

# Promoting Gender Equity in Health

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# Agenda

- The European Institute of Women's Health
- Women's Health and Gender Equity
- The ENGENDER Project
- Gender and Age Bias in Clinical Trials
- Steps for Action

# The EIWH: Who We Are

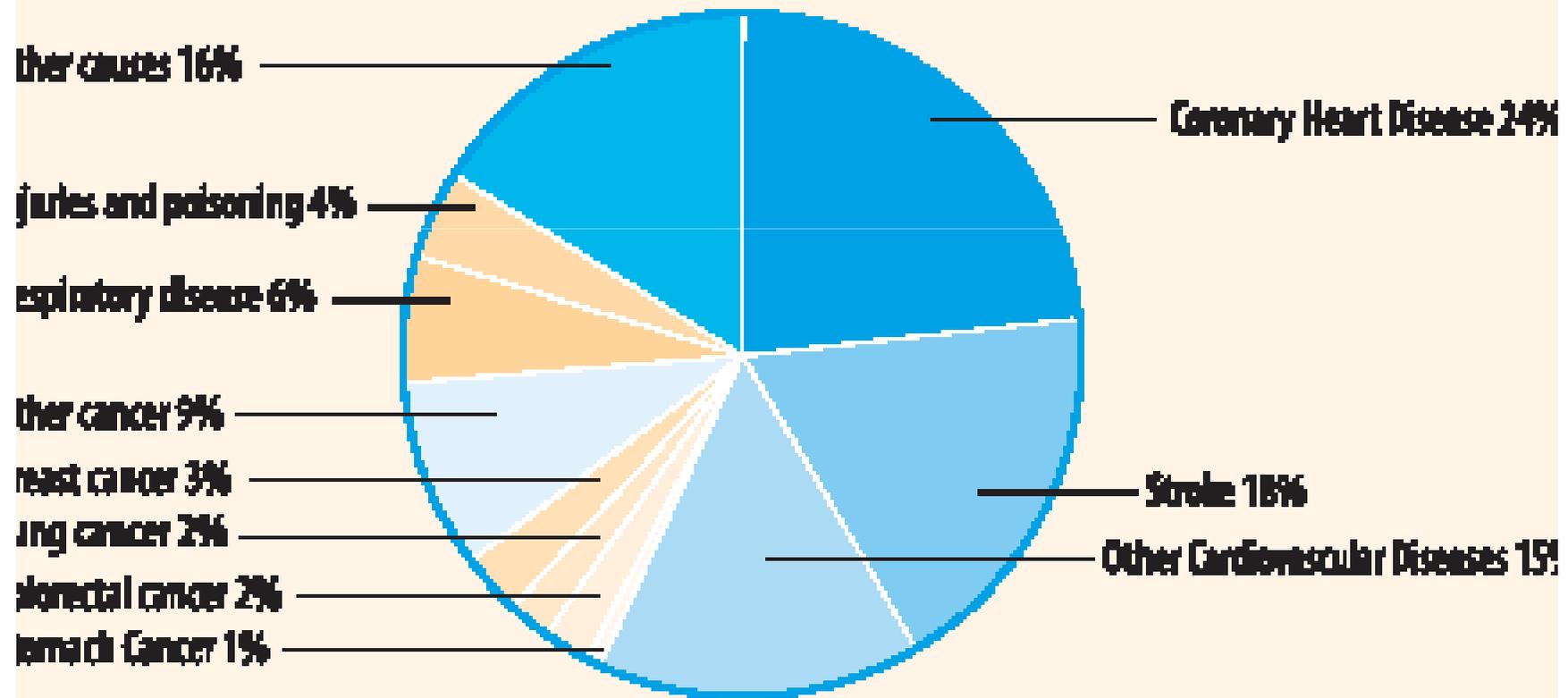
- The European Institute of Women's Health (EIWH) is a health NGO launched in 1996
- **Vision:** *Health for All*—across both diseases and lifespan
- **Organisation:**
  - Extensive multi-national, multi-disciplinary network of patient groups, health NGOs, researchers, gender experts, politicians, and medical professionals
  - Expert Advisory Board

# Defining Women's Health

- Women's health is more than reproductive health– it is health across the life-span.
- The incidence and prevalence of certain diseases are higher among women.
  - E.g. breast cancer, osteoporosis, auto-immune diseases, eating disorders.
- Others affect men and women differently.
  - E.g. lung cancer, diabetes, depression, cardiovascular disease.
- Cardiovascular disease is major killer in older women.

# Death By Cause in Women

Figure 8. Deaths by cause, women, latest available year, Europe<sup>17</sup>.



# Women's Health Matters

- Gender is a key determinant of health closely linked with socio-economic factors.
  - Socio-economic inequalities adversely affect health.
- Due to biological differences and varied gender roles, men and women have different health needs and face disparate obstacles and opportunities.
- Europe has the highest proportion of older women in the world.

# Women and Chronic Diseases

- Women outlive men by on average 6 years.
  - The EU average life expectancy is 82 for women and 76 for men.
  - The 80+ age group is mostly female.
- Healthy life expectancy differs only by 18 months between women and men.
- Women's later years often burdened by chronic diseases, disability, loss of independence.

# Gendered Inequalities

- Women may have less wealth and property, pensions, yet they carry heavier burdens of work and family care.
- Women are typically employed and segregated in lower-paid, less secure, more 'informal' occupations..
- Gender hierarchy governs how people live and what they believe and claim to know about what it means to be a girl or a boy, a woman or a man.



# Women as Health Custodians

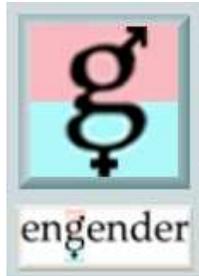
- Women are custodians of family health.
  - They care for their children, ageing parents, and husband/partners.
- Women's health affects that of future generations, that of their children.
- Women have nurturing role in society, teachers, nurses, long-term carers, both formal and informal.

# The ENGENDER Project

The ENGENDER Project:

- Researches gender-based inequities in health.
- Is co-funded by the European Commission.
- Consists of of 6 work packages coordinated by the Karolinska Institute.
- Comprises of 9 partners who are experts in research, public health, gender and health polic.
- Results in:
  - 6 Policy Briefs
  - A Database on Best Practice
  - Network of Experts

<http://engender.eurohealth.ie>



# Biological & Gender Differences in Health



- The differences between women and men in health vary in magnitude across various health conditions:
  - Some conditions are determined primarily by biological differences.
  - Others are the result of gendered differences.
- Many health differences reflect a combination of both the biological differences and gendered factors.
- Understanding the contribution of biology and gender is important for addressing effectively women and men's differential exposures and vulnerability of health risks.

# Interaction Between Sex and Gender

## **Biological Dimension**

- The biological sex differences between females and males are relevant for the diagnosis and treatment of various diseases and medical conditions.

## **Social Dimension**

- Important social issues with consequences for health include education, employment and family life.
- Socio-economic, educational cultural and ethnicity differences can impact on patterns of behaviour and access to resources.

# Policy Recommendations

**Combat health inequalities under current and future health programmes by introducing gender sensitive strands.**

- Suggest strategies to minimise the disparities across the EU.
- Ensure a gender-sensitive approach in relation to information, health literacy, health promotion, prevention and screening programmes.



# Policy Recommendations

**Encourage countries to make their health policies and programmes gender-sensitive, paying particular attention to marginalised groups of women and men such as the disabled, elderly, migrants and ethnic minorities.**

- Account for the differences in health patterns between men and women when designing health policies to ensure the health needs of the entire population are met.

# Policy Recommendations

**Make the inclusion of women in biomedical research and clinical trials explicit and the numbers included statistically relevant to allow for systematic analysis of sex differences.**

- Include women in clinical trials in numbers that match the prevalence of the disease in the general population.
- **Stratify analysis separately** for men and women to take into account the fact that a treatment may not only have a different effect in men and women, but secondary factors influencing efficacy, treatment adherence and side effects.

# Gender Bias in Research

**Nature**  
9 June 2010

*“Medicine as it is currently applied to women is less evidence-based than that to men.”*

**nature**

www.nature.com/nature

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## Putting gender on the agenda

Biomedical research continues to use many more male subjects than females in both animal studies and human clinical trials. The unintended effect is to short-change women's health care.

Differences in the physiology of males and females, and in their response to disease, have been recognized for decades in many species — not least *Homo sapiens*. The literature on these differences now encompasses everything from variations in gene expression between male and female mice, to a higher susceptibility to adverse drug reactions in women compared with men. Moreover, hormones made by the ovaries are known to influence symptoms in human diseases ranging from multiple sclerosis to epilepsy.

And yet, despite the obvious relevance of these sex differences to experimental outcomes, three articles in this issue (see pages 688–690) document that male research subjects continue to dominate biomedical studies. Some 5.5 male animal models are used for every female in neuroscience, for example. And apart from a few large, all-female projects, such as the Women's Health Study on how aspirin and vitamin E affect cardiovascular disease and cancer, women subjects remain seriously under-represented in clinical cohorts. This is despite reforms undertaken in the 1990s, when sex discrimination in human trials was first widely recognized as a problem.

Admittedly, there can be legitimate reasons to skew the ratios. For instance, researchers may use male models to minimize the variability due to the oestrous cycle, or because males allow them to study the Y chromosome as well as the X. And in studies of conditions such as heart disease, from which female mice are thought to be somewhat protected by their hormones, scientists may choose to concentrate on male mice to maximize the outcome under study.

However justifiable these imbalances may be on a case-by-case basis, their cumulative effect is pernicious: medicine as it is currently applied to women is less evidence-based than that being applied to men.

The research community can take a number of steps to address this problem. Journals can insist that authors document the sex of animals in published papers — the Nature journals are at present considering

whether to require the inclusion of such information. Funding agencies should demand that researchers justify sex inequities in grant proposals and, other factors being equal, should favour studies that are more equitable.

Funding agencies and researchers alike should also start thinking seriously about how to deal with the most fundamental sex difference: pregnancy. Pregnant women get ill, and sick women get pregnant. They need therapies, too, even though they are carrying a highly vulnerable fetus and their bodies are undergoing massive changes in hormonal balance, immune function and much else besides. Entering pregnant women in clinical trials is problematic in the extreme, for a host of ethical reasons. But ignoring the problem is not an answer either — the result is that physicians will prescribe drugs whose effects during pregnancy are poorly known. One possible solution is systematic retrospective data collection from women who have had no choice but to take an unproven drug while they were pregnant.

More generally, drug regulators should ensure that physicians and the public alike are aware of sex-based differences in drug reactions and dosages. And medical-school accrediting bodies should impress on their member institutions the importance of training twenty-first-century physicians in how disease symptoms and drug responses can differ by sex. Finally, speeding more women into the senior ranks of science, which they still struggle to reach (see page 832), could well have a salutary effect in creating an environment in which all such efforts can thrive.

These may be the first steps in the direction of truly personalized medicine — what, after all, is more personal than sex. But they are urgently necessary ones. ■

## Unknown quantities

It is in researchers' interests to help funding agencies quantify the economic benefits of their work.

When research agencies are pressed by politicians to quantify the economic value of scientific research, it is only natural that they reach for whatever numbers they can find and then report them as well-established fact. Natural, but wrong. The reality is that few of those numbers — typically, assertions that each unit of research investment will yield a certain amount of additional economic activity — rest on a secure basis (see page 682).

Economists can say with some certainty that basic scientific

research plays a substantial role in fostering innovation — by which they mean new technologies, services and business methods. They also have good evidence that innovation is essential for strong economic growth, especially when society faces constraints on key inputs such as labour, capital and materials.

Beyond that, they can't predict which disciplines of scientific research will lead to future innovation — that would require a time machine. Nor, thus far, can they trace how additional research investment will influence a society's ability to innovate.

The problem is that innovation is not a simple, linear system in which basic research begets technology, and technology begets innovation — although that has always been the easiest model for policy-makers to envisage. Innovation is a complex, highly nonlinear ecosystem, full of interdependencies and feedback loops that aren't

# WHO Recommendations on Gender and Research

- The WHO has called for research to systematically “*incorporate attention to sex and gender in design, analysis and interpretation of findings.*”
- WHO also recommends increasing the number of older women in clinical trials in order to establish both sex- and age-specific guidelines for treatment.

(WHO, 2009)

# Clinical Trials: Evidence-Biased Medicine?



Historically, there has been various struggles in clinical trials:

- Statistically significant under-representation of women in clinical trials.
- Systematic stratified analysis by gender is missing from many trials.
- There is a statistically significant under-representation of older people in trials for all cancer treatment (EORTC).
- The evidence-base for clinical decision-making in 65+ age group is poor even though older patients are the core business of health services.

# Women in Clinical Trials

- The statistically significant under-representation of women in clinical trials needs to be corrected.
- It is integral that women are included in clinical trials:
  - Women take more medicines than men.
  - Women have more ADR even when adjusted.
  - In Europe, 2/3 of those over 65 years are female.
  - In Europe, most of those over 80 years are female.

# Next Steps: Gender and Age in Research and Clinical Trials

## **Promote gender equity in health and research:**

- Include gender in Health for Growth, Horizon 2020
- Influence Revision of Clinical Trials Directive
- Influence Revision of EMA Guidelines for Women in Clinical Trials
- Participate in EMA Geriatric Advisory Group
- Include gender in medical school curriculae and training of physicians

# Reducing Health Inequalities in the EU

"Inequalities experienced in earlier life in access to education, employment and health care as well as those based on gender and cultural background can have a **critical bearing on the health status of people throughout their lives**. The combination of poverty with other vulnerabilities such as childhood or old age, disability or minority background further increases health risks and vice-versa, ill health can lead to poverty and/or social exclusion."

*European Parliament Report on Reducing Health Inequalities in the EU*  
Committee on the Environment,  
Public Health, and Food Safety (2011)



# Our Challenges

- Increase women's access to appropriate, affordable, quality healthcare throughout their lives.
- Promote gender equity in all research programmes, health and social strategies.
- Reduce health inequalities by integrating sex and gender-specific data into health policy, research design and healthcare planning, paying special attention to vulnerable and marginalised groups.

# Gender, Age and Clinical Trials

## **Demographic Ageing**

- Increase of older people aged 65+.
- Older people are heaviest medicine users.
  - Consume more than 30% of prescriptions and 40% of over-the-counter medicines.
  - Account for 60% of total pharmaceutical expenditure.

## **Co-morbidity and Polypharmacy**

- Highest risk of ADR.
- ADR cause 20% of physicians visit and 30% of hospital admission.
- Differences exist in pharmacodynamics by gender and sex.



# Healthcare Utilisation

- Very little gender-specific data available.
- Long way to go for official reporting systems.
- More research needed on women's access to, and utilisation of, healthcare service across the EU.

## Interaction Between Sex and Gender

- Gender differences have a direct impact on the health behaviours, exposures, needs and access to care of women and men.
  - Women are more likely to seek help from and disclose mental health problems to primary care physicians than men.
  - Men are more likely than women to seek specialist mental health care and are the principal users of inpatient care.
- Gender differences can lead to inequitable patterns of health risk, access to and use of health services and of health outcomes.
- Despite considerable progress in recent years at both national and international levels, gender inequalities in health remain in many areas across Europe.

# FDA & NIH Regulatory History

## 1988 Guideline

- Recommends data analysis by sex, race and age.

## 1992 GAO Report Women's Health

- FDA needs to ensure more study of gender differences in prescription drug testing.
- *“Less than half of publicly available prescription drugs were analysed for sex-related response differences.”*

## 1993 NIH requires:

- Women and minorities be included in all human subject research.
- Phase III clinical trials in numbers adequate to allow valid analyses of differences in intervention effect.
- Made funding requirement