Sex-Specific Analyses in Oral Abstracts from CROI 2019

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BACKGROUND

- Globally, 52% of people living with HIV are women (natal females) yet they are underrepresented in HIV research
- Scientific studies that generate the most relevant findings consider sex during study design, data collection, analysis, and when reporting findings
- It is important to know ***if*** and ***how*** results reported, such as those at CROI conferences, apply to different key populations for HIV
- CROI conference guidelines reference ICMJE for presentations and highlight consideration of whether results differ by sex
- Following CROI 2018, the WHISC evaluated oral abstract presentations to check the rate of compliance to leadership's recommendation[1].

Proportion of Abstracts at CROI 2018 presenting sex-specific results

Type of abstract	No. of Total (%)	Presented sex-specific distribution	Presented sex-specific results
Relevant only to one sex	16 of 83 (19%)	N/A	N/A
Relevant to both sexes	67 of 83 (81%)	42 of 67 (63%)	16 of 67 (24%)
Clinical Studies	54 of 67 (81%)	41 of 54 (76%)	16 of 54 (30%)
Animal or cell-based studies	13 of 67 (19%)	1 of 13 (8%)	0 of 13 (0%)

Of 51 not reporting sex-specific results, 8 provided an explanation for omission

[1]Gandhi, et al. JAIDS 2019;81 (5):e158-e 160

OBJECTIVES

- To evaluate the compliance to CROI guidelines on reporting by sex for oral abstracts presented at CROI 2019.
  - Reporting
    - Distribution of study sample by sex
    - Sex-specific results
  - Language
    - Clarity of abstract title
    - Use of correct terminology for sex
- To explore whether reporting varied by
  - Study type
  - Sample size
  - % of women enrolled

METHODS

- Sample: CROI 2019 oral abstracts (webcasts and slides)
  - Excluded if study objective was applicable to only one sex or not applicable to sex
- Information extracted by at least 2 WHISC committee members
  - Any discordant items were adjudicated by an additional reviewer

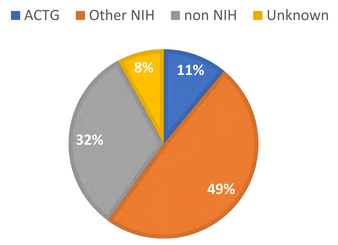
There was some improvement in reporting of sex-distribution and sex-specific analyses at CROI 2019 vs. 2018.

Pre-clinical studies do not report sex of animals.

Improvement will follow from consideration of sex when designing studies.

RESULTS: Studies Included

- 85 oral abstracts included in analysis (of 110 accepted)
- Type of Studies
  - 6 (7%) were pre-clinical (animal studies)
  - 45 (53%) were observational studies
  - 34 (40%) were clinical trials
- Funding Source



Sample Sizes of 85 Studies Included

Total sample size	Number of studies	%
< 10 participants/animals	4	5%
10-25	11	13%
26-100	21	25%
101-1000	20	24%
> 1000	24	28%
Unknown/not presented	5	6%

Studies reporting sex distribution and representation by women

Overall 67 (79% of 85) studies presented sex distribution of the study

Representation of women	Number of studies	%
100% (i.e. all women)	3	4.5%
76%-<100%	1	1.5%
51%-75%	15	22%
26%-50%	14	21%
11%-25%	16	24%
>0-10%	11	17%
0% (i.e. no women)	7	10%

Among 18 (21%) of studies not reporting sex distribution of study sample

6 (6 of 6 or 100%) were animal studies

8 (8 of 45 or 18%) were observational studies

4 (4 of 34 or 12%) were clinical trials

Sample size of those studies not reporting sex distribution	Number of studies
< 10 participants/animals	2
10-25	6
26-100	4
101-1000	2
>1000	2
Unknown/not presented	2

Language

- Of the 67 studies providing sex distribution of the sample:
  - 56 (84%) used the term sex
  - 7 (10%) used the term gender when referring to sex
  - 4 (6%) a determination could not be made whether the term used was appropriate
- Of 10 abstracts where only one sex was studied in a question relevant to both sexes:
  - 7 included only men – 4 did not have clear titles
    - THE PHASE 3 DISCOVER STUDY: DAILY F/TAF OR F/TDF FOR HIV PREEXPOSURE PROPHYLAXIS
  - 3 included only women – 1 did not have clear title
    - HIGH HIV VIRAL BURDEN PERSISTS IN CXCR3+ GCTFH DESPITE VERY EARLY ART INITIATION
  - Example of clear title:
    - INCIDENT SYPHILIS RATES AND PREDICTORS IN US WOMEN WITH HIV, 2005-2016

Presentation of Sex-Adjusted Analyses

Overall: 39 of 79 (49%) presented sex-specific results

	Observational Studies Overall: 29 of 45 (64%)	Clinical Trials Overall: 10 of 34 (29%)
< 25 participants	2 of 4 (50%)	0 of 6 (0%)
26-100 participants	1 of 6 (17%)	1 of 14 (7%)
101-1000 participants	5 of 12 (42%)	4 of 8 (50%)
> 1000 participants	17 of 18 (94%)	5 of 6 (83%)
Unknown size	4 of 5 (80%)	NA

Limitations and future directions

- Retrospective analysis using only posted webcast and slides as source
  - A few abstracts were excluded due to missing slides/webcast
  - e.g. single sex study could result from design restrictions or local recruitment realization
  - More restricted format than manuscript; not highly structured like clinicaltrials.gov
- CROI 2020 guidelines include following new language in **Requirements for Presentation Development**
  - Both sex and gender data should be provided in the presentation
  - Presentations of preclinical data including use of cell lines and animal studies should include the sex of the animals or the sex of the source of the cell lines

CONCLUSIONS

- Pre-clinical studies do not report sex of animals
- Some improvement noted for clinical studies presented in 2019 vs 2018:
  - 85% of studies presented sex distribution (vs 76% in 2018)
  - 49% presented sex-specific analysis (vs 30% in 2018)
- Larger clinical studies had higher rates of reporting sex-specific analysis
- Reporting did not seem to vary by % representation of women, except in large clinical trials
- There is still room for improvement
- Improvement will follow from consideration of sex when designing studies

Acknowledgements

Research community presenting at CROI conferences

Participants in all studies presented at CROI conferences