

Improving Gender Diversity and Representation in Clinical Trials

S. Ward, C. Evans, D. Castro, C. Burgin

OHSU Knight Cancer Institute

1. Background

The language we use when we talk with people about their bodies and lifestyles can contribute to inequalities and harm for transgender, non-binary, and gender-diverse individuals and people on the sexual orientation spectrum. Using inclusive language reduces biases in clinical and research practices; without inclusive language and practices, we risk systemic inequality.

In 2021, an investigator submitted reportable new information (RNI) to the OHSU IRB: two subjects withdrew from a study because the study team used language “too heteronormative” that made the subjects uncomfortable. The study team initiated corrective and preventive actions. Data Safety and Monitoring Committee (DSMC) and Protocol Review and Monitoring System (PRMS) administrators in the Knight Cancer Institute (KCI) clinical trials office (CTO) investigated KCI-wide language use.

KCI pursues research that affects all individuals and communities. We want all individuals and communities in clinical research so that studies are ethical and equitable, and the data we generate are generalizable. DSMC and PRMS administrators unfortunately discovered that most KCI templates relied on binary sex classifications and non-inclusive language that failed our LGBTQIA+ population.

2. Goals

Our primary goal was to uncouple gender from sex and replace non-inclusive language with inclusive language in materials, templates, and interactions.

Specific goals:

- Eliminate sex-based, gendered, heteronormative, non-inclusive terms; replace with inclusive terms that respect sexual orientation and gender identity
- Detect and reduce biases in KCI research operations and interactions
- Champion inclusive language at KCI, in the medical system, and with governing agencies

A rapid assessment of site medical records shows that as of March 2022, of about 4,000,000 patients, about 3,800 identify as male, female, or unknown; of those, 2,591 identify gender as other than male/female.

3. Solutions and Methods

CTO programs implemented changes to avoid conflation of sex and gender and normalize inclusive language.

- PRMS:
 - Revised KCI consent form template to use inclusive terms (e.g., changed “women of child-bearing potential” to “person who can become pregnant”)
 - At initial and subsequent reviews of study materials, identifying non-inclusive language and suggesting alternatives
- DSMC:
 - Including coaching on inclusive language in audits

Category: Trial Recruitment & Community Outreach and Engagement – Work in Progress

- Identifying non-inclusive language in study materials and suggesting alternatives
- Education & Onboarding:
 - Including principles of inclusive language in trainings
- Scientific Writing:
 - Updating all KCI protocol templates to use inclusive terms
- Informatics:
 - Evaluating data conventions
- Administration:
 - In public-facing materials, eliminating non-inclusive language (e.g., changing “Males and females” to “Individuals”)
 - Normalizing use of pronouns in interactions

4. Outcomes

Outcomes have been positive with no reported resistance. Inclusive language enhances clinical research communications and operations.

5. Lessons Learned and Future Directions

Inclusive language is achievable. The KCI CTO implemented changes quickly and inexpensively. KCI will continue to prioritize diversity, equity, and inclusion (DEI) because it demonstrates integrity, compassion, and leadership. KCI’s DEI work promotes a diverse and culturally competent workforce, embraces our responsibility to reduce health care disparities in our catchment area, and ensures that all are welcome in clinical research.