The Next Heart Fix

Finally, there's a lifesaving heart medication that works wonders in black people. But it's not without controversy. Chee Gates gets the lowdown on BiDil from B. Waine Kong, PhD, head of the Association of Black Cardiologists.

September 2, 2005 By Chee Gates

June 24, 2005 marked the first time any drug has been FDA-approved for a specific racial group. The pill: BiDil. The ailment: heart failure.The beneficiaries: black Americans. And after decades of drugs being designed for and tested only in white men, ain't it long past time? You certainly know someone who has one of the disease's infamous prerequisites: high blood pressure, high cholesterol, diabetes, obesity or a full-fledged heart attack.

A heart-failure diagnosis doesn't mean your ticker has totally flunked its function, but it does mean it isn't pumping as well as it should. Sufferers tire quickly and pant and wheeze—their vitality, shot. Many lose years off their lifespan. The good news is, there's hope.

The African-American Heart Failure Trial (A-HeFT) tested BiDil, a drug manufactured by NitroMed, on 1,050 black female and male heart-failure patients. It was the largest clinical trial ever performed on black Americans. Results showed that, when taken along with an ACE-inhibitor or beta blocker, medications often prescribed for heart failure, BiDil extended and improved quality of life. In fact, BiDil's lifesaving bang was so profound, the study was halted so the placebo group could receive treatment.

Critics think BiDil's approval is a step toward race-based medicine (as if that doesn't already exist) and fear the prescription of different treatments based on skin color.

We asked B. Waine Kong, PhD, JD and CEO of the Association of Black Cardiologists (ABC), the professional organization that partnered with A-HeFT researchers, to bring us up to date on the implications of this momentous occurrence.

Real Health: Why did the ABC team up with Nitromed?
Kong:Traditionally, drug companies have perceived it to be very, very difficult to recruit blacks to participate in clinical trials. The ABC has had a long tradition of being effective in motivating blacks to participate. In the old days, clinical trials were done on white men.With this study, we've changed the paradigm.

All1,050 patients in the study were black. But with our mixed ancestry and research showing that the racial categories we commonly use mean more socially than genetically, how did you define "black"?
If you said you're black, you're black. It's probably more a state of mind than anything else.

Are you implying that people of other races may benefit from the drug?
BiDilis probably for everybody. I'd have no problem prescribing it to white patients. But right now, we only have evidence that it works in people who call themselves black. If A-HeFT researchers had included whites in this study, it's possible that they would have had the same positive outcome.

BiDil was initially tested in the general population 23 years ago, but the results weren't as good—even among white folks—as they were in the A-HeFT trial. Were there any blacks in that initial study?
Yes, a small group.

So why wasn't BiDil as effective in them back then as it is now?
Blacks did do better than whites in that initial BiDil study. However, the results weren't as robust as they were in A-HeFT. Keep in mind that when BiDil was first tested in 1982, there were no ACE-inhibitors or beta blockers, the two best drugs now available for treating heart disease. There's a different racial response to those compounds as well. ACE-inhibitors and beta blockers have not been as effective in blacks. But when BiDil was added on top of those two drugs in the A-HeFT study, the effects were tremendous.

What does BiDil affect that makes the combination of drugs more effective?
We suspect BiDil increases the patient's nitric oxide, which relaxes the blood vessels and makes it easier for the blood to pump through .Assuming this theory is correct, if you're deficient in processing nitric oxide, BiDil may have a better chance of helping you.

Do blacks have a harder time processing nitric oxide than whites?
We don't know for sure. We're developing some very good databases to look into that further. The NitroMed folks had an inkling that BiDil, when mixed with the ACE-inhibitors and beta blockers, would work well in blacks. Even though the newer drugs weren't included in the '80s study, blacks still had better results than whites. So NitroMed tested it specifically in blacks.

It's been reported that NitroMed would receive an extended 13 years of patent protection from the FDA if the drug was approved for blacks only. Does it matter if they were motivated more by money than saving lives?
I think it's possible to help people and do well financially. But we shouldn't be motivated only by profit.

How would you respond to critics who call approving a drug for blacks only a step toward racial profiling in medicine?
Let's face it, racism is a crucial part of how we provide health care in this country. African

Americans are obviously not receiving equal care. The FDA's approval of BiDil benefits a group that has been harmed in the past. That's a good thing. It's a step toward tailored medicine,meaning medicine that's specific to its user.

But doesn't this lend credence to the argument that blacks and whites are genetically different?
You can take genetics off the table. Blacks and whites only have a 0.1% genetic difference. But socially, culturally, and environmentally we're not alike.

Why then are African Americans so much more at risk for heart disease?
The simple answer is we don't do as well with controlling risk factors: uncontrolled high blood pressure, stress, cholesterol, weight, smoking, inactivity, the usual culprits. So depending on what you eat, it will change your body chemistry. If you like to eat, you must exercise regularly to provide the balance. If you don't like to exercise, you should follow a more strict diet. Ideally, we should eat low-fat,low-sugar foods. Depending on how much stress you're under, it will change your body chemistry. It's different from young to old; it's different from rich to poor; it's different from people in certain geographic regions than others. There was a study testing the effects of stress on rats. One cage of rats was stressed repeatedly with electric shocks. The other cage of rats wasn't. And the stressed rats aged twice as fast as the ones who were not being shocked.

So metaphorically speaking, we'd be the stressed rats?
Yes. Environment really matters.

How can BiDil change things?
If you look at the data, 43% fewer people will die when they're on this drug. Thirty-nine percent have fewer first-time hospitalizations due to the disease. Quality of life goes up dramatically. People who were unable to do activities they loved because they were too strenuous will be able to enjoy those activities again. But I'm assuming it may not work for about 10–20% of African Americans.

Why not?
It's because you're different biochemically than I am. Some people will have fantastic results with BiDil, while some may not.

What other benefits can heart-failure patients expect from BiDil?
All those people who've been sleeping on four pillows to help them breathe,tossing and turning at night, coughing and running out of breath, can look forward to going back to work and doing the things they love.

Do you think BiDil will be retested in the general population?
We've recommended that the FDA move forward with that study. It will be done.Until then, there's no use keeping it from those who need it. My mother has heart failure and I can't wait for her to try this. I look forwardt o her feeling better and living a few more years.

If more black patients had been recruited into, or volunteered for,earlier clinical trials, would we

have had to wait so long for such a breakthrough?
It may or may not have worked in our favor. The ABC encourages higher enrollment of blacks in clinical trials. It's a good way to increase the probability of us getting the best and most recent treatment.

It's a shame we get better treatment through the side door of clinical studies rather than the front door of everyday care.
Yes, but at least we're getting somewhere.l

How to Prevent Heart Failure

Faith doesn't hurt: A 1999 study showed that African Americans who attended church regularly lived 14 years longer than those who didn't. Here are some additional prevention strategies:

- **Ask you doctor to check your blood pressure.** A reading of 120/80 is considered normal.
- **Manage your cholesterol.** Get a lipoprotein profile, which measures your good and bad cholesterol and other forms of blood fat.
- **Track your blood sugar.** A fasting plasma glucose test checks your likelihood for developing diabetes.
- **Eat smart.** Follow a low-fat diet, and exercise at least three times a week for 30 minutes.
- **Don't smoke.**

Heart-Failure Warning Signs

These symptoms from the Heart Failure Society of America (HFSA) may signal heart failure. Call your doctor if you experience these symptoms, often mistaken for normal signs of aging.

- Shortness of breath
- Trouble breathing when resting or lying down
- Waking up breathless at night
- Needing more than two pillows to sleep
- Tiring easily
- Swelling of feet ankles or legs
- General fatigue
- Frequent coughing

- Coughing that produces mucous
- Dry, hacking cough when lying down

For more information about managing and preventing heart failure, contact the Heart Failure Society of America (651-642-1633, www.hfsa.org), the American Heart Association (800-242-8721), www.americanheart.org) and the health center at the Black Women’s Health Imperative (202-548-4000, www.blackwomenshealth.org).
