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Health informatics — Sex and gender in electronic health records

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National foreword

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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.

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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.

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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.

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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]

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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

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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.

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