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Improving Minorities' Participation In Drug Trials Can Help Reverse Rising Healthcare Cost

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The road from the development of a new drug in a laboratory to shepherding it through a series of clinical trials and presenting research findings to the Federal Drug Administration (FDA) is a long and expensive one. The costs range from $100 million to several billions of dollars, and the entire process can drag on for more than a decade. Adding to that stress is the fact that all this money and time is spent at great risk to the drug companies and its investors. We work with several of the world's top pharmaceutical companies and Contract Research Organizations (CRO), and I can tell you this: there is no industry with more on the line. A product can fail at any point during the testing process, and everything invested up to that point is lost forever.

With so much at stake, and ever-increasing pressure on drug makers and the FDA to hasten the development of new drugs, why does a large percentage of biomedical research not reflect the American population? Too often, minority populations are underrepresented, even in clinical trials for new treatments of diseases that disproportionally affect them. This ethnic diversity gap exacerbates minority health issues and drives up the nation's health care costs. The health care industry must make increasing minority participation in clinical trials a top priority.

The nascent effort to remedy this national crisis -- and that's not hyperbole -- is long overdue. Passed 23 years ago, the National Institute of Health (NIH) Revitalization Act of 1993 mandates that all NIH-funded medical research include women and minorities, yet disproportions in both gender and minority remain in clinical trial participant populations. 2015 census data shows that minorities currently make up about 40% of the population. However, minorities only represent around 30% of enrollees in domestic NIH clinical research.

That statistic is even more discouraging when researchers break it down on the basis of clinical trials aimed specifically at diseases that disproportionately affect minority communities:

- Per the National Cancer Institute, African-American men are twice as likely as their white counterparts to die from prostate cancer but represent 4% of clinical trial participants.
- The CDC reports that suicide is one of the leading causes of death among Asian-American women under 45 years of age. Yet, Asian-Americans constituted less than 1% of trials for CDER-approved treatments of major depressive disorders in the last two years.
- Cancer is the leading cause of death among Hispanics, yet Hispanic cancer patients only make up 4% of participants in cancer clinical trials in the U.S., according to the National Cancer Institute.

As a result, it's virtually impossible to determine the effectiveness of a particular medication or medical device, because its efficacy can vary widely depending on ethnicity and gender (the gender gap, while not as wide as the one that separates minorities from relevant clinical trials, is unacceptable in many areas). For instance, particular blood pressure medications don't work well for many African-Americans. If African-Americans are not represented in the clinical trials, researchers won't discover those exceptions. The pandemic this lack of knowledge represents is having an immediate and negative impact on the country's health care system.

Without accurate data, doctors cannot prescribe drugs and other treatment options for diseases that affect their minority patients. Without access to effective (and less expensive) preventative drugs they can take at home, these patients will be unable to prevent their health from deteriorating. More will end up in hospitals to undergo much more extensive courses of treatments. Those patients without health insurance will require tax dollars to cover those costs that potentially could have been avoided altogether.

Solving this problem requires us to identify its root causes. First, there needs to be a more proactive and sustained nationwide outreach effort to raise awareness within minority communities. Many minorities never learn about the vital role these trials play, or don't realize they're eligible to participate. Other factors include a lack of transportation to and from clinical sites, and holding trials only in large city hospitals instead of community hospitals. These smaller facilities typically do not have the resources to support clinical trials, but they are where many minority patients seek treatment.

Fortunately, more drug manufacturers and government agencies have begun working to close this gap. The Food & Drug Administration recently launched the first phase of a campaign to encourage minorities to participate in clinical trials. The Center for Drug Development and Clinical Trials at Roswell Park Cancer Institute, with support from Eli Lilly, launched a training program for minority doctors to become principal investigators, based on the notion that recruiting minority physicians to care for minority communities will increase cultural comfort with clinical trials.

Finally, collecting and analyzing information is the key to advancement across all industries. That's why the National Minority Quality Forum (NMQF), a nonprofit research and educational organization, is taking a da-ta-driven approach. It uses its billions of patient records to determine what populations are at risk for particular diseases, such as diabetes, HIV, hepatitis C, and rare diseases and their locations nationwide. Sponsors use this data to help facilitate trial recruitment. New technologies that use transparent data analytics to select the right clinical trial sites -- those that can recruit representative patient populations for the disease -- will bring greater efficiency to the industry and, ultimately, get needed drugs to market faster.

There's still a lot of work to be done. The situation grows steadily worse as medicines become more precise and tailored to individual genomes. Increasing the participation of minorities and women in clinical trials is critical to creating new therapies and improving the likelihood that treatments may apply to similar and dissimilar groups. **More companies and public agencies need to throw their full weight behind programs aimed at reducing minority health disparities in order to realize a stronger overall public health benefit.**

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