

Are we making progress in the debate over racial and ethnic categories in biomedical research?

Susan M Wolf

Debate over the proper use of racial and ethnic categories in biomedical research has raged in recent years. With the Human Genome Project showing that human beings are more than 99.9% alike genetically, indicating that there is more genetic variation within 'races' than between them, many have come to doubt the scientific utility of such categories. Yet federal edicts such as Directive 15 from the US Office of Management and Budget mandate the continued use of such categories in research. Moreover, researchers studying health disparities argue that data collection using racial and ethnic categories is necessary to determine whether conditions and care vary by race and ethnicity. Epidemiologists, too, defend the use of racial and ethnic categories to understand contributors to disease such as the stress of experiencing racial prejudice and reduced access to care because of bias.

To make progress in this debate, the University of Minnesota's Consortium on Law and Values in Health, Environment & the Life Sciences with the University's Center for Bioethics convened a conference on 18 April 2005 to consider "Proposals for the Responsible Use of Racial and Ethnic Categories in Biomedical Research: Where Do We Go From Here?" The conference was cosponsored by the Office of Minority Health and Multicultural Affairs at the Minnesota Department of Health. In addition to comparing proposals, attendees discussed the role of communities that participate in research in determining the proper use of racial and ethnic categories and debated legal constraints on the categories that can be used.

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The University of Minnesota was a natural home for this conference, as Jay Cohn (Minneapolis, Minnesota, USA) was the lead investigator and inventor on a patent for BiDil (combining isosorbide dinitrate and hydralazine), which recently became the first drug approved by the Food and Drug Administration for individuals of a particular racial or ethnic group, in this case, African Americans with heart failure. Substantial controversy surrounds the drug and the Food and Drug Administration's action. Beyond that, researchers at large universities must meet federal research requirements, while addressing the concerns of research participants and generating solid data. Yet using Directive 15 categories may violate community expectations and generate data sorted by categories with questionable scientific validity.

Troy Duster (New York, USA and Berkeley, California, USA) began with historical perspective. He argued that whereas scientists and physicians can easily see that their fields were affected by social forces in the past (*e.g.*, slavery compromising mid-19th century sci-

ence and eugenics compromising early 20th century science), it is harder to recognize social forces at work now. He suggested that huge research investments in biotechnology and the development of pharmaceuticals shape contemporary biomedical science and its approach to race and ethnicity. Yet he advocated not rejecting entirely the use of race in biomedical research but instead determining under what conditions race should be used and how the data should be reported. The danger is that if researchers use conventional racial categories and then find a genetic difference, they may "reinvigorate 19th century ideas of racial differences."

Charles Rotimi (Washington, DC, USA) went farther in his rejection of race as a category in biomedical research. He argued that current data on genomic variation do not support the existence of races. Racial categories arbitrarily segment more continuous human variation and ignore relevant variables. Skin color is "not a good representation of what is actually relevant in... genetic studies," including ancestral history, geographical location



Conference speakers debating proposals and conferring with the audience.

and environmental factors. He suggested that 'ethnicity' was a more appropriate term, capturing culture, language, religion and lifestyle. Whereas racial categories wrongly suggest that different groups have unique genetic characteristics, ethnicity admits group fluidity and overlap, facilitating the study of subtle group differences in gene frequencies.

Mildred Cho (Palo Alto, California, USA) conceded that some studies might appropriately use racial or ethnic categories as a proxy for exposure to certain social interactions. But using those categories to define populations genetically is likely to be inaccurate. She urged care in defining population groups; if a research population is defined by geographical location, it should be described that way rather than by race. Care in study design and interpretation means that if researchers "find differences between populations...unexplained by factors other than the population membership...that doesn't necessarily mean that those differences are genetic or racial."

Raj Bhopal (Edinburgh, UK) urged the importance of racial and ethnic categories in epidemiology and public health. Conceding that these categories have not functioned well as epidemiological variables, he argued that "we should improve them." Indeed, given health inequalities around the globe, "it's irresponsible not to use these concepts.... It's irresponsible not to tell the world what's going on." He pointed to studies of smoking and of coronary heart disease to show the importance of analysis by race and ethnicity. He suggested that the goal should be to reduce health disparities by racial or ethnic group, while avoiding racism and ethnocentrism. "There is no reason why the white population should be the norm. In my view, the population with the best health should be the norm."

Margaret Winker (Chicago, USA) argued that "the use of race as a proxy is inhibiting scientists from...identifying the real environmental and genetic causes of disease.... Race or ethnicity should not be used as an explanatory variable when the underlying constructs can and should be measured directly." She described efforts by the Journal of the American Medical Association to encourage authors who use racial categories to clarify the relevance of race and how race was ascertained (preferably by self-designation), to articulate the rationale when race is

used as a proxy and to measure directly variables such as socioeconomic status.

Morris Foster (Norman, Oklahoma, USA) argued the importance of analyzing health practices at the community level. Community variation "can be glossed over by aggregative racial and ethnic categories." Yet "[s]ome local practices that may contribute to health status and outcome cross racial and ethnic categories." He noted that community members themselves may be concerned that larger categories of race or ethnicity will be used against them and will fail to capture important aspects of their lives relevant to health status. At the same time, community members may be aware of the importance of racial and ethnic categories in showing health disparities and claiming resources.

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Dorothy Roberts (Chicago, USA) analyzed the legality of using racial and ethnic categories in research. She acknowledged a number of requirements and incentives to use racial categories in research, including Directive 15, the US National Institutes of Health Revitalization Act of 1993 and rules from the Food and Drug Administration. She also suggested a role for law in constraining the use of such categories, to disapprove a biological definition of race but to further research on health disparities. Under the US Constitution, for example, race is a suspect category, and courts carefully scrutinize its use by federal and state governments. Applying this approach to biomedical research would require that any use of racial categories should further a compelling state interest and be narrowly tailored to accomplish that goal.

Finally, Gregg Bloche (Washington, DC, USA) and J. Cohn discussed the desirability of developing race-specific therapeutics, such as BiDil. G. Bloche said that considering race in prescribing medication may be

useful pending more precise identification of predictors of therapeutic efficacy. He also illuminated the market and regulatory incentives that have driven the emergence of this race-specific drug. By obtaining a patent for race-specific use of a drug already patented, the company delayed market entry of competing generic drugs by 13 years. But research has not established "that adding [BiDil] to conventional treatment yields greater benefits for blacks than for other racial or ethnic group." Furthermore, once a drug is patented and approved for a race-specific use, the pharmaceutical company has little incentive to do further research to pinpoint the relevant genetic, physiological or environmental variations producing differential response by racial or ethnic group, as pinpointing those variations may risk shrinking the market for the drug. Public funding for such research may be needed. J. Cohn countered with the history of BiDil. Once data showed lesser response to standard therapy with drugs to inhibit the rennin-angiotensin system among those individuals with heart failure who identified themselves as black, he reanalyzed trial data and found a marked benefit among those individuals from the drug combination in BiDil that increases nitric oxide activity. Ideally, all groups would then have been studied in a confirmatory trial, but the apparent response difference between those identifying themselves as black and those identifying themselves as white would have mandated separate randomization, and funding constraints limited the study to the group thought most likely to benefit. The study was "dramatically positive, and I would like to see people...get the benefit of the drug in the real world." G. Bloche agreed that those who could benefit should receive either BiDil or the cheaper, generic form of the drug combination. J. Cohn and G. Bloche also agreed that more federal funding for drug research and less dependence on pharmaceutical companies would be a step forward.

This conference found areas of unexpected agreement as well as continued disagreement, in an effort to make progress. The full symposium will appear in the Journal of Law, Medicine & Ethics. The conference video is available at <http://www.lifesci.consortium.umn.edu/conferences/categories.php?s=2>. ■