HIV NURSING 2019
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Women living with HIV in Clinical Research

Christina Antoniadi, RN, Chelsea and Westminster Hospital NHS Foundation Trust
Co-opted member of the NHIVNA Executive Committee
Disclosures

• All views are my own.
• This presentation is based on the research of others.
What we know

Every cell has a sex, and all bodies are influenced by gender. Integrating these factors into medical education, training and clinical practice will improve health care for all.

*Sex and Gender Women’s Health Collaborative* [http://sgwhc.org/](http://sgwhc.org/)
What we know

Dr. Alyson McGregor
Sex and Gender Women’s Health Collaborative

September 2014
A couple of questions:

• Are there different signs of heart attack in men and women?

• Which are they?
What we know

The Heart foundation: https://theheartfoundation.org/2017/03/29/heart-attack-men-vs-women/
What we know

Key points

• When it comes to CVD, a typical presentation may not be accurate for half of the population
• In CVD, sex and gender differences contribute to a lower perceived risk of morbidity in women than in men
• A typical presentation of CVD must be further defined to include the sex that it describes
• We need to reclassify typical and atypical presentations of CVD as this terminology contributes to bias that may lead to incorrect diagnoses

CONCLUSIONS:
Many of the trials that have established the efficacy and safety of statins were conducted predominantly or entirely in men, with results extrapolated to women. Additional research is needed to guide clinical recommendations specific to women.
Are there differences?

- Biological Differences:
  - Hormonal profile: affects the absorption, binding and distribution of medication
  - Smaller organs: affects the metabolism and elimination
  - More % fat: affects distribution
  - Varying plasma volume: affects distribution

- Socio-economic differences:
  - Costs (time off work, child care, travel expenses)
  - Knowledge + Referral
  - Recruitment from appropriate sites
  - Child bearing potential
  - Carer duties
Women living with HIV worldwide

UNAIDS: 37.9 million [32.7 million–44.0 million] people globally were living with HIV in 2018

UNAIDS: Infographics, 09/2019

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HIV: leading cause of death in women

UNAIDS (2019) ‘Women and HIV — A spotlight on adolescent girls and young women

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Barriers and opportunities

Conclusions

- The number of women in trials is still disproportionate to that of men.
- Higher incidence of women participating in observational rather than interventional trials.
- Lack of information available
  - Recruited v Enrolled

Recommendations

- Women’s needs can no longer be ignored.
- Hard Paternalism / Over protectionism is no longer a tenable position.
- Need for legislative changes which push for greater inclusion of women.
- Further research on additional barriers

M.J. Rapa et al., The participation of women living with HIV EATG 2018
Where are we now?

• **GRACE Study**: A Study to Compare the Effectiveness, Safety and Tolerability of PREZISTA (Darunavir)/Ritonavir by Gender and Race When Administered With Other Antiretroviral Medications in Human Immunodeficiency Virus (HIV) Positive Women and Men. (First results 2010) **67% women participants**

• **PRIME Study** - Positive transitions into the menopause : To explore the impact of the menopause on health and wellbeing of women living with HIV. (First results 2018)

• **ECHO Study**: Evidence for Contraceptive options and HIV Outcomes (first results 2019)
Is it a movement?

- **HIV activism**: research led by the needs of PLWHIV, Patient experts participating in research boards and as protocol reviewers
  - How many women among them?
  - Is research relevant to women? Is it guided by their needs?
  - Are protocols being developed to include women?

- **Women’s groups**: Sophia Forum, Women’s Action Group (Gilead), SWIFT, WAVE, International Community of Women living with HIV, Salamander Trust
Next steps

Women’s Involvement In Research

WiiR

Patients Advocacy Alliance

A training program open to activists who want to develop their knowledge about participation in clinical trials. Priority will be given to women (cis and trans) with an aim of 75% participation to the training.
References

• Kathryn Lindstrom and Theresa Rohr-Kirchgraber “Sex & Gender Impacts in Cardiovascular Disease: A “Typical” Presentation of Cardiovascular Disease?”, HealthManagement, Volume 19 - Issue 4, 2019
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• M.J.Rapa et al., The participation of women living with HIV EATG 2018
• Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium, “HIV incidence among women using intramuscular depot medroxyprogesterone acetate, a copper intrauterine device, or a levonorgestrel implant for contraception: a randomised, multicentre, open-label trial”, The Lancet June 13, 2019DOI: https://doi.org/10.1016/S0140-6736(19)31288-7
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Thank you

Christina Antoniadi, RN
Chelsea and Westminster Hospital NHS Foundation Trust
Co-opted member of the NHIVNA Executive Committee
Contacts Details: Christina.Antoniadi@nhs.net