

## EDITORIAL

## Recording sex and gender data in clinical settings

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On April 16, 2025, the United Kingdom (UK) Supreme Court ruled that the legal definition of “woman” refers to biological females; the judgment also stated that biological sex is “binary” [1]. Less than ten days later, on April 25, 2025, the *BMJ* published an editorial titled “Sex and gender should not be conflated in medical data” [2]. In the editorial, authors Margaret McCartney and Susan Bewley critique the interchangeable use of sex and gender in medical data collection — a practice prevalent in the recordkeeping of the National Health Service, UK — and argue that such a conflation runs the risk of medical practitioners making erroneous decisions and diagnoses [2]. While recognising that “A few people are found to have one of a small number of clinically recognized variations in sex development,” the authors too suggest that biological sex is a binary (“male or female”) [2].

Capturing sex data in clinical settings is undoubtedly important; as McCartney and Bewley argue, “multiple symptoms, differential diagnosis, laboratory reference ranges, imaging, and clinical risk calculators are sex specific” [2]. However, scientists and clinicians are yet to reach a consensus on how best to capture sex data. Some suggest that the collection of sex data — which is seen as a combination of biological variables — should take precedence over data collection on the lines of gender, which is commonly seen as socially constructed [2]. Others argue that “biological” sex is itself socially constructed [3], and yet others suggest an integrative approach that seeks to collect both sex and gender data in clinical settings [4].

In this editorial, I address the issue of recording sex and gender in clinical data collection. I highlight potential issues in the collection of sex data, including the limitations of (a) using binary categories (male/female) to record an individual’s sex and (b) using sex-assigned-at-birth (SAB) as a proxy for chromosomal, gonadal, gametic, hormonal, anatomical, morphological and functional states that together comprise an individual’s sex. I suggest that an accurate, ethical, and transgender- and intersex-affirmative medical practice entails the mandatory collection of both sex and gender data, and in more than two categories<sup>1</sup>.

**Sex is not binary**

Historians and philosophers of science have argued that the binary model of biological sex is a relatively recent invention of eighteenth-century anthropometry and comparative anatomy. For example, historian and sexologist Thomas Laqueur points out in *Making Sex* (1990) that the “two-sex model”, ie, the model of sex that saw “male” and “female” as distinct and incommensurable categories, emerged in eighteenth-century Europe as a result of epistemological and political developments (See [5] for details); prior to that, the “one-sex model”, which saw the female body as an interiorised rendition of the male body, was widely accepted [5]. This acceptance was evident even in the language early anatomists used to refer to male and female reproductive organs: for example, Laqueur mentions the Greek anatomist Galen using the same word — *orcheis* — to refer to both the ovaries and testicles [5].

By the nineteenth century, however, sexual dimorphism had emerged as one of the measures of racial supremacy; sexologist Richard von Krafft-Ebing, who pioneered the belief that homosexuality is a psychiatric disorder, wrote in 1886 that “the higher the anthropological development of the race, the stronger these contrasts between man and woman” [6]. Since then, the two-sex model was upheld through the nineteenth and twentieth centuries by referring first to the differences between male and female gonads and then the differences in “male” and “female” hormones [6]. Later, with the rise of genetics, a “unified theory of sex” emerged in the twentieth century, which brought together two variables — chromosomes and hormones — and solidified the two-sex model [6].

In stark contrast to the assertions of the UK court and McCartney and Bewley, biologists and clinicians are increasingly recognising that biological sex is not a binary [7, 8, 9, 10]. For example, bioethicist Christoph Rehmann-Sutter and endocrinologist Olaf Hiort along with several colleagues challenge the gametic conceptualisation of sex: the idea that since “there are only two kinds of functioning gametes...therefore, sex must be reduced to two mutually exclusive categories” [8]. Others argue that sex cannot be reduced to only gamete production, since individuals who do not produce functional gametes are also designated a sex category [8, 11] (for example, a male individual who does not produce functional sperm is still designated as “male”). Multiple other observations challenge the two-sex model. Biologist Ruth Hubbard pointed out in 1990 that anthropometric variables that are typically categorised as “masculine” or “feminine”, such as primary and secondary sexual characteristics, often show a bell-curve distribution instead of a discrete binary. Reporting mean differences in primary and secondary sexual characteristics between male and female groups obscures the within-group variability as well as the overlap between groups [6, 12]. Similarly, a slew of endocrinological discoveries in the twentieth century challenged the conception of

oestrogen and testosterone as “female” and “male” hormones; it is now well-accepted that these hormones are presented in all individuals in different percentages and that they perform many functions in the body that are not directly related to sexual development [6]. Further, large-scale population studies in the 1950s and 1960s identified as many as 27 karyotypes of sex chromosomes, including XO (only one X chromosome), XXY (two X and one Y chromosome), XXX (three X chromosomes), and XYY (one X and two Y chromosomes) [6], challenging the neat division of biological sex along chromosomal lines.

### Sex (assigned-at-birth) is not enough

That said, this editorial neither posits itself against the collection of sex data, nor does it argue against a complete disavowal of the categories of male and female. My goal, instead, is to highlight the issues in current practices of sex data collection in clinical settings. One such issue is the difference between what the term “sex” means versus what it invokes. Human sex is a combination of chromosomal, gonadal, gametic, hormonal, anatomical, morphological and functional attributes: That is, an individual's sex is dependent on the combination of sex chromosomes they possess (chromosomal sex), the expression of genes in the chromosomes (and not only sex chromosomes), the formation of gonads (gonadal sex), the production of gametes (gametic/reproductive sex), the production of specific amounts of sex hormones (hormonal sex), the body's response to these hormones through proteins called receptors, and the formation and maturation of internal reproductive organs (reproductive sex) and external genitalia (genital/morphological sex) [3].

However, in clinical settings, an invocation of sex typically refers to “sex assigned at birth” (SAB): the sex that is assigned to a newborn by a medical practitioner upon their evaluation of the newborn's genitalia. However, genitals are neither the only markers of sex nor does sex development begin — or stop — at the birth of an individual. This calls into question whether recording SAB is adequate for accurate clinical practice.

In many cases, when the different “layers of sex” [3] — ie, chromosomal, gonadal, hormonal, etc — align with each other, documenting SAB in clinical data might be adequate for a medical practitioner or researcher to gain insight into an individual's sex. For example, an individual with an XY combination of chromosomes develops functional male gonads and reproductive organs and expresses male secondary sexual characteristics. The picture, however, gets complicated when these layers do not align. Consider the case of androgen insensitivity. In this case, even though the foetus has a chromosomal sex of XY and the foetal gonads produce androgens (such as testosterone), a variation in the androgen receptor leads to other cells in the body not responding to these androgens [13]. As a result, and depending on the extent of androgen insensitivity, an individual may either develop a vulva, a penis and a scrotum, or some form of ambiguous genitalia. In fact, a person with complete androgen insensitivity might be assigned female sex at birth, even though they have a chromosomal sex of XY, and a male gonadal sex. In such a case, documenting SAB does not accurately capture the individual's sex.

Androgen insensitivity is one example of what are called “variations in sexual development” (VSDs) or “variations in sex traits” (VSTs) that lead to an individual being intersex. While clinicians differ on the exact number of such variations, the National Academies of Sciences, Engineering, and Medicine, United States of America (NAS, USA) listed 33 clinically documented “intersex conditions” in a 2022 report [14]. Conservative estimates suggest that one in every 5000 people in the USA is intersex [15]. Reliable statistics for the number of intersex persons in India are not available, but according to one media report, 10,000 intersex babies are born in the country every year [16]. Even though the report does not mention the total number of babies born that year — a number crucial to compute what percentage of babies are born intersex, activists have argued that this number is an undercount, since “parents often do not register their baby as intersex” and because “infanticide, abandonment and mutilation” of intersex babies is common [16]. Further, many VSTs are discovered only later in life, by which time the individual has already been assigned a sex at birth.

Therefore, using binary categories of SAB (male or female) as a proxy for different variables that comprise sex has several limitations: one, it does not provide a complete picture of an individual's sex and only indicates an individual's genital state at the time of birth. Two, it does not record VSTs, which in turn invisibilises intersex people.

In fact, there are instances when using SAB as a proxy runs the risk of inaccurate interpretation of clinical data. For instance, it has been reported that cervical cancer incidence and mortality calculations wrongly retain female individuals who have undergone hysterectomy while counting the number of individuals at risk; this leads to an underestimation of the actual incidence and mortality rates of cervical cancer [17, 18]. This is because the at-risk population is tracked by its SAB (ie, female) instead of its more relevant anatomical configuration (ie, presence or absence of a cervix). According to one estimate, the cervical cancer mortality rate for black women in the USA almost doubled after it was corrected for individuals who had undergone a hysterectomy [18]. Similarly, it is typically believed that male individuals are at a higher risk of cardiovascular diseases as compared with female individuals [19]. This masks the actual correlate of cardiovascular risk: the cardioprotective role of oestrogen [19]. Indeed, it has been found that postmenopausal women and women over the age of 75 are at a higher risk of strokes and hypertension as compared with men of the same age group [19]. Further, a male individual with higher

oestrogen levels might be better protected against cardiovascular risks as compared with a male individual who has lower oestrogen levels. These examples suggest that capturing SAB data alone does not de facto imply better clinical decision making and diagnosis. This is why the 2022 NAS report on measuring sex, gender identity and sexual orientation argues that “Direct measures of sex traits better represent specific biological mechanisms that can produce observed sex differences.” [14] Doing this in all clinical scenarios might not be feasible but can improve clinical data interpretation and practice in cases such as those highlighted above.

### Gender data matters

Having discussed the limitations of relying on SAB as a proxy for biological correlates of an individual's sex, I will discuss why it is important to collect self-reported gender data, especially when it comes to clinical decision-making for transgender and intersex individuals.

Transgender and intersex people might require clinical interventions that differ from those required by cisgender people. These clinical interventions include not only gender-affirming procedures but also specific considerations in routine clinical cases [20]. For example, a transgender woman might be taking a combination of testosterone blockers and oestrogen supplementation as a part of her medical transition journey. In such a case, a clinician may have to decide whether a certain drug commonly used for treating a symptom interacts with either of these two pharmacological agents. Such clinical decision-making is important for successful patient care, and it requires a knowledge of a person's gender — and in some cases, a detailed account of their gender transition journey — in addition to their SAB.

Collecting gender data could also be the first step in regaining transgender and intersex people's trust in the medical establishment. Several studies, globally and in India, show that gender- and sexually marginalised communities face continuing discrimination at the hands of healthcare professionals [21, 22, 23, 24]. This has led to an erosion of trust that transgender and intersex people have in the healthcare system. Consider the case of Covid-19 vaccine hesitancy among transgender people in India. It has been reported that this hesitancy stemmed partly from the incorrect and disrespectful category used to collect gender data by the vaccine appointment booking portal CoWIN: The portal did not have the category “transgender” listed under “Gender”; it instead used the ambiguous category “others” in addition to “male” and “female” [24]. “Such nebulous data categories can be stigmatizing, unclear and othering,” the researchers D'souza et al write [24]. This highlights not only the importance of collecting gender data in medical interventions but also doing so in ways that are affirmative and respectful of transgender and intersex persons.

### Recommendations

In this editorial, I have highlighted why collection of sex data through binary categories of male and female is a problematic practice, why using SAB as a proxy for the different variables that comprise an individual's sex might obscure more than it reveals, and why collecting gender data — in addition to sex data — might be important for making clinical practice transgender- and intersex-affirmative. One question, then, remains: how do we collect sex and gender data in a manner that is accurate, ethical, and cognisant of transgender and intersex people? In what follows, I offer as a response four principles. I also draw upon the 2022 NAS report titled *Measuring sex, gender identity, and sexual orientation* to provide examples of how these principles may be translated into questionnaires.

#### ***Simultaneous collection of sex and gender data***

Leaving out either sex or gender data can lead to the conflation of two different conceptual categories that are also experienced differently by different people (for instance, transgender people often report feeling a sense of dysphoria with their SAB — an experience that is uncommon among cisgender people). In contrast, collecting both sex and gender data can aid in identifying and enumerating intersex and transgender populations and tailoring clinical services to their needs.

To collect both sex and gender data effectively, the 2022 NAS report recommends a “two-step approach” [14]. This approach involves the use of two questions: one that asks an individual their sex assigned at birth, and the other that asks their current gender identity. This approach, which has been tried successfully in several clinical settings (see [14] for details), recognises both sex and gender as temporally shaped variables, and can identify not only those people who explicitly identify as transgender, but also those who use different terms to describe their gender-diverse experience [14].

#### ***Collection of sex and gender data in more than two categories***

Since neither sex nor gender can be categorised neatly into the male-female or man-woman binaries, it is imperative that sex and gender data be collected in more than two categories. For instance, the 2022 NAS report suggests collecting SAB data in at least three categories: male, female, and intersex [14]. Likewise, it suggests that current gender identity be captured through

multiple categories: man, woman, transgender, non-binary, and a blank space where an individual can state a gender identity not captured accurately by the other terms [14]<sup>2</sup>.

The 2022 NAS report recognises that for some indigenous communities, such as Native American or Alaskan natives, the word “transgender” might not accurately capture culture-specific gender-diverse experiences. Hence, the report suggests the inclusion of “two-spirit” as another category under current gender identity [14]. In the Indian context too, gender and sexuality studies scholars have pointed out that the use of the umbrella term “transgender” to refer to indigenous gender-diverse communities, such as the *hijras*, *kothis*, *jogappas*, and *shivashaktis*, wrongly homogenises people with different experiences of gender, community, and identity [25]. Therefore, questionnaires recording gender identity in an Indian context should also include these terms as categories.

### **Complementing SAB data with more refined and relevant sex traits/attributes**

Given that a very miniscule percentage of intersex people are assigned intersex at birth, the “intersex” option under SAB discussed above might not be adequate to identify intersex individuals [14]. Therefore, the 2022 NAS report recommends including separate questions that ask individuals (a) whether they have sexual traits that “do not fit the typical definition of male or female”; and (b) whether they have been identified to have VSDs by medical professionals. In addition, more refined data on the exact kind of VSD/VST can be recorded using a question that lists commonly recognised VSDs (such as androgen insensitivity) along with a blank space where an individual can mention a VSD not included in the list<sup>3</sup>.

### **Sensitisation of healthcare professionals**

The success of these approaches is contingent on the presence of clinicians and support staff sensitive to the healthcare needs of transgender and intersex persons. Unfortunately, prior studies suggest that healthcare personnel in India are not well-acquainted with transgender [20] and intersex people [26]. Coupled with prejudicial and discriminatory attitudes of healthcare professionals against transgender and intersex people, this leads to gender- and sex-diverse people facing barriers in accessing healthcare, including invisibilisation of their transgender or intersex identities [20, 26]. This underscores the need for sensitising healthcare professionals on the lived experiences of transgender and intersex people, their healthcare needs, and transgender- and intersex-affirmative data collection protocols (such as those recommended by the 2022 NAS report).

Overall, these recommendations, if implemented, can lead to more refined sex and gender data collection in clinical settings, recognise and enumerate transgender and intersex people effectively, and aid physicians in tailoring services to the needs of these communities long marginalised in healthcare settings.

#### **Notes:**

<sup>1</sup> This editorial focuses only on adult transgender and intersex people, and not transgender, intersex, gender non-conforming or questioning children and youth. For clinical guidelines on the latter, please see [27, 28, 29].

<sup>2</sup> During discussions with other working editors of the *Indian Journal of Medical Ethics*, one clinician pointed out an alternative approach to collecting gender data without succumbing to the binary categories: using a blank space where individuals can self-report their gender identity without listing any categories. One potential challenge in this approach is that people might self-report their gender in different ways (for example, a transgender woman might use the terms “transgender”, “transgender woman”, “trans woman”, “third gender”, etc. to report her gender). This might lead to challenges in data compilation. Thus, I suggest that gender identity be documented in clinical settings using a combination of well-accepted categories and a blank space. However, the exact approach for documenting gender data should be developed by clinicians in consultations with transgender and gender non-conforming people.

<sup>3</sup> Like in the case of gender identity, alternative approaches to documenting VSDs/VSTs include using only a blank space where individuals can self-report VSDs/VSTs that they have been identified to have. Once again, instead of recommending one approach over the other, I suggest that intersex people be consulted while deliberating on the exact approach for documenting sex traits/attributes.

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