

THE NORMAN LEAR CENTER | USC ANNENBERG HOLLYWOOD, HEALTH & SOCIETY

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Tip Sheet: Diversity in Clinical Trials

Topic: Diversity in Clinical Trials

What is the problem/issue?

When we get sick, we usually take different medications to help us recover. When we have an injury, different therapies and treatments help us get back in good shape. The medications, therapies, and treatments that we use to deal with different illnesses and injuries have been studied using clinical trials. This type of research study should involve different groups of people (e.g. males and females, different races or ethnic groups) and provides information on how safe and effective medications and treatments are for the public.

Unfortunately, the people who often volunteer to participate in clinical trials rarely include those from underrepresented backgrounds - African Americans, Hispanics/Latinos, and people living in rural areas. According to the U.S. Food and Drug Administration (FDA), African Americans represent 12% of the U.S. population but only 5% of clinical trial participants and Hispanics/Latinos make up 16% of the population but only 1% of clinical trial participants.

This lack of diversity in clinical trials hinders opportunities for discovering medication and treatment effects that may only occur in underrepresented populations. Considering that some medications and treatments affect people in different ways, including diverse groups in clinical trials helps researchers understand the reasons behind these differences. Diversity in clinical trials is also especially important in the development of new medications and treatments as we are in the age of personalized medicine, which involves tailoring treatments using a person's genetic and clinical information. Without information on how different groups of people react to certain treatments or medications, it will be very difficult to individualize treatments.

What's the cause?

The lack of diversity in clinical trials can be attributed to several barriers that often make it difficult for people from underrepresented backgrounds to participate in these studies.

Many people are uneasy about clinical trials due to the history of unfair and inappropriate treatment of volunteers for clinical trials. One major barrier that has prevented underrepresented populations from participating in clinical trials and other types of research is mistrust. Historically, there have been researchers who have treated their study participants in unfair and inhumane ways. Accounts of these incidents, such as the Tuskegee Syphilis Experiment, which involved the mistreatment of African American study volunteers, contribute to the fear and uncertainty many communities of color have about clinical trials. This historical mistrust has been renewed in recent years, particularly with the publication

of the book, *The Immortal Life of Henrietta Lacks*. Henrietta Lacks was a poor, African American tobacco farmer whose cells were taken and used without her knowledge by scientists. Her cells became one of the most important tools for advancing medicine and helped scientists develop the polio vaccine, gene mapping, and more. The attention this book received only made individuals, particularly those from the African American community, more fearful of research and the health system in general.

Also, many individuals are simply unaware of the different aspects of a clinical trial, and educational materials regarding these studies are often very difficult to understand and lack culturally inclusive information (Thomson & Hebert, 2014). Also, physicians who serve communities of color are often unaware of clinical trials occurring in the area and are unable to inform their patients.

Other barriers: Time commitment, transportation, linguistic (for non-English speaking populations)

Can it be prevented?

Solving this issue of diversity in clinical trials will require education to address the fears and misconceptions communities have about these studies. By using simple and clear communication materials, specifically materials that are written in the native language of the target population, communities will better understand the purpose of clinical trials and the safeguards put in place to protect volunteers. Researchers must also clearly communicate the importance of clinical trials and the potential benefits for the volunteer and his or her community (Ford et al., 2008).

Education is not only important for the volunteer, but is necessary for researchers as well. As new researchers are being trained, it is important to educate them about constructive ways to conduct research with underrepresented populations, by including information on cultural competency and understanding the community's values and fears in regards to research.

Other strategies that can help improve diversity and access to clinical trials include providing incentives and reimbursement for travel/parking, providing transportation, and providing childcare, which can be very helpful for communities where economic constraints are an additional barrier to participating in research.

The Bottom line

- There is a historical lack of representation of underrepresented populations in clinical trials.
- In the early years, women were excluded from clinical trials, and were viewed as less stable than men.
- The lack of diversity in clinical trials prevents researchers from getting the information needed to help prevent and treat illnesses that mainly affect underrepresented/ethnic populations.

Case Example

Regina and her 10-year old twin boys were just on their way out of the local hospital after visiting the doctor for their annual check-up. Right before they reached the exit, they were approached by a research assistant about a new clinical trial focused on asthma in children. Considering that her boys have had issues with asthma in the past, Regina was interested but was also very hesitant. Being a part of the African American community, she has known families who have had bad experiences with clinical trials. She takes the study flyer and decides to contact her doctor to ask more questions. Have you heard about this clinical trial? How does it work? What if something happens to my boys? These were a few of the questions she asked her doctor. Regina's doctor was able to answer her questions and help alleviate her fears by ensuring her that safety measures are in place to prevent any bad reactions. After thinking it over, Regina decided that participating in the clinical trial could help researchers develop better asthma medications for kids. Then she gave the research assistant a call.

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