**Forum:** UN Women

**Issue:** Adapting testing mechanisms of medicine and safety measures to reduce bias against women

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## Introduction:

With the ongoing pandemic situation, the world is paying closer attention to the medical testing field. Throughout the course of history, often in the field of medical testing, trials were primarily conducted upon a biologically male group of individuals. This misrepresentation, or simply the lack of representation of women in said testings, led to numerous concerns about whether medicines used or treatments explored are safe for both genders. According to the National Library of Medicine, out of the chosen selection of 137 drugs, all approved by the Food and Drug Administration (FDA), only 38 had sufficient data reported and made publicly available. Of the 38 drugs, 10 (26%) drugs had a greater than 20% difference between the proportion of females affected with the disease compared with representation in clinical trials. This phenomenon of male dominance in medical testing is known as ‘male bias’ in medical treatments. The so-called ‘male bias’ fails to acknowledge the evident difference between male and female biological anatomy, where similar symptoms may require different approaches to ensure the treatment is equally effective. The immense difference in representation may result in knowledge gaps on the effect of medicine and treatment on women, influencing the doctor’s judgment when diagnosing and treating the patient. Therefore, it is crucial to address the current disparity of male and female representation in medical testing and clinical trials and explore various ways to balance them out to prevent any potential misdiagnosis in women.

## Definition of Key Terms:

1. **Clinical trials:** Clinical trials are a series of tests new medications, drugs and treatments go through to determine whether they are safe and effective for their purpose.
2. **Misdiagnosis:** A medical error that falsely identifies a person's medical condition, which may have adverse effects, leading to incorrect or delayed treatment.
3. **Gender blindness:** The lack of awareness and the failure to acknowledge the differences between males and females about their biological anatomy, roles, needs, status and more.
4. **Knowledge gaps:** Knowledge gaps in medicine means the doctors have less knowledge about females and members of the LGBTQ+ community compared to males due to the lack of inclusivity in research.

## Background Information

### History

It is without a doubt that there is an imbalance between male and female representation in clinical trials. Between 1997 and 2000, 10 prescription drugs were taken off the market by the United States Food and Drugs Administration (FDA) due to their adverse effects. 8 of the 10 drugs were discovered to have caused greater health risks in women. Later research conducted in 2018 revealed that this was a result of "serious male biases in basic, preclinical and clinical research".

The idea of gender blindness has been perpetuated throughout the history of medicine. One of the primary reasons why women are often excluded from clinical trials is because they introduce too many variables to the study. In the early 20th century, the endocrine system, which produces hormones, was discovered. The discovery presented another difference between male and female biology other than the reproductive system. But the converse implication that if the medicine is safe for men, then it will be the same for women persisted. This fallacy brought

together a group of female scientists in the United States during the 1980s, forming a society to campaign for better representation of women and involvement in health research, now called the Society for Women's Health Research (SWHR). This newfound society worked to draw attention to the "discrepancies in medical research and the effect on women's health". Thanks to their tireless work and efforts, the SWHR was able to bring to light some of the most male-biased studies and research. In her 2018 book Doing Harm: The Truth About How Bad Medicine and Lazy Science Leave Women Dismissed, Misdiagnosed and Sick, Maya Dusenbery revealed, "[In the early 60s] Observing that women tended to have lower rates of heart disease until their oestrogen levels dropped after menopause, researchers conducted the first trial to look at whether supplementation with the hormone was an effective preventive treatment. The study enrolled 8,341 men and no women ... And a National Institutes of Health-supported pilot study from Rockefeller University that looked at how obesity affected breast and uterine cancer didn't enroll a single woman."

These examples are only a few of the many. However, the campaign garnered more and more support from the public, eventually having the influence to have an effect within the US. In 1993, the FDA (Food and Drugs Administration) and the NIH (National Institute of Health) mandated female participation in clinical trials. Although it was only the beginning, this was a sign of change and progress in the field of medical testing.

## Current Situation

Much progress has been made in the last 20 years regarding the inclusion of women in clinical trials, but there is still room for improvement.

### Changes made

It is true that we have seen great improvements in the representation of women in clinical trials over the last few years. And new strategies are being submitted that have the potential to further women's representation in said clinical trials. Several countries, like the US, where most of the discussions have been held, have created a specific department responsible

for addressing the lack of women's participation in clinical trials and implementing methods to resolve the issue.

| Year | Event |
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| 1962 | Thalidomide tragedy in Europe results in United States Congress to pass the Kefauver-Harris Amendment to mandate changes in drug development and strengthen the authority of the FDA |
| 1975 | National Commission for the Protection of Human Subjects and Biomedical and Behavioral Research promulgates new rule which includes pregnant women as a vulnerable research subjects |
| 1977 | FDA guideline "General considerations for the clinical evaluation of drugs" essentially bans women of child-bearing potential from participating in early phase clinical research, except for life-threatening conditions |
| 1985 | Report from U.S. Public Health Service Task Force on Women's Health concludes "research should emphasize disease unique to women or more prevalent in women" |
| 1986 | NIH advisory committee recommends to grant applicants that women be included in studies; if women are not included, clear rationale must be provided |
| 1988 | FDA "Guideline for the format and content of the clinical and statistical sections of new drug applications" specifies the importance of examining data within NDA databases for differences in safety or efficacy in subgroup populations, including gender |
| 1990 | Office of Research on Women's Health established at the NIH |
| 1993 | FDA guideline "Guideline for the study and evaluation of gender differences in the clinical evaluation of drugs" reverses the 1977 guidance |
| 1993 | Congress mandates adequate inclusion of women in NIH-sponsored clinical trials to determine differences between the sexes |
| 1994 | Office of Women's Health Established at the FDA |
| 1994 | IOM report, "Women and health research" calls attention to two forms of historical gender bias in the design and implementation of clinical trials |
| 1998 | FDA regulation "Presentation of safety and effectiveness data for certain subgroups of the population in investigational new drug application repots and new drug applications" states that NDAs must present safety and efficacy data by sex; FDA has the authority to refuse to file any NDA that does not analyze the safety and efficacy data appropriately by sex. Demographics of participants in its clinical trials must also be included in IND annual reports. |
| 2000 | FDA regulation "Investigational new drug applications: amendment to clinical hold regulations for products intended for life-threatening disease and conditions" gives FDA authority to place a trial for a life-threatening disease or condition on clinical hold if sponsors exclude men or women only because of reproductive potential. |
| 2001 | IOM report, "Exploring the biological contributions to women's health: does sex matter?" establishes importance of sex-based biology. |
| 2010 | IOM report, "Women's health research: progress, pitfalls, and promise" highlights areas of advancement and remaining deficiencies in women's health research |

**Image 1. A timeline of significant events in the history of women's participation in clinical trials in the US**

Other changes, such as the introduction of regulations that require diversity and representation of minority groups, are indeed promising changes. With more attention from the general public, it puts pressure on the nations to act. Furthermore, changes in perspective, scientific and ethical, led to the medical society being more willing to accept these new regulations.

### Remaining issues to be addressed

With that being said, there are still issues that remain. The most controversial and sensitive of the remaining issues is the involvement of pregnant women in such clinical trials. From both an ethical and medical perspective, pregnant women in medical testing is a matter that should be handled with the utmost care. Fetal protection has been and remains an essential priority, but the reality is that lots of drugs in pregnancy have not been tested sufficiently in that population. Therefore, there is a heated debate about whether or not pregnant women should be involved in clinical trials, and if so, what the limitations are or the specifics it would require.

### Moving forward

Reaching or mandating the perfect 50% participation of women in clinical trials would be improbable. Thus, countries and organisations are seeking to move towards this idealistic goal by implementing methods that would help reach the goal eventually. For instance, the FDA

(Food and Drugs Administration) and the OWH (Office of Women's Health) of the US are outlining several strategic plan goals such as:

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| **Goal 1:** Increase sex differences research in basic science studies |
| **Goal 2:** Incorporate findings of sex/gender differences in the design and application of new technologies, medical devices, and therapeutic drugs |
| **Goal 3:** Actualize personalized prevention, diagnostics, and therapeutics for girls and women |
| **Goal 4:** Create strategic alliances and partnerships to maximize the domestic and global impact of women's health research |
| **Goal 5:** Develop and implement new communication and social networking technologies to increase understanding and appreciation of women's health and wellness research |
| **Goal 6:** Employ innovative strategies to build a well-trained, diverse, and vigorous women's health research workforce |

These specified plans will provide a concrete step-by-step approach to achieving greater female participation and involvement in clinical trials. But most importantly, it shows how nations are making a conscious effort to attain their goals. With greater participation and attention from nations, the future of resolving the issue is bright.

## Major Parties Involved and Their Views

### UN Women

UN Women is an international organisation seeking equality and justice for women in all fields. Unfortunately, there hasn't been active participation from the UN Women when it comes to medical testing and clinical trials. However, they have been and remain a strong advocate for ensuring safety for women in medical treatments. If there were to be the need for any international organisation under the UN to facilitate or oversee any processes regarding the issue at hand, UN Women would be the ideal organisation to be given that responsibility.

### United States

The United States is one of the frontrunners in striving for equal female representation in clinical trials. With the involvement of the FDA (Food and Drugs Administration) and the NIH (National Institute of Health), the US implemented several effective regulations to ensure a more balanced environment in medical testing. The FDA also has an Office of Women's Health (OWH), which was created by the 1994 Congressional mandate. The OWH has two overarching goals: 1) to protect and advance the health of women through policy, science, and outreach and 2) to advocate for the participation of women in clinical trials and for sex, gender, and subpopulation analyses. As mentioned in the "Background Information" section, in 1993, the FDA and the NIH mandated female participation in clinical trials. This introduction of such regulation was a pivotal moment in the history of medicine in the US, where clinical trials now required women's participation, allowing more changes to follow. To this day, the US is seeking to adapt various testing mechanisms to reduce bias against women.

## UN Involvement, Relevant Resolutions, Treaties and Events

Although the UN is a global advocate of gender equality, it has done little to directly address the issue of the lack of female participation in clinical trials. There has been no official resolution submitted by the UN specifically targetting the issue, but there are other works by the UN that refer to or are briefly related to the matter at hand.

- Sustainable Development Goals, #5 - Gender Equality - 1 January 2016
- Mainstreaming a gender perspective in drug-related policies and programmes, 15 March 2017 (CND/RES/59/5)
    - This resolution is not related to clinical trials in any way whatsoever. However, it still highlights the need for a different approach to treating women compared to men, acknowledging the difference between male and female requirements in treatments. This resolution can be referred to in case of the need for an example requiring how such measures should be taken.

## Possible Solutions

1. **Creation of an international body/committee (or a sub-committee under UN Women or WHO):** This committee will seek to explore and implement various methods agreed upon by the members to set up a global standard for involving women in clinical trials and ensuring such measures are implemented.
2. **Encourage and advertise volunteering opportunities for clinical trials:** Through advertisements, more women can have the opportunity to participate in clinical trials should they wish to do so. This means there are more female volunteers available for clinical trials, making it easier for research programs to involve such volunteers in their clinical trials.
3. **Educational campaigns and programs:** Educating the public on the current situation regarding the imbalance of male and female representation in clinical trials raises awareness of the issue. This may lead to more pressure from the general public on firms to balance the male and female ratio in clinical trials. Furthermore, it can make women more knowledgeable about treatments and medicine and consult with their doctors more carefully, preventing potential misdiagnosis.
4. **Government funding in research programs/clinical trials:** Instead of enforcing firms to include women, the government can potentially incentivise firms through subsidies or tax deductions to encourage female participation in such clinical trials.

## Bibliography

### Useful Links

- The official website for the Society for Women's Health Research
- A comprehensive article outlining the history of women's involvement in medical testing (Guardian)
- Brief article to provide background information (Healthline)

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