Race-based medicine?

**African American heart drug study raises questions about benefits of racially targeted trials**

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http://www.the-scientist.com/?articles.view/articleNo/25688/title/Race-based-medicine-/

A recent [study](http://www.lejacq.com/Search_articleDetail.cfm?aid=jch%5F7548%2Epdf) on the effects of a hypertension drug in African Americans has shone the spotlight on the value of single race studies in medicine. While some praise such studies for reaching out to groups disproportionately affected by a disease, others say grouping trial participants by [race](http://www.the-scientist.com/supplement/2006-11-1/) attributes health disparities to the wrong cause. While clinical trials often look at associations between race and outcomes, it is uncommon for them to be prospectively race-specific. This study compared several different doses of the drug nebivolol - a beta blocker approved in a number of European countries - against placebo, and found the drug significantly lowered blood pressure in African Americans. Beta blockers are thought to be less effective in African American patients than in white Americans. Race-based studies offer "a window of opportunity to understand nuances in medicine," [Keith Ferdinand](http://www.controlhypertension.org/about/bios/item.php?bio_id=135), the chief science officer of the Association of Black Cardiologists, told *The Scientist*. In addition to a weaker response to beta blockers, African Americans have a higher prevalence and a more severe pathophysiology of heart disease than do white Americans. While medical outcomes might be due to factors such as access to care, economic stress, or diet, they tend to segregate by race, which therefore provides a useful marker for testing the efficacy of drugs, Ferdinand said. In the past, African American-only trials have received considerable attention. The heart disease drug [BiDil](http://www.the-scientist.com/article/display/15896/), for example, which Ferdinand helped to study, was the first drug in the US approved for and marketed to just one race of patients. [Jonathan Kahn](http://law.hamline.edu/dr-jonathan-kahn.html), a law professor at Hamline University in St. Paul, Minn., who has been an outspoken critic of BiDil's marketing approach, said that "it sends dangerous messages that race is somehow genetic." Which it is not, [Charles Rotimi](http://www.genomecenter.howard.edu/units/Genetic_Epidemiology/default.htm), the director of the National Human Genome Center at Howard University in Washington, DC, told *The Scientist*. While race can be useful to understand how diseases manifest in certain groups, hinging studies on race distracts from the underlying causes of health disparities, Kahn said. But [Frank Douglas](http://mitsloan.mit.edu/newsroom/newsbriefs-0605-douglas.php), the former director of MIT's Center for Biomedical Innovation, said that regardless of the underlying causes of health disparities, testing a drug's efficacy by racial identification can benefit patients. In the case of nebivolol, Douglas told *The Scientist*, "If you find a beta blocker that works in a patient subset that traditionally hasn't responded well to others, why would you...lose focus on patients who need the drug and get involved in a [social discussion](http://www.the-scientist.com/article/display/53636/)? That I don't understand." Unlike BiDil, nebivolol will not be marketed as a beta blocker specifically for African Americans, said Charles Triano, the vice president of investor relations at Forest Laboratories, nebivolol's manufacturer. "Nebivolol, we think, is a product that will demonstrate blood pressure reduction in a very broad population," he told *The Scientist*. (The US Food and Drug Administration is currently reviewing the drug for approval; Triano said he expects a decision at the end of this month, and prescriptions to become available in January 2008.) Instead, the study, commissioned by Mylan Pharmaceuticals, was conducted in order to demonstrate that nebivolol works well in African American patients, despite the fact that it is a beta blocker, said lead author [Elijah Saunders](http://www.ishib.org/AI_board_esaunders.asp) of the University of Maryland School of Medicine. He examined the drugs efficacy exclusively in African American patients, and found that nebivolol "basically did a wonderful job to lower blood pressure," he told *The Scientist*. The study did not compare nebivolol to other [beta blockers](http://www.the-scientist.com/article/display/19316/). Nor did it compare the efficacy of nebivolol in white versus African American patients, although previous trials have shown a comparable benefit for both groups taking the drug, the authors wrote. While beta blockers work significantly better in white patients than African American patients, the overall difference in efficacy is still quite small - only about 10 percent, said [Jay Kaufman](http://www.sph.unc.edu/research/spotlight_on_jay_kaufman_phd_484_1668.html) of the University of North Carolina School of Public Health. One [study](http://www.the-scientist.com/pubmed/10737282) found the beta blocker atenolol was effective in about half of hypertensive African American patients. "So if you deny Black patients these drugs, a big chunk of patients aren't getting drugs that would work for them," Kaufman said. But the problem Rotimi sees with using race as a marker is that any one self-identified group is never homogeneous - there are always more variations genetically within a racial group than between them, he said. "[Human variations](http://www.the-scientist.com/article/display/15791/) do not overlap with our notions of race," Rotimi said. The nebivolol study included patients who self-identified as African Americans, which Rotimi noted is a very heterogeneous group. "That is the key message. It is not for us to ignore differences, but understand differences and interpret them correctly."

By Kerry Grens mail@the-scientist.com

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