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## Towards statistical best practices for gender and sex data

**Suzanne Thornton, Dooti Roy, Stephen Parry, Donna LaLonde, Wendy Martinez, Renee Ellis and David Corliss** call for a more inclusive – and informative – approach to collecting data on human gender and sex

**W**hen teaching introductory statistics, many instructors encounter the question: why do we typically use a significance level of 0.05 (or 0.01 or 0.10)? The answer is simple but not very gratifying: this is a matter of convention. Helpful guidelines are well established, but there are infinitely many possible significance levels a researcher could decide to use. A similar conundrum occurs when collecting data on socially defined attributes such as race or gender. Merriam-Webster defines the term “social construct” as “an idea that has been created and accepted by the people in a society”. Scientific endeavours must recognise that many qualitative human characteristics fit this definition and, as researchers, we are responsible for practising extra care when considering these traits as variables of interest in our studies.

This article is intended to equip statisticians and statistical practitioners alike with some basic concepts to help us move towards better practices for collecting and analysing data about human gender and sex. This is a pressing issue not just for marketing and public policy but also for scientific researchers who study human health.<sup>1</sup> To effectively implement the suggestions in this article one must first understand the terminology and concepts related to human sex and gender. We offer suggestions for implementing respectful terminology in data collection procedures and for writing questions that are appropriate for the concept being measured. Finally, we caution for the need to plan in advance of data collection for statistical measurement and disclosure issues arising from potentially small population sizes.

### Context and terminology

Figure 1 (page 42) is a Venn diagram representing three different aspects of sex and

gender identity. For many people, all three characteristics overlap; however, for gender and sex minorities (GSM) one or more of these characteristics may not align with the others.

### Gender

Though a nuanced understanding of gender may seem a new trend to some, the recognition of gender as a continuum actually has roots that stretch across the globe and into the ancient past.<sup>2,3</sup> In advocating for an understanding of gender identity that extends beyond a binary classification system, modern science is catching up with global historical and cultural wisdom.

The concept of gender can be broken into two components: gender expression and gender identity. Respecting someone’s gender identity is an ethical practice that honours the individual’s sense of self. Gender identity is a personal understanding of oneself; it comes from within. Gender expression refers to many possible expressions of gender, including attributes such as clothing, hair, mannerisms, and postures. Gender expression is like art in that it may be formed by an individual who wants to communicate something particular but whose work is subject to the interpretation of viewers who may or may not understand the individual’s intent. Furthermore, an individual’s gender identity and gender expression can change with time. For these reasons it is best never to assume any individual’s gender identity from their gender expression alone.

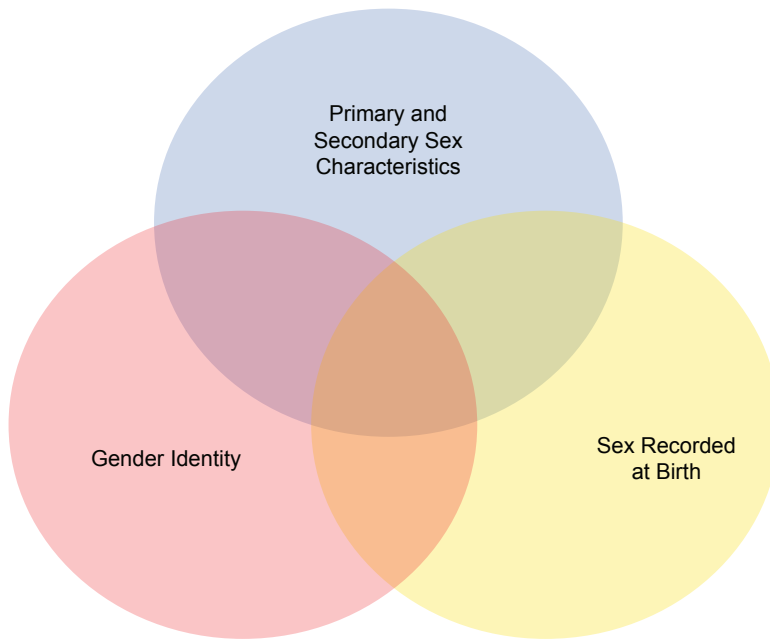
The enormity of gender identity is an immutable factor of the human experience, but the language with which we describe that experience is non-constant and changes with generations. Nevertheless, the purpose of data collection has always been to understand a population by capturing information in bite-sized, digestible pieces. Although information



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**Figure 1:** A Venn diagram representing three different aspects of sex and gender identity.

for their sex without further clarification, they risk losing important information by making the assumption that all participants understand the term in the same way. This is true not only for intersex participants but also potentially for transgender participants who may have undergone gender-confirming surgery. When collecting data on attributes that can have different meanings, the statistically trained researcher will be as explicit as possible about any working definitions to avoid misclassification bias.

### A multifaceted argument for inclusive data

Among the many reasons why researchers may want to be more inclusive in their data collection process, here we focus on two: the ethical treatment of human subjects, and the collection of better-quality data. While we do not claim to be experts in ethics, data is our specialty, and we have found that these two arguments overlap. Any ethically responsible researcher must be aware of the language needed to correctly identify different segments of the population under study. The fundamental goal of statistics is to articulate information about some population through the collection and analysis of data. According to the American Statistical Association, the ethical statistician must use “methodology and data that are relevant and appropriate, without favoritism or prejudice, in a manner intended to produce valid, interpretable, and reproducible results” (bit.ly/3GLuRt8). There is potentially much scientific information to be learned from the gender and sex qualities of human subjects – provided these characteristics are measured respecting the variability in identities and experience. Consider the following clinical trial example.

*Problem.* For clinical trials concerning treatments for mental illnesses, it is crucial to identify individuals who may have a higher risk of certain adverse events, including GSM. Transgender and non-binary patients may undergo hormone therapy as they transition to their true identity. Hormone therapy may significantly influence and impact the safety or efficacy of a drug, but most modern clinical trials are not designed to identify transgender patients, even if the patient voluntarily self-identifies as such. Furthermore, any additional data collected within a clinical

loss is inevitable when we apply this process to gender, a critical statistical goal is to design surveys and experiments to capture the most relevant bits of information.

### Sex

Despite the overwhelming tendency to treat sex as a binary variable, the term “biological sex” is not quite so cut and dried. When sex characteristics of individuals are of interest in a study, this can refer to primary or secondary sex attributes, genetic information, sex assigned at birth by a medical professional, or other characteristics. The most common use of “biological sex” seems to refer either to a person’s chromosomes or to their genitalia at birth, neither of which are actually binary.<sup>4</sup> A consensus statement published in 2005 endorsed the terminology “disordered/different sex development” (DSD) to describe individuals with congenital conditions in which the development of chromosomal, gonadal, or anatomic sex is atypical.<sup>5</sup>

However, the term “intersex” is preferred by many activists and advocates since it is not affiliated with a derogatory connotation like the word “disorder” which implies something that needs fixing (bit.ly/3oTx9QP).

Intersex people can be born with the differences mentioned above, or they may develop these differences later in childhood. People with ambiguous or atypical sex characteristics are often coerced into changing their bodies, usually at a very young age. Most surgeries to change intersex traits happen in infancy, and it is possible that an adult may not be aware of this procedure in their medical history.<sup>6</sup> This fact, together with an ever-changing definition of the term “intersex”, makes estimating the incidence rate incredibly difficult. Although estimates of the prevalence of intersex births vary, some studies estimate the prevalence to be as high as 2% of the population.<sup>7,8</sup>

We mention these points to illustrate that when researchers ask study participants

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**Table 1:** Common terms relevant to GSM. Definitions are derived from the National LGBTQIA+ Health Education Center ([bit.ly/3m3EISU](http://bit.ly/3m3EISU)) and the Human Rights Campaign ([bit.ly/3GHXgjt](http://bit.ly/3GHXgjt)).

<b>Cisgender</b>	An adjective used to describe a person whose gender identity aligns with the gender assigned to them at birth.
<b>Gender-affirming surgery</b>	Surgery that is performed to modify a person's body to be more aligned with that person's gender identity. This may include chest and genital surgeries, facial feminisation, and/or hair removal.
<b>Gender expression</b>	The many ways in which someone may express their gender identity. This can include clothing, behaviour, and mannerisms, which may be intentionally or unintentionally ambiguous.
<b>Gender identity</b>	One's innermost concept of self as male, female, a blend of both or neither; how individuals perceive themselves and what they call themselves. A person's gender identity can be the same as or different from their sex assigned at birth. Gender identity cannot reliably be inferred from gender expression.
<b>Gender non-conforming (GNC)</b>	A broad term referring to people who do not behave in a way that conforms to the traditional expectations of their gender, or whose gender expression does not fit neatly into a category. While many also identify as transgender, not all GNC people do.
<b>Gender or sex minority</b>	A catch-all phrase that includes transgender, non-binary, other gender non-conforming, and intersex people.
<b>Different sex development</b>	See <i>intersex</i> .
<b>Intersex</b>	An adjective that describes someone who has chromosomes, anatomy, or other sex characteristics that do not fit the typical definitions of female or male. This can include people with genetic predispositions to androgen sensitivity or people with hormones and genetics that indicate one sex but an anatomy that is typical of another sex.
<b>Misgender</b>	A verb that describes the action of referring to a person by a pronoun or other gendered term (e.g., Ms/Mr) that incorrectly indicates that person's gender identity. This is a significant source of emotional harm for transgender individuals.
<b>Non-binary</b>	A term for people whose gender identity exists outside of the gender binary of male or female. Many non-binary people identify as transgender since their gender identity is likely to be different from the sex assigned to them at birth.
<b>Sex assigned at birth</b>	The sex (typically male or female, but occasionally a neutral X) assigned to a newborn. Most often, this designation is based on the infant's anatomical characteristics.
<b>Sexual orientation</b>	An inherent or immutable enduring emotional, romantic or sexual attraction to other people. This concept is distinct from primary and secondary sex characteristics.
<b>Transgender</b>	An adjective used to describe a person whose gender identity is different from the gender they were assigned at birth. Note that although intersex and transgender identities may overlap, they are not necessarily co-occurring identities.
<b>Transition</b>	The often lengthy process whereby a transgender person begins to acknowledge their true gender identity in their private and/or public life.

trial setting (such as whether or not a patient is transgender or cisgender) is subject to a potentially lengthy review process.

**Solution.** Collecting information on both the sex assigned at birth and the gender identity of clinical trial patients can identify transgender participants while respecting their identities. Researchers can then examine these sub-populations to determine if there is an adequate representation within the sample and to investigate whether the efficacy and safety of the test drug are different for this group. This information is valuable to clinical practitioners who may be reluctant to prescribe what could otherwise be life-changing medication for their transgender and gender-non-conforming (GNC) patients.

It will take time and effort to transition to more inclusive – and informative – data collection practices. However, once this is achieved, the statistical models that

result may be useful for a wider range of the population. Furthermore, such careful attention to data collection will improve the ability of statistical analyses to differentiate signals from noise.

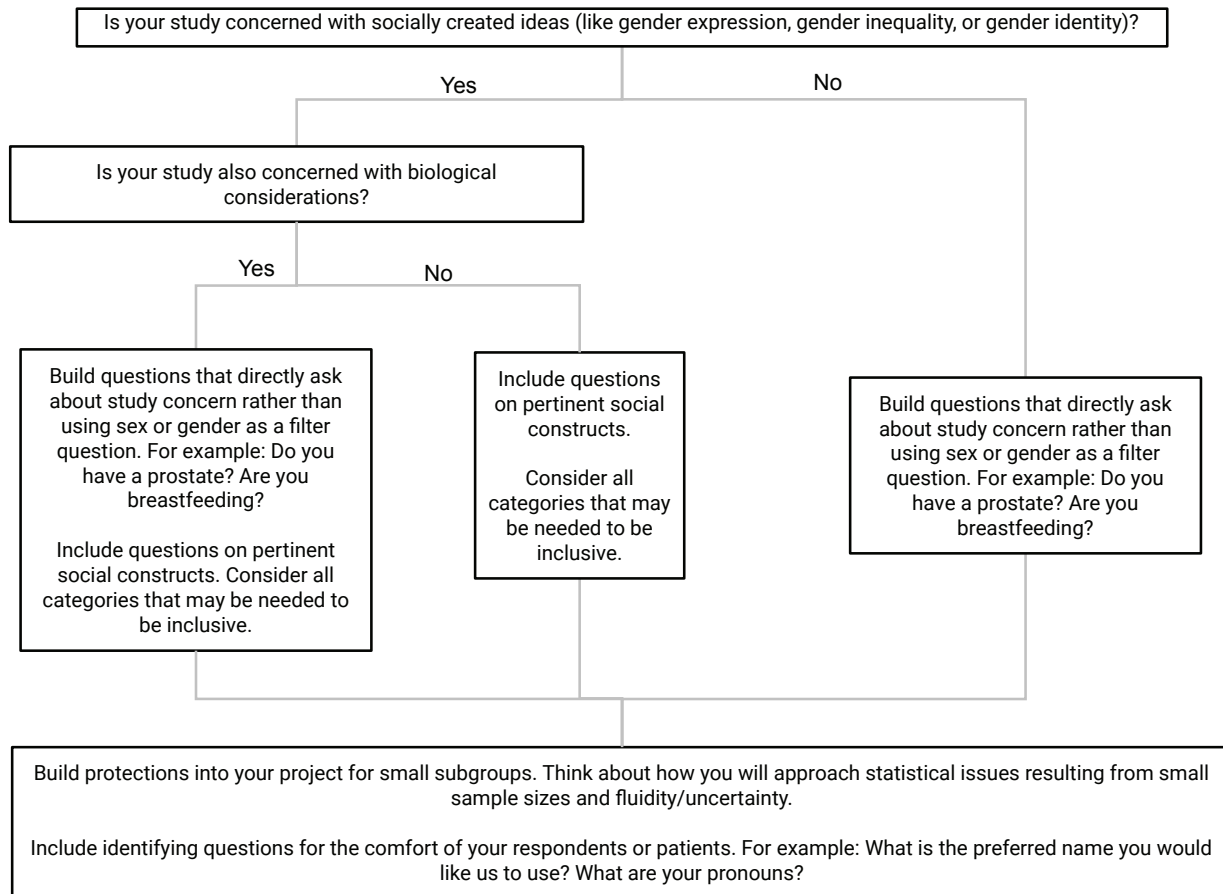
### Statistical considerations and practical guidelines

#### Consideration 1: Identify relevant information

Researchers often use the words “sex” and “gender” as interchangeable characteristics. This is a dangerous practice in that it will most certainly lead to some type of misclassification bias. If gender or sex are relevant features of a statistical model, the researcher must dig deeper and ask what is relevant to their study: gender or sex or both? This is merely an example of the more general statistical best practice that before collecting data, researchers should understand explicitly what

the variables of interest measure for each observational unit.

Gender and sex information does not necessarily need to be included in every study. Before beginning a project, researchers should determine whether it is possible that gender or sex may affect the efficacy of a treatment, say. If there is no reason to believe that gender or sex can moderate an effect, then they may not need to ask for this sensitive information. On the other hand, in cases where gender identity or sex characteristics are suspected to influence the efficacy of a treatment, a responsible researcher will explicitly state the underlying mechanisms of influence. For instance, if sex may affect the efficacy of some treatment, the researcher should identify which sex characteristics in particular are hypothesised to affect the treatment. Or perhaps whether or not someone is receiving hormone therapy treatment is the important factor. ▶



**Figure 2:** A flow chart outlining how to identify the relevant gender and sex information for a particular study.

► As a general guideline, it is better to ask a more specific question about these particular attributes than to use the words “gender” or “sex” as catch-all terms in the data collection process, because this avoids potential misclassification errors and data loss. For example, cisgender women, transgender women, and transgender men may all need breast cancer screening. Therefore, a survey that asks participants for their gender identity only will exclude transgender men and, conversely, a survey that asks participants for their sex assigned at birth only will exclude transgender women. Figure 2 outlines general steps for evaluating what information is relevant for differently motivated studies.

### Consideration 2: Centre inclusivity and respect

The Belmont Report identifies “respect for persons” as a basic ethical principle of

research, defined by two fundamental ethical convictions: that individuals should be treated as autonomous agents and that persons with diminished autonomy are entitled to protection.<sup>9</sup> It is crucial for researchers across disciplines to take extra measures to ensure that the respectful treatment of human subjects is an intrinsic feature of any of their human-centric scientific endeavours.

One important measure that expresses respect to participants is the explicit communication of the purpose behind collecting sensitive data. Participants have the right to understand why their information

is being collected and how it is going to be used and their identities protected. Another important consideration is to recognise that questions about sex and gender may cause an undue amount of stress or confusion for transgender and GNC respondents. If it is necessary to question a study participant about their sex, the researcher should clearly define what is meant by “sex” in a way that does not coerce the participant to adopt an inappropriate gender identity but instead emphasises specific sex characteristics without gendered language. (For example, asking whether or not a participant has ovaries is not gender-specific, whereas asking a participant if they are a woman is.)

In situations where the data analyst has no control over the data collection procedure, such as a meta-analysis, the analyst is responsible for noting any ambiguities or possible sources of bias in the data at hand.

**It is better to ask a more specific question than to use the words “gender” or “sex” as catch-all terms**

## There is potentially much scientific information to be learned from the gender and sex qualities of human subjects – provided these characteristics are measured respecting the variability in identities and experience

If gender information was collected but there were no options for people who did not identify as a man or a woman, this is important to note because the study is limited by not applying to GNC populations. If the study collected information on the sex of subjects, the data analyst should strive to understand this variable in the context of the original study. In the resulting analysis, the researcher can still demonstrate respect for the human subjects by discussing how sex was coded and what particular sex characteristics were probably of interest.

### Consideration 3: Protect the participant and the data

We regularly find ourselves being asked to provide our sex for events such as doctor's appointments, filling out census forms, registering a profile on a social media page, or applying for a job. For cisgender people, these questions may not cause a second thought, but for transgender and GNC people, these questions can elicit not just mild discomfort, but feelings of dread and fear for personal safety. There are many reasons why a person may not want to publicly reveal that their sex assigned at birth does not align with their gender identity.<sup>10,11</sup> If a person is verbally asked to identify their sex and/or gender identity in, say, a doctor's waiting room, a transgender patient may feel vulnerable to harassment. From a statistical perspective, when protection and personal privacy cannot be guaranteed for the sub-populations most vulnerable to the greatest degrees of harm from data misuse, a study will likely suffer from severe non-response bias. This is especially true if an individual feels their safety is threatened. More generally, ethical scientists recognise that data collection should not cause undue levels of stress to participants.<sup>12</sup>

In practice, data privacy is complicated by a lack of general, consistent standards, and the typical safety standards of one group may not be adequate to protect the identities of transgender individuals.<sup>13</sup> The US Department

of Homeland Security, for example, protects "sexual orientation" and "lifestyle information" without mentioning sex identity data.<sup>14</sup> This conflicts with data privacy standards for other departments, including the Department of Health and Human Services and the Department of Education.

In general, the privacy policies of US government agencies focus on information capable of uniquely identifying an individual more than sensitive information about that individual: for instance, Department of Education standards protect the address of a student's parents but not the student's grades. The privacy of personal information, especially in small studies, can leave minorities vulnerable to discovery if the information collected is too specific. For example, a transgender patient's identity may be identifiable from unnamed data if, say, it includes particular hospital information or information about a specific treatment type. It is possible that GSM may be identified even if a study adheres to health information privacy requirements.<sup>15</sup> Thus, it is important that security and privacy measures are taken into account at the data collection stage.

### In summary

Transgender people and other gender and sex minorities have always been part of society, even if these identities have not been encoded in previous data collection efforts. It is a scientific reality that much research is focused on response variables that can be moderated by gender identity, sex characteristics, or both. It is time to end the erasure of GSM in our standard data collection procedures both for the sake of inclusivity and for the sake of decreasing measurement error and bias. The actionable steps we implore statistical practitioners to take include identifying which information is relevant and understanding the importance of respecting and protecting participants' identities. ■

### Disclosure statement

The authors declare no competing interests.

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