

Women's Health - from Research to Healthcare deliver



Peggy Maguire, Director General,
European Institute of Women's Health
RCN Centenary Conference
Wednesday: 23rd November 2016

Agenda

- About the EIWHD
- Our Work for Women's Health
- Chronic Disease in Women
- 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.

EIWH Representation



- Various European Commission Expert Advisory Groups such as Ageing and Disability, H2020 SC1-Demographic Change Health and wellbeing
- European Medicines Agency - eligible organisations
- WHO expert group on Womens Health 2016
- European Public Health Alliance, member of Policy Co-ordination Group
- European Patients Forum, member of Policy committee

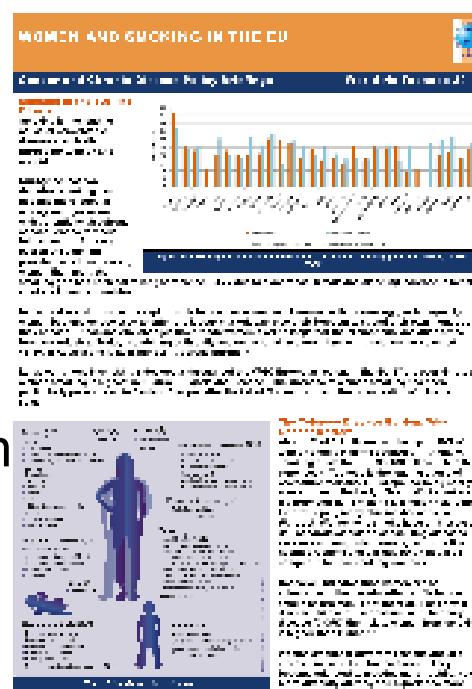
EMA - Eligible patient & Consumer organisation

- Review European Public Assessment Report and Package leaflet
- Participate in Scientific Advisory group (SAG) meetings
- Clinical Trials Transparency Working group
- EudraCT data base
- Annual training session for patient and consumer organisations
www.ema.europa.eu/Patients/PCWP.htm

EIWH Policy Briefs

Increasing Women's health literacy

- Major chronic diseases and how they differ in women
 - Women and CVD, Asthma, Diabetes, Lung Cancer, etc
 - Cervical Cancer, HIV/AIDS
- Prevention and important health issues for women
 - Vaccination across the lifespan
 - Women and Smoking, including pregnant women
 - Women and Alcohol, effect on foetus.



Why Women's Health?

"The health of women has a direct bearing on the health of the future generation, their families, and communities, and ultimately, the health of societies."

NIH Office of Research on Women's Health, 2010

http://orwh.od.nih.gov/ORWH_Strategic-Plan_Vol_1_508.pdf

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.

Social Determinants



- 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.
- Although women achieve higher educational levels, there is still a gender gap in pay and leadership positions
- 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.

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



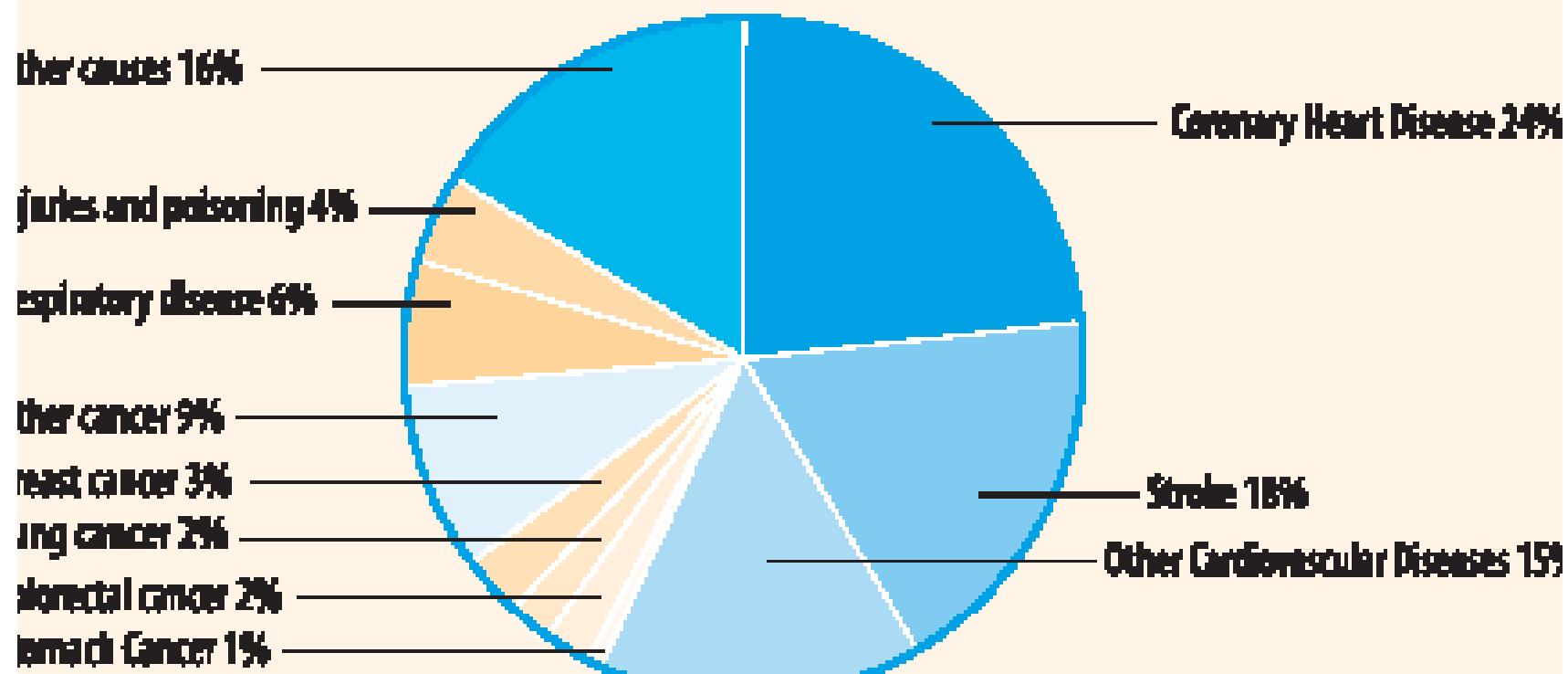
Others affect men and women differently

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, Europe¹⁷.



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

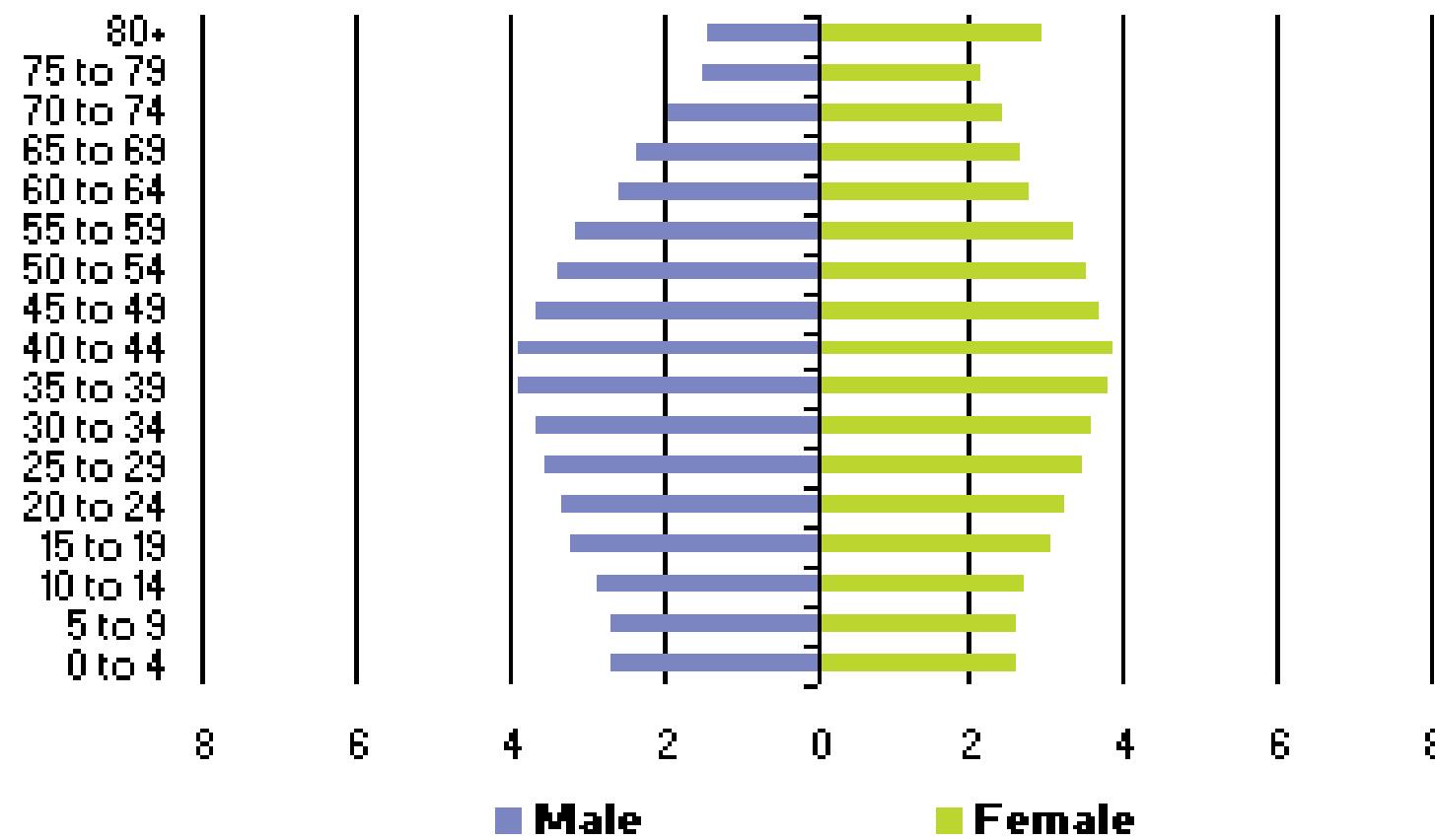


Healthcare Utilisation

- 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
- More research with a variety of methodologies needed to complement biomedical and public health research; also, more focus on intersectional research.



Europe's Ageing population 2030



Demographic Ageing

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



Prevention across the Lifespan

- Prevention across the lifespan is an important public health strategy. However, few prevention programmes include preconception health.
- As a better understanding of how the preconception environment can affect the health of the unborn child is gained, more efforts must be made to invest in prevention already at the preconception stage.
- The EIWH has highlighted various issues related to pregnancy, such as the dangers of smoking and alcohol consumption as well as chronic disease, including gestational diabetes. The current obesity epidemic also requires urgent action to prevent the transgenerational transmission of diabetes risk during pregnancy

Safety of Medicines in Pregnancy

- The safe use of medication during pregnancy is an unmet medical and societal need.
- There is little information available to determine the risks to both mother and child. Instead, the package information leaflets that accompany medicines carry a general warning that the medicine has not been tested in pregnant women and women are advised to consult their doctors.
- Approximately 90% of medications currently have no information about their potential to cause birth defect.

Medicines Regulation

- The EUGenMed, a FP7-funded project, examined the sex and gender differences in biomedical and public health research.
- Within the project, the Workshop on Medicines Regulation highlighted the current information gap about women including with regard to medicine use during pregnancy.
- The Workshop recommended that a robust regulatory and pharmacovigilance framework should be developed for safe use of medicines during pregnancy, which should include a comprehensive system for post-marketing data collection.

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.

Why consider Sex and Gender

- Medicines are safer and more effective for everyone when clinical research includes diverse population groups of all ages
- Women are underrepresented in many clinical trials and if included, robust analysis is often lacking
- Treatment guidelines are largely based on data gathered from men
- Sex differences of tissues and cells

Clinical Trials regulation

- Both population groups who are the heaviest users of medicines will now have to be included in clinical studies, and if not included, the reasons have to be justified.
- We hope that the new legislation will strengthen the protection of patients/clinical trial subjects and streamline the clinical trials process in Europe
- Bring more evidence-based medicines to the patient faster while providing greater protection for them.

Clinical Trials regulation

- The salient points of the new legislation are:
- Women and older people will have to be included in clinical studies and if not included, the reasons have to be justified.
- In future all clinical trial applications in the EU will have to go through an EU portal developed by the European Medicines Agency (EMA). There will be one application only, regardless of the number of Member States the trial will take place in. This replaces individual submissions to both regulators and ethics committees in Member States.

WHO Recommendations on Gender & 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)

Health Professional Education



- The failure to acknowledge the impact of sex and gender (S&G) differences affects the quality of health care provision.
- There must be a commitment to mainstream an evidence-based gender perspective throughout curriculum.
 - Including in graduate, medical, nursing, rehabilitation, pharmacy, continuing medical education and continuing nursing education programmes.
- This workshop examined how S&G consideration can be best integrated into curricula.

Health Professional Education

- By exposing medical students to the importance of sex and gender, considering these variables will become an integral part of the medical process and therefore improve health care
- Each EU country has its own regulatory body that accredits, regulates and evaluates medical education
- The vague pan-European regulatory situation makes it harder to influence stakeholders on a European level, as each country has their own set of standards and regulations for medical education.



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.

Next Steps: Sex&Gender and Age in Research & Clinical Trials

Promote gender equity in health and research:

- Include gender in biomedical and health research.
- Influence Revision of EMA Guidelines for Women in Clinical Trials.
- Include sex&gender in health professional school curriculae and training of physicians.





Congratulations to RCN

Thank You