

Rectifying Institutional Bias in Medical Research

INCREASING THE REPRESENTATION OF WOMEN AND racial and ethnic minorities in human research has become a national priority. Federal agencies have made inclusion of women and minorities an explicit criterion on which applications for clinical research funding are judged.¹ The need for this affirmative action stems from a historical bias favoring white men. As with most other institutions in the United States, medical research no longer actively excludes women and minorities. But the history of these institutions, the way they were designed and built—predominantly by and for white men—slants them in a way that continues to limit access for other groups.

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Federal efforts to remedy this institutional bias have not been very successful. Data from cancer clinical trials suggest that minority representation in research has not only failed to increase but has actually declined over time.²

Distrust of research and researchers is commonly believed to be a major, ongoing impediment to minority participation. African Americans in particular have many reasons to distrust the medical research enterprise. These reasons include the persistence of racially segregated medical facilities into the 1960s and the infamous Tuskegee Syphilis Study. In that 40-year study, federally funded investigators, in the name of understanding how syphilis behaved in African Americans, purposefully withheld effective treatment from infected African American men. The study was finally stopped in 1972 after a whistleblower divulged the story to the press.³

Some might wonder whether these decades-old events still affect attitudes today. In the current era of the Belmont Report, the federal Office for Human Research Protections, and vigilant institutional review boards, does minority distrust in research persist? In this issue of *Archives*, the study by Rajakumar and colleagues⁴ reminds us that it does. In a survey of parents visiting an academic pediatric clinic, African American parents expressed greater distrust in research than white parents did. Parental distrust was in turn associated with less positive attitudes toward research and less willingness to enroll children in a clinical study.

There are many reasons that these results should not be surprising. Although it has been over 40 years since civil rights legislation was passed, this is a relatively short time to heal the wounds of the preceding 400 years.⁵ Moreover, recent studies show that minority patients continue to experience racial discrimination in health care

settings and receive lower quality care than the white majority.⁶ In this light, one might wonder why distrust of medical care and research among African Americans is not greater than it is.

In fact, the study by Rajakumar et al may underestimate the true prevalence and impact of distrust of medical research among African Americans. Parents surveyed in this study felt enough trust to bring their children to a clinic affiliated with a research institution and to participate in this survey. Other studies suggest much greater distrust in medical care and research among African Americans. For instance, alarmingly high proportions of African Americans endorse genocidal theories about HIV/AIDS^{7,8} and birth control.⁹

It is important to note that the negative attitudes observed in the study by Rajakumar et al applied to the research enterprise—the people and institutions carrying out research—not to the concept of research per se. Although many parents, especially African American parents, endorsed the notion that participation in medical research carries excessive risk, nearly identical numbers believed that participants in research received better medical care than nonparticipants. The vast majority, even among those with high levels of distrust, had positive views about research.⁴

Given these generally positive attitudes, it is worth asking whether minority distrust in the research enterprise represents an important problem. The standard reasoning is that distrust leads to lack of participation in research, and that lack of participation limits the generalizability of research findings. However, a recent analysis of participation in clinical trials raises questions about whether distrust is a significant contributor to low participation in research among minorities.¹⁰ In addition, few have challenged the assumption that underrepresentation of minority groups limits generalizability. In the realms of biomedical and clinical research, the notion that generalizability requires broad racial representation suggests that race is an important biological trait that strongly influences the physiology, natural history, diagnosis, and treatment of medical illness. The biological conception of race underlying this assumption is the same one that motivated the presumably well-intentioned scientists who conceived the Tuskegee Syphilis Study. How often does the course of an illness or the effectiveness of treatment truly vary by patient race? Collective data from drug trials among adults with congestive heart failure—an area in which race is often cited as an important variable—suggest that drug effectiveness does not vary substantially by patient race¹¹ and that the problem of general-

izability of basic and clinical research findings across racial groups is largely overstated.

This is not to say that minority distrust is not a cause for concern. While limited participation by Americans of a minority race or ethnicity probably does not substantively affect the generalizability of basic and clinical research, the same is not true for social, behavioral, and health services research, in which socioeconomic, cultural, and experiential differences across racial and ethnic groups play important roles. Limited minority participation also impedes scientific progress on conditions like sickle cell disease and HIV/AIDS, which disproportionately affect minority populations. Among those who do participate in research, mistrust may affect the validity of study findings if participants' wariness affects their adherence to experimental protocols or their responses to questions.¹² Perhaps most importantly, distrust in medical research may reflect an underlying distrust in our health care system, which may in turn contribute to disparities in health care and health status.

We must be careful not to dismiss distrust as unwarranted or as a misperception that we should address by trying to change patient and parental attitudes. Given the prevalence of racial disparities in the quality of health care and ongoing concerns about the quality of informed consent in clinical research,¹³ distrust is far from unwarranted. Rather, it should be viewed as a reflection of the trustworthiness of our own institutions.¹⁴

Viewing the problem as a matter of institutional trustworthiness, rather than patient or parental trust, opens the door to potential solutions. If distrust stems from a historical bias that slants our research institutions, then trust will come only if we rectify those institutions, by redesigning them and strengthening the foundation on which they are built. Most importantly, we must shift ownership of the research enterprise, such that scientists and research participants, and academic centers and communities, become equal partners. As suggested by Rajakumar et al, research participants and the communities in which they live and with whom they affiliate should have a major role in the governance of research projects and in decision-making. This model, known as community-based participatory research, has long been a standard approach in certain scientific disciplines. The medical research enterprise—to use Everett Rogers' terminology for diffusion of innovations¹⁵—has been a laggard with respect to community-based participatory research. It is high time for us to accelerate adoption of this progressive approach. Imagine if in 1947, after penicillin had been established as effective therapy for syphilis, the men participating in the Tuskegee study, or perhaps their families and community leaders, had been at the table with the research scientists, helping to make the decision whether to administer curative therapy or to continue to withhold it.

Community-based participatory research, however, is only part of the solution. From the perspective of minority communities, research institutions will continue to have a biased slant until more people from their communities are part of those institutions. Many minority groups are grossly underrepresented in the health care professions and in the research enterprise. If we want our study samples to be broadly representative, then we should make every effort to make our institutions equally representative by increasing the presence of minority clinicians, scientists, and members of research teams and institutional review boards. If we want minority communities to participate in our work, we must first fix the racial and ethnic imbalance that continues to tilt our ivory towers.

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REFERENCES

1. NIH Revitalization Act. Subtitle B:§131-133; 1993.
2. Murthy VH, Krumholz HM, Gross CP. Participation in cancer clinical trials: race-, sex-, and age-based disparities. *JAMA*. 2004;291(22):2720-2726.
3. Gamble VN. Under the shadow of Tuskegee: African Americans and health care. *Am J Public Health*. 1997;87(11):1773-1778.
4. Rajakumar K, Thomas SB, Musa D, Almario D, Garza MA. Racial differences in parents' distrust of medicine and research. *Arch Pediatr Adolesc Med*. 2009; 163(2):108-114.
5. DeGruy-Leary J. *Post Traumatic Slave Syndrome: America's Legacy of Enduring Injury and Healing*. Milwaukie, OR: Uptone Press; 2005.
6. Institute of Medicine. *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*. Washington, DC: National Academy Press; 2003.
7. Klonoff EA, Landrine H. Do blacks believe that HIV/AIDS is a government conspiracy against them? *Prev Med*. 1999;28(5):451-457.
8. Ross MW, Essien EJ, Torres I. Conspiracy beliefs about the origin of HIV/AIDS in four racial/ethnic groups. *J Acquir Immune Defic Syndr*. 2006;41(3):342-344.
9. Thorburn S, Bogart LM. Conspiracy beliefs about birth control: barriers to pregnancy prevention among African Americans of reproductive age. *Health Educ Behav*. 2005;32(4):474-487.
10. Wendler D, Kington R, Madans J, et al. Are racial and ethnic minorities less willing to participate in health research? *PLoS Med*. 2006;3(2):e19.
11. Shekelle PG, Rich MW, Morton SC, et al. Efficacy of angiotensin-converting enzyme inhibitors and beta-blockers in the management of left ventricular systolic dysfunction according to race, gender, and diabetic status: a meta-analysis of major clinical trials. *J Am Coll Cardiol*. 2003;41(9):1529-1538.
12. Whittle J, Conigliaro J, Good CB, Joswiak M. Do patient preferences contribute to racial differences in cardiovascular procedure use? *J Gen Intern Med*. 1997; 12(5):267-273.
13. Joffe S, Cook EF, Cleary PD, Clark JW, Weeks JC. Quality of informed consent in cancer clinical trials: a cross-sectional survey. *Lancet*. 2001;358(9295):1772-1777.
14. Wynia MK, Gamble VN. Mistrust among minorities and the trustworthiness of medicine [published online ahead of print May 30, 2006]. *PLoS Med*. 2006; 3(5):e244-e245.
15. Rogers EM. *Diffusion of Innovations*. 5th ed. New York, NY: Free Press; 2003.