

Genomes, race and health

Racial profiling in medicine might just be a stepping stone towards personalized health care

Howard Wolinsky

In 2005, the US Food and Drug Administration (FDA; Bethesda, MD, USA) approved BiDil—a combination of vasodilators to treat heart failure—and hailed it as the first drug to specifically treat an ethnic group. “Approval of a drug to treat severe heart failure in self-identified black population is a striking example of how a treatment can benefit some patients even if it does not help all patients,” announced Robert Temple, the FDA’s Director of Medical Policy. “The information presented to the FDA clearly showed that blacks suffering from heart failure will now have an additional safe and effective option for treating their condition” (Temple & Stockbridge, 2007). Even the National Medical Association—the African-American version of the American Medical Association—advocated the drug, which was developed by NitroMed, Inc. (Lexington, MA, USA). A new era in medicine based on racial profiling seemed to be in the offing.

By January 2008, however, the ‘breakthrough’ had gone bust. NitroMed shut down its promotional campaign for BiDil—a combination of the vasodilators isosorbide dinitrate, which affects arteries and veins, and hydralazine hydrochloride, which predominantly affects arteries. In 2009, it sold its BiDil interests and was itself acquired by another pharmaceutical company.

In the meantime, critics had largely discredited the efforts of NitroMed, thereby striking a blow against the drug if not the concept of racial profiling or race-based medicine. Jonathan Kahn, a historian and law professor at Hamline University (St Paul, MN, USA), described the BiDil strategy as “a leap to genetics.” He demonstrated that NitroMed, motivated to extend its US patent scheduled to expire in 2007, purported to discover an advantage for a subpopulation of self-identified black people (Kahn, 2009).

He noted that NitroMed conducted a race-specific trial to gain FDA approval, but, as there were no comparisons with other populations, it never had conclusive data to show that BiDil worked in black people differently from anyone else.

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“If you want to understand heart failure, you look at heart failure, and if you want to understand racial disparities in conditions such as heart failure or hypertension, there is much to look at that has nothing to do with genetics,” Kahn said, adding “that jumping to race as a genetic construct is premature at best and reckless generally in practice.” The USA, he explained, has a century-old tradition of marketing to racial and ethnic groups. “BiDil brought to the fore the notion that you can have ethnic markets not only in things like cigarettes and food, but also in pharmaceuticals,” Kahn commented.

However, despite BiDil’s failure, the search for race-based therapies and diagnostics is not over. “What I have found is an increasing, almost exponential, rise in the use of racial and ethnic categories in biotechnology-related patents,” Kahn said. “A lot of these products are still in the pipeline. They’re still patent applications, they’re not out on the market yet so it’s hard to know how they’ll play out.”

The growing knowledge of the human genome is also providing new opportunities to market medical products aimed at specific ethnic groups. The first bumpy steps

were taken with screening for genetic risk factors for breast cancers. Myriad Genetics (Salt Lake City, UT, USA) holds broad patents in the USA for breast-cancer screening tests that are based on mutations of the *BRCA1* and *BRCA2* genes, but it faced challenges in Europe, where critics raised concerns about the high costs of screening.

The European Patent Office initially granted Myriad patents for the *BRCA1* and *BRCA2*-based tests in 2001, after years of debate. But it revoked the patent on *BRCA1* in 2005, which was again reversed in 2009. In 2005 Myriad decided to narrow the scope of *BRCA2* testing on the basis of ethnicity. The company won a patent to predict breast-cancer risk in Ashkenazi Jewish women on the basis of *BRCA2* mutations, which occur in one in 100 of these women. Physicians offering the test are supposed to ask their patients whether they are in this ethnic group, and then pay a fee to Myriad.

Kahn said Myriad took this approach to package the test differently in order to protect its financial interests. However, he commented, the idea of ethnic profiling by asking women whether they identify themselves as Ashkenazi Jewish and then paying extra for an ‘ethnic’ medical test did not work in Europe. “It’s ridiculous,” Kahn commented.

After the preliminary sequence of the human genome was published a decade ago, experts noted that humans were almost the same genetically, implying that race was irrelevant. In fact, the validity of race as a concept in science—let alone the use of the word—has been hotly debated. “Race, inasmuch as the concept ought to be used at all, is a social concept, not a biological one. And using it as though it were a biological one is as much an ethical problem as a scientific problem,”



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commented Samia Hurst, a physician and bioethicist at Geneva University Medical School in Switzerland.

Citing a popular slogan: “There is no gene for race,” she noted, “there doesn’t seem to be a single cluster of genes that fits with identification within an ethnic group, let alone with disease risks as well. We’re also in an increasingly mixed world where many people—and I count myself among them—just don’t know what to check on the box. If you start counting up your grandparents and end up with four different ethnic groups, what are you going to do? So there are an increasing number of people who just don’t fit into those categories at all.”

Still, some dismiss criticism of racial profiling as political correctness that could potentially prevent patients from receiving proper care. Sally Satel, a psychiatrist in Washington, DC, USA, does not shy away from describing herself as a racially profiling physician and argues that it is good medicine. A commentator and resident scholar at the nonpartisan conservative

think tank, the American Enterprise Institute (Washington, DC, USA), Satel wrote the book *PC, M.D.: How Political Correctness is Corrupting Medicine*. “In practicing medicine, I am not color blind. I take note of my patient’s race. So do many of my colleagues,” she wrote in a *New York Times* article entitled “I am a racially profiling doctor” (Satel, 2002).

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Satel noted in an interview that it is an undeniable fact that black people tend to have more renal disease, Native Americans have more diabetes and white people have more cystic fibrosis. She said these differences can help doctors to decide which drugs to prescribe at which dose and could potentially lead researchers to discover new therapies on the basis of race.

Satel added that the mention of race and medicine makes many people nervous. “You can dispel that worry by taking pains to specify biological lineage. Simply put, members of a group have more genes in common than members of the population at large. Some day geneticists hope to be able to conduct genomic profiles of each individual, making group identity irrelevant, but until then, race-based therapeutics has its virtues,” she said. “Denying the relationship between race and medicine flies in the face of clinical reality, and pretending that we are all at equal risk for health problems carries its own dangers.”

However, Hurst contended that this approach may be good epidemiology, rather than racial profiling. Physicians therefore need to be cautious about using skin colour, genomic data and epidemiological data in decision making. “If African Americans are at a higher risk for hypertension, are you not going to check for hypertension in white people? You need to check in everyone in any case,” she commented.

Hurst said European physicians, similarly to their American colleagues, deal with race and racial profiling, albeit in a different way. “The way in which we struggle with it is strongly determined by the history behind what could be called the biases that we have. If you have been a colonial power, if the past is slavery or if the past or present is immigration, it does change some things,” she said. “On the other hand, you always have the difficulty of doing fair and good medicine in a social situation that has a kind of ‘them and us’ structure. Because you’re not supposed to do medicine in a ‘them and us’ structure, you’re supposed to treat everyone according to their medical needs and not according to whether they’re part of ‘your tribe’ or ‘another tribe.’”

Indeed, social factors largely determine one’s health, rather than ethnic or genetic factors. August A. White III, an African-American orthopaedic surgeon at Harvard Medical School (Boston, MA, USA) and author of the book *Seeing Patients: Unconscious Bias In Health Care*, noted that race is linked to disparities in health care in the USA. A similar point can be made in Europe where, for example, Romani people face discrimination in several countries.

White said that although genetic research shows that race is not a scientific concept, the way people are labelled in society and how they are treated needs to be taken into account. “It’d be wonderful at some point if we can pop one’s key genetic information into a computer and get a printout of which medications are best of them and which doses are best for them,” he commented. “In the meantime though, I advocate careful operational attempts to treat everyone as human beings and to value everyone’s life, not devalue old people, or devalue women, or devalue different religious faiths, etc.”

Notwithstanding the scientific denunciation, a major obstacle for the concept of racial profiling has been the fact that the word ‘race’ itself is politically loaded, as a result of, among other things, the baggage of eugenics and Nazi racism and the legacies of slavery and colonialism. Richard Tutton, a sociologist at Lancaster University in the UK, said that British scientists he interviewed for a Wellcome Trust project a few years ago prefer the term ethnicity to race. “Race is used in a legal sense in relation to inequality, but certainly otherwise, ethnicity is the preferred term, which obviously is different to the US” he said. “I remember

having conversations with German academics and obviously in Germany you couldn’t use the R-word.”

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Jan Helge Solbakk, a physician, theologian and medical ethicist at the University of Oslo in Norway, said the use of the term race in Europe is a non-starter because it makes it impossible for the public and policy-makers to communicate. “I think in Europe it would be politically impossible to launch a project targeting racial differences on the genetic level. The challenge is to find not just a more politically correct concept, but a genetically more accurate concept and to pursue such research questions,” he said. According to Kahn, researchers therefore tend to refer to ethnicity rather than race: “They’re talking about European, Asian and African, but they’re referring to it as ethnicity instead of race because they think somehow that’s more palatable.”

Regardless, race-based medicine might just be a stepping stone towards more refined and accurate methods, with the advent of personalized medicine based on genomics, according to Leroy Hood, whose work has helped to develop tools to analyse the human genome. The focus of his company—the Institute for Systems Biology (Seattle, WA, USA)—is to identify genetic variants that can inform and help patients to pioneer individualized health care.

“Race as a concept is disappearing with interbreeding,” Hood said. “Race distinction is going to slowly fade away. We can use it now because we have signposts for race, which are colour, fairness, kinkiness of hair, but compared to a conglomeration of things that define a race, those are very few features. The race-defining features are going to be segregating away from one another more and more as the population becomes racially heterogeneous, so I think it’s going to become a moot point.”

Hood instead advocates “4P” health care—“Predictive, Personalized, Preventive and Participatory.” “My overall feeling about the race-based correlations is that it is far more important to think about the individual and their individual unique spectra

of health and wellness,” he explained. “I think we are not going to deal in the future with racial or ethnic populations, rather medicine of the future is going to be focused entirely on the individual.”

Yet, Arthur Caplan, Director of the Center for Bioethics at the University of Pennsylvania (Philadelphia, PA, USA), is skeptical about the prospects for both race-based and personalized medicine. “Race-based medicine will play a minor role over the next few years in health care because race is a minor factor in health,” he said. “It’s not like we have a group of people who keel over dead at 40 who are in the same ethnic group.”

Caplan also argued that establishing personalized genomic medicine in a decade is a pipe dream. “The reason I say that is it’s not just the science,” he explained. “You have to redo the whole health-care system to make that possible. You have to find manufacturers who can figure out how to profit from personalized medicine who are both in Europe and the United States. You have to have doctors that know how to prescribe them. It’s a big, big revamping. That’s not going to happen in 10 years.”

Hood, however, is more optimistic and plans to advance the concept with pilot projects; he believes that Europe might be the better testing ground. “I think the European systems are much more efficient for pioneering personalized medicine than the United States because the US health-care system is utterly chaotic. We have every combination of every kind of health care and health delivery. We have no common shared vision,” he said. “In the end we may well go to Europe to persuade a country to really undertake this. The possibility of facilitating a revolution in health care is greater in Europe than in the United States.”

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