophthalmos, micropenis or clitoromegaly, and cryptorchidism, among others.
Gonadal dysgenesis — Complete gonadal dysgenesis — 46,XX complete gonadal dysgenesis — 46,XY complete gonadal dysgenesis — Mixed gonadal dysgenesis	Any of various conditions in which the gonads develop in unexpected ways, usually resulting in fibrous tissue known as streak gonads. Such gonads can develop to varying degrees in certain forms of the condition, resulting in streak ovaries and dysgenic testes, among other forms.
Hypospadias	A difference of development in which the urethra occurs on an unexpected location on the phallus.
Jacobs syndrome	A condition in which an individual expresses a 47,XYY karyotype. Such a karyotype usually leads to few symptoms, although occasionally acne, increased height, and an increased chance of learning difficulties have been observed.
Kallmann syndrome	A condition which falls under the umbrella of conditions known as hypogonadotropic hypogonadism. Its distinguishing feature is anosmia, but it can also lead to a lack of development of secondary sexual characteristics and an increased risk of developing osteoporosis.
Klinefelter syndrome (KS)	A condition in which an individual expresses a 47,XXY karyotype. Such a karyotype can be subtle and unrecognized, although in other cases signs can be more prevalent, involving poor motor coordinator, less secondary body hair development, and development of breasts.
Leydig cell hypoplasia (LCH)	An autosomal recessive condition occurring in 46,XY individuals. It is characterized by the body not responding to the gonadotropin luteinizing hormone (LH). Therefore, individuals can have differently developed genitalia, experience hypergonadotropic hypogonadism, and have a lack of development of secondary sexual characteristics.

Name	Description
Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome — MRKH type 1 — MRKH type 2	A condition affecting individuals who are 46,XX. It is primarily defined by the lack of development of the uterus and vagina, when a functioning set of ovaries and external genital structures are present. Often, those with MRKH syndrome can also be amenorrheic.
Micropenis	A general term referring to a penis perceived as being smaller than normally expected; other than societal intersex phobia, there are usually not many issues associated with having a smaller penis, other than potential difficulty with penetrative sexual intercourse.
Mosaicism, genetic — Mosaicism, allosomal — 45,X/46,XX mosaicism — 45,X/46,XY mosaicism — 45,X/47,XXX mosaicism — 47,XXY/46,XX mosaicism — 47,XXY/46,XY mosaicism	Any of various conditions in which an individual possesses more than one genetic line. In humans, some observed allosomal mosaicisms are considered intersex, but many are not.
Müllerian aplasia	A condition occurring in individuals who are 46,XX, in which the Müllerian ducts experience a significant difference in development.
Ovotestes	A gonad which is observed to have both testicular and ovarian aspects.
Persistent Müllerian duct syndrome (PMDS)	A (typically) autosomal recessive condition observed in individuals who are 46,XY. The condition involves the presence of derivatives of the Müllerian ducts (such as the fallopian tubes or uterus).
Polycystic ovarian syndrome (PCOS)	A condition observed in individuals who are 46,XX, in which cysts can form on the ovaries. Individuals with PCOS can experience irregular menstrual cycles, heavier menstrual bleeding, excessive secondary hair growth, acne, pelvic pain, among other symptoms.
Progestin-induced virilization	A condition in which a gestational parent's use of certain androgenic compounds or androgenic synthetic progestogens related to testosterone can cause differences in development of the external genital of the foetus, potentially resulting in clitoromegaly or ambiguous genitalia.
Swyer syndrome	A type of gonadal dysgenesis and hypogonadism occurring in individuals who are 46,XY. Individuals with Swyer syndrome often have a functioning clitoris, vagina, labia, and vulva, alongside streak gonads.
Triple-X syndrome	A condition characterized by the karyotype 47,XXX. Fewer than 10 % of those with this karyotype are diagnosed, and the signs are relatively mild in most cases. Some individuals with the karyotype experience differences in learning ability, hypertelorism, clinodactyly, and early menopause.
Turner syndrome (TS)	A condition in which an individual has a 45,X karyotype. Signs of such a karyotype often vary greatly, ranging from a webbed neck, low-set ears, shorter stature, and swollen hands are birth. Individuals usually do not begin menarche or breast development without usage of exogenous hormone therapy.
Vaginal agenesis	Any of various conditions in which the vagina is closed or absent which it is expected to be open and present.

Annex D
(informative)

Published data elements for gender and sex international standards

The terms sex and gender in most of the references below are used in a way that appears they are interchangeable.

Standard	Data Element Name	Data Element Description	Purpose of the Data Element	Notes/guidance from the Standard
ISO/TS 22220:2011; Health informatics — Identification of subjects of health care	Sex	The sex of the subject. Sex is the biological distinction between male and female. Where there is an inconsistency between anatomical and chromosomal characteristics, sex is based on anatomical characteristics.	It defines the data used to identify subjects of care and the business processes associated with this activity, whether computerized or manual. It is intended to be used both to support the processes of the identification of subjects of care by individuals and computerized identification in automated matching systems.	**Guide for use**: This data element indicates the sex of the person for administrative or general communication purposes and can be much less specific than the values used in clinical care. **Collection Method**: Operationally, sex is the distinction between male and female, as reported by a subject or as determined by an interviewer. When collecting data on sex by personal interview, asking the sex of the respondent is usually unnecessary and might be inappropriate, or even offensive. It is usually a simple matter to infer the sex of the respondent through observation, or from other cues such as the relationship of the subject(s) accompanying the respondent, or first name. The interviewer can ask whether subjects not present at the interview are male or female. A person's sex can change during their lifetime as a result of procedures known alternatively as sex change, gender reassignment, transsexual surgery, transgender reassignment or sexual reassignment. Throughout this process, which might be over a considerable period of time, sex could be recorded as either male or female.
ISO 27269:2021 Health informatics — International patient summary	Administrative Gender		.... can be used individually or collectively to identify, or to ensure the identity of a person and/or patient to an attending clinician at the point of care, to inform of any preferences or insurance and to introduce a new patient to an attending clinician.	Some countries require 'gender' as part of their identification of the patient. It shall not be used to record a person's sex. This item should not be used to record the 'sex' of a person. 'Sex' is a clinical term but not always provided or collected at source. It can be included as an optional attribute in the next iteration of this standard

Standard	Data Element Name	Data Element Description	Purpose of the Data Element	Notes/guidance from the Standard
HL7 Version 2.9	Administrative Sex	The domain of possible values for a patient's sex.	Concepts specifying a patient's sex for administrative purposes.	Gender of patient – can be provided as an observation. In the lab domain Sex for Clinical Use (SFCU) can also be sent as an observation (OBX)
HL7 FHIR Release 4.0.1	Patient.gender	Administrative Gender - the gender that the patient is considered to have for administration and record keeping purposes.	Needed for identification of the individual, in combination with (at least) name and birth date.	The gender might not match the biological sex as determined by genetics or the individual's preferred identification. Systems providing decision support or enforcing business rules should ideally do this on the basis of Observations dealing with the specific sex or gender aspect of interest (anatomical, chromosomal, social, etc.) However, because these observations are infrequently recorded, defaulting to the administrative gender is common practice. Where such defaulting occurs, rule enforcement should allow for the variation between administrative and biological, chromosomal and other gender aspects. For example, an alert about a hysterectomy on a male should be handled as a warning or overridable error, not a "hard" error. Context for use of additional elements, such as Clinical Sex, Clinical Gender, Gender Identity (GI), Sex Assigned at Birth (SAAB) and Legal Sex are also described to encapsulate a broader range of social and biological patient attributes across the health care spectrum. For further information, visit the HL7 FHIR Release 4/8.1 Resource Patient - Content web page.
DICOM	Patient's Sex	Sex of the named Patient	The usage is not explicitly specified, but the implicit usage is clinical.	
OpenEHR	Sexual health summary Version V0	Summary or persistent information about an individual's sexual health and history.	n/a	