

Women in clinical trials

Clearinghouse Connector – June 2016

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Introduction

Women have been historically underrepresented in clinical trials for new drugs, treatments and devices in Australia and around the world.¹ In instances where women have been present in trials, the influence of sex and gender is often not analysed and reported.² The resultant lack of evidence around women's experiences in clinical trials may have withheld effective treatment and exposed women to harmful side effects.^{3 4}

Physiological differences between women and men often result in differing drug responses. When insufficiently researched drugs hit the market, women may experience a higher incidence of adverse drug reactions.^{5 6}

Reasons cited for excluding women include the perceived hormonal complexity of the menstrual cycle,⁴ and reproductive concerns regarding women of child bearing age (even if she is using contraception). When thalidomide was found to cause birth defects in the 1970s, women of child-bearing potential were banned from participating in clinical trials.³ Though this ban was lifted in 1993 and the US mandated the inclusion of women in such trials for government-funded research, drug companies (who fund the majority of trials) were not required to comply.^{3 2}

Progress towards adequate representation and analysis of women in medical research continues to be slow.^{2 7} In 2014, it was still reported that from animal trials to human trials, “[t]he science that informs medicine – including the prevention, diagnosis, and treatment of disease – routinely fails to consider the crucial impact of sex and gender.”⁷

In 2008, a report found that Australian human rights and ethics committees (HRECs) did not enquire as to the numbers of male and female participants in clinical trials and had no set questions about sex dimensions of research in application forms.⁴ The same report showed that opinions were also divided on whether research cost and convenience justified excluding women from research.⁴ As it stands, the Australian National Health and Medical Research Council (NHMRC) currently has no policy comparable to those of the US National Institute of Health (NIH) or Health Canada on requiring studies to test on both men and women.

Overview

[Equal but not the same: a male bias reigns in medical research](#) The Conversation, 2015.

[The medical research gender gap: how excluding women from clinical trials is hurting our health \[US\]](#) The Guardian, 2015

[Sexism in the doctor's office starts here](#) Huffington Post Australia, 2015

[Sex-specific medical research: why women's health can't wait \[US\]](#) Mary Horrigan Connors Center for Women's Health and Gender Biology at Brigham and Women's Hospital, 2014

[A fix for gender-bias in animal research could help humans \[US\]](#) Shots: Health News from NPR (National Public Radio), 2016

Drug trials and marketing

[Women's involvement in clinical trials: historical perspective and future implications \[US\]](#) Pharmacy Practice, 2016

[Alyson McGregor: why medicine often has dangerous side effects for women \[Video\]\[US\]](#) TED Talk, 2015

[Gender bias in clinical research, pharmaceutical marketing, and the prescription of drugs \[Spain\]](#) Global Health Action, 2014

[Drug problem: women aren't properly represented in scientific studies \[US\]](#) Slate, 2010

[Sex differences in the expression of drug-metabolizing and transporter genes in human liver \[US\]](#) Drug Metabolism and Toxicology, 2012

Sexual and reproductive health

[Flawed data behind regulation of high-risk women's health devices \[US\]](#) Science Daily, 2016

[Thalidomide taught us to use medications with care during pregnancy – not to stop using them](#) The Conversation, 2015

[The desperate need to include pregnant women in clinical research: proposed recommendations to increase enrollment of pregnant women in research \[US\]](#) Law School Student Scholarship, 2015

[Recruitment and retention of pregnant women into clinical research trials: an overview of challenges, facilitators, and best practices \[US\]](#) Clinical Infectious Diseases, 2014

[Addyi's alcohol safety was tested mostly on men \[US\]](#) NY Mag, 2015

[The science of turning her on \[US\]](#) Only Human WNYC Podcast, 2016

Sex-specific response to disease and treatment

[Strategies and methods to study female-specific cardiovascular health and disease: a guide for clinical scientists \[US\]](#) *Biology of Sex Differences*, 2016

[Diabetes trials unnecessarily exclude women, study says \[US\]](#) United Press International, 2016

[Women are missing from HIV drug trials \[US\]](#) Reuters, 2015

Recruitment and retention in women-only trials

[Clinical trial accrual: obstacles and opportunities \[gynaecological cancer\] \[US\]](#) *Frontiers in Oncology*, 2016.

[Barriers to accrue to clinical trials and possible solutions \[breast reconstruction\] \[UK\]](#) *British Journal of Cancer*, 2013.

Research reporting and review

[Sex and gender matter in health research: addressing health inequities in health research reporting](#) *International Journal for Equity in Health*, 2015

[Sex And Gender Equity in Research: rationale for the SAGER guidelines and recommended use](#) *Research Integrity and Peer Review*, 2016

[Gender in research content and knowledge production \[EU\]](#) GenPORT Consortium, 2015

[The challenges of including sex/gender analysis in systematic reviews: a qualitative survey \[Canada\]](#) *Systematic Reviews*, 2014

Monitoring and evaluation

[Twenty years and still counting: including women as participants and studying sex and gender in biomedical research \[US\]](#) *BMC Women's Health*, 2015.

[How the FDA let women down \[US\]](#) Drugwatch, 2015

[National Institutes of Health: Better oversight needed to help ensure continued progress including women in health research \[US\]](#) United States. Government Accountability Office, 2015

[Does a change in health research funding policy related to the integration of sex and gender have an impact? \[Canada\]](#) *PLoS One*, 2014

International guidance

[Guidance document: considerations for inclusion of women in clinical trials and analysis of sex differences](#)
Health Canada, 2013

[Online courses: integrating sex and gender in health research \[Website\]](#) Canadian Institutes of Health Research. Institute of Gender and Health, 2016

[How to engage, recruit and retain women in clinical research \[Toolkit\]](#) U.S. National Institutes of Health. Office of Research on Women's Health, 2016

[Standing Committee of European Doctors \(CPME\) policy on sex and gender in medicine](#) Standing Committee of European Doctors, 2016

[Federal Drug Administration \(FDA\) action plan to enhance the collection and availability of demographic subgroup data \[by sex, age, race, ethnicity\]\[US\]](#) Food and Drug Administration, 2014

Australia*

[Australian Government clinical trials initiatives \[Webpage\]](#) Australia. National Health and Medical Research Council, 2016

[Healthier lives, stronger economy: Victoria's health and medical research strategy 2016-2020](#) Victoria. Department of Health, 2016 – ‘Clinical trials’ pp. 12-13

[National statement on ethical conduct in human research \(2007\) – \(Updated May 2015\)](#) Australia. National Health and Medical Research Council, 2015

See: [Chapter 4.1 – Women who are pregnant and the human foetus](#)

See: [Chapter 5.1.29 – Composition of Human Research Ethics Committees \(HRECs\) \(equal numbers of men and women\)](#)

[Australian clinical trials website: review of the literature on participation in clinical trials: barriers and incentives for health care practitioners and consumers](#) Biotext, 2012

[Fair inclusion of men and women in Australian clinical research: views from ethics committee chairs](#) Medical Journal of Australia, 2008

*As it stands, Australia currently has no policy comparable to those of the US National Institute of Health (NIH) or Health Canada on requiring studies to test on both men and women.

Related websites

[Australian clinical trials](#) Australian Government

[Monash Alfred Psychiatry Research Centre](#) National Register of Antipsychotic Medications in Pregnancy

[U.S. Food and Drug Administration](#) The inclusion of women in clinical trials

[U.S. National Institute of Health](#) Inclusion of women and minorities in clinical research

[Society for Women's Health Research \(US\)](#) Clinical trials

[European Gender Medicine Network \(EUGenMed\)](#)

Footnotes

1. Katherine A. Liu and Natalie A. Dipietro Mager (2016). [Women's involvement in clinical trials: historical perspective and future implications](#). Pharmacy Practice. Accessed on 27/05/2016. ↵
 2. Carolyn M. Mazure and Daniel P. Jones (2015). [Twenty years and still counting: including women as participants and studying sex and gender in biomedical research](#). BMC Women's Health. Accessed on 27/05/2016. ↵
 3. Michelle Llamas (2015). [How the FDA let women down](#). Drugwatch, Florida. Accessed on 27/05/2016. ↵
 4. . Angela J. Ballantyne and Wendy A. Rogers (2008). [Fair inclusion of men and women in Australian clinical research: views from ethics committee chairs](#). Medical Journal of Australia. Accessed on 27/05/2016. ↵
 5. Peter Rogers (2015). [Equal but not the same: a male bias reigns in medical research](#). The Conversation, Australia. Accessed on 27/05/2016. ↵
 6. Lun Yang, Yan Li, Yan, Huixiao Hong, et al (2012). [Sex differences in the expression of drug-metabolizing and transporter genes in human liver](#). Drug Metabolism and Toxicology, Australia. Accessed on 27/05/2016. ↵
 7. Paula Johnson, Therese Fitzgerald, Alina Salganicoff et al (2014). [Sex-specific medical research: why women's health can't wait](#). Brigham and Women's Hospital. Mary Horrigan Connors Center for Women's Health and Gender Biology, Massachusetts, p 5. Accessed on 27/05/2016. ↵
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