The Reporter: Social Justice Law Center Magazine

Volume 2023 Article 6

2023

Diverse Representation in Clinical Research Matters

Nneka Onyekwuluje

"Diverse Representation in Clinical Research Matters"

Superficial diversity in medicine is not only misleading the public– it's killing marginalized communities. In recent years, the health and wellness industry has become a trending topic. Yet, the sheer lack of diversity within clinical trials and research begs the question: who are the intended beneficiaries of this movement? Influential media outlets like Vogue, Cosmopolitan, and Vanity Fair are among many that contribute to the booming wellness industry. Editorials touting the newest skincare products, celebrity-endorsed vitamins, and holistic rituals guaranteed to offer the healthiest lifestyles seem to be the shiny bow atop a historically exploitative and exclusionary industry. On the surface, black and brown hands hold medicine vials or stand in lines for vaccines in commercials, but behind the scenes, the healthcare industry continues to perpetuate racist practices by excluding minority populations from clinical research, making the notion of a medical treatment obsolete.

Ironically, although contemporary clinical research excludes people of color at alarming rates, many areas of specialized medicine were developed at the expense of this population's trauma and exploitation. For instance, many historians recognize Dr. James Marion Sims as "the father of modern gynecology." In the early 1800's Sims began his career experimenting on the bodies of enslaved Black women.[1] He operated on these women without anesthesia or any regard for the excruciating levels of pain he inflicted upon them.[2] Sims spent years repeating these inhumane procedures on various enslaved women until he was confident they were perfected and worthy of performing on white women. Based on his work, Sims later became established as the country's preeminent gynecological surgeon.[3]

---

[1] Zellars, Rachel. "Black Subjectivity and the Origins of American Gynecology." African American Intellectual History Society (AAIHS), 31 May 2018, https://www.aaihs.org/black-subjectivity-and-the-origins-of-american-gynecology/. Accessed 29 March 2023.

[2] I cannot, in good conscience, omit the chilling history of enslaved children leased to James Sims. While sources (unsurprisingly) do not confirm the paternity of the children, research suggests Sims may have impregnated his enslaved patients to find cures for obstetrical fistula. Scholars note, even in the absences of explicit evidence, this may allude to further unethical practices and methods Sims employed. *Id.*

[3] *Id.*

Sims was far from alone. In fact, he was amongst countless ‘medical founding fathers’ who used similar practices on people of color to pave the way for modern medicine. "We are moving toward a view of experiments on slaves as something more systematic," said Todd Savitt, a medical historian at the Brody School of Medicine at East Carolina University.[4] In the summer of 1989, construction workers unearthed 10,000 bones from a basement belonging to the Medical College of Georgia in Augusta.[5] According to his findings, forensic investigators quickly discovered the bones were the legacy of five decades of grave robbing intended to provide medical students before and after the Civil War with cadavers from ‘slave hospitals’ for anatomical lessons. This practice didn't end until the early 20th century.[6]

So how did we get here? Decades removed and the medical field not only whitewashed this gruesome history, but also practically excluded marginalized groups from medical research altogether. In 2013, at Congress’ request under the Food and Drug Administration Safety and Innovation Act (FDASIA) section 907, the FDA published a report investigating the exclusion of demographic subgroups in clinical trials. The results came as no surprise to industry professionals and academics alike. Instead, the study affirmed that “whites represented a high percentage of clinical trial study participants for biologic, drug, and medical device applications and in many cases, other racial subgroups were underrepresented.[7]”

While the statistics are chilling, the effects of underrepresentation in clinical trials are even more damning. Underrepresentation compromises the generalizability of clinical research findings to the U.S. population and makes it difficult to identify early safety signals for adverse events for

---

[4] Vergano, Dan. “Cruel Medical Experiments On Slaves Were Widespread In The American South.” BuzzFeed News, 28 April 2015, https://www.buzzfeednews.com/article/danvergano/cruel-medical-experiments-on-slaves-were-widespread-in-the-a. Accessed 29 March 2023.
[5] *Id.*
[6] *Id.*
[7] https://www.fda.gov/media/86561/download

patients in these groups.[8] Over the latter half of the 20th century, the medical community regarded randomized controlled trials as the gold standard in evidence-based medicine to determine the safety and efficacy of investigational medical therapies. Initially, the results from these trials were broadly generalizable to all patient populations.

Specifically, research has demonstrated that many groups who were underrepresented or excluded in clinical research can have different disease presentations or health circumstances that affect how they will respond to an investigational drug or therapy. Such differences contribute to variable therapeutic responses and necessitate targeted efficacy and safety evaluation.[9]

Similar issues were faced in the development of HPV (Human Papillomavirus) vaccine. The HPV vaccine is a preventative vaccine that helps to protect against several strains of the HPV virus that can cause cervical cancer, as well as other types of cancer and genital warts.[10] While the vaccine is generally considered safe and effective, there have been concerns raised about its safety and efficacy in certain populations, particularly in regard to its clinical trial data.[11]

One of the main issues with the clinical trials for the HPV vaccine was the lack of diversity in the study population. The initial clinical trials for the vaccine included mostly white and Asian women, and there were few participants from other racial and ethnic groups. It was later found that transgender women were not included in the trials at all.[12] This raised questions about the generalizability of the clinical trial data. If the vaccine is only tested in a limited population, it may not be clear whether the vaccine will be equally effective and safe for other populations.

---

[8] "Lack of Diversity in Clinical Trials: A Patient's Guide | LCFA." Lung Cancer Foundation of America, https://lcfamerica.org/lung-cancer-info/lack-of-diversity-in-clinical-trials/. Accessed 4 April 2023.
[9] "Why Diverse Representation in Clinical Research Matters and the Current State of Representation within the Clinical Research Ecosystem." NCBI, National Academy of Sciences, 2022, https://www.ncbi.nlm.nih.gov/books/NBK584396/. Accessed 4 April 2023. Beglinger, 2008; Crawley et al., 2003; Garcia et al., 2016; Ramamoorthy et al., 2015).
[10] Usyk, Mykhaylo, Christine P. Zolnik, Philip E. Castle, Carolina Porras, Rolando Herrero, Ana Gradissimo, Paula Gonzalez et al. "Cervicovaginal microbiome and natural history of HPV in a longitudinal study." PLoS pathogens 16, no. 3 (2020): e1008376.
[11] *Id.*
[12] *Id.*

Second, the exclusion of various groups of women from the clinical trials perpetuates health disparities and inequality. Women of color and transgender women, who were not included in the initial trials, are already at higher risk for HPV-related cancers and other health issues. Without data on the safety and efficacy of the vaccine in these populations, it is difficult to ensure that everyone who could benefit from the vaccine is able to receive it.

Similarly, the pre-exposure prophylaxis (PrEP) given to individuals at risk of HIV-1, included only cisgender men and transgender women in its Phase III PrEP study, and presented the FDA with an extrapolation of data from two Phase I pharmacokinetic studies to support approval of the drug for cisgender women. As a result, the label explicitly excludes from the PrEP indication "individuals at risk of HIV-1 from receptive vaginal sex because effectiveness in this population has not been evaluated" (FDA, n.d.).[13]

Acknowledging these gapping inconsistencies in trials, Congress passed the 2023 omnibus spending bill (Public Law 117-328) requiring diverse action plans for the clinical trials used by the Food and Drug Administration to decide whether drugs are safe and effective.[14] The law marks the first step in addressing decades of testing drugs primarily on white men and the first time that there is a statutory requirement for diversity in clinical trials.[15]

---

[13] "Why Diverse Representation in Clinical Research Matters and the Current State of Representation within the Clinical Research Ecosystem." NCBI, 2022, https://www.ncbi.nlm.nih.gov/books/NBK584396/.
[14]Diversity in Clinical Trials at FDA Gets a Boost From New Law." Bloomberg Law News, 19 January 2023, https://news.bloomberglaw.com/pharma-and-life-sciences/diversity-in-clinical-trials-at-fda-gets-a-boost-from-new-law. Accessed 4 April 2023.
[15] *Id.*

While these congressional initiatives are progressive at best, more must be done to show that diverse representation in clinical research matters. Plans encourage thought. Mandates require action. If Congress is invested in bringing about substantial changes in clinical research and, ultimately, the health and wellness of marginalized individuals, it must mandate policies that truly benefit them rather than perpetuate the latest trends.