

Low Rate of Sex-Specific Analyses in CROI Presentations in 2018: Room to Improve

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BACKGROUND

- Over 50% of world's HIV infections are in women
- Sex differences in HIV acquisition, pathogenesis, reservoir, treatment response, antiretroviral pharmacokinetics and toxicities seen¹
- But adequate sex representation not always achieved in studies, nor sexspecific analyses performed
- NIH "expects that sex as a biological variable will be factored into research designs, analyses, and reporting"

NIH Policy on Sex as a Biological Variable

The 4 Cs of Studying Sex to Strengthen Science



or explain why it isn't









Characterize

Analyze
sex-based data

Communicate
Report and

publish sex-based data

Boston | March 4-7, 2018

- CROI 2018 program committee requested investigators to consider sex as a biological variable and asked oral presenters specifically to include sex-specific analyses when feasible
- This analysis examined compliance with this recommendation

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METHODS

- CROI 2018 held in Boston, MA, March 4-7, 2018; each oral presentation video-taped with the talk and slides made available as a webcast
- Instructions to oral abstract presenters: Please consider whether there is substantive evidence of differences in effect by sex or other key demographic groups. If so, a stratified analysis should be made available during the presentation of the abstract at CROI
- Women's Health Inter-Network Scientific Committee (WHISC) is a working group of two NIH-funded clinical trials networks -the AIDS Clinical Trials Group (ACTG) and International Maternal Pediatric Adolescent AIDS Clinical Trials Network (IMPAACT)- focused on HIV among girls and women
- At least 2 WHISC members reviewed each of the CROI 2018 oral sessions
 - 1) Whether the abstract's scientific question/objective was relevant to both sexes
 - 2) Whether the study included human participants, animals, or was preclinical, but still included specimens from humans or animals
- If both criteria met, reviewers assessed
 - 1) Whether the reported study demographics included sex '
 - 2) If sex-delineated outcomes or sex-stratified analyses were presented
 - 3) If results by sex not presented, whether an explanation for omission was provided

RESULTS

- Of 83 original oral abstracts presented at CROI 2018, 16 (19%) deemed relevant to one sex only and were excluded from this analysis.
- Of the remaining 67 oral abstracts relevant to both sexes, 35 (52%) included the distribution of the study sample by sex; 7 (10%) presented sex distributions, albeit mislabeled as "gender"; and 25 (37%) did not present or address sex distributions
- Sex distribution was reported in human observational studies and clinical trials the majority of the time (41/54, 76%) but only 1/13 of pre-clinical studies included sex-distribution
- Only 16 (24%) of all oral abstracts presented at CROI 2018 relevant to both sexes included sex-stratified analyses or sex-delineated outcomes

Type of abstract	Number of total (%)	Presented sex distribution	Presented sex- specific results
Relevant to one sex only	16 of 83 (19%)	NA	NA
Relevant to both sexes	67 of 83 (81%)	42 of 67 (63%)	16 of 67 (24%)*
Human studies	54 of 67 (81%)	41 of 54 (76%)	16 of 54(30%)
Animal/cell-based studies	13 of 67 (19%)	1 of 13 (8%)	0 of 13 (0%)

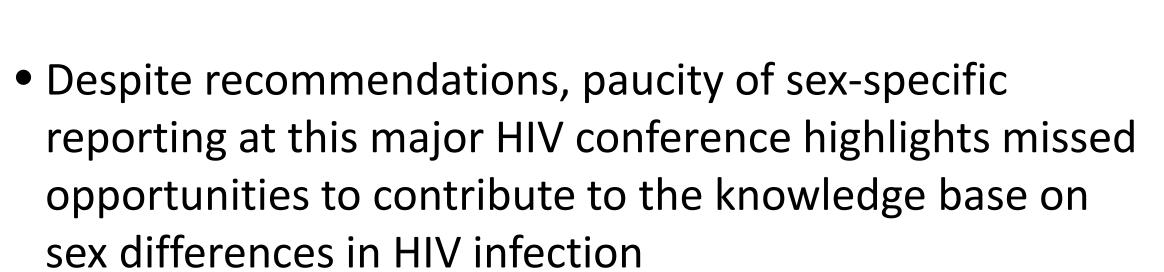
Of 51 which did not present sex-specific results, only 8 provided an explanation of why this wasn't done

KEY POINTS.

- •Sex-specific analyses can provide insight into whether HIV prevention, treatment, cure and the management of HIV-associated conditions should be tailored by sex.
- •NIH, FDA, Institute of Medicine all recommend sex-specific reporting
- Over 52% of HIV infections worldwide are in women
- Despite CROI 2018 providing guidelines on reporting by sex, more than a third of oral presentations at this conference last year failed to report sex demographics and only a quarter included sex-stratified analyses

DISCUSSION

- Sex differences in HIV exist when examined
- CROI program committee has aligned its recommendations to abstract presenters with NIH, Institute of Medicine and FDA policies





- Sex rarely reported for animal or cell-based studies, but genetic differences by sex even in somatic cells and epigenetic effects of hormones may influence HIV responses
- Sex and gender, ideally, should be reported separately

Conclusion: Researchers should incorporate NIH recommendations on sex inclusion/sex-reporting into study design and conferences/journals should enforce these guidelines

REFERENCES and ACKNOWLEDGEMENTS

- 1. Scully E et al. Current HIV/AIDS Rep 2018
- 2. National Institutes of Health. NIH Policy on Sex as a Biological Variable; https://orwh.od.nih.gov/sex-gender/nih-policy-sex-biological-variable
- 3. Institute of Medicine. *Does Sex Matter?* Exploring the Biological Contributions to Human Health. 2001
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