Care Considerations for Inclusion of Gender Diversity within Medical Laboratory Services

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1. INTRODUCTION

This document is intended to provide guidance for medical laboratory professionals and laboratory collection centre personnel on the ethical, scientific and clinical challenges for the appropriate care of patient populations with diverse gender identities along the path of the laboratory process. The steps in the laboratory process and the issues within each are summarized in Figure 1.

**Figure 1. Steps in the laboratory process with summary of issues related to gender identity**

<table>
<thead>
<tr>
<th>Test Order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-disclosure of non-binary gender</td>
</tr>
<tr>
<td>Lack of information provided to laboratory by the health professional ordering the test</td>
</tr>
<tr>
<td>Lack of available fields on laboratory requisitions to specify gender identity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient Presentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environment not inclusive</td>
</tr>
<tr>
<td>Assumptions of gender identity</td>
</tr>
<tr>
<td>Incorrect use of pronouns</td>
</tr>
<tr>
<td>Lack of process for the collection of additional demographic information</td>
</tr>
<tr>
<td>Inability of information system to capture additional demographics</td>
</tr>
<tr>
<td>Repetition of assumptions with subsequent healthcare encounters</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample Accessioning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and demographic incongruence</td>
</tr>
<tr>
<td>Inappropriate cancelation of tests</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible variance in testing procedure (pathology, genetics, transfusion medicine)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of data on reference intervals</td>
</tr>
<tr>
<td>Lack of appropriate guidance for test interpretation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretation by the Clinician</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of data on effects of hormone therapy and/or trans-related surgeries that affect physiology</td>
</tr>
<tr>
<td>Lack of direction on interpretation</td>
</tr>
</tbody>
</table>
The foundation of this document is the distinction between sex and gender. The Working Group embraces a gender affirming approach to access and delivery of healthcare to gender diverse populations. Sex refers to the biologically assigned identity based on external genitalia, chromosomal phenotype, and secondary sexual characteristics. Gender is an inherent identification as male, female, non-binary and is understood as a social construct.¹

Societal norms tend to condition thinking about gender as binary. Traditionally at birth, one is assigned either to the category of female or male based on certain biological characteristics and is expected to grow up to fit societal notions and gender stereotypes pertaining to being a woman or a man. Females and males are expected to adhere to social expectations of being feminine and masculine, respectively.

This traditional model of gender, sex, and sexual attraction/orientation is shown in Table 1.²

<table>
<thead>
<tr>
<th>Table 1: Traditional Model of Gender, Sexual Orientation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biological Sex</td>
</tr>
<tr>
<td>Gender Identity</td>
</tr>
<tr>
<td>Gender Expression</td>
</tr>
<tr>
<td>Sexual Attraction/Orientation</td>
</tr>
</tbody>
</table>

Our notions of sex and gender are shaped by social context, are often dependent on circumstance, and can change over time. Sex and gender are separate dynamic phenomena that — like gender expression and sexual orientation — exist on a continuum. A broader understanding of these concepts is crucial for healthcare and laboratory professionals to be better prepared and to provide gender-affirming care to those persons whose gender identity and/or expression may not necessarily correspond with their biological sex. As health professionals, it is important to recognize our personal feelings, values, and biases. We are encouraged to be mindful of how these preconceived ideas can impact the quality of care delivered to trans-identified and gender diverse patient populations.

As health professionals, our obligations are not towards mere recognizing what identities our patients may identify with and assuming how they experience healthcare, but to be cognizant of the diverse narratives we may be unaware of and to ensure respect, compassion and equity are the founding principles of all patient interactions.
There are three general barriers that impede the ability to offer gender-affirming care as it relates to the medical laboratory:

1. The lack of understanding of concepts around sex and gender identity, and that gender diverse patient populations may have unique healthcare issues or needs that should be addressed with inclusivity.

2. Existing laboratory information systems do not reflect adequate fields, nor are structured to include data that distinguishes sex and gender or that clinically corresponds to the needs of non-binary genders.

3. There is a lack of reference intervals covering gender diverse patients, which can lead to inappropriate decision making, not only where the unique healthcare needs of transgender persons must be addressed, but also for clinical care for any diagnosis that follows testing, treatment, and prognostication based on gender-binarism.

2. PROPOSED USERS

- Medical laboratory technologists
- Medical laboratory assistants/technicians
- Laboratory managers
- Laboratory collection center personnel
- Medical/Scientific Staff
- Medical directors
- Laboratory directors
3. **GLOSSARY OF TERMS**

This glossary should not be taken out-of-context and is not intended to convey the breadth and depth of any concept. Readers are cautioned that these terms and their definitions are merely a starting point for deeper discourse. The majority of this glossary was created in reference to the Alberta Health Services Human Resources from the Guide to Creating Safer and More Welcoming Places for Sexual & Gender Minority (LGBTQ2S+) People³ and The 519’s Glossary of Terms [http://www.the519.org/education-training/glossary](http://www.the519.org/education-training/glossary).⁴

**LGBTQ2S+ / LGBTQ+ / LGBTQ**

Acronym for “lesbian, gay, bisexual, transgender, queer/questioning, two-spirit.” Sometimes “*” or “+” is used at the end to represent the many diverse sexual orientations and gender identities that are part of this community, some of which are:

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesbian</td>
<td>Queer</td>
</tr>
<tr>
<td>Gay</td>
<td>Questioning</td>
</tr>
<tr>
<td>Gender Queer</td>
<td>Asexual</td>
</tr>
<tr>
<td>Bisexual</td>
<td>Ally</td>
</tr>
<tr>
<td>Transsexual</td>
<td>Androgynous</td>
</tr>
<tr>
<td>Transgender</td>
<td>Intersex</td>
</tr>
<tr>
<td>Two-Spirit</td>
<td>Pansexual</td>
</tr>
<tr>
<td>Agender</td>
<td>Pangender</td>
</tr>
</tbody>
</table>

**Agender**

Someone who does not identify with a specific gender or have recognizable gender expression.

**Allyship**

The practice of unlearning and relearning; and is a lifelong process of building relationships based on trust, consistency, and accountability with marginalized individuals or groups.⁵

**Cisgender/Cis**

A person whose gender matches the sex they were assigned at birth. Cis can also be used as a prefix to an assortment of words to refer to the alignment of gender identity and the assigned at birth sex status including; cisnormativity, cissexual, cisgender, cis male, and cis female.
The term “cisgender” originates from the Latin-derived prefix cis-, meaning “on this side of”, the opposite of which is trans-, meaning “across from” or “on the other side of.” This usage can be seen in the cis–trans distinction in chemistry and the cis–trans or complementation test in genetics.

**Cisnormativity**

Cisnormativity (“cis” meaning “the same as”) refers to the commonplace assumption that all people are cisgender and that everyone accepts this as “the norm”. The term *cisnormativity* is used to describe systemic prejudice against trans. This form of systemic prejudice may go unrecognized by the people or organizations responsible.

**Duty to Accommodate**

The legal obligation that employers, organizations, service providers and public institutions have under human rights legislation to ensure fair and equal access to services in a way that respects the dignity of every person, if to do so does not create undue hardship. The principle of dignity strives to maximize integration and promote full participation in society, in consideration of the importance of privacy, confidentiality, comfort, autonomy, individuality and self-esteem.

**Differences of Sex Development/Intersex**

Genetic conditions present at birth (congenital), in which the development of chromosomal, gonadal or anatomic sex is atypical.6

**Equality**

The practice of ensuring equal treatment to all people, without consideration of individual and group diversities.

**Equity**

Fairness and impartiality towards all concerned, based on the principles of even-handed dealing. Equality and equity refer to similar but slightly different concepts. Equality generally refers to equal opportunity and the same levels of support for all segments of society. Equity goes a step further and refers to offering varying levels of support depending upon need to achieve greater fairness of outcomes.
Gender

Social and cultural expectations of roles and presentation. For most people their gender matches the sex they were assigned at birth. Others identify as being transgender or gender diverse. The social norms related to gender can vary depending on the culture and can change over time.

Gender Binary

A social system whereby people are thought to have either one of two genders: “boy/man” or “girl/woman.” These genders are expected to correspond to birth sex: male or female. In the gender binary system, there is no room for living between genders or for transcending the gender binary. The gender binary system is rigid and restrictive for many people whose sex assigned at birth does not match up with their gender, or whose gender is fluid and not fixed.

Gender Expression

External and public presentation of a person's gender expressed through an individual's name, pronouns, clothing, haircut, behaviour, voice, or body characteristics. Gender expression also includes using facilities (such as washrooms and change rooms) that correspond with their own sense of gender. Society identifies these cues as masculine and feminine, although what is considered masculine and feminine changes over time and varies by culture. People who are transgender may also take medically supportive steps to align their body with their gender identity.

Gender Fluid

The gender identity, behaviours and appearance of a person moves along a gender spectrum and/or challenges gender restrictions and norms. Related terms can include gender queer, gender non-conforming, gender neutral, pangender, tri-gender, agender, non-binary gender.

Gender Identity

One’s internal, deeply held sense of one’s gender. For transgender people, their own internal gender identity does not match the sex they were assigned at birth. Some people have a gender identity of man or woman (or boy or girl). For some people, their gender identity does not fit neatly into one of those genders. They may identify as agender, without gender, among other terms. Some people may not identify with a gender at all. Unlike gender expression, gender identity is not visible to others.
Gender Queer/Gender non-conforming/Gender variant

A person who may identify and express themselves beyond what is typically associated with their sex/gender assigned at birth. People who are gender queer may not identify as transgender.

Heterosexism

Discrimination based on the assumption that all people are heterosexual and cisgender and that these are the normal and/or superior sexual orientation and gender identities.

Inclusion

An approach that aims to reach out to and include all people, honouring the diversity and uniqueness, talents, beliefs, backgrounds, capabilities and ways of living of individuals and groups.

Intersectionality

Intersectionality considers that various forms of social stratification, such as class, race, skin colour, sexual orientation, age, religion, creed, disability and gender, do not exist separately from each other but are woven together.7

Marginalization

To relegate individuals or groups to an unimportant or powerless position within a society or group by excluding them from meaningful participation and/or confining them to the outer edges of society.

Non-binary

Refers to gender identities that are not exclusively male or female.

Oppression

The obvious and subtle ways dominant groups unjustly maintain status, privilege and power over others, using physical, psychological, social or economic threats or force. Frequently an explicit ideology is used to sanction the unfair subjugation of an individual or group by a more powerful individual or group, which causes injustices in everyday interactions between marginalized groups and the dominant group.

Form of injustice that occurs when one social group is subordinated while another is privileged, and oppression is maintained by a variety of different mechanisms including social norms, stereotypes and institutional rules.1
Oophorectomy

Surgical procedure to remove the ovaries to eliminate most estrogen production. Induces further masculinisation. The surgery is also called ovariectomy, but this term is mostly used in reference to animals.

Orchiectomy/Orichidectomy

Surgical removal of the testes to eliminate androgen production; induces further feminization.

Phalloplasty

Surgical procedure to create a functional penis from a sexual and aesthetic perspective; may or may not include functional neourethra.

Privilege

Unearned power, benefits, advantages, access and/or opportunities that provide unfair advantage for members of the dominant group(s) in society. People are not always aware of the privileges they have. Examples include: cissexual privilege, straight privilege, male privilege, white privilege.

A particular benefit, advantage, or immunity enjoyed by a person or class of people that is not shared with others. A power of exemption against or beyond the law. It is not a right but, rather, exempts one from the performance of a duty, obligation, or liability.¹

Pronouns

They/Them

A non-gendered, singular or plural personal pronoun.

Ze/Hir

Alternate pronouns that are gender neutral and preferred by some gender variant persons. Pronounced /zee/ and /here/ they replace “he”/“she” and “his”/“hers”, respectively.

Queer

A reclaimed term used by some people who identify as sexual and/or gender diverse and also used as a positive, inclusive term to describe communities and social movements.

Questioning

A person who is exploring, or is unsure of, their sexual orientation or gender identity.
Sex

Categories (male, female, intersex) to which people are typically assigned at birth based on external anatomy, chromosomes, organs and/or hormones and may appear on proof of identity documents, unless a person has documentation changed.

Sexual Orientation

Describes a person’s emotional and/or sexual attraction to others. Gender identity and sexual orientation is not the same thing. For many, their sexual orientation can be fluid and may change over time. Sexual orientation may or may not reflect sexual behaviours.

Transgender (Trans, Trans-identified)

An umbrella term for people whose gender identity and/or gender expression differs from what is typically associated with the sex they were assigned at birth. Not all people identify as transgender and some people may describe themselves using one or more of a wide variety of terms.

Transsexual

An older term that originated in the medical and psychological communities. This term has been most often associated with someone who has undergone some medical and/or surgical procedures. Although still preferred by some, unlike transgender, transsexual is not an umbrella term. Many transgender people do not identify as transsexual and prefer the word transgender.

Transition

The process of a transgender individual who publicly changes their gender presentation in society is known as “transitioning.” Transgender people may choose from a range of changes to express their gender such as:

- Change of names (legally and/or socially) and use of pronouns
- Expression, e.g. clothing, jewellery, mannerisms, voice, and vocabulary
- Anatomy and physiology, which can include hormones, surgery, or gender confirming surgery, i.e. male to female or female to male.

Trans people may select one, all or none of the example listed above for a variety of reasons. Every journey is unique and valid.
Trans Man (FTM) / Trans Woman (MTF)

A person whose sex assigned at birth is “female” and identifies as a man may identify as a trans man or transgender man (female-to-male, or FTM). A person whose sex assigned at birth is “male” and identifies as a woman may identify as a trans woman or transgender female (male-to-female, or MTF).

Two-Spirit (2S)

Traditionally in Indigenous or Aboriginal cultures, this person was one who had received a gift from the Creator — the privilege of housing both male and female characteristics within their spirit. Today, it is used to describe First Nations and Métis people who are known in non-Aboriginal society as either gay, lesbian, bisexual, intersex or trans.

Vaginoplasty

Surgical procedure to create a vagina and vulva that are fully functional from a sexual and aesthetic perspective.

4. TERMS AND PHRASES TO AVOID

Genetically Male/Female, Born a Man/Woman

These terms oversimplify a very complex subject. A person’s sex and gender are determined by a variety of factors — not simply genetics. On the rare occasion that it’s necessary to refer to an individual’s gender history, many transgender people prefer a phrase similar to “...assigned male/female at birth but is a woman/man.”

Lifestyle

There is no single lesbian, gay, bisexual or transgender lifestyle. A phrase which includes “lifestyle” is often used to attack the character of an individual by suggesting that their orientation is a choice or a phase.

Transgendered (verb), Transgender (noun)

Using transgender as a verb suggests that being transgender is something that happened to a person rather than reflecting who they actually are. For example, we don’t say “John Smith is a gayed man”, therefore; we wouldn’t say “Joanne Smith is a transgendered woman.”
Similarly, we wouldn’t use transgender as a noun. For example, we wouldn’t say “we have many transgenders who work here” nor would we say “she is a transgender.”

The word transgender should only be used as an adjective as in “Joanne Smith is transgender woman.”

**Tranny, She-Male, He/She, It**

These are generally considered defamatory words which dehumanize transgender people and should never be used by staff. However, there are some trans people who use these terms to describe themselves. The criteria for using these derogatory terms should be the same as those applied to other vulgar words which are used to target other groups such as race, religious beliefs, colour, gender, gender identity, gender expression, physical disability, mental disability, age, ancestry, place of origin, marital status, source of income, family status and sexual orientation. Discrimination and harassment are not defined by the intent of the behaviour or word but the impact it has on the individual.

**Transgenderism**

This term should not be used as it is often a term used by anti-transgender activists to dehumanize transgender people and reduce who they are to a “condition.”
5. **ETHICAL CONSIDERATIONS**

In abiding by professional and ethical obligations to uphold the rights of patients towards self-determination and access to equitable care, it is incumbent upon all health professionals, including those practicing within laboratory services, to acquire the necessary knowledge, skills, and capacity to care for trans-identified and gender diverse patient populations.

Through increasing education, activism, and community participation, there has been acknowledgment of the dearth of education during training and practice towards understanding the healthcare needs of trans-identified and gender diverse persons. The following summarize the key ethical issues that deserve greater understanding and attention:

**MARGINALIZATION OF GENDER DIVERSE POPULATIONS**

In healthcare, where clean categories of quantifiable data are the norm, concepts that must be understood as falling on a spectrum are often misunderstood. Gender diverse persons, particularly those who identify as transgender, have been medically underserved and socially marginalized populations. As a patient population, they face discrimination, prejudice and stigma resulting in poor quality of care and barriers to accessing required health services.

Passive erasure refers to the gap in knowledge of healthcare issues pertaining to trans-identified and gender diverse persons, and the assumption that information about their gender identity is neither important nor relevant to care being provided.

Active erasure refers to the range of explicit responses from visible discomfort to refusal of services to violent responses towards trans-identified and gender diverse persons.

**HEALTHCARE AVOIDANCE, REFUSAL OF CARE, HARASSMENT OR VIOLENCE IN HEALTHCARE SETTINGS**

Trans-identified and gender diverse persons are likely to experience higher instances of bullying and trauma than their cis-gender peers; be estranged from their families when coming out; face social isolation and unemployment; be vulnerably housed; and as a result are at a much higher risk of experiencing mental health illness like anxiety, depression, and suicidality. As a direct result of experiencing prejudice, harassment, or violence in health care settings, healthcare avoidance may be pronounced due to fear of discrimination and lack of safety, resulting in health disparities. This includes avoiding healthcare settings, including laboratory services, that are not trans-inclusive or gender affirming or, worse, indifferent to the dignitary harms and rights violations trans-identified and gender diverse persons encounter.
UNDERESTIMATION OF THE NUMBER OF PERSONS WHO ARE IN A GENDER DIVERSE POPULATION

Among healthcare providers, the lack of awareness and preparation to care for trans-identified and gender diverse patients stems in part from inaccurate current estimates of the size of the gender diverse populations. This is compounded by the fact that persons with stigmatized identities may be reluctant to disclose their identities to researchers or for census purposes. As rights protections increase and stigma decreases in society, the likelihood of disclosure increases. The number of trans and gender-diverse persons in Canada have been conservatively estimated to be 0.6 % of the population, extrapolated to 2016 Canadian census counts — 200,000 trans individuals aged 18 and older living in Canada, 77,000 in Ontario. The TransPulse Project in Ontario inquired into the perceptions and experiences of trans persons navigating the healthcare system in Ontario. This study showed great heterogeneity of sex, gender, and transition status among trans Ontarians.

The continuing under-estimation of the size or strength of gender diverse populations allows for assumptions that re-structuring the system is not necessary to be gender affirming, and that trans people can be dealt with on an individual basis. As a result, when a trans or gender diverse patient accesses healthcare, clinicians and healthcare teams are unprepared to offer nuanced care.

In response to these ethical issues, the IQMH Working Group supports a gender-affirming approach to healthcare delivery, which may be understood as the processes through which a health care system cares for and supports an individual, while recognizing and acknowledging their gender identity and expression. Gender-affirming care ensures that all persons accessing our healthcare system are treated with respect, dignity, and compassion. Further, gender identity and expression have been recognized and prohibited grounds of discrimination under the Canadian Human Rights Act since 2017. In addition, under the Ontario Human Rights Code people are protected from discrimination and harassment because of gender identity and gender expression in employment, housing, facilities and services, contracts, and membership in unions, trade or professional associations.

VALUES UNDERLYING GENDER-AFFIRMING APPROACHES TO HEALTHCARE

Within gender-affirming approaches to healthcare, upholding the three values underlying the practice of allyship are crucial — trust, consistency, and accountability.
proving trustworthiness is more important before trust can be linked and built into the relationship.\textsuperscript{19} Consistency must be applied to all approaches to constantly convey honest intent to prove trustworthiness. Accountability must be embodied within action, word, and disposition, to re-enforce trustworthiness and consistency as professionals who stand by fair and just delivery of healthcare.

### A. IQMH WORKING GROUP RECOMMENDATIONS

1. Revise applicable organizational policies to include gender identity/expression.
2. Ensure staff members have both awareness and preparation to care for gender diverse persons with respect, compassion and equity. Include gender diversity in ethics training programs.
3. Encourage staff to report any incidents of harassment or discrimination.

### 6. LABORATORY REQUISITIONS AND INFORMATION SYSTEMS

Obtaining demographic information regarding non-binary gender individuals is important. It helps the laboratory provide appropriate guidance regarding test interpretation as well as ensuring a positive patient experience.

The medical decision-making process is often based on a patient’s gender as many laboratory tests are interpreted using gender specific reference intervals. Therefore, the availability of appropriate patient gender information will improve patient care as the laboratory medical staff can provide lab test and pathology interpretation guidance that is relevant and useful for treatment of all patients.

Most institutions do not have policies, processes, or the informational technology (IT) functionality to collect, store, or display gender identity data. While legal name and sex are often required for billing or other purposes, the ability to capture information that allows the patient to be addressed in the manner they choose will greatly improve their healthcare experience.

This guideline seeks to cover gender functionality recommendations with respect to electronic medical records, diagnostic testing requisitions, hospital and laboratory information systems following the practical examples of many hospital and healthcare organizations in Canada that have been moving towards such inclusion.\textsuperscript{20,21,22,23}

#### ELECTRONIC MEDICAL RECORD

In 2015 the US Office of National Coordinator for Health Information Technology and the Centers for Medicare & Medicaid Services (CMS) added sexual orientation and gender identity to the list
of required fields for electronic health software for it to be considered for Meaningful Use.\textsuperscript{24,25} The World Professional Association for Transgender Health (WPATH) has also published recommendations for vendors, developers, and users of electronic medical record systems with respect to transgender patients.\textsuperscript{26} While these recommendations are relevant, they only address electronic medical record systems, and are currently uncommon.\textsuperscript{27}

**LABORATORY TESTING REQUISITIONS**

The laboratory requisition serves as the most practical and convenient way to acquire appropriate demographic information. Options to clarify non-binary genders on the laboratory requisition can facilitate improved healthcare in several ways. The indication of gender incongruence on the laboratory requisition can alert the laboratory to provide guidance with regard to test interpretation. Alternatively, it could allow the health care provider to request which reference intervals they would like displayed on the report. Additionally, it can serve to encourage health care providers to collect and store this information on their patients if it is required to complete laboratory requisitions. Lastly, the test requisition can be the first step to alerting the laboratory staff of gender incongruence. If a patient is identified as having a non-binary gender identity on the requisition form, this information can serve to alert the phlebotomy staff of inclusive care considerations.

Several strategies have been proposed on how best to capture this data on lab requisitions. One approach is outlined in the Fenway Institute’s two-step process:\textsuperscript{28,29}

What sex were you assigned at birth on your original birth certificate? (Check one):

- [ ] Male
- [ ] Female
- [ ] Decline to Answer

Do you think of yourself as:

- [ ] Male
- [ ] Female
- [ ] Female-to-Male (FTM)/Transgender Male/Trans Man
- [ ] Male-to-Female (MTF)/Transgender Female/Trans Woman
- [ ] Genderqueer, neither exclusively male nor female
The IQMH Working Group recognizes that the Fenway Institute's two-step process may not be practical or necessary for laboratory requisitions. One solution could be to allow space for the following three selections:

1. Sex at birth
2. Administrative/legal gender (needed for billing purposes)
3. Gender identity (if different from administrative/legal gender) (optional)

Sex at birth and legal gender can serve as an indication of gender incongruence and either can be used as a guide for laboratory interpretation and reporting (see Section 10). Legal gender is also often needed for billing purposes. Gender identity can be offered as “optional” and serve to facilitate quality patient interactions by alerting specimen collection and laboratory staff to ask appropriate questions (Section 8).

LABORATORY INFORMATION SYSTEMS

Most laboratory information systems (LIS) are limited to documenting binary gender (male vs. female) and are unable to capture non-binary gender options. LIS systems typically use a patient's legal name, date of birth, health card number, accession number, or surgical pathology number as key identifiers (NOTE: sex or gender should never be used as a patient identifier). Many people have names that differ from their legal name. For transgender individuals, their name may match their gender identity both of which may be different from their legal name and sex. Additional information including pronouns and clinical details related to transition can also be useful for medical and laboratory staff to facilitate better patient care.

Most LIS systems will require modifications to accommodate gender identity options which should include the information collected: legal gender, gender identity and sex at birth when available. The option to capture pronouns should also be considered. The LIS system should also be programmed in such a way to allow modifications to these fields as the legal gender may change over time.²⁶

Other system modifications should include the removal of any rules automatically cancelling tests based on gender.³⁰ In addition, user alerts should be programmed to notify the user of preferred name and pronouns.²⁶ This would facilitate the phlebotomy staff in providing positive patient experiences and alert histology and cytology staff of samples from transgender patients.
ADDITIONAL DATA COLLECTION

Regardless of an institution’s ability to capture data in their EMR, Hospital Information System (HIS) and/or LIS, gender identity data should still be obtained in order to facilitate positive patient interactions. The additional information collected could include gender identity, preferred name, and pronouns31 (See section 8). In the absence of changes to information systems and requisitions, this type of data collection is the best interim solution to provide inclusive care to individuals with diverse gender identities.

Such collection of additional gender identity data not on the requisition could occur at patient intake. This can be done by having the patient answer questions in a private space, by filling out a form for laboratory or hospital staff to transcribe, or by allowing the patient to self-register either through a web portal or self-serve kiosk. The latter two are preferred unless the questions can be asked discreetly as to ensure the privacy of the patient.31

A large study to examine patients’ reactions to routinely being asked about their gender identity was conducted in Toronto. The report from this study, published in 2019, supports a 2-part gender identity question in which patients are asked about their sex at birth (male or female), followed by their current gender identity which includes a free-text option for clarification. The report emphasised the need to train staff, to state how the information will be used and to ensure the environment is an inclusive space.32

POLICY CHANGES

Policies should be developed to address gender identity data collection and subsequent IT system modifications for diverse gender identities. These policies will not only serve to facilitate the required changes and modifications but will also serve to educate medical and laboratory staff.
B. IQMH WORKING GROUP RECOMMENDATIONS

Long Term
1. Requisitions should be modified to be inclusive of trans, gender-diverse and non-binary individuals by including fields for:
   - Sex at birth
   - Administrative/legal gender (needed for billing purposes)
   - Gender identity (if different from administrative/legal gender) (optional)

2. EMRs, HIS and LIS systems should be modified to be inclusive of trans, gender-diverse and non-binary individuals by including fields for:
   - Sex at birth
   - Administrative/legal gender (needed for billing purposes)
   - Gender identity (if different from administrative/legal gender) (optional)

Short Term
3. It is recognized that modifications to information systems and requisitions will take time. In the absence of these modifications; laboratories and hospitals should consider solutions to collect relevant gender identity information on patient intake. (See section 8)
7. INCLUSIVE ENVIRONMENTS FOR LABORATORY COLLECTION CENTRES AND HOSPITALS

Ensuring laboratory collection centres and hospitals provide a welcoming and inclusive environment is a key enabler of access to lab services for gender minorities. Specimen collection centres are the main site of direct interaction of individuals with laboratory staff and services, and as such play a crucial role in reflecting gender diverse spaces.

In a survey on transgender individuals’ non-use of emergency departments, several key barriers to care due to the medical environment were identified. Based on these findings, suggestions to improve the inclusivity of medical environments include:

- To offer gender-neutral spaces, including hospital rooms and restrooms, in all areas of the hospital;
- For health care providers to ask sensitive questions in private spaces only;
- Consider solutions to avoid calling out names in group areas, and never use prefixes or honorifics (Mr/Mrs/Miss), e.g. alpha-numeric queue system.

In Alberta, the Alberta Health Services Human Resources Guide to Creating Safer and More Welcoming Places for Sexual & Gender Minority (LGBTQ2S+) People also includes recommendations for medical environments, which include:

- Displaying hospital/institutional ‘respect in the workplace’ posters that are visible to staff and patients, and signage on how to provide feedback to management regarding concerns about care;
- To consider if common areas (waiting rooms, washrooms, administrative areas, clinical areas) reflect sexual and gender diversity by what is displayed in these areas;
- To consider if the literature and magazines in common spaces reflect the gender diversity of the patients and employees;
- To display welcoming symbols (i.e. rainbow stickers) in inclusive spaces, and/or on employees (e.g. badges) to indicate individual competency.

A particularly important enabler is the provision of an inclusive (gender neutral) washroom at the laboratory collection site. An inclusive washroom can be a private or single-stall washroom that is identified as inclusive by a non-gendered sign. Inclusive washroom signs have been developed by the Canadian Standards Associations (CSA) for inclusive signage in health care facilities.
Regardless if an inclusive washroom is provided or not, it is a protected legal right to use a segregated washroom that corresponds to a person’s gender identity.\textsuperscript{17}

In summary, laboratory collection centres should provide private locations for sensitive conversations and offer an inclusive (gender neutral) washroom space, ideally a single-stall private washroom marked as inclusive/gender neutral by use of an appropriate sign. Laboratory collection centres should endeavour to provide inclusive waiting room environments through use of inclusive and welcoming signage, and gender inclusive literature within the collection centre or as provided by the collection centre to patients (i.e. documents/brochures).

C. IQMH WORKING GROUP RECOMMENDATIONS

1. Provide gender-neutral restrooms in hospitals and collection centres with appropriate signage.
2. Provide a private space for asking sensitive questions and/or implement a system where patients can enter demographic information privately.
3. Consider solutions to avoid calling out names in group areas, and never use prefixes or honorifics.
4. Display “respect in the workplace” posters that are gender inclusive and are visible to staff and patients.
5. Display welcoming symbols (i.e. rainbow/positive space stickers) in inclusive spaces and/or on employee badges to indicate individual competency.
8. INCLUSIVE PATIENT INTAKE AND COMMUNICATION

Often, the patient’s first point of contact with the laboratory will be at registration where they are greeted, and their demographic information and test requests are data entered in an information system. This simple interaction can be complicated by an employee uncertain with how to handle gender incongruence — the name on the patient’s health card and/or requisition may not match the physical presentation of the patient.

Due to implicit or unconscious biases that endorse gender-binarism, healthcare professionals may mis-identify gender diverse patients based on visual presumptions of gender expression and stereotypes. This can be detrimental to the therapeutic relationship but also lead to mislabelling, incorrect sample handling, or errant entries into health information systems. Unless identified, trans persons are usually not immediately recognizable to health care providers. More often than not, assumptions of gender-binarism lead to health professional referring to patients with the wrong pronoun or honorifics. This constitutes erasure, conveys disrespect, causes emotional distress and trauma to the patient, and results in healthcare avoidance, lack of trust in the healthcare system, and furthers health inequities.

Assumptions regarding gender identity can potentially lead to confusion and negative experiences for both the patient and the laboratory staff. Specimen collection staff should receive training and instruction on how to facilitate a positive interaction in situations where assumptions about gender expression might not match requisition information. It is recommended that sensitivity/diversity training programs be developed and implemented to ensure that staff members are trained regarding the concepts of gender identity and expression and that policies and processes be documented and shared.

INCLUSIVE PROTOCOLS TO COLLECT THE NEEDED INFORMATION

In the absence of changes to laboratory information systems and requisitions, it is recommended that the laboratory still make efforts to collect gender inclusive data. To be inclusive of patient wishes, choices and ensure privacy and confidentiality, opportunities to enter demographic information through a self-serve kiosk or web portal system can offer a sense of safety to patients and increase the likelihood of collecting accurate, patient identified information. This, however, must be carefully implemented, including patient engagement. Any similar efforts ought to be presented as a choice for patients as opposed to forcing identification of sensitive data, particularly around gender identity and sexual orientation.

Currently, best practices recommend that all patients ought to be asked about their birth-assigned sex and gender identity as two distinct questions. This is known as the “two-step” process and is
superior to a single step that provides choices of “male” and “female” and “transgender”, as many Trans persons may identify as both male or female and transgender. All patients, irrespective of gender expression, should be able to identify among options presented under gender identity, and be offered the option to identify with another term should they choose so.32, 36

**ASKING QUESTIONS**

The approach and quality of the initial interaction with the health care setting can set the tone for trust, safety, and deeply influence the therapeutic relationship. It is recommended that while in a private setting, health professionals approach all patients by positively identifying their own name, pronouns, and role within the healthcare setting. This should be followed by requesting the patient to clarify what name and pronouns they would want to be identified with, and to clarify especially if this differs from the official health documents presented or available to the health professional in the moment. Patients should always be provided ample and affirming opportunity to refuse to respond to questions around pronouns and gender identity if they are not ready to disclose or feel unsafe to do so. Such an approach is crucial in letting the patient know they have entered within a safe space where their gender identity and sexual orientation will be respected, and that they will not be discriminated against. Dialogue in this manner fosters respectful communication and signals to the patient that the health professional(s) treating them are worthy of being trusted.

**COMMUNICATING AFTER INITIAL INTAKE**

Following initial communication where name and/or pronouns and gender identity have been clarified, a system should be in place to notify subsequent providers and staff of a patient’s correct name and/or pronouns. Systems should include a recognizable notation or bolding of correct name that conveys to the intended staff of the appropriate information and how to utilize it, but in a way that does not label patients and further stigmatize them. Patients who are repeatedly having to reorient themselves to new staff and possibly re-educate each new person, will experience fatigue and frustration.37 Accordingly, this approach should be consistently and equitably applied to all patients who receive care in the particular healthcare setting, and not solely implemented based on assumptions about a patient’s gender identity or gender expression.
D. IQMH WORKING GROUP RECOMMENDATIONS

1. Revise applicable policies to include gender identity/expression.

2. Provide staff with training on how to facilitate a positive interaction in situations where assumptions about gender expression might not match healthcare and/or requisition information.

3. In the absence of changes to laboratory information systems and requisitions, implement a system where patients can enter demographic information privately.

4. Implement a system that enables consistent use of a patient’s correct name and/or pronouns to subsequent staff.

9. SAMPLE ACCESSIONING

Two issues can arise once samples arrive into the laboratory for accessioning:

1. A mismatch between name and sex on the requisition could be identified and samples could be rejected.

2. A decision could be made to cancel a test based on a mismatch. The laboratory should not cancel tests based on sex specific tests (e.g. hCG, PSA, pap smear). For some esoteric tests such as genetics, the laboratory may need to conduct a query to confirm birth-assigned sex.

E. IQMH WORKING GROUP RECOMMENDATIONS

1. Review and revise accessioning procedures and acceptability criteria to include specific instructions for issues surrounding non-binary gender identities.

2. The laboratory should not cancel tests based on sex specificity (e.g., hCG, PSA, pap smear).
10. CLINICAL AND SCIENTIFIC CONSIDERATIONS

THE IMPORTANCE OF LABORATORY MONITORING OF TRANSGENDER PERSONS

As recently noted, transgender health care is gaining recognition, and there is a growing awareness of patient discrimination and lack of professional education regarding transgender patient care. The importance of eliminating these barriers to transgender health care is recognized in Canada, led by Bill C-16 and signed into the law on June 19, 2017, which protects Canadians from discrimination based on gender identity and expression. This is also specified in provincial laws, for example, under the Ontario Human Rights Code people are protected from discrimination and harassment because of gender identity and gender expression in employment, housing, facilities and services, contracts, and membership in unions, trade or professional associations.

Unfortunately, to date there is little published literature on the importance of accurate laboratory test interpretation, and its relationship to improved health care outcomes in transgender individuals. A striking example of the importance of accurate laboratory test interpretation and collaboration between clinicians and laboratorians is presented in a case of a delayed kidney transplant intervention in a transgender man. In this case, the estimated glomerular filtration rate (eGFR) was used according to clinical guidelines for male patients, in spite of patient’s small stature, vegan diet, and female sex at birth, all of which influence creatinine level used to calculate eGFR. The use of sex-dependent methods for kidney transplant assessment, and lack of consultation between the clinicians and the laboratory, led to delayed transplantation and prolonged patient suffering.

Another poignant example of importance of appropriate laboratory testing in transgender individuals includes a recently reported case of locally advanced cervical cancer in a transgender male due to lack of appropriate medical advice on cervical cancer screening by Papanicolau (pap) smear.

CHALLENGES SPECIFIC TO LABORATORY TEST INTERPRETATION

The current binary approach to data entry and result reporting represents a major challenge for medical laboratory professionals in providing timely and accurate clinical interpretations and surgical or anatomical pathology results for transgender individuals or other diverse gender groups.

In addition to creatinine and eGFR, many other laboratory tests have different reference intervals for males and females including hematological parameters (e.g. complete blood count, ferritin,
iron), hormones (e.g. sex steroids and associated pituitary hormones, prolactin, growth hormone, IGF-1) and enzymes (e.g. alkaline phosphatase, alanine aminotransferase). Result interpretation for these tests presents a significant challenge in the context of transgender individuals undergoing hormone treatment.30,41

Further complicating interpretation and reporting are diagnostic tests that are traditionally intended for specific sex, such as PSA for males, or pap smear and pregnancy hCG for females. These tests are commonly cancelled by an LIS when ordered on the “wrong” sex.

Finally, anatomical pathology testing interpretation is challenging in transgender individuals, primarily due to difficulties in obtaining specimens (attributed to physical changes induced by hormone treatment and provider/patient discomfort with the exam), and lack of standardized handling and reporting.42

There is paucity of data on transgender laboratory result interpretation due to a lack of large-cohort studies but those that have been conducted show that hormone therapy does not simply result in laboratory values that switch to match the reference interval of the gender identity of the individual. Recently, several peer-reviewed publications have evaluated the changes in multiple test levels in transgender individuals undergoing hormone treatment (Table 2). The largest study included 183 transgender women and 119 transgender men and found that the impact of hormone therapy is not always predictable. The study concluded that “Some laboratory values changed to match the gender identity, whereas others remained unchanged or were intermediate from baseline values.”41 Another study of 55 male-to-female patients has indicated that following transition, some laboratory markers may fall within male reference intervals, some may fall within female reference intervals, and some may be different from both.43 During transition, marker levels may change over time.30 Additionally, differences may exist based on hormone treatment modalities, age at the onset of treatment44, or due to non-standardized methods and non-harmonized reference intervals among laboratories. Therefore, defining “normal” marker levels in transgender individuals adds to the known complexity laboratories face when determining reference intervals in diverse demographic groups (see “Reference intervals” below).

Hormone treatment is common in transgender individuals and requires periodic clinical and laboratory monitoring.44 In spite of the lack of data on laboratory parameters in transgender individuals, several guidelines and associated on-line resources are available to clinicians and laboratorians.44,45 It is notable that these recommendations are largely based on expert opinion. While World Professional Association for Transgender Health (WPATH), within its comprehensive Standards of Care, indicates the need for laboratory monitoring related to risks associated with
hormone therapy\textsuperscript{45}, the University of California San Francisco Center of Excellence for Transgender Health provides more specific information on laboratory monitoring parameters and expected male or female ranges in transgender men and women undergoing hormone treatment.\textsuperscript{44} The Endocrine Society Guidelines\textsuperscript{47} provide detailed prescriptive recommendations on the timing and type of endocrine and non-endocrine markers to monitor during hormone treatment of transgender individuals. In addition, suggested laboratory screening and monitoring due to increased risks associated with hormone treatment in both cis- and transgender patients is provided.\textsuperscript{47}

A review of limited available clinical studies indicated the following risks:

- An increased risk of venous thromboembolism in transgender women\textsuperscript{46};
- Risk of elevated triglycerides in transgender women\textsuperscript{46};
- Erythrocytosis in transgender men;
- Insulin resistance and Type 2 diabetes in both transgender men and women\textsuperscript{35};
- Multiple case studies suggested increased risk of pituitary tumors, including prolactinoma
- Contradictory data exists on the risks of reproductive tissue hyperplasia.\textsuperscript{35}

Expert opinion monitoring recommendations for transgender males include testing protocols for:

- Testosterone;
- Hematocrit and hemoglobin for polycythemia\textsuperscript{30};
- Triglyceride concentration\textsuperscript{30};
- Screening for osteoporosis if testosterone treatment is stopped;
- Screening for cardiovascular risk factors;
- Screening for breast and cervical cancer as in cisfemales when the tissue is present.\textsuperscript{47}

For transgender females, monitoring recommendations include:

- Testosterone;
- Estradiol;
- Prolactin;
• Electrolytes if treated with spironolactone;30
• Screening for osteoporosis;
• Screening for cardiovascular risk factors;
• Screening for prostate cancer if transitioning occurred after age 20.47

A call has been made for laboratorians to reach out to clinical organizations that set practice guidelines to include information on laboratory test interpretation into the future guidelines for transgender patient care, including test limitations and alternate laboratory test.48

**CHALLENGES SPECIFIC TO TEST REFERENCE INTERVALS**

Many general chemistry, special chemistry and hematology have sex-specific reference intervals. Currently there is little published literature regarding reference intervals that are appropriate for transgender patients. The lack of established reference intervals creates difficulty for health care providers to determine healthy vs. pathologic states for this patient population. Due to the unique physiology and great diversity among this demographic, establishment of these intervals will take time and careful planning. The Clinical and Laboratory Standards Institute (CLSI) Guidelines for establishment of reference intervals recommend using samples from 120 presumably healthy individuals for each demographic group to establish reference intervals, and 20 presumably healthy individuals to verify existing reference intervals.49 Similarly to issues surrounding establishment of pediatric reference intervals50, it is difficult to obtain samples from presumably healthy transgender individuals due to reluctance to access health care and irregular laboratory monitoring. More research is needed to understand which reference intervals are appropriate to report in transgender individuals, and how to change the information systems to allow more flexibility in reporting.11,41

In the absence of reference intervals, laboratories should provide alternative guidance to health care providers with regard to test interpretation when applicable. Studies show that neither male or female reference intervals applied across all tests are most appropriate when hormone transitioning of non-binary gender individuals, since some markers will fall within the male reference intervals and others within the female, with results will changing over time as transition progresses.27,30,43,51 Due to the paucity of literature on reference intervals for transgender patients, clinicians will need to use clinical judgement in interpretation of results.30

The published literature provides the following suggestions regarding reference intervals in non-binary gender individuals:
• Use the reference interval associated to the patient’s sex at birth if it is known that the individual is not on hormonal treatment or undergone surgery that affect physiology (oophorectomy/orchiectomy). This may be a decision only the clinician can make since the laboratory may not be provided with clinical information on transition.29

• One reference source suggests using the sex opposite to the sex at birth for transgender patients who have undergone hormone therapy and have undergone surgery.29 This advice may not be ideal since not all markers will convert. Caution is required because the available studies do not always correlate laboratory values to reference intervals, but instead just look for changes in concentration from baseline (see Table 2).30,41

• Creatinine concentration changes are important because of the effect on estimation of glomerular filtration rate, drug dosing, disease staging and qualification or transplantation. The largest study41 shows the following:
  o Transitioning from female to male: Creatinine similar to cisgender males
  o Transitioning from male to female: Creatinine statistically different, but intermediate between cisgender males and cisgender females. These results are in contrast to another published study by Roberts et al 43 which reported no difference between transwomen and cisgender males.
  o The authors of the larger study suggest that reference intervals for creatinine cannot be simply switched from male to female range for transwomen, and must be interpreted with caution.41

The IQMH Working Group suggests that laboratories report the reference intervals that correspond to the patient’s sex at birth. A comment could then be added to all reports to inform laboratory users that the reference intervals reported may not apply to all patients. For example: “As different demographic populations can be very physiologically diverse (e.g. gender non-binary individuals), reference intervals provided on this report may not apply to all patients.”

A gender non-binary patient’s legal gender may differ from sex at birth, but this does not imply the patient is undergoing hormone therapy. Reporting reference intervals corresponding to the patient's sex at birth is suggested as this may be the best reflection of the patient’s physiology. Moreover, as previously stated, reference intervals are not available for gender diverse individuals undergoing hormone treatment or who have had physiology altering surgery.
Laboratories should also consider providing health care providers with guidance on how best to interpret lab tests on gender non-binary patients undergoing hormone therapy treatment or who have had physiology altering surgery (see Table 3). Suggestions could include a website link to published literature or expert opinion.

**Table 2: Summary of Published Changes in Laboratory Values of Analytes from Baseline for Transgender People on Hormone Therapy**

<table>
<thead>
<tr>
<th>Marker</th>
<th>Male to Female</th>
<th>Female to Male</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Decreases 41, 43, 51, 52, 53</td>
<td>Increases 41, 51, 52, 54, 55</td>
</tr>
<tr>
<td>Hematocrit</td>
<td>Decreases 41, 43, 51, 52, 53</td>
<td>Increases 41, 51, 52, 54, 55</td>
</tr>
<tr>
<td>Red Cell Count</td>
<td>Decreases 41, 52</td>
<td>Increases 41, 52</td>
</tr>
<tr>
<td>Platelets</td>
<td>Increases 41</td>
<td>Decreases 41</td>
</tr>
<tr>
<td>MCV</td>
<td>Unchanged 41</td>
<td>Unchanged 41</td>
</tr>
<tr>
<td><strong>Electrolytes and Renal Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Albumin</td>
<td>Decreases 41</td>
<td>Unchanged 41</td>
</tr>
<tr>
<td>Calcium</td>
<td>Decreases 41</td>
<td>Unchanged 41, 52</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Decreases 41, 51, 52</td>
<td>Increases 41, 51, 52</td>
</tr>
<tr>
<td></td>
<td>Unchanged 43</td>
<td></td>
</tr>
<tr>
<td>Potassium</td>
<td>Unchanged 41, 43, 52</td>
<td>Unchanged 41</td>
</tr>
<tr>
<td><strong>Liver Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AST</td>
<td>Decreases 51</td>
<td>Increases (small effect) 41, 51, 54</td>
</tr>
<tr>
<td></td>
<td>Unchanged 41, 43, 52</td>
<td></td>
</tr>
<tr>
<td>ALT</td>
<td>Decreases (small effect) 41, 51, 52</td>
<td>Increases (small effect) 41, 51, 54</td>
</tr>
<tr>
<td></td>
<td>Unchanged 43</td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase (ALP)</td>
<td>Decreases 41</td>
<td>Unchanged 41</td>
</tr>
<tr>
<td></td>
<td>Unchanged 43</td>
<td></td>
</tr>
<tr>
<td><strong>Lipids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Density Lipoproteins (HDL)</td>
<td>Increases 52, 56</td>
<td>Decreases 41, 52, 51, 54, 57</td>
</tr>
<tr>
<td></td>
<td>Decreases 41, 57</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Unchanged 41, 43</td>
<td></td>
</tr>
<tr>
<td>Low Density Lipoproteins (LDL)</td>
<td>Increases 57</td>
<td>Increases 41, 51, 52, 55</td>
</tr>
<tr>
<td></td>
<td>Decreases 41, 56</td>
<td></td>
</tr>
</tbody>
</table>
### Table 2: Summary of Published Changes in Laboratory Values of Analytes from Baseline for Transgender People on Hormone Therapy

<table>
<thead>
<tr>
<th>Marker</th>
<th>Male to Female</th>
<th>Female to Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglycerides</td>
<td>Increases 43, 57 Decreases 51, 53 Unchanged 41, 52</td>
<td>Increases 41, 51, 57 Unchanged 52</td>
</tr>
<tr>
<td>Total Bilirubin</td>
<td>Decreases 41</td>
<td>Unchanged 41</td>
</tr>
<tr>
<td>Total cholesterol</td>
<td>Increases 57 Decreases 51, 53 Unchanged 41, 43</td>
<td>Increases 41, 51, 57</td>
</tr>
</tbody>
</table>

**Endocrine**

<table>
<thead>
<tr>
<th>Marker</th>
<th>Male to Female</th>
<th>Female to Male</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogen</td>
<td>Increases 51</td>
<td>Decreases 51</td>
</tr>
<tr>
<td>Prolactin</td>
<td>Increases 51</td>
<td>Decreases 51</td>
</tr>
<tr>
<td>Sex Hormone Binding Globulin (SHBG)</td>
<td>Increases 51</td>
<td>Decreases 51, 54, 58</td>
</tr>
<tr>
<td>Testosterone</td>
<td>Decreases 51</td>
<td>Increases 51, 54, 58</td>
</tr>
<tr>
<td>Follicle Stimulating Hormone (FSH)</td>
<td>Decreases 51</td>
<td>Increases 58</td>
</tr>
<tr>
<td>Luteinizing Hormone (LH)</td>
<td>Decreases 51</td>
<td>Decreases 51, 54</td>
</tr>
<tr>
<td>DHEAS</td>
<td>Decreases 51, 53</td>
<td>Increases 51, 54</td>
</tr>
<tr>
<td>AMH</td>
<td></td>
<td>Decreases 58</td>
</tr>
</tbody>
</table>

Note: Table 2 adapted from Balion C.59
### Table 3: IQMH Interpretation Recommendations for Analytes with Sex-specific Reference Intervals for Known Transgender People on Hormone Therapy

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Male to Female</th>
<th>Female to Male</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Female reference interval most appropriate but interpret with caution.</td>
<td>Male reference interval most appropriate but interpret with caution.</td>
</tr>
<tr>
<td>Hemocrit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Red Cell Count</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Renal Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>Reference interval for male-female transgender patients is intermediate between the cis-male and cis-female intervals. Clinical judgment must be used to assess abnormal laboratory values. Both male and female reference intervals have been supplied.</td>
<td>Male reference interval most appropriate but interpret with caution.</td>
</tr>
<tr>
<td><strong>Liver Function</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkaline Phosphatase</td>
<td>Male reference interval most appropriate but interpret with caution.</td>
<td>Female reference interval most appropriate but interpret with caution.</td>
</tr>
<tr>
<td>AST</td>
<td>Male reference interval most appropriate but interpret with caution.</td>
<td>Female reference interval most appropriate but interpret with caution.</td>
</tr>
<tr>
<td>ALT</td>
<td>Male reference interval most appropriate but interpret with caution.</td>
<td>Female reference interval most appropriate but interpret with caution.</td>
</tr>
<tr>
<td><strong>Lipids</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Density Lipoproteins (LDL)</td>
<td>Female reference interval most appropriate but interpret with caution.</td>
<td>Reference intervals for female to male transgender patients have not been established, hormone status and clinical judgment must be used to assess abnormal laboratory values. Both male and female reference intervals have been supplied.</td>
</tr>
<tr>
<td>High Density Lipoproteins (HDL)</td>
<td>Reference intervals for transgender patients have not been established, hormone status and clinical judgment must be used to assess abnormal laboratory values.</td>
<td>Reference intervals for transgender patients have not been established, hormone status and clinical judgment must be used to assess abnormal laboratory values.</td>
</tr>
<tr>
<td>Triglycerides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 3: IQMH Interpretation Recommendations for Analytes with Sex-specific Reference Intervals for Known Transgender People on Hormone Therapy

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Male to Female</th>
<th>Female to Male</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Both male and female reference ranges have been supplied.</td>
<td>Both male and female reference intervals have been supplied.</td>
</tr>
</tbody>
</table>

### Endocrine

- Estrogen
- Prolactin
- Sex Hormone Binding Globulin (SHBG)
- Testosterone
- Follicle Stimulating Hormone (FSH)
- Luteinizing Hormone (LH)
- DHEAS
- AMH

Female reference interval most appropriate but interpret with caution.

Male reference interval most appropriate but interpret with caution.

**PATHOLOGY/CYTOPATHOLOGY**

The interpretation of breast biopsies, prostate biopsies, and pap smears from transgender patients can be challenging and prone to error. Pathologist assessment may be difficult as the effect of exogenous hormone therapy on these tissues is not fully understood. Moreover, many institutions have limited experience with these samples and lack the ability to identify them.42 Laboratory facilities should expect to receive tissue samples from transgender individuals as it is recommended that transgender patients follow the same screening guidelines for prostate, breast, and cervical cancer as their cisgender counterparts.42,60 In fact it’s likely that many laboratories already receive these samples for review but are not aware the sample is from a transgender patient. The ability of the LIS system to capture gender identity information and alert the pathologist or laboratory staff will enable identification of these samples and therefore create awareness and experience with these samples.

**MICROBIOLOGY**

**Vaginal Flora — Transgender Men**

A study published in 2019 compared the vaginal floras of transgender men to cisgender women and found that *Lactobacillus* was identified as the primary genus (>90%) inhabiting the vagina of cisgender women, but transgender men prescribed testosterone were less likely to have *Lactobacillus* as their primary genus (<2%). This same study noted that intravaginal estrogen
administration may promote colonization of *Lactobacillus*, critical to a healthy vaginal microbiome, reducing bacterial vaginosis (BV) and reducing the risk of HIV transmission.\(^{61,62}\)

**Vaginal Flora — Transgender women**

The vaginal micoflora of transgender women who have undergone gender affirming surgery has been shown in one study to be a mixed micoflora of aerobe and anaerobe species usually found either on skin, in the intestinal microflora or with bacterial vaginosis.\(^{63}\)

Information regarding the transition status of transgender men and women may be useful for the provision of clinical advice related to abnormal vaginal swabs for bacterial vaginosis, however the laboratory use of the Nugent Score for the identification of bacterial vaginosis has not been validated for these populations.

**GENETIC TESTING**

Certain genetic tests are directed to identification of genetic changes where the interpretation depends on the sex-chromosome (X, Y) makeup of the individual being tested. For example, X-chromosome linked inherited disorders are interpreted differently for XY individuals (assigned male at birth) than XX Individuals (assigned female at birth). In X-linked disorders caused by mutations in genes on the X-chromosome, test results for an XX individual would typically be interpreted as an unaffected carrier female when a pathologic genetic variant is present in one of the two X chromosomes, due to the compensation of the other X chromosome in the XX configuration. Similarly, results for an XY individual would typically be interpreted as an affected male if a pathologic genetic variant occurred in a gene on the single X chromosome. Due to these issues, for certain genetic tests it may be necessary to collect information on an individual’s birth-assigned sex to ensure the accurate interpretation of genetic test results. Consideration should be given to the best way in which to report such tests, and to ensure that tests are not cancelled due to mismatch of the test requested with the patient identifiers provided on test requisitions.

In some cases, the genetic test itself may directly or indirectly reveal the X and Y chromosome makeup of an individual (for example, identity tests that include polymorphic genetic markers on the X and Y chromosomes). In the case of transgender individuals, the detection of X or Y chromosome material through such testing may not match with the identifiers provided on test requisitions or other patient documentation. It is important that laboratories recognize that a potential possibility for this discrepancy may be due to gender expression and consider the best way in which to appropriately investigate.
**Diversity of Sex Development**

In rare cases, the typical development of sex organs in a fetus may be disrupted by genetic abnormalities in the structure of genes on the X or Y sex chromosomes, or by hormonal imbalances during gestation, known collectively as disorders of sex development. In these situations, these rare cases may be detected at birth due to atypical anatomic sex features, or have atypical gonads detected during puberty. Disorders of sex development can include having genitalia of the opposite sex compared to the sex chromosomes (e.g. female genitalia with XY chromosomes) or having genitalia that are neither clearly male nor female. While individuals with disorders of sex development detected at birth are typically assigned one sex based on various features, more recently there is recognition that delaying this decision, for example by postponing the registration of sex of a newborn, may be of long term benefit to the child.

It is important to note that disorders of sex development are not the same as gender diverse identity. Some individuals identify with their assigned sex (if one has been assigned at birth), while others do not, and some choose to identify as intersex. Intersex people may or may not identify as transgender.

**BLOOD TRANSFUSION**

Blood transfusion processes for transgender patients have been given less attention and little is published about these practices. It is important that sex identification be clear in situations where emergency blood transfusion is needed. Most, if not all emergency transfusion protocols will issue O negative blood to all women of childbearing age in an emergency situation. These emergency transfusion protocols should also include transgender men who have retained their reproductive organs. Therefore, institutional transfusion policies should include issuing type O, Rh negative blood to any individual with assumed ability to become pregnant in order to prevent D alloimmunization.

**Blood donation**

In 2016 Canadian Blood Services implemented national blood donation criteria specific to the transgender population and these standardized criteria now apply to all transgender donors nationally. The criteria take into account two main risk factors — risk of HIV transmission and risk of transfusion associated acute lung injury (TRALI). Additionally, the eligibility to donate is based on the patient’s history of surgical transition. It is recommended that any blood collection organization develop blood donation criteria specific to the transgender population to facilitate inclusion of this demographic.
F. IQMH WORKING GROUP RECOMMENDATIONS

1. The laboratory should not cancel tests based on sex (e.g. hCG, PSA, Pap smear). Tumour markers and pregnancy tests should be performed without sex specificity.

2. Due to the paucity of literature on reference intervals for transgender patients, clinicians will always need to use clinical judgement in interpretation of results.

3. Use the reference intervals associated with the patient’s sex at birth if the person is not on hormonal treatment or undergone physiology altering surgery. This may be a decision only the clinician can make since the laboratory may not be provided with clinical information on transition.

4. Neither male nor female reference intervals are most appropriate when it is known that an individual is gender non-binary undergoing hormonal transition as some markers will fall within the male reference intervals and others within the female and results will change over time as transition progresses. Laboratories could consider adding a comment to all reports, for example “As different demographic populations can be very physiologically diverse (e.g. non-binary gender individuals), reference intervals provided on this report may not apply to all patients.”

5. Laboratories should also consider offering health care providers guidance on how best to interpret laboratory tests on gender non-binary patients undergoing hormone therapy treatment or who have had physiology altering surgery. Suggestions could include a website link to published literature or expert opinion.

6. Ensure cytology and histology staff expect the possibility of receiving tissue samples from transgender persons.

7. Ensure genetic testing is not cancelled due to mismatch of the test requested with the patient identifiers.

8. For certain genetic tests it may be necessary to collect information on an individual’s sex at birth to ensure the accurate interpretation of genetic test results.

9. Transfusion policies should include issuing type O, Rh negative blood to any individual with assumed ability to become pregnant.

10. Blood collection organizations should develop donation criteria specific to the transgender population.
### 11. SUMMARY

<table>
<thead>
<tr>
<th>Issues</th>
<th>IQMH WORKING GROUP RECOMMENDATION(S)</th>
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<tbody>
<tr>
<td><strong>Ethics and legal</strong></td>
<td>Revise applicable organizational policies to include gender identity/expression.</td>
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<td>Ensure staff members have both awareness and preparation to care for gender diverse persons with respect, compassion and equity. Include gender diversity in ethics training programs.</td>
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<td></td>
<td>Encourage staff to report any incidents of harassment or discrimination.</td>
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<tr>
<td><strong>Test order</strong></td>
<td>Requisitions should be modified to be inclusive of trans, gender-diverse and non-binary individuals by including fields for:</td>
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<tr>
<td>Non-disclosure of non-binary gender</td>
<td>• Sex at birth</td>
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<tr>
<td></td>
<td>• Administrative/legal gender (needed for billing purposes)</td>
</tr>
<tr>
<td></td>
<td>• Gender identity (if different from administrative/legal gender) (optional)</td>
</tr>
<tr>
<td>Lack of information provided to laboratory by the health professional ordering the test</td>
<td>EMRs, HIS and LIS systems should be modified to be inclusive of trans, gender-diverse and non-binary individuals by including fields for:</td>
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<td>It is recognized that modifications to information systems and requisitions will take time. In the absence of these modifications, laboratories and hospitals should consider solutions to collect relevant information during patient intake.</td>
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<td><strong>Patient presentation</strong></td>
<td>Revise applicable policies to include gender identity/expression</td>
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<tr>
<td>Environment not inclusive</td>
<td>Provide gender-neutral restrooms in hospitals and collection centres with appropriate signage.</td>
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<tr>
<td>Assumptions of gender identity</td>
<td>Provide a private space for asking sensitive questions and/or implement a system where patients can enter demographic information privately.</td>
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<tr>
<td>Incorrect use of pronouns</td>
<td>Consider solutions to avoid calling out names in group areas, and never use prefixes or honorifics.</td>
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<tr>
<td>Lack of process for the collection of additional demographic information</td>
<td>Display “respect in the workplace” posters that are gender inclusive and are visible to staff and patients.</td>
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<td>Display welcoming symbols (i.e., rainbow/positive space stickers) in inclusive spaces and/or on employee badges to indicate individual competency.</td>
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### Issues

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<th>Inability of information system to capture additional demographics</th>
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<td>Provide gender-inclusive literature.</td>
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<td>Provide staff with training on how to facilitate a positive interaction in situations where assumptions about gender expression might not match health card and/or requisition information.</td>
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<tr>
<td>In the absence of changes to laboratory information systems and requisitions, implement a system that enables consistent use of a patient’s correct name and/or pronouns to subsequent staff.</td>
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<th>Repetition of assumptions with subsequent healthcare encounters</th>
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<td>Review and revise accessioning procedures and acceptability criteria to include specific instructions for issues surrounding non-binary gender identities.</td>
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<td>The laboratory should not cancel tests based on sex specificity (e.g., hCG, PSA, pap smear).</td>
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<th>Sample accessioning Name and demographic incongruence</th>
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<td>interpretation</td>
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12. REFERENCES


59. Balion C. Interpretation of laboratory test results when gender is important: a case of a transgender man, Clinical Chemistry Rounds, McMaster University, November 17, 2017.


