

Participation of women in clinical studies pertinent to HIV cure

Rowena Johnston, amfAR

Background

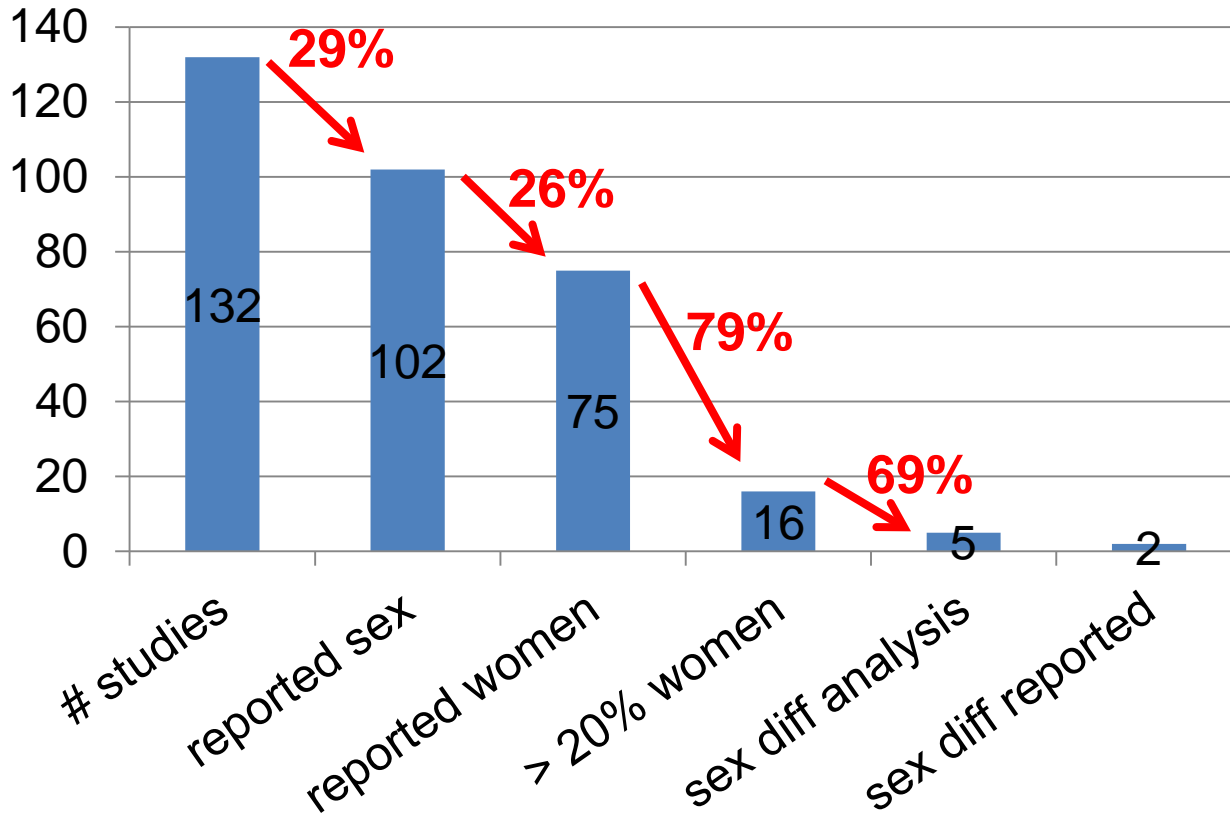
Health and medical intervention outcomes can differ between men and women (influenced by biological and social factors):

- Penile-vaginal HIV acquisition ♀ > ♂
- VL, controlling for CD4 ♀ < ♂
- CD4, controlling for VL ♀ > ♂
- NVP side effects ♀ > ♂
- ART discontinuation ♀ > ♂
- Cytotoxic T-cell activity, humoral responses, inflammation ♀ > ♂

Methods

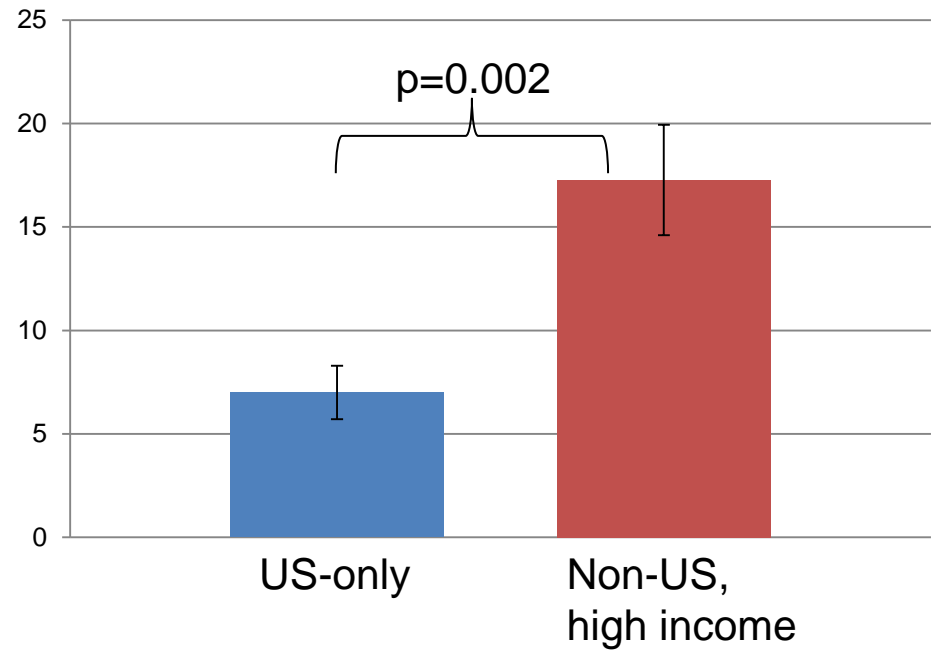
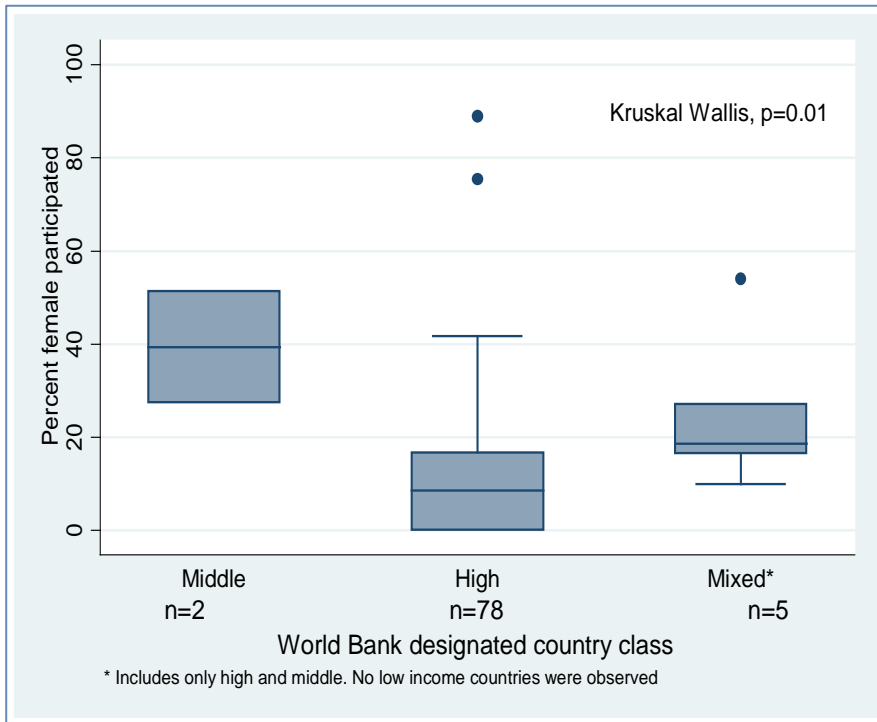
- PubMed and lit search
- Clinical trials/studies
- Both sexes eligible
- Published in English
- Through end 2012
- Study goal(s) = affect persistence/reservoir and/or achieve viral control in absence of t_x
 - Early treatment
 - Gene therapy
 - Immune therapy
 - Reactivation
 - STI
 - T_x vaccine
 - T_x intensification

Results

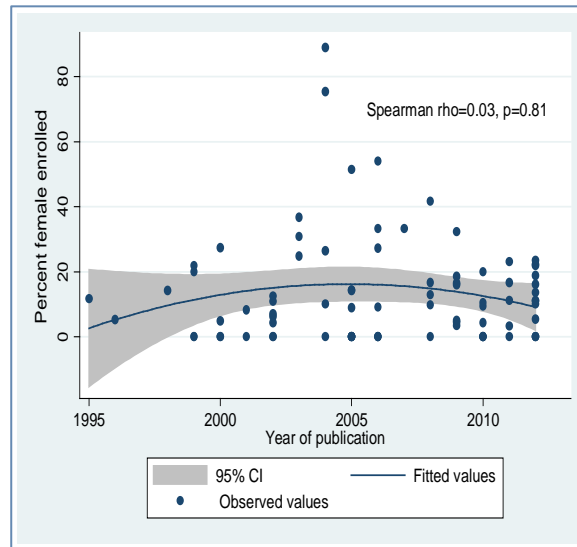
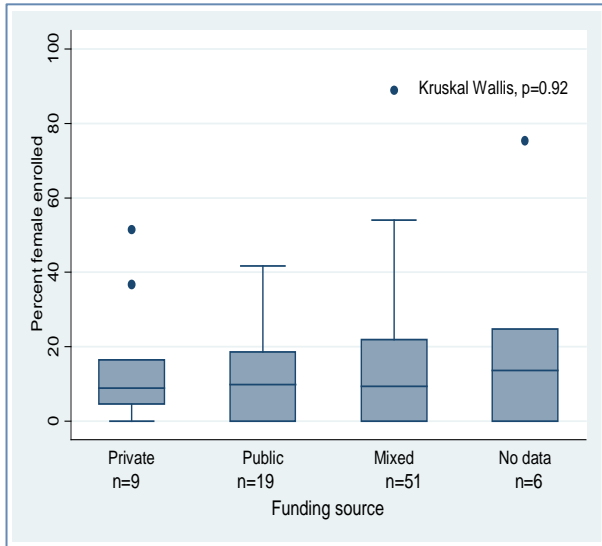


Of 102 studies:
19,549 participants
4,319 women (22.1%)
Median partic = 30
Median fem = 4

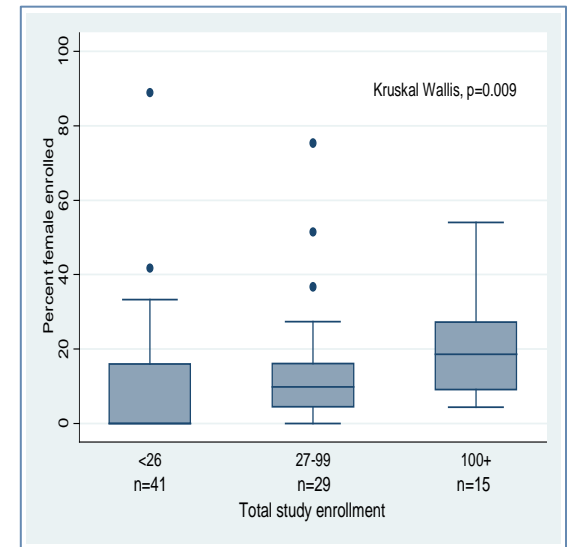
Results



Results



Note: for US studies, mid-point of recruitment period also showed no relationship with % females



Conclusions

- Women are under-represented in cure clinical studies: median 9.9% (ART = 19.2%; VACC = 38.2%)
- Recommendations:
 - Researchers should plan to include more women in clinical studies
 - Reviewers should check for adequate female representation before funding/publication
 - Funders should require and enforce adequate female representation
 - IRBs/regulatory agencies should avoid “over-protecting” women
 - Editors should ensure female enrolment reported consistently