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# Law, policy, biology, and sex: Critical issues for researchers:

Researchers should be aware of how sex-difference science is (mis)applied in legal and policy contexts

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The interplay between legal and bioscientific understandings of sex is prolific and complex. Biological evidence and reasoning circulate in lawmaking and policy-making across an array of politically contested issues, including health care, education, and LGBTQI+ rights and protections. There is often a substantial disjoint, however, between how scientists define and operationalize sex differences in their research and how lawmakers and policy-makers make sense of these definitions and concepts as they strategically seek to bolster or challenge legal governance. Medical and life scientists who routinely incorporate sex-related variables in their research cannot eliminate superficial or malicious misuse of research by lawmakers and policy-makers, but awareness of the legal and policy landscape can clarify the possible downstream consequences of researchers' choices about how to operationalize sex-related variables in their studies.

When lawmakers and policy-makers are required to define "sex" in rules and policies, they often rely on definitions found in professional literature from the life and health sciences. As an example, the US Department of Health and Human Services (HHS) proposed a rule in 2019 to amend the anti-discrimination section in the Affordable Care Act (ACA) to allow discrimination on the basis of gender identity or sexual orientation. The proposed rule referenced biomedical research articles on brain, liver, and cardiovascular diseases that presented sex differences as strictly biological and binary. In other cases, lawmakers and policy-makers build on the authority of scientists and on assertions about "proven science" more generally. A proposed bill in 2019 to prohibit gender-affirming care under the age of 18 in the state of Illinois stated that "Scientists and other medical professionals have

recognized that biological sex is a neutral, objective, and immutable fact of human nature." Many states have proposed or passed laws that restrict the definition of sex to specific biological criteria such as "anatomy" and "genetics" at the time of birth. Policy-makers and legislators have heavily relied on biological definitions of sex when making laws that seek to limit access to public bathrooms on the basis of sex assigned at birth. These laws define sex as determined by "genetics," a "person's chromosomes," "anatomy," or "as biologically defined" (1).

Social movement leaders and public advocates who participate in legal and public debates also rely on medical and scientific statements when writing court amicus briefs, submitting comments on a rule, and advocating in other policy arenas. Such groups often use statements made by medical associations and scientific studies about sex, gender, and sexuality to convey their agenda. For example, in the high-profile court case of Gavin Grimm, a trans boy who was barred from using the boys' common bathroom at school, advocates for Grimm argued for an understanding of gender identity as innate and biological, citing medical and scientific literature about gender dysphoria (a term referring to persistent distress or discomfort about one's gender, often in relation to one's sex assigned at birth or bodily characteristics) and studies or theories connecting gender and the brain (such as the concepts of "brain sex" or "biological gender") (1, 2).

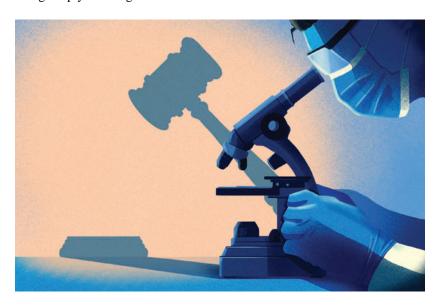
Using biological definitions in the law may sound like responsible governance, but it can result in harmful or illogical outcomes. This can occur through a variety of means, including taking biological sex categories out of context and applying them to cases of human legal rights where they are not relevant; uncritical use of binary sex categories in science; and ignoring bioscientific evidence about the complexity, mutability, context specificity, and plurality of sex and gender. In light of such concerns, we outline here central debates over conceptualizing sex in relation to biology in the law. Although we focus on US law and advocacy, reference to biomedical research on sex differences to limit or expand legal recognition of gender and sexual minorities is an emergent global strategy employed by international governing bodies, religious institutions, and national legislators, reflected, for instance, in Hungary's anti-transgender legislation passed in 2020.

Understanding how their work may be interpreted by others can help scientists identify areas where they can be more explicit about what assumptions or positions their work can, or cannot, support. These considerations are relevant for biomedical researchers and clinicians not only at the level of conducting and communicating basic and applied science, but also for ethically reflecting on the impact of scientific research on peoples' opportunities to lead full, flourishing, healthy lives.

#### CONTESTED AND COMPLEX

In both the science and in law, sex is a contested and complex category. Sex is a ubiquitous category across the life and health sciences, with data routinely tagged as male or female. But increasingly it is recognized in the biomedical sciences that a strict sex binary fails to describe the variation present in human biology across domains long assumed to be strongly sexed (3). From neuroscience (4) to endocrinology (5) to preclinical research (6),

scientists are exploring the limitations of the sex binary as a categorical system to describe and explain the variation present in humans. For example, in contrast to widespread beliefs that humans have "sexed" brains, recent work within neuroscience reveals that human brains do not exhibit binary sex. Even in brain regions that show slight differences between females and males in aggregate, individual brains are not "male" or "female" but rather mosaic, exhibiting mixtures of "female" and "male" characteristics (7). Some "sex differences" in disease or health outcomes have been revealed to be accounted for by factors like age or body size (8, 9). This is not to say that studying sex differences does not retain usefulness in certain areas of inquiry. Biologists routinely use "sex" as a concept, and in some narrowly defined research areas, such as scientific studies of the reproductive tract, a binary works relatively well to describe the variation in humans. However, in many areas, the premise that sex deeply pervades most aspects of human biology and cleaves humans into two essential types is being deeply challenged within scientific research.



When US law categorizes people according to sex, it usually classifies them as either male or female. Sex classifications referencing biological criteria are codified throughout state and federal laws, and regulations are sometimes found in surprising places. For example, in its 2014 regulation "Standards To Prevent, Detect, and Respond to Sexual Abuse and Sexual Harassment Involving Unaccompanied Children," the federal Office of Refugee Resettlement (ORR) defines "sex" using strictly binary groupings of "sex chromosomes, gonads, internal reproductive organs, and external genitalia."

US laws and policies vary across time, jurisdiction, and context, and so do definitions of sex in the law. For example, a recent landmark Supreme Court decision in *Bostock* v. *Clayton* held that protection from discrimination "on the basis of sex" in Title VII of the Civil Rights Act includes sexual orientation and transgender status. The HHS subsequently announced that they will apply the same interpretation to the ACA. Despite this, much legal policy continues to reductively conceptualize "sex" as binary and to source biological science as the basis for this determination.

#### SEX IN LAW: THREE APPROACHES

In the face of these complexities and contestations, legal actors must make situated and often value-laden choices about the use of sex classifications. Here, we characterize three broad-stroke approaches to sex classification in the law employed by lawmakers and policy-makers, which we call essentialist, abolitionist, and pluralist. Appreciating the distinctions between these approaches can inform scientists' considerations in offering constructive guidance when their expertise is invited in a law or policy setting and can clarify decisions about how to include, operationalize, interpret, and translate findings regarding sex-related variables.

An essentialist approach to sex assumes that sex is a strictly binary and essential property of people defined by biological science. Administrative classifications of sex, such as the examples of the ORR given above, exemplify the sex essentialist approach. Essentialist conceptions of sex are often used in US state anti-LGBTQI+ legal initiatives aimed at determining who is permitted to use which bathrooms or to play which youth sports, and to generally enforce and justify segregation in sexed spaces, such as prisons, locker rooms, and homeless shelters. Binary sex essentialist approaches frequently rely on selective biological claims about sex and invoke the authority of science. For example, a 2021 law passed in West Virginia requires classification of sports competitions according to "biological sex," defined as "an individual's physical form as a male or female based solely on the individual's reproductive biology and genetics at birth."

In strong juxtaposition to essentialism is abolitionism, which considers sex classifications to be an unremitting harm and aims to remove them from law and policy. Prominent examples of this stance in action include recent efforts to remove sex from official identification documents such as drivers' licenses or birth certificates, to convert sex-based bathrooms into gender-neutral or all-gender ones, and to endorse mixed-sex sport competitions. Another form of abolitionism can be found in laws that aim to replace sex classifications with different, perhaps more relevant, criteria: Instead of giving parenting-related benefits or special health care to "mothers," it gives them to the "primary family caregiver," "pregnant person," or based on lactation status (10, 11).

Such initiatives are often endorsed by medical experts and associations that attest to the complexity of gender and sex or to biological sex's lack of necessity in the specific context. For example, in June 2021 the American Medical Association resolved to "advocate for the removal of sex as a legal designation on the public portion of the birth certificate," arguing that this removal will not harm the collection of vital statistics needed for public health purposes and will help protect the privacy of and prevent discrimination against intersex, trans, and nonbinary people.

In contrast to both essentialism and abolitionism is a pluralist approach. This approach accepts that different contexts call for different definitions of sex. Pluralism is not essentialism, because it rejects that sex is a universally binary and biological property of individuals. Instead, definitions and conformations of sex-related categories are expected to vary according to the pragmatic needs of the policy or social context. But pluralism

is also not abolitionism, because it recognizes that the need for and characterization of sex classifications vary with context, and that in situated cases, sex classifications may be relevant and necessary—for example, to help extend rights and protections to vulnerable groups.

Such policies create sex classifications that may change over time, perhaps retaining male and female but adding further categories to accommodate those who do not fit the binary, or expanding the definition of males and females beyond biologically essentialist ones. Examples include policies that add a third gender/sex category, as seen in some identification documents. Dana Zzyym, an intersex nonbinary individual, recently became the first US citizen to receive a passport with an "X" gender/sex marker, designated for nonbinary, intersex, and gender-nonconforming people. Similarly, a pluralist approach may support sex classifications for particular protected classes, such as in same-sex education or in sex-discrimination statutes designed to protect vulnerable populations in the workplace. In this sense, some who may endorse abolitionism in the long run may choose a pluralist course in the short run. A pluralist approach means that in any particular case of gender or sex categorization in law and policy, it is necessary to build an empirically grounded definition of sex specific to the context.

#### RESPONSIBLE SCIENCE

How might scientists who study sex-related variables incorporate within their own research practice an awareness and sensitivity to how their work may be taken up in these debates? The first step is to recognize that scientific claims about sex are frequently and variously mobilized in a wider policy, regulatory, and administrative space, and that "sex" has different meanings across these realms and over time. For this reason, it is important to contextualize and appropriately qualify uses of sex categories in research claims, including in publications, pedagogy, and engagement with the media, public, or policy-makers (12).

Where possible, biomedical researchers should consider reducing unnecessary use of sex categories in the design, conduct, and interpretation of scientific studies. Often, sex categories are retained in data merely because they come tagged with sex, even if sex is not a central or relevant category of analysis. Frequently, researchers use sex as a proxy for other variables, either because other variables are more challenging to collect or because sex is readily available in the data as a category of analysis. Rather than using crude sex categories as a proxy, scientists should use variables that are hypothesized as part of the direct mechanistic explanation for the condition of interest. This could mean, for example, reporting on hormone levels, weight, anatomy, presence or absence of gonads, or pregnancy status, instead of relying on male-female sex categories as a coarse means of capturing variability.

Although it may seem self-evident that such practices are simply good science, they are actually rarely observed in studies investigating and reporting sex differences. For example, aiming to improve women's health outcomes by correcting the historical record of androcentrism in biomedical research, in 2016 the US National Institutes of Health (NIH) introduced a Sex as a Biological Variable (SABV) funding mandate requiring preclinical

biomedical researchers working with cells, tissues, and model organisms to include male and female materials and to disaggregate data by sex. As analyses of the pronounced increase in studies of sex differences since the implementation of the mandate have shown, disaggregation by sex without proper statistical power and without an a priori reason in the study design contributes to a muddle of contradictory results and false positives (13, 14). Given this, and the likelihood that a proliferation of scientific reports of sex-disaggregated findings may fuel sex essentialist law and policy, research funders and publishers should work to better align the imperative of conducting carefully contextualized studies of well-defined sex-related variables with SABV policies, including in journal publication guidelines such as Sex and Gender Equity in Research (SAGER) (12).

Finally, investigators of sex-related variables should strive to incorporate discussion of, and where possible, variables related to gender (norms, beliefs, behaviors, and structures related to masculine and feminine gender roles and identities) and other social factors. For example, when studying sex disparities in disease, it is prudent to consider gendered behaviors and structural variables that contribute to risk of disease exposure, health care access, and likelihood of reporting certain symptoms. Understanding sex and gender in a biosocial framework (5) can help prevent unwarranted essentialist interpretations that pose sex and gender as simple binaries, immutable and hardwired by biology.

## REFLECTIVE, ETHICAL, ACCOUNTABLE

As the broad and dynamic field of legal and policy activity reviewed here demonstrates, practices in the science of sex differences matter because conceptions of binary sex as an uncontested, simple biological fact are presently playing a central role in anti-discrimination policy and human rights law critical to protections for women and sexual and gender minorities. When scientific uses of biological sex concepts lack clarity, precision, and rigor, this increases the risk that legal advocates will misunderstand and misrepresent scientific research on biological sex. Reflective, ethical, and accountable practices surrounding how sex differences are discussed, contextualized, and applied in scientific studies are vital when science may be used to justify harmful and discriminatory policy.

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