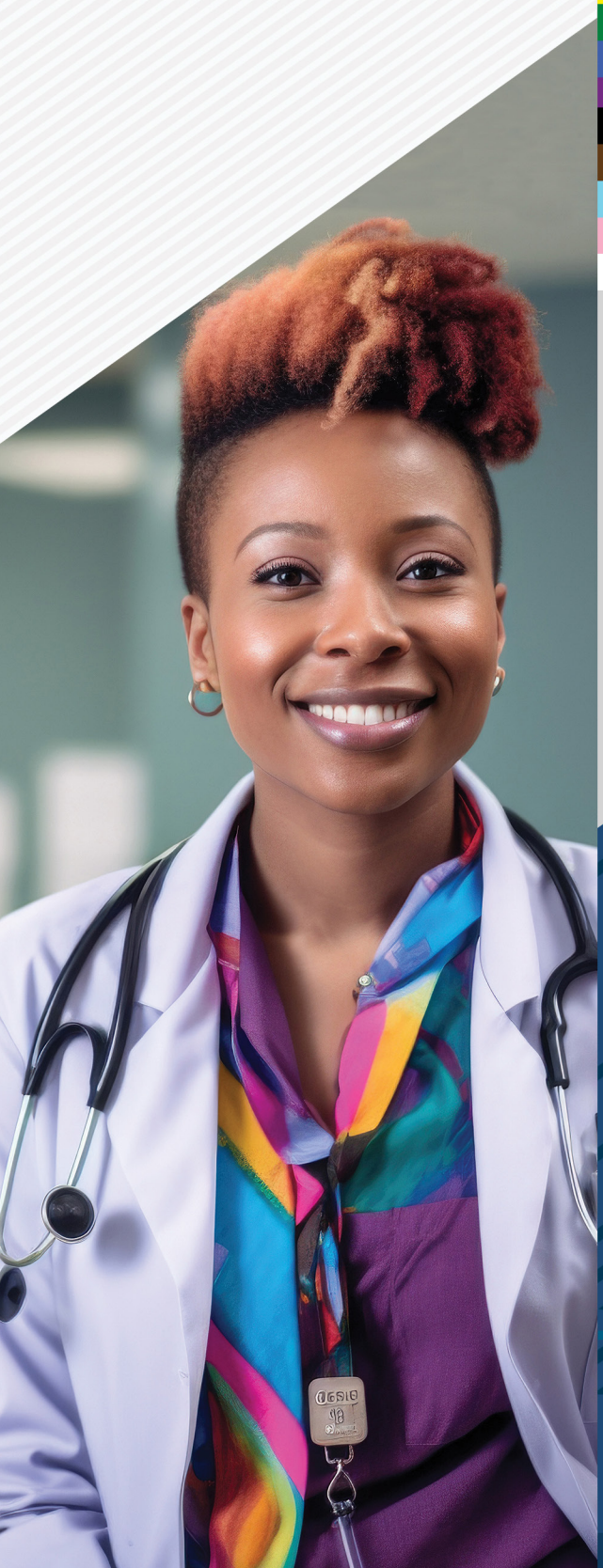

REPORT

Cervical and Breast Cancer Screening:

Evidence and Guidelines to Support Inclusive Quality Measures

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Contents

Executive Summary

High-quality health care must be equitable health care.[1] As such, efforts to measure high-quality care must also center equity considerations. This can take a variety of forms, from identifying individuals who are engaged in developing and setting performance targets, to direct measurement of unmet social needs that contribute to inequitable outcomes, to transparency through stratified metrics. One fundamental way equity and quality intersect is in how a measure's denominator is defined; for example, quality measure denominators are typically targeted to specific populations and are based on clinical guidelines. But the method used to translate those denominators into technical specifications can inadvertently perpetuate inequities (e.g., by using gendered denominator language), leading to the exclusion of individuals from quality improvement initiatives.

Historically, quality measures have relied on a single data element, referred to in data standards as "Administrative Gender," to collect data on both sex and gender for clinical and administrative purposes. Using a single data element to represent these discrete concepts can misrepresent patients and result in confusion about a person's actual clinical needs, which in turn may contribute to disparities in care for some communities (e.g., transgender and gender-diverse communities). Evidence pointing to disparities in care has motivated the National Committee for Quality Assurance (NCQA) to take steps to further inclusion for transgender and gender-diverse patients in health care quality measures.

After evaluating HEDIS®[1] quality measures with gendered population definitions, where gender-inclusive approaches may be warranted, NCQA initially focused on measures assessing preventive screening rates. To inform this effort, NCQA reviewed the clinical literature and guideline recommendations for breast and cervical cancer to assess the available evidence base supporting gender inclusivity. We also evaluated the availability of clinical data standards to support more nuanced approaches to sex and gender, to assess the feasibility of updating measure specifications. We found that most breast and cervical cancer screening guidelines called for transgender and gender-diverse patients to receive the same standard of care as cisgender patients, based on the presence of relevant organs. Clinical data standards (e.g., HL7, USCDI) also support distinguishing between clinical needs based on sex and gender identity. Based on these findings, NCQA released revised measure specifications for Breast Cancer Screening and Cervical Cancer Screening for measurement year 2024. These revised specifications use newer, more specific data elements that allow for more accurate, precise and inclusive measurement.

To support our health care system's continued path to equitable care and outcomes, NCQA encourages organizations involved in developing clinical guidelines to address sex and gender separately, and to explicitly include transgender and gender-diverse members in recommendations. In cases where evidence is lacking, or may not meet traditional standards, there are opportunities to learn from approaches that leverage alternative evidence, such as high-quality observational data, and to advocate for funding to support additional research to understand the clinical needs of these communities.

[1]HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

Introduction

To achieve a goal of equitable, high-quality health care, everyone must have a fair and just opportunity to attain their best possible health. The National Committee for Quality Assurance (NCQA) seeks to promote health equity through performance measurement, and strives to ensure that all individuals who need routine preventive screening are considered in the HEDIS®[1] prevention measures. For measures such as Breast Cancer Screening and Cervical Cancer Screening, where denominators have traditionally been defined with gendered language such as "women," this means considering whether more inclusive approaches are supported by the evidence and are feasible using standardized clinical data; specifically, whether current measurement approaches facilitate equitable care for transgender and gender-diverse members for whom such screenings may be recommended. This report outlines findings from a review of guidelines pertaining to breast and cervical cancer screening for transgender and gender-diverse patients, and summarizes data standards for documentation and exchange of sex and gender data.

UNDERSTANDING IMPACTED POPULATIONS

Approximately 1.6% of U.S. adults identify as transgender or nonbinary.[2] "Transgender" is an umbrella term often used to refer to people whose gender identity and sex assigned at birth do not correspond; "cisgender" refers to people whose gender identity aligns with the sex they were assigned at birth. Some individuals may prefer or also identify with other terms like "non-binary," "gender diverse" or "genderqueer."[3] Transgender and gender-diverse patients systematically experience structural barriers to care, marginalization, discrimination and social stigma in the health care system, resulting in disparities in care and poorer health outcomes. Structural barriers to care result in lower rates of preventive screenings for transgender and gender-diverse patients, compared to cisgender patients.[4] Disparities for transgender and gender-diverse patients are exacerbated by frequent misclassification of this population in the data and the resulting exclusion from quality measurement and improvement efforts.[5] This occurs in part because sex and gender are often conflated, leading to the absence of sufficient context to accurately identify patient clinical need.

While these concepts are distinct and serve discrete functions, it is common for patients to be asked a single, nonspecific question about sex or gender. This can lead to confusion or discomfort for patients who must interpret what is being asked.[6] A single-question approach can also lead clinicians and health plans to make assumptions about a patient's clinical needs or identity that may not be accurate. The use of a single sex/gender value is common throughout the health care system, including in how research is conducted, guidelines are developed and quality measures are specified.

There are increasing calls to disaggregate sex and gender in clinical care and data collection. The U.S. Preventive Services Task Force (USPSTF) stated that it will consider both biological sex and gender identity when developing recommendations, and will clarify whether birth sex or gender identity should be used when determining the population to which recommendations

Sex refers to the categories (male, female) to which people are typically assigned based on clinical traits—chromosomes, hormones or reproductive anatomy. Sex may be referred to by concepts such as sex assigned at birth, birth sex or sex recorded on original birth certificate, to provide context for estimation of a patient's clinical needs.

Gender refers to the intersection of an individual's gender identity (how an individual perceives themselves) and gender expression (how a person signals their gender to others).[9] For providers, knowing this information (along with a patient's name and pronouns) can enable delivery of affirming and patient-centered care.

[1]HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

apply.[7] The National Academies of Sciences, Engineering and Medicines (NASEM) issued a report, endorsed by 190 LGBTQIA+ organizations,[8] recommending that (when necessary) both sex assigned at birth and gender identity be collected from patients.[9] The Fenway Health and Center for American Progress resource guide for collecting sexual orientation and gender identity (SOGI) data emphasizes that collection of both gender identity and sex assigned at birth is critical to delivering appropriate care to transgender patients.[10] These recommendations acknowledge that conflating sex and gender obscures patient clinical need, masks disparities in care and may not foster a welcoming and affirming care environment. Disaggregation of sex and gender data may help identify patient clinical need across care contexts.

APPROACH TO REVIEW

NCQA identified eight HEDIS measures that could benefit from reevaluation focused on disaggregating sex and gender (refer to the Appendix). *Breast Cancer Screening* and *Cervical Cancer Screening* were selected for further evaluation due to the clinical evidence base available for the measures' focus and their extensive and continued use in the health care system, including broad use in health care quality programs (Table 1) administered by both NCQA and the Centers for Medicare & Medicaid Services (CMS).

TABLE 1: Breast and Cervical Cancer Screening Measure Program Use

BREAST CANCER SCREENING	CERVICAL CANCER SCREENING
Medicare Advantage Star Ratings	Medicaid Adult Core Set
Medicaid Adult Core Set	CMS Marketplace
CMS Universal Foundation	Consensus Core Set: Accountable Care Organizations and Primary Care
CMS Marketplace	
Consensus Core Set: Accountable Care Organizations and Primary Care	

Over the past year, NCQA conducted targeted literature, evidence and guideline reviews, and engaged with clinical, quality and LGBTQIA+ community stakeholders. The information gathered informed NCQA's direction and furthered goals of inclusion, while raising broader awareness of and support for measure changes. Engagement included direct outreach as well as posting specific changes to the HEDIS *Breast Cancer Screening* and *Cervical Cancer Screening* measure denominators to include transgender and gender-diverse members for public comment. Findings from this review for each measure, as well as an assessment of the clinical data standards available to support updated measure specifications, are described below.

Breast Cancer Screening

Breast cancer rates for transgender men have been found to be lower than for cisgender women, but higher than for cisgender men.[11] Conversely, transgender men who have not had a bilateral mastectomy are likely to have a breast cancer risk similar to cisgender women who have not received a bilateral mastectomy;[12] however, more research is needed on breast cancer rates among transgender individuals and the impact of gender-affirming hormone therapy on cancer rates. While citing the lack of adequate quantification, a 2023 systematic review found that transgender women are at higher risk of developing breast cancer than cisgender men, but are at lower risk than cisgender women.[13]

Transgender women have a lower incidence of breast cancer than cisgender women, but a higher incidence than cisgender men,[11] given the potentially increased risk from gender-affirming hormone exposure.[14,15]

The duration of estrogen exposure at which risk increases is variable in the literature. In a nationwide retrospective study in the Netherlands, Blok et al. observed a median of 18 years of estrogen exposure at breast cancer diagnosis among transgender women.[11] Though not limited to transgender patients, the Nurse's Health Study found a statistically significant increase in breast cancer risk after 15 years of exposure to estrogen.[16] In addition, the median age for breast cancer diagnosis in transgender women is younger than observed in cisgender women, with some studies finding a median age of diagnosis at around 50 years of age (compared to 60+ in cisgender women).[17]

Evidence indicates that breast cancer screening rates are lower among transgender adults recommended for screening, compared to their cisgender counterparts.[18] Missed preventive screenings may result in poorer outcomes, such as more advanced disease at diagnosis. Few studies have been conducted on the impact of missed breast cancer screening among transgender patients specifically, but studies have shown that the absence of breast cancer screening in the general population can result in more advanced stage at diagnosis.[19] A study of survivorship among transgender and gender-diverse cancer survivors found that this population experiences complex challenges and higher rates of risk factors for poor survival than cisgender cancer survivors.[20] Breast cancer screening gaps for transgender individuals are influenced by barriers to access, as well as lack of provider knowledge of screening guidelines for transgender patients.[21]

Summary of Guidelines

Guidelines recommend breast cancer screening for transgender and gender-diverse patients assigned female at birth, or with breasts from natal puberty, as well as for transgender and gender-diverse patients assigned male at birth with at least 5–10 years of exposure to gender-affirming estrogen therapy, excluding those with bilateral mastectomy or chest reconstruction.[22–24] Table 2 outlines the full recommendation statements.

TABLE 2: Breast Cancer Screening Guidelines

Population	Recommendation	Grade
United States Preventive Services Task Force (2016)[25]		
Women 50-74	The USPSTF recommends biennial screening mammography for women aged 50-74 years.	**B** • The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.
United States Preventive Services Task Force Draft Recommendation (2023)[26]		
Women 40-74	The USPSTF recommends biennial screening mammography for women aged 40-74 years. USPSTF uses the term "women" to refer to cisgender women as well as all people "assigned female at birth (including transgender men and nonbinary persons)."	**B—Draft** • The USPSTF recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.
University of California San Francisco (UCSF) Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2016)[22]		
Transgender women	It is recommended that screening mammography be performed every 2 years, once the age of 50 and 5-10 years of feminizing hormone use criteria have been met. Screening mammography is the primary recommended modality for breast cancer screening in transgender women.	**Grading: T O W** • T: At least some data in transgender population • O: Strongest available evidence is from observational studies • W: Weak
Transgender men	Transgender men who have not undergone bilateral mastectomy, or who have only undergone breast reduction, should undergo screening according to current guidelines for non-transgender women.	**No grading.** Grading of guidelines for non-transgender women apply.
Fenway Medical Care of Transgender and Gender Diverse Adults (2021)23		
Transgender and gender-diverse patients assigned female at birth	In patients assigned female at birth (AFAB) who have not undergone chest reconstruction (including those who have had breast reduction), breast/chest screening recommendations are the same as for cisgender women of a similar age and medical history.	**Consensus-based**

TABLE 2: Breast Cancer Screening Guidelines (cont.)

Population	Recommendation	Grade
Transgender and gender-diverse patients on estrogen	In transgender and gender-diverse patients on estrogen, consider initial screening mammography starting at age 50, and only once on estrogen therapy for greater than 5 years. Thereafter, mammograms are recommended every 2 years, following screening guidelines for cisgender women.	**Consensus-based**
World Professional Association for Transgender Health (WPATH) Standards of Care Version 8 (2022)[24]		
Transgender and gender-diverse patients who have received estrogens	We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender-diverse people who have received estrogens, taking into consideration the length of time of hormone use, dosing, current age, and the age at which hormones were initiated.	**Grade: Strong recommendation. Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:** • The evidence is of high quality • Estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice) • There are few downsides of therapy/intervention/strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies
Transgender and gender-diverse patients without chest surgery	We recommend health care professionals follow local breast cancer screening guidelines developed for cisgender women in their care of transgender and gender diverse people with breasts from natal puberty who have not had gender-affirming chest surgery.	**Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:** • The evidence is of high quality • Estimates of the effect of an intervention/ therapy/strategy (i.e., there is a high degree of certainty that effects will be achieved in practice) • There are few downsides of therapy/ intervention/strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies

Cervical Cancer Screening

The literature does not suggest a difference in the prevalence of cervical cancer among transgender and gender-diverse patients compared to the overall population, though there is evidence of care gaps in cervical cancer screening. The 2016 National Transgender Survey found that most transmasculine individuals retain their cervix, but are not up to date with cervical cancer screenings.[27,28] Inadequate preventive screenings can lead to worse outcomes and more advanced stages of illness at diagnosis.[29]

Evidence indicates that transgender patients recommended for cervical cancer screening may have lower rates of screening than their cisgender counterparts.[18] These gaps in care are driven by structural barriers to accessing care.[30] A lack of recognition of guidelines for the care of transgender individuals among both providers and patients, and traditional gender representations in screening outreach and procedures, have been found to play a role in low screening uptake.[31] One study found that while transmasculine individuals possessed high levels of knowledge and awareness of the facts and importance of cervical cancer screening, poor experiences with provider attitudes presented a barrier to accessing screening.[32]

Summary of Guidelines

Recommended guidelines for cervical cancer screenings are more straightforward than those for breast cancer screening: Cervical cancer screening is recommended for all people with a cervix. Overall, the literature recognizes that people with a cervix need cervical cancer screening, and recommendations suggest that all individuals with a cervix should be included in cervical cancer screenings, following the guidelines for screening of cisgender women.[22,23,27,33] Screening is not recommended for patients who have had a hysterectomy and no longer have a cervix. Refer to Table 2 for full guideline statements.

TABLE 3: Cervical Cancer Screening Guidelines

Population	Recommendation	Grade
United States Preventive Services Task Force Cervical Cancer Screening Recommendation[29]		
Women aged 21–65 years* *This recommendation statement applies to all asymptomatic individuals with a cervix	The USPSTF recommends screening for cervical cancer every 3 years with cervical cytology alone in women aged 21-29 years. For women aged 30-65 years, the USPSTF recommends screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone or every 5 years with hrHPV testing in combination with cytology (cotesting).	**Grade: A** The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
UCSF Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People (2016)[22]		
Transgender men	Cervical cancer screening for transgender men, including interval of screening and age to begin and end screening follows recommendations for non-transgender women as endorsed by the American Cancer Society, American Society of Colposcopy and Cervical Pathology (ASCCP), American Society of Clinical Pathologists, U.S. Preventive Services Task Force (USPSTF) and the World Health Organization.	**Grade: X C S** **X:** No data (expert opinion only) **C:** Consensus expert opinion **S:** Strong
Fenway Medical Care of Transgender and Gender Diverse Adults (2021)[23]		
Transgender and gender-diverse patients	TGD patients who have a cervix are recommended to have regular cervical pap tests as per the published guidelines for cisgender women.	**Consensus-based**
World Professional Association for Transgender Health (WPATH) Standards of Care Version 8 (2022)[24]		
Transgender and gender-diverse patients	We recommend health care professionals offer cervical cancer screening to transgender and gender diverse people who currently have or previously had a cervix, following local guidelines for cisgender women.	**Grade: Strong Recommendation** **Strong recommendations ("we recommend") are for those interventions/therapy/strategies where:** • The evidence is of high quality • Estimates of the effect of an intervention/therapy/strategy (i.e., there is a high degree of certainty effects will be achieved in practice) • There are few downsides of therapy/intervention/strategy • There is a high degree of acceptance among providers and patients or those for whom the recommendation applies.
American Cancer Society (2020)[33]		
Asymptomatic individuals with a cervix, including those who have undergone supracervical hysterectomy and transgender men who retain their cervix, aged 25–65	The ACS recommends that individuals with a cervix initiate cervical cancer screening at age 25 years and undergo primary HPV testing every 5 years through age 65.	**Strong recommendation.** A strong recommendation conveys the consensus that the benefits of adherence to that intervention outweigh the undesirable effects that may result from screening.

Sex and Gender in Clinical Data Standards

"Data standards" refers to a common set of agreed-on data elements and definitions that can be implemented in a standardized, structured and interoperable way. Data standards can support quality measurement by providing a common understanding of how data are defined, represented and shared across organizations, settings and systems.

Historically, a single data element has been used as an accepted standard to represent patient gender and patient sex in the context of health care. However, multiple newer data standards have been developed and implemented to create ways for patient sex and gender to be differentiated and clearly communicated across clinical contexts.

The most accurate measure of routine screening needs is an anatomical inventory: an individualized assessment of a patient's unique clinical characteristics.[4] Anatomical inventories document a patient's organs and help reduce the need to make assumptions about clinical needs based on gender identity.[34,35] Anatomical inventories can also facilitate care for individuals who have diverse sex characteristics or differences in sex development, such as intersex individuals. However, they are not widely implemented across the health care system, and there is no standard approach for documenting and exchanging such data.

Several data standards relate to sex and gender, which may support identification of members recommended for routine breast and cervical cancer screening. Standards generally recommend collection of patient gender; most also recommend collection of sex-related data to support clinical care. The National Academies of Sciences, Engineering and Medicine guidance on collecting sex and gender-related data recommends a two-step method that asks about sex and gender separately, and only asks for information necessary in context.[9]

In quality measurement, specific data on clinical sex, separate from gender, is important to ensure that appropriate care is planned and takes place. Data standards that enable collection of disaggregated sex- and gender-related data may improve accurate identification of patients recommended for routine screening in such use cases.

FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR®) U.S. CORE IMPLEMENTATION GUIDE

FHIR is a data standard maintained by Health Level 7 (HL7®). In the latest FHIR *US Core Implementation Guide*, version 6.1.0, every "Patient"[36] profile must include a patient gender defined using the "gender" data element that is bound to an "Administrative Gender"[37] value set.[38]

TABLE 4: HL7 FHIR Data Standards

Data Element	Definition	Response Options	Standardized Terminology
Gender	The gender that the patient is considered to have for administration and record keeping purposes.	• Male • Female • Other • Unknown	Administrative Gender

The "gender" element is a single gender value intended to be used for administrative purposes; it does not specify whether the value corresponds to gender identity or sex assigned at birth. The FHIR specification notes that additional, more specific sex or gender data, such as birth sex or gender identity, may be documented[36] using extensions.[2] In acknowledgment of these limitations, Fenway Health's *Do Ask Do Tell* toolkit recommends that the "gender" element only be used for billing purposes, and never to identify patient needs or communicate with patients.[10]

NCQA's digital HEDIS measures align with the currently mandated FHIR *US Core Implementation Guide*, version 3.1.1, and leverage the same "gender" data element when defining patient characteristics for measure specifications. While this data element is broadly used by health plans to record member demographic data and understand member care needs, its ability to accurately identify patient clinical needs is limited because it does not clearly distinguish between patient sex and gender. It also assumes patients' sex and gender remain static over the life course. As a result, health plans—and quality measures—that rely on this data element alone may incorrectly identify members and their care needs.

UNITED STATES CORE DATA FOR INTEROPERABILITY

The United States Core Data for Interoperability (USCDI) outlines a standardized set of data elements for enabling interoperable exchange of health care data. USCDI is maintained by the Office of the National Coordinator for Health IT (ONC). Version 1 of the USCDI and the FHIR *US Core Implementation Guide*, version 3.1.1 (which exposes the Version 1 data elements via Application Programming Interfaces or APIs),[39] have been adopted as a mandated health IT standards by the ONC.[40] As of December 31, 2022, health IT systems that are certified according to ONC health IT certification criteria must support USCDI version 1,[41,42] which includes a data element for documenting patient sex assigned at birth.[43] The FHIR *US Core Implementation Guide*, version 3.1.1 exposes this USCDI element under its "Patient" profile as the "us-core-birthsex" extension.[44,45]

TABLE 5: USCDI Version 1 Standards

Data Element	Definition	Response Options	Standardized Terminology
Sex Assigned at Birth	The sex assigned to a patient at birth, typically based on observation of external anatomy.	• Male • Female • Unknown	Birth Sex

GENDER HARMONY PROJECT

The Gender Harmony Project is an HL7 initiative aimed at developing data standards for sex and gender. One standard field developed by the project is "Sex Parameter for Clinical Use."[46] The project recommends collection of a Sex Parameter for Clinical Use[3] data element in addition to gender identity, name to use and pronouns. Sex Parameter for Clinical Use applies to a particular clinical scenario. It encourages clinicians to reference specific clinical observations (anatomical inventory, hormone levels, chromosome analysis)[47] to determine the appropriate classification for a given clinical activity. As such, this data element offers greater specificity than other options described in this paper, and allows different values to be used as appropriate in different clinical contexts.

[2] Extensions provide a standard way of documenting additional data beyond the minimum requirement.

TABLE 6: Gender Harmony Project Data Standards

Data Element	Definition	Response Options	Standardized Terminology
Sex Parameter for Clinical Use	A summary sex classification element based on one or more clinical observations, such as organ survey, hormone levels and chromosomal analysis.	• Male-typical • Female-typical • Specified • Unknown	FHIR Extension
Anatomical Inventory	A detailed element based on one or more clinical observations, such as organ survey, surgical history and chromosomal analysis.	Under development	Under development

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NASEM published a consensus report recommending use of a two-step data collection approach in federal surveys. While not a clinical data standard in its own right, the report provides guidance on best practices for data collection that should ideally align with the clinical data standards in use.[48] NASEM recommends collection of both sex assigned at birth and gender identity, but notes that sex assigned at birth should only be collected when clinically necessary. It also recommends asking about differences in sex development, to assess intersex status, while acknowledging that more research is needed to determine a standard question to be used to assess status.

TABLE 7: NASEM Sex and Gender Data Collection Recommendations

Data Element	Definition	Response Options	Standardized Terminology
Sex Assigned at Birth	The sex assigned to a patient at birth, typically based on observation of external anatomy.	• Male • Female • Unknown	Birth Sex
Differences in Sex Development/Intersex Status	Have you ever been diagnosed by a medical doctor or other health professional with an intersex condition or a difference of sex development (DSD) or were you born with (or developed naturally in puberty) genitals, reproductive organs, or chromosomal patterns that do not fit standard definitions of male or female?	• Yes • No • Don't Know • Prefer not to answer	None currently available

Lack of harmonization between data standards is an ongoing issue across the health care system. Interoperability challenges, where some data elements are not equally or adequately supported across different electronic health record systems, pose obstacles to widespread adoption and use of new data elements such as Sex Assigned at Birth and Sex Parameter for Clinical Use.

In 2022, participants in the Gender Harmony Project and NASEM recommendations co-authored a publication addressing harmonization between these standards. The authors conclude that the Gender Harmony Project data elements for gender identity and Sex [Parameter] for Clinical Use "provide the most flexibility and durability in sex/gender data collection."[48] At a minimum, organizations should collect these values, but may also collect sex assigned at birth and intersex status, as outlined in the NASEM recommendations, to best support patient care.

[3] Formerly titled "Sex for Clinical Use."

Looking Ahead

Breast and cervical cancer screening are examples of clinical and measurement use cases for which existing methods of sex and gender data collection may misidentify patient screening needs. Up to HEDIS measurement year (MY) 2023, the *Breast Cancer Screening* and *Cervical Cancer Screening* measures assess screening among members with an administrative gender of female. This may result in exclusion of transgender and gender-diverse members who require screening but do not have an administrative gender of female, and vice versa. In spring of 2023, NCQA posted proposed changes to both measure denominators for public comment. Of 124 comments, 109 supported the proposed changes. Some feedback, including a joint letter from 33 LGBTQIA+ and allied organizations in support of the changes, also posed modifications, including adoption of organ-based inclusion criteria and updates to other measures specified using a gender data element. As a result of this work, in HEDIS MY 2024, NCQA will replace "women" with "members… recommended for routine [breast or cervical] cancer screening" in the measure description, and will leverage more specific clinical data elements to define the denominator using the data elements:

- Gender or Administrative Gender (current).
- Sex Assigned at Birth (new).
- Sex Parameters for Clinical Use (new).

This approach retains the Administrative Gender-based definition to support continued feasibility of measure reporting; however, specification logic prioritizes the use of more nuanced data (e.g., Sex Assigned at Birth or Sex Parameters for Clinical Use) when present. For example, an individual with Administrative Sex of male but Sex Assigned at Birth of female would be included in the *Cervical Cancer Screening* measure denominator unless another exclusion (e.g., removal of cervix) was documented.

NCQA will closely monitor results of these changes, and will continue to expand the approach used in the *Breast Cancer Screening* and *Cervical Cancer Screening* measures to other HEDIS measures with specification criteria referencing gender (refer to the Appendix). As both the data standards and the availability of more precise clinical data improve, NCQA will continue to evolve measure specifications to move toward more-inclusive approaches. For example, as anatomical inventory data standards mature and more data become available, definitions based on the data may be added into quality measures as well.

In addition to evolution of clinical data standards, the ability to advance gender-inclusive quality measurement will also be facilitated—or stymied—by updates to clinical guidelines to clarify and expand recommendation statements. Guidelines that fail to distinguish between sex and gender can lead to omitting transgender and gender-diverse members from corresponding quality measurement and clinical decision support efforts. Some guideline organizations, such as the USPSTF, have begun to clarify such language, but limited evidence remains a barrier to specific recommendations for these populations. Limitations may take the form of a total lack of evidence (populations going unexamined), or a lack of quality evidence typically prioritized by guideline organizations (e.g., randomized controlled trials). These larger issues directly impact the ability of efforts to ensure equitable quality outcomes.

Conclusion

Transgender and gender-diverse patients experience more disparities in care than cisgender patients and the overall population, including in accessing preventive care. Disparities may be driven in part by current data collection methods that insufficiently identify patient clinical need due to conflating sex and gender. Historic data collection methods did not adequately distinguish between sex and gender, and assumed clinical need from administrative gender data, leading to reduced visibility of patient need.

New data standards offer more precise methods of identifying patient need by disaggregating sex and gender concepts. In conjunction with collection of gender identity, collection of sex-related concepts like Sex Assigned at Birth and Sex Parameters for Clinical Use may improve accurate identification of patients recommended for breast and cervical cancer screening. As data standards evolve and develop, NCQA will continue to seek new approaches that have the potential to support improved accuracy in sex and gender data collection.

In addressing this issue in breast and cervical cancer screening quality measures, NCQA reviewed clinical literature and guidelines and assessed research gaps. Finding overall agreement among guidelines for standards of care to apply based on relevant organ systems, NCQA enacted measure specification changes using new data standards. This is the first step of a larger effort to make quality measures more inclusive, and to ensure they support all communities in achieving their best possible health.

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Appendix

The eligible populations in some HEDIS measures are defined by the HEDIS definition of gender criteria. In these instances, the intent is to identify individuals who require certain services based on the presence of particular organ systems, not to specifically focus the measures on individuals who identify as women and men. The table below contains a complete list of measures and associated measure language.

MEASURE TITLE	MEASURE LANGUAGE
Osteoporosis Management in Women who had a Fracture	The percentage of women 67-85 years…
Osteoporosis Screening in Older Women	The percentage of women 65-75 years…
Breast Cancer Screening	The percentage of women 50-74 years…
Cervical Cancer Screening	The percentage of women 21-64 years…
Non-Recommended Cervical Cancer Screening in Adolescent Females	The percentage of adolescent females 16-20 years…
Non-Recommended PSA-Based Screening in Older Men	The percentage of men 70 years…
Statin Therapy for Patients with Cardiovascular Disease	Males 21-75 years of age and females 40-75 years…
Chlamydia Screening in Women	The percentage of women 16-24 years…

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