

# 21-22 September 2019 • Rome, Italy

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# Women living with HIV in Clinical Research

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### 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/

#### What we know



Dr. Alyson McGregor

<u>Sex and Gender Women's Health</u>

<u>Collaborative</u>



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: <a href="https://theheartfoundation.org/2017/03/29/heart-attack-men-vs-">https://theheartfoundation.org/2017/03/29/heart-attack-men-vs-</a>



### 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

#### **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 recommendations specific clinical women.



HealthManagement, Volume 19 - Issue 4, 2019

Sex & Gender Impacts in Cardiovascular Disease: A "Typical" Presentation of Cardiovascular Disease?



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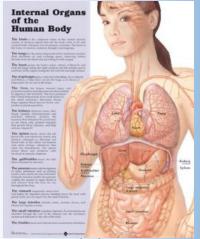
### Are there differences?

#### 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

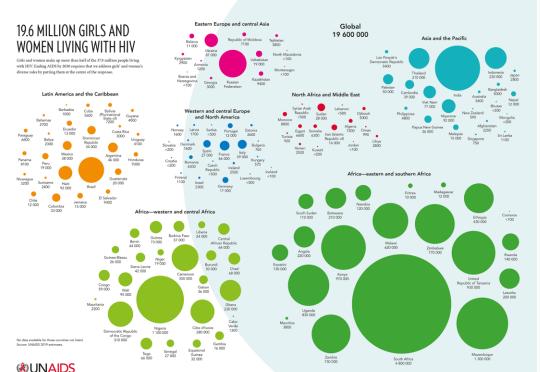
#### Socio-economic differences:

- Costs (time off work, child care, travel expenses)
- Knowledge + Referral
- Recruitment from appropriate sites
- Child bearing potential
- Carer duties



**Anatomical Chart Company** 

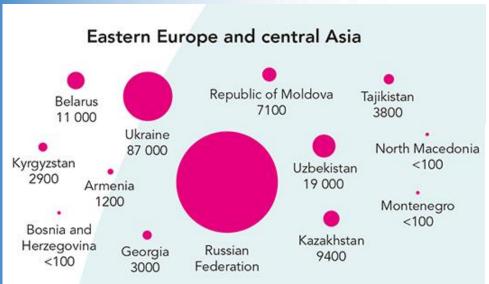
# Women living with HIV worldwide



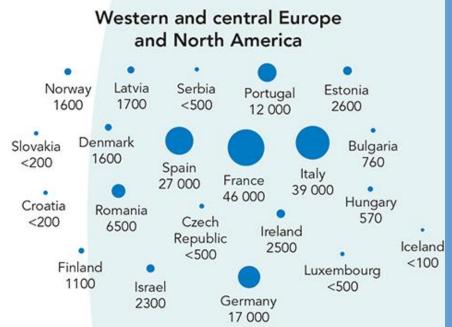
UNAIDS: 37.9 million [32.7 million-44.0 million] people globally were living with HIV in 2018

**UNAIDS:** Infographics, 09/2019





UNAIDS: Infographics, 09/2019

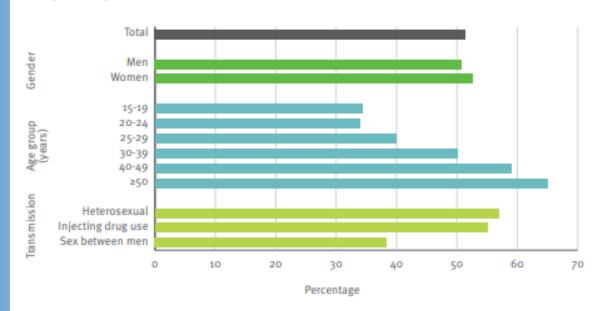




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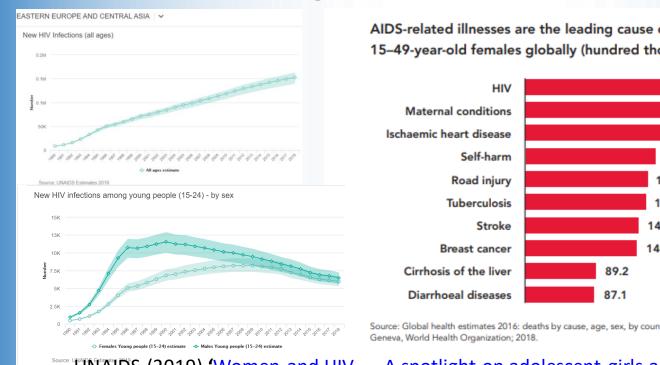
# Late presenters

Figure C: Proportion of persons diagnosed late (CD4 cell count < 350 per mm³) by gender, age and transmission, WHO European Region, 2016

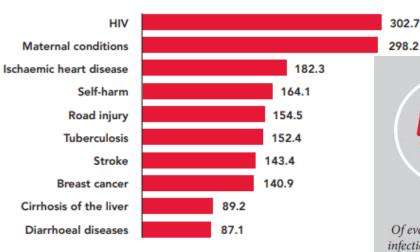


ECDC – WHO
HIV/AIDS
surveillance in
Europe 2018 2017 data

## HIV: leading cause of death in women



AIDS-related illnesses are the leading cause of death among 15-49-year-old females globally (hundred thousands)



Source: Global health estimates 2016: deaths by cause, age, sex, by country and by region, 2000-

Of every five new HIV infections among young people (15-24 years), three are among young women.

UNAIDS (2019) 'Women and HIV — A spotlight on adolescent girls and young women, NAIDS 2018 estimates.



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# HIV Specific research

Representation of Women and Pregnant Women in HIV 2011 Research: A Limited Systematic Review Daniel Westreich12.7, Molly Rosenberg1, Sheree Schwartz1, Geeta Swamy1 Department of Epidemiology, University of North Carolina at Chapel Hill, Chapel Hill, North Carolina, United States of America, 2 Department of Obstetrics and A Systematic Review of the Inclusion (or Exclusion) of Women in HIV Research: From Clinical Studies of Antiretrovirals and Vaccines to Cure Strategies Mirjam J. Curno, PhD,\*† Samuela Rossi, MSc,\*† Ioannis Hodges-Mameletzis, DPhil,\*§ Rowena Johnston, PhD, Matt A. Price, PhD, 9# and Shirin Heidari, PhD\*\*\* EA TG 2016

WOMEN'S PARTICIPATION BY TYPE OF HIV RESEARCH Antiretroviral therapy Vaccination

Dr. Shema Tariq, 2018



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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

- Faubion S'S et al, "Statin therapy: does sex matter?", Menopause, 2019 Sep 9. doi: 10.1097/GME.00000000001412
- <u>Kathryn Lindstrom</u> and <u>Theresa Rohr-Kirchgraber</u> "Sex & Gender Impacts in Cardiovascular Disease: A "Typical" Presentation of Cardiovascular Disease?", HealthManagement, Volume 19 Issue 4, 2019
- UNAIDS (2019) Infographics https://www.unaids.org/en/resources/infographics/girls-and-women-living-with-HIV
- ECDC WHO (2018) Regional Office in Europe "HIV/AIDS surveillance in Europe 2018 2017 data"
- UNAIDS (2019) 'Women and HIV A spotlight on adolescent girls and young women'
- Westreich D et al, "Representation of Women and Pregnant Women in HIV Research: A Limited Systematic Review", PLoS One. 2013; 8(8): e73398
- Curno MJ et al, "A Systematic Review of the Inclusion (or Exclusion) of Women in HIV Research: From Clinical Studies of Antiretrovirals and Vaccines to Cure Strategies", J Acquir Immune Defic Syndr. 2016 Feb 1;71(2):181-8. doi: 10.1097/QAI.00000000000000842
- Solomon D et al, "Cardiovascular disease in women living with HIV: A narrative review", Maturitas. 2018 Feb;108:58-70. doi: 10.1016/j.maturitas.2017.11.012. Epub 2017 Nov 14
- M.J.Rapa et al., The participation of women living with HIV EATG 2018
- Currier J et al, "Sex-based outcomes of darunavir-ritonavir therapy: a single-group trial", <u>Ann Intern Med.</u> 2010 Sep 21;153(6):349-57. doi: 10.7326/0003-4819-153-6-201009210-00002
- Tariq S et al, "The menopause transition in women living with HIV: current evidence and future avenues of research.", J Virus Erad. 2016 Apr; 2(2): 114–116
- 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: <a href="https://doi.org/10.1016/S0140-6736(19)31288-7">https://doi.org/10.1016/S0140-6736(19)31288-7</a>

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- UNAIDS, infographics and data analysis
- Dr. Shema Tariq, postdoctoral clinical research fellow and honorary consultant HIV physician, Institute for Global Health, University College London
- Mark Josef Rapa, LL. D LL.M Healthcare Ethics and Law, University of Manchester
- Damian Kelly, Patients Advocacy Alliance

# Thank you

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