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 sex-specific analyses performed
- NIH “expects that sex as a biological variable will be factored into research designs, analyses, and reporting”

- 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

METHODS
- CROI 2018 held in Boston, MA, March 4-7, 2018; each oral presentation videotaped 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
- Of 83 original oral abstracts presented at CROI 2018, 16 (19%) deemed relevant to one sex only and were excluded from this analysis.

RESULTS
- 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 1/3 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
- Of 51 which did not present sex-specific results, only 8 provided an explanation of why this wasn’t done

TABLE: Proportion of abstracts at CROI 2018 presenting sex-specific results

| Type of abstract | Number of total (%) Present sex distribution Presented sex-specific results |
|-----------------|-------------------------------|-------------------------------|
| Relevant to one sex only | 16 of 83 (19%) | 42 of 67 (63%) | 16 of 67 (24%)* |
| Relevant to both sexes | 67 of 83 (81%) | 54 of 67 (81%) | 41 of 54 (76%) | 16 of 54 (30%) |
| 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%) |

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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

REFERENCES and ACKNOWLEDGEMENTS
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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
- Despite recommendations, paucity of sex-specific reporting at this major HIV conference highlights missed opportunities to contribute to the knowledge base on sex differences in HIV infection
- 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