

Reporting of Sex and Gender in Clinical Trial Protocols and Published Results

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Objective

To assess how the concepts of “sex” (biological factors) and “gender” (sociocultural factors) were used in protocols compared to corresponding publications.

Background

- Research funders and journals increasingly recognize the importance of assessing and reporting the effect of sex and gender on health outcomes in clinical trials.
- According to prior literature reviews, sex and gender
 - Have been reported infrequently in publications,
 - But the reviews did not assess the use of these concepts in protocols.
- This study incorporates protocols into the analysis.

Study Design/Method

Selected 10 ICMJE journals with full study protocols publicly available for reported clinical trials.



Selected a convenience sample of 80 articles:

- Published in *NEJM* & *JAMA* in 2014/2015.
- Reported results of non-phase 1 drug trials.
- Provided access to full protocols online.



Searched and identified the use of the terms “sex” and “gender” in the entire protocol and corresponding article.

Findings

- “Sex” and “gender” not defined in any protocol or article and used interchangeably in 32/80 (40%) protocols.
 - 28 of 32 corresponding articles used “sex” only.
 - 4 of 32 corresponding articles used neither term.
 - No article used both terms.
- “Gender” only used in 23/80 (29%) protocols and in 1 article.
- “Sex” only used in 59/80 (74%) articles.
- Neither “sex” nor “gender” used in 14/80 (18%) articles reporting studies that were not sex-specific:
 - 10/80 (13%) used terms such as “men” or “women,” but unclear whether sex or gender was meant.

Table 1: Sex/gender reporting in 80 trial protocols and corresponding publications

Protocols	Publications				
	Sex	Gender	Both	Neither	Total
Sex	6	0	0	5	11
Gender	16	1	0	6	23
Both	28	0	0	4	32
Neither	9	0	0	5	14
Total	59	1	0	20	80

Limitations

- Generalizability of findings from sample to the broader clinical research enterprise may be limited.
- Instructions to authors from *JAMA*, but not the *NEJM*, specifically addressed sex/gender reporting.
- How constructs were used in research was not assessed.

Table 2: Sex/gender reporting in 80 trial protocols and publications

Terms Used	No. (%)
Clinical Trial Protocols	
Protocols that use the term "sex" only	11 (13.8)
Protocols that use the term "gender" only	23 (28.8)
Protocols that use both “sex” and “gender” interchangeably	32 (40.0)
Protocols that use neither term	14 (17.5)
Sex-specific studies (such as breast cancer)	4 (5.0)
Not sex-specific studies – other phrase used	7 (8.8)
Not sex-specific studies – no other phrase used	3 (3.8)
Publications	
Publications that use the term "sex" only	59 (73.8)
Publications that use the term "gender" only	1 (1.3)
Publications that use both “sex” and “gender” interchangeably	0 (0)
Publications that use neither term	20 (25.0)
Sex-specific studies (such as breast cancer)	6 (7.5)
Not sex-specific studies – other phrase used	10 (12.5)
Not sex-specific studies – no other phrase used	4 (5.0)

Conclusion

- Apparent imprecision in use of “sex” and “gender” in study protocols.
- Supports need for continuing efforts to standardize “sex” and “gender” and ensure appropriate use in biomedical research.

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