The Importance of Women and Diversity in Clinical Trials

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Clinical trials are key to finding and learning if medical treatments are safe and effective. These treatments include medicines, medical devices, procedures, and lifestyle changes, such as diet. All new medical treatments must go through clinical trials before they can be approved by the FDA. Despite the importance that comes from clinical trials there is a drawback: the people who enroll in trials do not always represent key patient populations like women and minorities. Read on to learn more.

The impact of the lack of diversity

Many factors can affect the way a person responds to a medicine. These include age, gender, genetics, lifestyle habits, and other medical issues a person may have. As a result, medical treatments may be known to be safer and more effective for everyone when clinical trials include diverse patient populations. For example, a medicine for heart failure was found to work better in African-Americans than in Caucasians, likely as a result of different genetics between the two groups. More genetic diversity in clinical trials can help uncover learnings such as that.

Patient participation by the numbers

The authors of a study of diversity in medical research found that minority patient populations are under-represented in clinical trials for a variety of reasons. This is the case even though racial and ethnic minorities represent almost 4 out of every 10 people in the United States. Examples of this lack of diversity include the following:

Less than 2% of 10,000+ clinical trials for cancer, funded by the National Institutes of Health (NIH), included enough minority participants to meet the agency's own goals. Less than 5% of research for breathing diseases funded by the NIH reported including racial/ethnic minorities. While the medical issues from being HIV positive are usually worse among African-American women, clinical trials of a possible treatment included mostly white men.

Why isn't there more diversity on clinical trials?

There are a number of barriers that limit broader enrollment in clinical trials. These include:

Limited access among minority patients to care centers that are the referral sources for clinical trials. Financial issues. Concerns about possible exploitation in medical research. Cultural and language barriers.

Possible barriers to women participating in clinical trials

Researchers suggest that there are a number of possible reasons why women are less likely to be enrolled or to enroll in clinical trials compared with other patient populations. These include:
Lack of understanding of the effects of the disease in women which can lead to under-diagnosing or not referring women to a study. The misperception among study sponsors and investigators that it takes more time and money to recruit women. Fear of harm to an unborn baby if a woman becomes pregnant during the clinical trial. Unintentionally excluding women from participating in a clinical trial due to various study restrictions

(e.g., study that excludes people with smaller body surface areas can exclude women patients). Family responsibilities that limit the amount of time a woman is available to participate.

The positive side of participating in a clinical trial

Most people don't pay attention to or consider clinical trials until they are seriously ill. It's the medical breakthroughs that often get the spotlight instead. However, advances in medicine are the result of clinical trials and research. Every year, thousands of people are helped because they chose to enter into a clinical trial. Their participation also has a ripple effect, helping millions more benefit from effective treatment.

"In order to better help patients and to understand their needs from a clinical trial, we need to make sure that the patients in the trial truly represent the age, race, and gender of those who have the disease."

Ricardo Rojo Clinical Trial Diversity Lead at Pfizer Medical

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