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Impact of the use of self-perceived gender identity versus biological gender on the interpretation of laboratory tests: clinical and safety implications intransgender individuals

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ABSTRACT

Laboratory medicine relies on sex-specific reference ranges for accurate interpretation. However, electronic records often register legal or self-identified gender, which may not reflect biological sex. This discordance can lead to misclassification of laboratory results and represents a potential patient-safety risk, particularly in transgender individuals. A retrospective cross-sectional study was conducted including 385 adults from a tertiary hospital. Thirty-eight sex-dependent laboratory parameters were analyzed. Each result was first interpreted using biological-sex reference ranges and then reassessed under the opposite sex to simulate potential misclassification. Significant differences occurred in 76.3% of parameters. In 23.3% of tests, discrepancies exceeded twenty percent, especially in sex hormones, renal function markers, and tumor markers. These divergences were clinically relevant when values fell within pathological ranges, indicating a meaningful risk of diagnostic error. Using gender identity alone for laboratory interpretation can result in diagnostic and therapeutic mistakes. Clinical practice should integrate biological sex, self-identified gender, and hormonal treatment status. Healthcare systems must adapt electronic health records and laboratory information systems to incorporate multiple sex-related fields to improve diagnostic accuracy and patient safety.

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Transgender health; laboratory medicine; gender identity; patient safety; diagnostic misclassification

Introduction

Modern medical practice is grounded in the integration of clinical, imaging, and laboratory data to achieve accurate diagnoses and guide effective therapeutic decisions. Within this process, the clinical laboratory plays a crucial role by providing objective, quantitative information about the patient's physiopathological state. Accurate interpretation of laboratory test results requires careful consideration of biological variables such as age, physiological status, and, most importantly, biological gender. Numerous parameters including hemoglobin concentration, creatinine levels, estimated glomerular filtration rate (eGFR), plasma lipids, and hepatic enzymes are physiologically modulated by gender due to genetic, hormonal, and body composition differences (Buttarello, 2016; Hembree et al., 2017; Lippi et al., 2007; Soldin & Mattison, 2009; van den Berg et al., 2020; Zhang et al., 2020).

In this context, the legal recognition of gender identity, which in many jurisdictions allows individuals to change their legal gender marker without requiring medical or surgical intervention has introduced a new layer of clinical complexity. Although this legal recognition represents significant progress in terms of human rights, it may lead to a disconnect between the legally registered gender and the biological gender, with potentially adverse consequences in clinical care. This is particularly relevant in settings

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where electronic health records (EHRs) and clinical decision systems rely on gender fields for automated operations (Deutsch, 2016; Deutsch and Buchholz, 2015; Reisner et al., 2016; Safer & Tangpricha, 2019).

One of the most affected areas is laboratory medicine, where gender specific reference ranges are automatically assigned based on the recorded gender marker. The absence of a clear distinction between self-perceived gender and biological gender may result in misinterpretation of results with clinical consequences. For instance, a trans woman legally registered as male may present hemoglobin levels that fall within the male reference range but would be considered elevated or even pathological in a female physiological context that has not been fully masculinized (Getahun et al., 2018; Unger, 2016). Similarly, kidney function estimation using equations like CKD-EPI varies by gender and may overestimate or underestimate glomerular filtration rate, potentially altering therapeutic decisions (Levey et al., 2009).

In laboratory medicine, a culture of safety is widely implemented and aimed at preventing adverse events that affect patients.

From a patient safety standpoint, this scenario represents a predictable and preventable clinical risk. Laboratory safety frameworks describe three key phases in the analytical process: preanalytical, analytical, and postanalytical. Among these, the preanalytical phase accounts for up to 70% of laboratory errors, with incorrect demographic data (age, sex/gender, diagnosis, medications) being one of the most common causes (Carraro & Plebani, 2007; Lippi et al., 2011; Plebani, 2006). In this regard, the exclusive use of self-perceived gender in electronic records without an explicit field for biological gender or clinically relevant characteristics constitutes a systematic preanalytical error, potentially leading to diagnostic, prognostic, and therapeutic misjudgments (Lippi & Plebani, 2018).

Despite ongoing progress in laboratory digitization and automation, the lack of standardization in collecting and using gender versus sex data introduces uncontrolled variability, which compromises the traceability, reproducibility, and clinical reliability of results. The laboratory risk management literature emphasizes the importance of implementing quality control systems, standardized operating procedures, and verification algorithms to mitigate such errors (ISO 15189:2022, 2022; Sciacovelli et al., 2011). Since the publication of the report To err is human, which referred to medical errors affecting patient care, much progress has been made. Although laboratories contribute to less than two percent of errors, it should be noted that more than eighty-five percent of these errors are preventable. Within quality criteria, much progress has been made in the use of reference values not only by gender, but also by age, population, and patient status. Incipiently, people with self-perceived gender are beginning to be considered as patients who should also be taken into account. Not from the point of view of patients undergoing hormone treatment who need to be monitored, but as patients with unique characteristics. Not all transgender patients undergo hormone therapy or surgical interventions, and this has implications for the interpretation of laboratory results. Moreover, a culture of patient safety requires that these new sources of risk be formally recognized, and that institutional policies be designed to collect both biological gender and self-perceived gender in a confidential, respectful, and operationally useful manner (Institute of Medicine, 2000; James et al., 2016).

The vision of patient safety culture, coupled with the need to obtain increasingly accurate and reliable laboratory results, means that progress must be made in establishing reference values adapted to the needs of the entire population (Cardillo et al., 2024).

This article explores the emerging problem arising from the misalignment between self-perceived gender and biological gender in the clinical laboratory setting, within the framework of patient safety and preanalytical error management. The incidence of this problem in Spain is estimated at 0.1%, which means that more than four million people are affected. It also proposes operational recommendations for implementing safe, inclusive, and scientifically robust practices, in line with international guidelines.

Materials and methods

We designed a retrospective, cross sectional, observational study to analyze the impact of self-perceived gender on the interpretation of laboratory parameters sensitive to biological gender. Our hypothesis assumed that using a gender marker that differs from biological gender could lead to errors in classifying results as normal or pathological in clinical laboratory settings.

The study was conducted at the Regional University Hospital of Málaga, which serves a population of over 600,000 residents and acts as a referral center for more than 1.2 million inhabitants in the province. The hospital has more than 1,200 beds and provides care across all medical and surgical specialties, including the laboratory. This represents a broad, representative, and diverse sample of the population. The study used data from the Servolab v.4 Laboratory Information System (LIS) by Siemens Healthineers, covering the full calendar year of 2024 (January to December). The sample size was calculated based on a population of 749,546 patients, assuming 50% heterogeneity, a 5% margin of error, and a 95% confidence level. The estimated required sample size was 385 patients. This data was applied to every test and gender.

The parameters selected for analysis were those with gender specific reference values as defined by the reagent manufacturers and included in the laboratory's service portfolio. The following analytes were studied:

General Biochemistry: Uric acid, creatinine (Jaffe method), urinary creatinine, creatine kinase (CK), alkaline phosphatase (ALP), gamma glutamyl transferase (GGT).

Tumor and Specific Markers: Prostate specific antigen (PSA), human epididymis protein 4 (HE4), calcitonin.

Lipids and Plasma Proteins: Apolipoprotein A1 (Apo A1).

Sex and Related Hormones: Estradiol, 17 OH progesterone, androstenedione, dehydroepiandrosterone sulfate (DHEAs), follicle stimulating hormone (FSH), luteinizing hormone (LH), progesterone, testosterone, anti Müllerian hormone (AMH), sex hormone binding globulin (SHBG), leptin, growth hormone (GH), pregnenolone.

Hematology: Hemoglobin.

These analytes were chosen for their well-documented physiological variation by gender, and their clinical relevance in the diagnosis, screening, or monitoring of endocrine, metabolic, oncological, and reproductive disorders (Buttarello, 2016; Hembree et al., 2017; Lippi et al., 2007; Soldin & Mattison, 2009; van den Berg et al., 2020; Zhang et al., 2020) (Table 1).

Exclusion criteria and patient selection

Patients under the age of 18 were excluded from the study. A random number generator was used to select the number of patients required to meet the minimum sample size for each analyte, 385 patients per test and gender. When a test did not reach the minimum sample size, it was excluded from the final analysis. Throughout the process, access to the patient's identifying data was blocked except for age and gender.

The guidelines of the Helsinki Declaration were followed throughout the process.

Analytical procedure

For each analyte, patients of both genders were classified as having either normal or abnormal (pathological) values based on gender specific reference intervals established by the laboratory. These classifications were applied according to the original gender recorded at the time of the test request, considering age adjustments when required by the assay.

There is no possibility of error in the collection of gender data, as it is automatically captured from the regional health system database.

Subsequently, the recorded gender of each patient was switched to the opposite category (male to female, or female to male), and the same results were reclassified using the reference ranges corresponding to the modified gender.

For analytes in which reference ranges depend on the hormonal cycle in females, and such clinical information was unavailable, both the minimum and maximum cutoff values were used to simulate classification under the opposite gender. This ensured that all considered values remained definitively outside the corresponding normal reference ranges when testing under the altered gender.

Table 1. Analytical tests whose normal values depend on the patient's sex and age.

Parameters	Units	Male	Female
Uric acid	mg/mL	<60 years: 4.4–7.6 >60 años: 3.6–8.3	<60 years: 2.3–6.6 >60 years: 2.2–7.7
Androstendione	ng/mL	0.4–3.5	0.3–2.4
AMH	ng/mL	0.77–14.5	20–24 years: 1.22–11.7 25–29 years: 0.89–9.85 30–34 years: 0.57–8.13 35–39 years: 0.15–7.49 40–44 years: 0.027–5.47 45–50 years: 0.01–2.71
Apo A1	mg/mL	110–205	125–215
Calcitonin	pg/mL	0–12.69	60–140
CK	U/L	<11 years: 150–499 11–17 years: 94–499 >17 years: 39–305	<14 years: 94–391 14–17 years: 53–269 >17 years: 26–192
Creatinine	mg/mL	>12 years: 0.7–1.3	>12 years: 0.55–1.02
Urine creat.	mg/mL	70–150	60–140
DHEAs	ng/mL	10–14 years: 244–2470 14 – 19 years: 702–4920 19–24 years: 1600–4920 24–44 years: 900–4490 44–64 years: 443–3310 64–74 years: 336–2490 74–99 years: 162–1230	10–14 years: 339–2800 14 – 19 years: 651–3680 19–24 years: 1480–4070 24–44 years: 609–3400 44–64 years: 189–2560 64–74 years: 150–2460 74–99 years: 150–1540
Estradiol	pg/mL	0–40	Follicular phase: 19–144 Luteal phase: 56–214 Ovulation: 64–3 Menopause: <32
Alkaline phosph.	U/L	13–17 years: 115–471 17–19 years: 53–149 >19 years: 45–117	13–17 years: 53–255 17–19 years: 43–86 >19 years: 45–117
FSH	mUI/mL	1.5–14	Follicular phase: 3–10 Luteal phase: 1.9–9 Ovulation: 5.20 Menopause: >30
GGT	U/L	15–85	5–55
GH	ng/mL	0.02–1.23	0.06–6.88
Hemoglobin	g/dL	13.2–16.6	11.6–15
Leptin	ng/mL	2–6	3.12
LH	mUI/mL	1.4–7.7	Follicular phase: 1.5–10 Luteal phase: 0.10 Ovulation: 5.20 Menopause: >14
Pregnenolone	ng/mL	Prepuberty: 0.13–2.05 Postpuberty: 0.23–1.73	Prepuberty: 0.14–2.25 Postpuberty: 0.15–1.32
Progesterone	ng/mL	0.27–0.9	Follicular phase: 0.41–1 Luteal phase: 0.41–16.18 Menopause: 0–1
17OH Prog.	ng/mL	0.1–2	0.2–2.9
PSA	ng/mL	0.3–3	N/A
SHBG	nmol/L	15–50	26–110
Testosterone	ng/mL	0–12 years: 0.1–1 >12 years: 2.7–10	>12 years: 0.1–0.8

Statistical analysis

Data were processed using spreadsheet software and statistical packages (IBM SPSS v.26 and Microsoft Excel). The following statistical metrics were calculated: absolute and relative frequencies of reclassified results; percentage difference in abnormal result prevalence between original and modified gender and categories. For sufficient sample sizes, Z tests for the comparison of proportions were applied.

It was decided not to apply multiple comparison correction because, according to the study design, 385 patients of each different sex were selected for each test. This method prevented the required number of patients from being reached in most tests.

No clinical interventions were performed, and no patient identifiers were used. The dataset was double anonymized, and the study was considered exempt from informed consent requirements, in accordance with institutional regulations governing retrospective studies. The study did not involve any procedures that could affect patient care or present ethical conflicts; therefore, approval from the institutional ethics committee was not required.

Results

A total of 38 gender dependent laboratory parameters were evaluated. For the leptin, anti-Müllerian hormone, alkaline phosphatase, and pregnenolone tests, the necessary number of samples was not obtained. In the case of progesterone, no results were obtained from male patients. No results were obtained in PSA studies assigned to female patients. In the remaining tests, the necessary number of patients for the analysis was obtained.

Statistically significant differences ($p < 0.05$) were found in 29 of these parameters when comparing pathological classification using the patient's biological gender versus self-perceived gender. Notably, 23.3% of all tests showed reclassification rates greater than 20%, suggesting substantial clinical impact.

Parameters with the highest reclassification rates

Testosterone

In female patients, 86.3% of results were reclassified as abnormal when male reference values were applied. The transition from male to female is the most common, so in this case, an abnormal result could lead to suspicion of polycystic ovaries, ovarian or adrenal tumors, and prompt unnecessary additional tests, since the biological gender corresponds to a male. In male patients, the reclassification rate was 37.3%. This was the parameter with the greatest discordance, and misclassification could lead to serious diagnostic errors such as misdiagnosing hyperandrogenism or hypogonadism if gender specific physiological context is not considered.

Estradiol

Reclassification occurred in 62.3% of female patients and 29.0% in males when switching reference ranges. Estradiol is highly gender specific and misinterpretation may alter the diagnostic approach to hypogonadism, menopause, infertility, or gynecomastia. In this case, we may also initiate additional tests that could be avoided if we had complete information.

FSH and LH

In females, 31.4% and 30.0% of results, respectively, were reclassified as abnormal when gender was altered. In males, the abnormal classification rate dropped by 17.7% for FSH and 25.0% for LH. These are essential markers of gonadal function, and misinterpretation can result in erroneous diagnoses of ovarian failure, menopause, or pituitary disorders.

SHBG and progesterone

SHBG had a reclassification rate exceeding 33%, and progesterone over 43.4% in females. As both are highly influenced by sex hormones, using inappropriate reference ranges may lead to incorrect clinical conclusions, particularly in transgender patients undergoing hormone therapy.

Clinically significant parameters with moderate impact

Creatinine

Reclassification occurred in 16% of males and 21.3% of females. In transgender women, using male reference ranges may underestimate renal dysfunction, delaying appropriate management. Failure to detect renal failure early can lead to significant disease progression by the time symptoms become apparent, requiring additional measures that could have been avoided.

Calcitonin

Discordance reached 20.7% in males and 15.7% in females. In transgender women, use of female reference ranges may result in missed detection of elevated calcitonin, with implications for medullary thyroid cancer screening. The ten-year survival rate for stages I and II is 90–100%, while for stage III it drops to 70% and for stage IV it is two to three years.

Androstenedione

As a key precursor to sex hormones, this parameter showed a 16% reclassification rate in males and 17.7% in females, reflecting its sensitivity to hormonal milieu.

Growth hormone (GH)

Although the impact was less pronounced, reclassification still reached 6.3% in males and 19.7% in females. This is relevant for specific endocrine disorders, despite GH being more critical in pediatric populations.

Prostate specific antigen (PSA)

In transgender men registered as female, PSA testing may be automatically excluded by LIS filters, due to perceived gender incongruence. This poses a risk of omitting prostate cancer screening in transgender men patients who retain their prostate despite gender transition.

Parameters not significantly affected

Some analytes showed no clinically relevant variation when switching sex categories, indicating low sensitivity to gender marker error:

Uric acid, Apo A1, CK, Urine creatinine, DHEAs, GGT, Hemoglobin, 17 OH progesterone.

These parameters appear robust to sex misclassification in routine analysis.

The complete results are summarized in Table 2, showing the frequency, direction, and statistical significance of reclassification for each analyte.

Table 2. Statistical analysis of the parameters studied with biological gender and self-perceived gender.

Parameters	Biolol. gender (%)	Self-perc. gender (%)	Δ%	Z	p value	Significative
Uric acid (H)	19.2	18.7	−0.5	−0.17	0.86	No
Uric acid (M)	8.7	35.3	+26.6	9.47	<0.00001	Yes
Androstendione (H)	24.0	40.0	+16.0	4.44	<0.00001	Yes
Androstendione (M)	44.7	27.0	−17.7	−4.92	<0.00001	Yes
Apo A1 (H)	11.0	21.7	+10.7	3.36	0.0008	Yes
Apo A1 (M)	22.0	27.3	+5.3	1.68	0.093	No
Calcitonin (H)	20.0	40.7	+20.7	5.74	<0.00001	Yes
Calcitonin (M)	28.7	13.0	−15.7	−4.62	<0.00001	Yes
CK (H)	22.3	20.0	−2.3	−0.77	0.44	No
CK (M)	14.7	20.3	+5.6	1.84	0.065	Límit
Creatinine (H)	27.7	43.7	+16.0	4.43	<0.00001	Yes
Creatinine (M)	26.7	48.0	+21.3	5.91	<0.00001	Yes
Urine creat. (H)	60.0	53.0	−7.0	−2.28	0.022	Yes
Urine creat. (M)	61.7	64.3	+2.6	0.88	0.38	No
DHEAs (H)	16.3	19.7	+3.4	1.34	0.18	No
DHEAs (M)	19.0	20.0	+1.0	0.35	0.72	No
Estradiol (H)	36.3	7.3	−29.0	−9.83	<0.00001	Yes
Estradiol (M)	14.0	76.3	+62.3	15.98	<0.00001	Yes
FSH (H)	36.7	19.0	−17.7	−4.89	<0.00001	Yes
FSH (M)	2.3	33.7	+31.4	10.51	<0.00001	Yes
GGT (H)	23.7	28.0	+4.3	1.42	0.15	No
GGT (M)	19.7	29.7	+10.0	3.15	0.0016	Yes
GH (H)	16.0	9.7	−6.3	−2.28	0.023	Yes
GH (M)	6.0	25.7	+19.7	6.08	<0.00001	Yes
Hemoglobin (H)	39.7	35.7	−4.0	−1.30	0.19	No
Hemoglobin (M)	31.7	30.3	−1.4	−0.43	0.66	No
LH (H)	27.3	2.3	−25.0	−8.72	<0.00001	Yes
LH (M)	30.3	60.3	+30.0	8.94	<0.00001	Yes
17 OH prog. (H)	19.3	15.0	−4.3	−1.52	0.13	No
17 OH prog. (M)	13.7	23.0	+9.3	2.93	0.0034	Yes
Progesterone (M)	3.3	46.7	+43.4	12.42	<0.00001	Yes
PSA (H)	34.7	0.0	−34.7	−11.48	<0.00001	Yes
SHBG (H)	27.3	43.0	+15.7	4.42	<0.00001	Yes
SHBG (M)	21.7	54.7	+33.0	7.43	<0.00001	Yes
Testosterone (H)	42.0	79.3	+37.3	7.75	<0.00001	Yes
Testosterone (M)	7.7	94.0	+86.3	17.71	<0.00001	Yes

Discussion

This study highlights a systemic challenge at the intersection of laboratory medicine, gender identity policy, and patient safety: the interpretation of laboratory parameters based exclusively on self-perceived gender can seriously compromise the clinical validity of results, particularly for transgender and non-binary individuals. These findings indicate that interpreting laboratory results based solely on self-perceived gender without considering biological gender or current hormonal status may lead to clinically relevant misclassification errors in a significant proportion of patients.

This risk is especially relevant in a global context in which gender self-perceived has been legally recognized in many countries, but clinical and digital systems have not yet been fully adapted to manage this complexity in an operational and safe manner (van den Berg et al., 2020).

Beyond the numerous and statistically significant differences observed, the study reveals a deeper structural misalignment between the legal/administrative representation of a patient's gender and their actual physiology. In daily clinical practice, laboratory systems operate largely in an automated fashion, applying gender specific reference intervals to numerical results. If the gender marker in the system reflects legal or self-perceived gender rather than biological gender or current hormonal context this may lead to misclassification in a substantial proportion of cases, with potentially severe clinical consequences.

This phenomenon should be classified as a systematic preanalytical error: it occurs before the test is processed, stems from incomplete or incorrect demographic data entry, and affects multiple downstream phases of the diagnostic process. According to international quality standards in laboratory medicine, preanalytical errors account for up to 70% of diagnostic mistakes and often have a higher potential for harm than analytical errors (Soldin & Mattison, 2009).

Aware of the complexity of meeting the demands of transgender patients, laboratory medicine has made progress in developing protocols to ensure unambiguous patient identification, cross-referencing the laboratory test request, patient identification, and questioning the patient about their condition and the reason for the blood test. Although patient data is obtained automatically, the moment of blood collection should be used to corroborate all patient information, especially in cases where the requested tests do not match the patient's self-perceived gender, and to provide this information to the laboratory, thus avoiding a source of error.

In transgender patients, this vulnerability is particularly acute for several reasons. First, their hormonal and phenotypic profiles may diverge from binary gender categories assigned at birth, undermining the traditional dichotomy that underpins most reference ranges. Second, most electronic health records (EHR) and laboratory information systems (LIS) do not allow the simultaneous registration of multiple sex/gender dimensions for instance, gender assigned at birth, legal gender, gender identity, current hormonal status, and organ inventory. The lack of such granularity forces clinicians and systems to choose a single gender category, thus increasing the risk of misinterpretation.

The issue is further compounded by automated validation rules within LIS/EHR platforms. For example, some systems automatically block PSA testing for patients registered as female, or pregnancy tests for those registered as male, even when such tests are clinically appropriate. This means that a significant number of patients who identify as women, even though their biological sex is male, would not be able to access this test to determine their risk of benign prostatic hypertrophy or prostate cancer. This is regardless of whether or not they have decided to undergo sex reassignment surgery. These are not simply technical glitches but structural omissions that can obscure clinically relevant pathologies such as prostate cancer in trans women or pregnancy in trans men.

From an ethical perspective, this tension challenges the principles of autonomy, beneficence, and non-maleficence. While legal recognition of gender identity is a fundamental human right, it should not come at the expense of diagnostic safety. False negatives, false positives, or inappropriate clinical decisions are avoidable if systems are designed to respect both identity and biology. Achieving this requires not only technological upgrades but also targeted education and training for healthcare professionals on how to clinically manage gender diversity (Lippi et al., 2007; Zhang et al., 2020). It should also be noted that these minorities suffer stress due to the social stigma they face because of their sexual orientation. Although they are becoming more socially accepted, there are still social situations in which gender

choice causes rejection. On the other hand, from a patient safety perspective in laboratory medicine, all necessary measures must be taken to ensure that the possibility of error is as low as possible. Unambiguous patient identification is a fundamental element in ensuring safe care.

Several institutions have already implemented inclusive strategies. For example, Kaiser Permanente in the U.S. has introduced EHR forms that collect gender identity, sex assigned at birth, and current use of hormone therapy. This structure allows clinical algorithms to interpret laboratory values more accurately and appropriately (Buttarello, 2016).

Such models require coordinated efforts among endocrinologists, laboratory specialists, health informaticians, and transgender community members with lived experience.

Operationally, there is an urgent need to update EHR and LIS platforms to include clinically relevant metadata such as:

- Biological gender (if available)
- Legal sex and self-perceived gender
- Organ inventory (e.g. prostate, uterus, ovaries, breasts)
- Current hormonal status (e.g. testosterone, estrogen, hormone therapy regimen)
- Duration of gender affirming treatment

This multidimensional approach would enable the development of personalized reference ranges, as is already done for pregnancy, pediatric age, or elderly populations. Precedents exist: both the Endocrine Society and WPATH recommend using reference intervals aligned with the affirmed gender for patients undergoing sustained hormone therapy, basing interpretation on functional phenotype rather than legal designation (Deutsch, 2016; Hembree et al., 2017; Reisner et al., 2016).

In parallel, clinical safety alerts should be embedded in LIS platforms to prevent automatic cancellation of tests based on gender incongruence, and instead prompt professional review. These cases should be treated as potential patient safety events within quality assurance systems for clinical laboratories.

From a public health standpoint, this issue reveals a new form of structural inequality in access to accurate and safe diagnostic care for transgender individuals. It is not merely a technical matter it reflects a critical gap in inclusive clinical systems where mismatches between administrative data and physiological realities may result in missed diagnoses, inappropriate treatments, and ultimately, avoidable harm (Deutsch & Buchholz, 2015).

Limitations of the study

Although we believe that the study design is applicable in other settings, aspects such as healthcare organization, safety culture, and social perceptions of this problem must be taken into account.

Conclusion

This study identifies a significant and underrecognized source of clinical error in transgender healthcare: the automated interpretation of laboratory results based on biological gender. The magnitude of reclassification observed along with its implications for key diagnostic processes highlights the need for a comprehensive review of how clinical information systems process sex and gender data.

The solution does not lie in choosing between identity and biology, but rather in designing systems that integrate both respectfully, safely, and evidence based. Achieving this will require rethinking infrastructure, training healthcare teams, and building operational frameworks that respond to the real diversity of patient profiles.

Author contributions

Conceptualization: FJMT, SSMM, DDC, JPP, EEMC; Methodology: FJMT, SSMM, DDC; Formal análisis: FJMT, SSMM; Investigation: FJMT, SSMM, DDC; Data curation: SSMM; Writing – original draft: FJMT; Writing – review and editing: FJMT, EEMC; Project administration: FJMT, JPP.

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Data availability statement

The data that support the findings of this study are openly available in repository 'Data base impact transgender' at https://doi.org/10.57760/sciencedb.28559.

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