



Gender & Sex Considerations in Research

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Agenda

- Introduction
- Background
- Study design and data collection
- Ethical practice
- Practical Examples

A woman with dark skin and curly hair is shown in profile, looking towards a whiteboard. The whiteboard has faint red diagrams, including a circle with an arrow and some text. She is holding a yellow marker.

Objectives

- Describe differences between sex and gender
- Explain how sex and gender evolved over time in research
- Determine which sex and gender-specific factors are critical to account for in your own research
- Identify where to find resources to learn more

How did we get here?

Historical focus on male research animals and cells

Key sex differences that could guide clinical studies are obscured

Women experience higher rates of adverse drug reactions & reduced treatment effectiveness

Irreproducibility in preclinical biomedical research

Lack of development of diagnostic tests, criteria that are sex and gender aware

How did we get here?

1993 NIH Revitalization
Act
(Public Law 103-43)

Requires appropriate
participation of women and
URM in clinical studies

Sex and Gender Equity in
Research (SAGER)
guidelines

Promote systematic reporting
of sex and gender across
biomedical disciplines

How did we get here?

2016: NIH Sex as a Biological Variable (SABV) Policy

1. Factor SABV into research designs, analyses, reporting
2. Provide strong justification for single-sex investigations



Terms Defined

Sex:

The sex (male or female) assigned at or before birth, most often based on anatomical and other biological characteristics. Intersex is also a sex designation. Sometimes referred to as birth sex, natal sex, biological sex, or sex; however, sex assigned at birth is the recommended term.



Terms Defined

Gender:

The characteristics and roles of women and men according to social norms. While sex is described as female, male, and intersex, gender can be described as feminine, masculine, androgynous, and much more to represent a spectrum.

Broadening the Gender Construct

- Gender **role** – the ways we behave
- Gender **identity** – how we see and experience ourselves
- Gender **expression** – how we present ourselves
- Gender **perception** – how others view us



Gender Identity

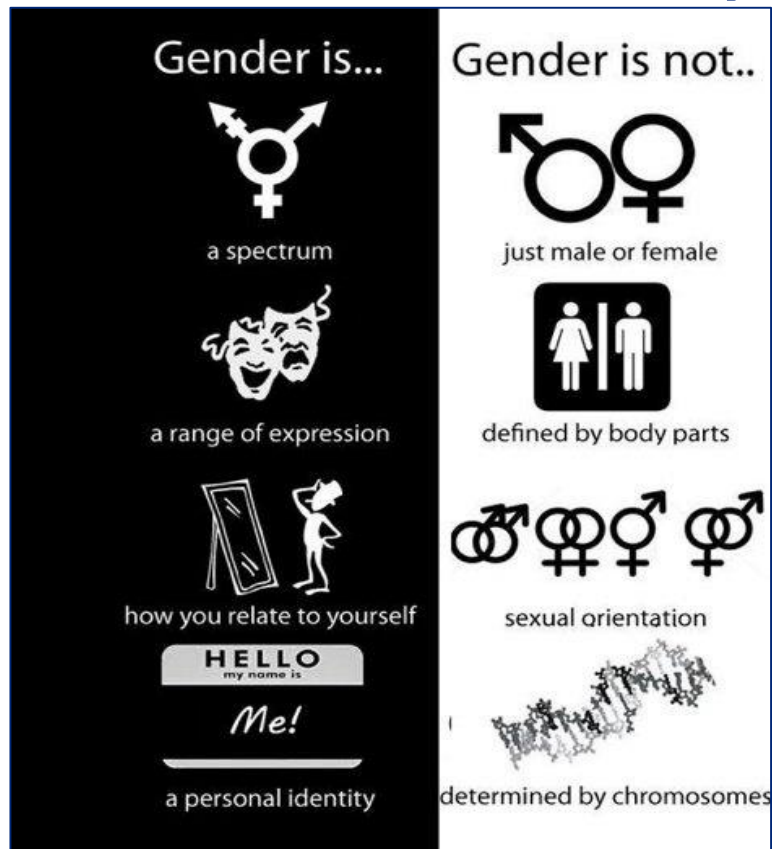


Image credit: www.arewehuman.me

Language and terminology

EMI NATIONAL LGBTQIA+ HEALTH
EDUCATION CENTER
A PROGRAM OF THE FENWAY INSTITUTE

LGBTQIA+ Glossary of Terms for Health Care Teams

Publication

Published on 3 February 2020

Becoming familiar with terms used by lesbian, gay, bisexual, transgender, queer, intersex, asexual, and other sexual and gender minorities (LGBTQIA+) can help you provide patients with the highest quality care. In this glossary, you will find terms relevant to the health care and identities of LGBTQIA+ people.

Download this Publication

Filed under Introduction to LGBTQIA+ Health



<https://www.lgbtqiahealtheeducation.org/publication/lgbtqia-glossary-of-terms-for-health-care-teams/>

Transgender is used as an **adjective**, not a noun or a verb: “**a transgender person**” vs. “**a transgender**” or “**a transgendered person**”



Study Design

- **Define your hypothesis based on your research question.**
 - does sex, gender, or both matter?
- **Select study design:** experimental or observational?
 - cannot assign gender or sex -> never can test the causal impact of these factors on outcomes



Study Design: inclusion & exclusion criteria

- no group should be excluded from participation unless there is good reason to do so (e.g., they are at greater risk).
- the protocol must contain additional safeguards for vulnerable populations, if included

A woman with dark hair tied in a bun, wearing a white lab coat, is shown in profile, looking out a window. The setting appears to be a clinical or laboratory environment, with a sink and a window visible in the background.

Study Design: primary data

I'm doing qualitative research. I'd like to include gender-diverse people in my sample.

Representativeness: consider implications of word choice in your screener and how your recruitment materials look

Study Design: recruitment



RESEARCH STUDY

Did you zuo yue zi (坐月子) in the past 5 years?

If so, consider taking part in this study on postpartum Chinese mothers.

Interview/Photo Activity

In a 60-90 minute interview (via Zoom), you will be asked to share your thoughts on your body during the postpartum period, the practice of zuo yue zi, and participate in a photo sharing activity to illuminate the realities of postpartum motherhood.

Qualifications

Must be 18+ years old, have completed zuo yue zi in the past two years, live in the United States, and have access to Internet. A translator can be provided.

Participants will receive an Amazon gift card.

For more information about this study, or to volunteer, please contact:

Giannina Ong
giannina.ong@mail.utoronto.ca



RECRUITING NEW MOTHERS FOR INTERVIEW AND PHOTO ACTIVITY

This study has been reviewed and received ethics clearance through the University of Toronto Research Ethics Committee.

Participate In An Allergy Research Study

Help advance research around treating allergies.

What is this study about?

Researchers are developing a new treatment that may be similar to an already approved medication for allergic asthma or chronic idiopathic urticaria.

Why Participate?

- You may help those with allergic asthma or chronic idiopathic urticaria in the future.
- You will be compensated for participating in this study.
- You will contribute valuable information that may advance skin health research.

Who Can Participate?

- Healthy men and women aged 18 to 55 years old
- Able to attend 12 study visits at the research site for over approximately 18 weeks

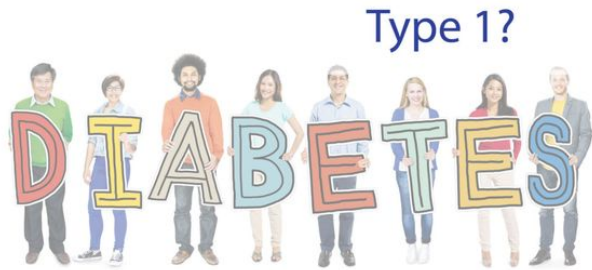


Interested? Join Now

Visit us at
trialfacts.com/allergy



Study Design: recruitment



Enroll in a Research Study

Enrolling now for a study using a novel investigational insulin combination designed to help lower blood sugar for Type 1 Diabetics.

QUALIFIED PARTICIPANTS MUST:

- Be between 18 years or older
- Have been diagnosed with Type 1 diabetes for at least 12 months
- Be using insulin

QUALIFIED PARTICIPANTS RECEIVE:

- Compensation for time and travel
- Study-related care from a board-certified physician, exams, glucose meter and supplies and study medication at no cost

CALL NOW!
210-949-0122



APPLY ONLINE!
SARESEARCH.COM

African Americans and Clinical Research

If you have ever taken a pill or been treated for an illness, you have seen the benefit of clinical trials. Each year, thousands of African Americans take part in clinical trials to help find ways to prevent, treat, and cure illness. Clinical trials help African Americans and all people enjoy better health.



The Center for Information and Study
on Clinical Research Participation





Study Design: primary data

How do I collect data on sex and gender on my survey?

- **Sample size check:** gender diverse and trans people make up an estimated 0.6% of the population (higher among youth & urban areas)
- Will you collect less than 3000 respondents overall? (1% of 3000 = 30 -> large enough to publish)

Guidelines for Data Collection

Two step approach

What is your sex assigned or assumed at birth: (select one)

- Female
- Male
- Intersex
- Something else not listed: (please specify)
- Prefer not to state


What is your Gender Identity:

(select one)

- Man / Transman
- Woman / Transwoman
- Gender diverse / Nonbinary/ Genderqueer
- Something else not listed: (please specify)
- Prefer not to state

Guidelines for Data Collection

Federal surveys lag best practices


 **Health Affairs** @Health_Affairs · Jun 14

It's #PrideMonth and today we are highlighting a Health Affairs paper from July 2018. Janelle Downing of @UofSC + coauthors compared the health of #transgender & cisgender US veterans, a topic with little previous research. Read more here: bit.ly/3q04W9S

HealthAffairs health equity

There are an estimated 163,000 transgender veterans in the United States. In contrast to prior research, few differences in health was found between transgender veterans and cisgender veterans. More nationally representative research is needed on transgender veterans to inform readiness policies.

- Janelle Downing et al. #PrideMonth



Behavioral Risk Factor Surveillance System (BRFSS)

Do you consider yourself to be transgender?^{1,2}

Yes, Transgender, male-to-female

Yes, Transgender, female-to-male

Yes, Transgender, gender non-conforming

No

Don't know/not sure

Refused

7.1

Indicate sex of respondent. Ask only if necessary.

- | | |
|---|--------|
| 1 | Male |
| 2 | Female |

Study Design: secondary data

Electronic Health Records

Hyperspace - ACH EMERGENCY DEPT (aka ACH ED) - POC Environment - NURSE F.

Epic Launch Dragon Dragon Logout Telephone Call Refill Send Letter Patient

Willow, Lucy

Chart Review

Encounters Notes Labs Imaging Cardiology

Lucy Willow
Legal: Luigi Willow
Female 19 y.o., 12/18/2000
MRN: 50053543
Code: Order needed (no ACP docs)

Search

PCP: None
Active FVIs: None
ALLERGIES
Not on File

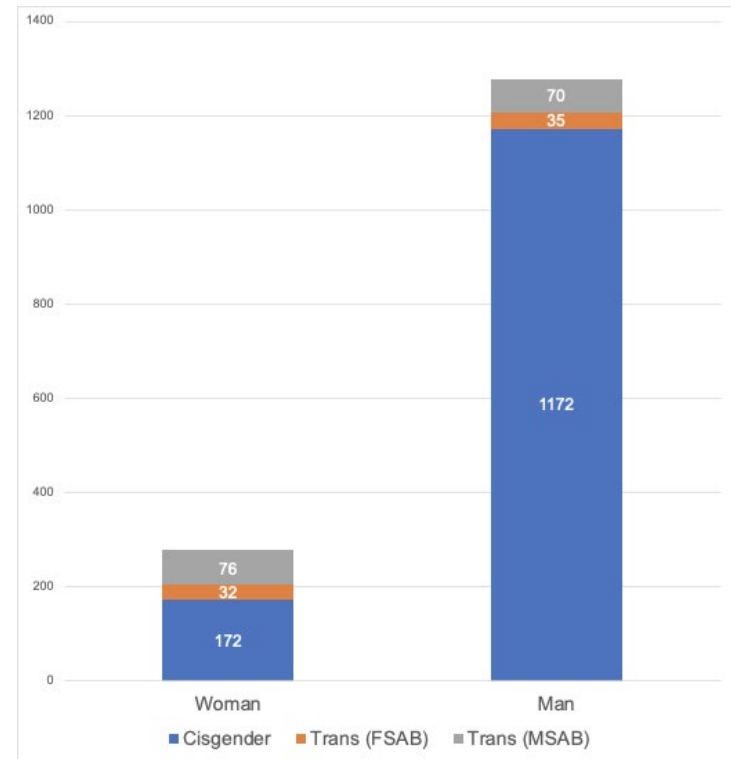
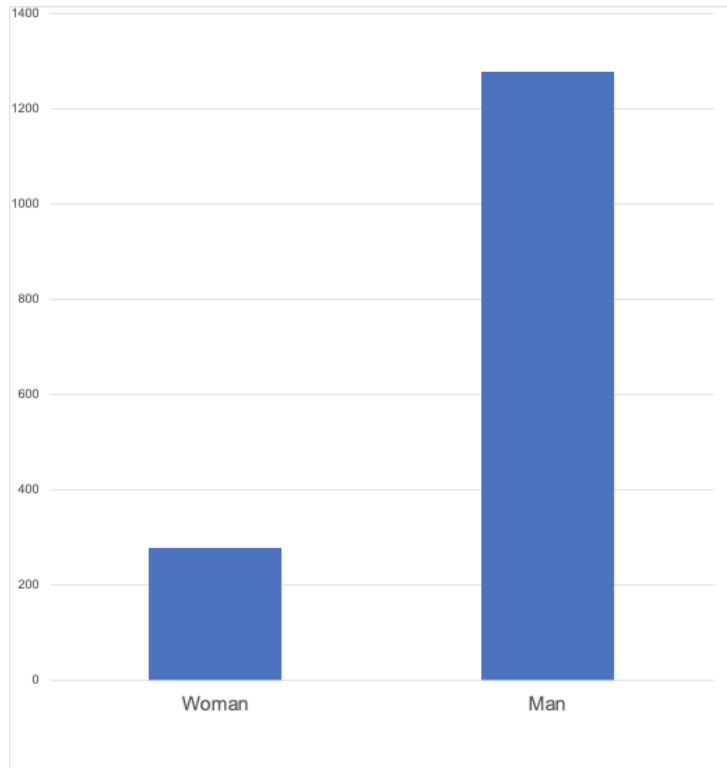
Lucy Willow
Legal Name: Luigi Willow
19 y.o., 12/18/2000
Pronouns: she/her/hers
Gender Identity: Female (Sensitive)
Legal Sex: Male (Sensitive)
Sex Assigned at Birth: Male (Sensitive)
MRN: 50053543
CSN: 42805

Insurance Claims Data

Description	ICD-9	ICD-10
Trans-sexualism	302.5	F640
Trans-sexualism with asexual history	302.51	
Trans-sexualism with homosexual history	302.52	
Trans-sexualism with heterosexual history	302.53	
Gender identity disorder in childhood	302.6	F642
Gender identity disorder in adolescence and adulthood	302.85	F641
Other gender identity disorders	N/A	F648
Gender identity disorder, unspecified	N/A	F649
Personal history of sex reassignment	N/A	Z87.890

Study Design: secondary data

PrEP users in Oregon's Medicaid Program



Ethics in SGM Research

Informed consent: be explicit about requirements, risks, and benefits for study participants. Legacies of harm and mistrust from gender diverse communities exist as it relates to healthcare and clinical research.

Examples:

- Physical exams may carry unique risk for TGD communities.
- Incorporate trauma informed principles in research activities that may be intrusive.
- Make explicit that declining to participate will not interfere with access to gender affirming care

Ethics in SGM Research

Prevent community harm: Seek meaningful collaboration with TGD stakeholders when conducting TGD specific research and/or including TGD communities in clinical research.

Examples:

- Prevent results from your study to be used to perpetuate stigma or lead to harmful policies.
- Determine if and how results from your study can be disseminated to inform healthcare and policy that are positively impactful for TGD communities.

Ethics in SGM Research

Rationale for inclusion/exclusion: be explicit and transparent about why certain communities will or will not be part of the research

Example:

- If your study will not meaningfully contribute to the body of knowledge, don't include communities in the study just to be "inclusive"
- If measures or questionnaires are not validated for TGD individuals exclusion may be necessary

Ethics in SGM Research

Recognize TGD community diversity: Respect TGD communities as heterogeneous and plan accordingly.

Examples:

- Promote inclusion by engaging data collection practices that move beyond the gender binary, won't conflate gender identity, sexuality, sexual behaviors, and/or individual anatomy.
- Consider unique needs exist across TGD communities and if research may be distressing plan for appropriate culturally inclusive community resources.

What are you asking?

Why are you asking it?

How will you use it?

Mental Health

Women are twice as likely as men to experience depression – some women experience mood symptoms related to hormone changes during puberty, pregnancy, menopause.

Women are more likely to admit negative mood states and seek treatment for mental health, in contrast to men.

Poll:
Sex or gender?

Smoking Cessation

Women have a harder time quitting smoking than men do. Women metabolize nicotine, the addictive ingredient in tobacco, faster than men. Differences in metabolism may help explain why nicotine replacement therapies, like patches and gum, work better in men than in women. Men appear to be more sensitive to nicotine's pharmacologic effects related to addiction.

Although men are more sensitive than women to nicotine's addiction-related effects, women may be more susceptible than men to non-nicotine factors, such as the sensory and social stimuli associated with smoking.

Poll:
Sex or gender?

Osteoporosis

Osteoporosis in men older than 50 can go undetected and is often undertreated because patients and providers think of osteoporosis as a “woman’s disease.”

Osteoporosis is more common in women because they have less bone tissue than men and experience a rapid phase of bone loss due to hormonal changes at menopause.

Poll:
Sex or gender?

Arthritis

Walking in high-heeled shoes increases stress on the knee joint, placing women at increased risk of developing osteoarthritis.

Women and girls are more likely to injure their knees when playing sports, in part due to their knee and hip anatomy, imbalanced leg muscle strength, and looser tendons and ligaments. Knee injuries such as ACL tears dramatically increase a person's risk of developing osteoarthritis later in life.

Poll:
Sex or gender?

How SEX and GENDER Influence Health and Disease

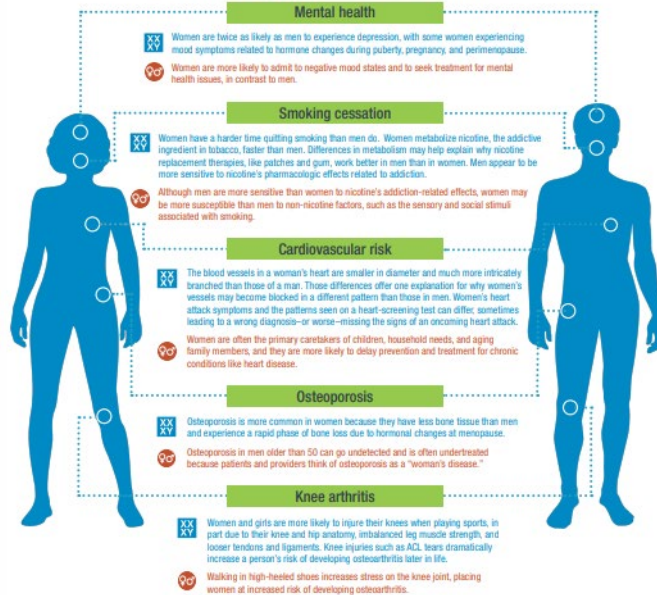
Sex and gender can influence health in important ways. While sex and gender are distinct concepts, their influence is often inextricably linked. The scientific studies that generate the most complete data consider sex and/or gender influences in study design, data collection and analysis, and reporting of findings.

Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex—making up tissues and organs, like your skin, brain, heart, and stomach. Each cell is either male or female depending on whether you are a man or a woman.

Gender refers to the socially constructed roles, behaviors, expressions, and identities of girls, women, boys, men, and gender diverse people. It influences how people perceive themselves and each other, and how they act and interact. Gender is usually conceptualized as binary (girl/woman and boy/man), yet there is considerable diversity in how individuals and groups understand, experience, and express it.

Visit [NIH.gov/women](https://orwh.nih.gov/women) to learn how studying sex and gender strengthens science.

Examples of SEX and GENDER influences



NIH National Institutes of Health
Office of Research on Women's Health

NIH.gov/women @NIH_ORWH #SexinScience

Sources: Institute of Medicine, Canadian Institutes of Health Research, World Health Organization, National Institute on Drug Abuse, NIH Osteoporosis and Related Bone Diseases National Resource Center, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Kargman, G.C., Johnson, J.L., Boyd, M.S., Ross, J.A., Della-Croce, U., & Wang, F.D. (2005). Moderate-to-heavy shoes and knee joint temperature: relevance to the development and progression of knee osteoarthritis. Archives of Physical Medicine and Rehabilitation, 86(2), 371-375.

https://orwh.od.nih.gov/sites/orwh/files/docs/SexGenderInfographic11x17_508_Final_2.pdf

NIH.gov/women





Thank You