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[UN Women]

Committee: UN Women

Topic: Developing and implementing international guidelines to combat the clinical and commercial exclusion of women from medical research

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INTRODUCTION

For decades, women have been underrepresented in medical research. Historically, clinical trials primarily focused on men, and results were generalized to accommodate for both genders. This was mainly due to health concerns regarding issues to do with childbirth and care. This has lead to serious consequences with women often receiving incorrect dosages of medicine, diagnoses and treatment that are less effective or even harmful for women.

The exclusion of women from both clinical and commercial research reflects broader gender inequalities in science, healthcare, and policymaking. Addressing this issue is vital for improved health treatments for both genders and achieving gender equality.

This issue is not only a scientific oversight but a structural gender inequality. When women are excluded from research, healthcare outcomes become unequal. Women experience higher rates of adverse drug reactions, delayed diagnoses, and inadequate treatment protocols. Addressing this imbalance is essential to achieving gender equality in global health.

As the United Nations entity dedicated to gender equality, UN Women plays a critical role in advocating for international frameworks that promote inclusive and gender responsive medical research. Collaboration with the World Health Organization (WHO) and member states is essential to develop enforceable global standards.

DEFINITION OF KEY TERMS

Clinical exclusion: the underrepresentation or omission of women in clinical trials and medical research studies

Commercial exclusion: the lack of investment, testing, and product development for women's specific health needs in the pharmaceutical and biotechnology industries

Sex-disaggregated data: data that is collected and analysed separately for men and women

Gender sensitive research: research that considers biological and social differences between genders in study design analysis

Regulatory Framework: a system of rules and guidelines governing research approval, monitoring, and compliance

Reproductive Health Research Gap: the disparity in funding and innovation related to conditions affecting women's reproductive systems

Evidence based medicine: medical decisions made based on the best available scientific evidence

BACKGROUND ON THE ISSUE

Historically women were excluded from clinical trials due to concerns about pregnancy and hormone differences, this led to medical research being defaulted to the male physiology as the universal standard. The roots of this bias trace back to 1962 when the thalidomide tragedy led to a blanket ban by the Food and Drug Administration (FDA) in 1977 on including women of childbearing age in early phase clinical trials. This exclusion has proved detrimental to the lives of many women as it has often left them in life-or-death situation due to lack of adequate data on safety and efficiency. Pregnancy introduces significant physiological changes that can impact the body's ability to absorb and send out medication to where it is needed.

Women are seven times more likely than men to have a heart condition misdiagnosed and are also less likely to be prescribed further medication. A study by the University of Leeds showed women with a total blockage of a coronary artery were 59% more likely to be misdiagnosed than men and found that more than double the rate of death in the 30 days following heart attack compared with men.

Furthermore, the Sex and Gender in Research (SAGER) guidelines were developed a decade ago to provide a framework for research and journals on how to design studies and report data that accounts for sex and gender. In the United States the NIH Revitalization Act of 1993 mandated the inclusion of women in federally funded research, setting a precedent that other nations are beginning to follow. However none of adherence remains voluntary.

GLOBALLY:

Women experience nearly twice the rate of adverse drug reactions compared to men.

Cardiovascular disease symptoms in women often differ from those observed in men, leading to misdiagnosis.

Autoimmune diseases disproportionately affect women, yet funding remains limited.

Clinical trials in low-income countries often fail to ensure gender balance.

The issue intersects strongly with the United Nations Sustainable Development Goals, particularly:

SDG 3: Good Health and Well-being

SDG 5: Gender Equality

Case Study: Cardiovascular Disease Research

Cardiovascular disease (CVD) has long been perceived as a predominantly male illness. Early research studies primarily included male participants. As a result:

Diagnostic criteria were developed based on male symptoms (e.g., chest pain).

Women presenting with different symptoms (e.g., fatigue, nausea, back pain) were often misdiagnosed.

Clinical trials for heart medications underrepresented women.

This led to higher mortality rates among women from heart disease due to delayed diagnosis and inadequate treatment.

The case of cardiovascular research illustrates how exclusion results in systemic healthcare inequalities. It demonstrates the urgent need for sex-specific data analysis and inclusive research standards.

RELEVANT INTERNATIONAL ACTIONS

The WHO through its Special Programme in Human Reproduction (HRP), has been a pioneer in promoting best practices for the ethical inclusions of pregnant and breastfeeding women in research. WHO has recently established a global Task Force aimed at achieving the timely and ethical inclusion of this demographic in clinical research by 2030. Building on efforts for specific diseases like malaria, TB and HIV.

POSSIBLE SOLUTIONS

1.Mandate Binding International Standards for Inclusion and Reporting:

The creation of a new UN resolution establishing minimum standards for clinical trial inclusivity. This resolution should:

- Require that all publicity and privately funded research include women proportionate to the disease prevalence in the population, unless a valid scientific justification for exclusion exists
- Mandate the adoption of the SAGER guidelines as a non-negotiable requirement for publication in all UN-affiliated health and medical journals and for the consideration of research by national regulatory bodies
- Requires sex-disaggregated data in all regulatory submissions, ensuring that results are analysed and reported to show how treatments affect women and men differently

2.Redesign the Clinical Trial Pipeline for Pregnancy:

The current practise of excluding women from phase1 safety trials creates an unacceptable evidence gap. A new global standard is required dedicating phase1 maternal-fetal safety trials after traditional adult trials.

3. Establishing a Permanent Multi-Stakeholder Task Force on Implementation:

Being inspired by the UK's Message Project, the creation of a permanent global multi-stakeholder taskforce under UN Women. This body would include representatives from regulatory agencies (the likes of the FDA and EMA), funders (like the NIH and national research bodies), pharmaceutical industry leaders, journal editors, and patient advocates. Its mandate would be to break the cycle of "first mover paralysis" where each actor waits for another to act by coordinating simultaneous, binding commitments from all sectors to ensure the coherent implementation of inclusion guidelines.

WORKS CITED

Below are sources I have referred through the research report in no particular order:

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