Generic drugs key to US overseas HIV relief: researchers

July 9 2012

The President's Emergency Plan for AIDS Relief (PEPfAR) began in 2003 with good intentions, but it was not until the U.S. government's massive overseas public health campaign adopted generic drugs that it became a success, according to a new article by Brown University researchers in the July issue of the journal *Health Affairs*. Nearly a decade later, expanding the availability of generics remains urgent, especially as doctors in the field encounter resistance to first-line treatment regimens.

"By 2002 generic drugs had been shown to work, so there was not a question of whether they were efficacious," said Kartik Venkatesh, an M.D./Ph.D. graduate student and the paper's lead author. "So then it was a question of how do we expand access to treatment so that more than 5 to 10 percent of those in need of treatment were getting it. Now two out of three individuals who need treatment in the 15 PEPfAR countries are getting it."

That's because the program, which primarily bought proprietary medicines from major U.S. manufacturers in the early years, eventually made the transition to much cheaper generics, said Venkatesh who will speak about the paper as part of a Health Affairs briefing July 10 that features Nils Daulaire, director of global health affairs in the Department of Health and Human Services, and Eric Goosby, U.S. global AIDS coordinator.

Generics slashed the program's costs, allowing it to vastly expand care

delivery. In their review article, Venkatesh and his co-authors cite data that PEPfAR has reduced its annual per person spending on antiretroviral medicines to $300 this year from $1,100 in 2005.

PEPfAR, launched by President George W. Bush and then reauthorized by President Obama, is a multibillion-dollar effort to deliver HIV treatment and other related health services to people in 15 developing nations, including 12 in sub-Saharan Africa.

Early on, the program did not have a mechanism in place to allow for the adoption of generics. Instead the program only purchased antiretrovirals that the FDA had approved for use in the United States. Whether that was because of concerns about drug quality or industry politics or a combination of both seemed a matter of debate.

"There was tremendous concern at the beginning that antiviral medications bought by PEPfAR would be limited to branded drugs, purchased from the U.S. pharmaceutical industry," said Dr. Charles Carpenter, professor of medicine in the Warren Alpert Medical School of Brown University and a physician at The Miriam Hospital.

The FDA subsequently agreed to evaluate and to give tentative approval, when appropriate, to qualifying foreign-made generic antivirals so that they could be bought by PEPfAR and used exclusively overseas. The program also expanded drug availability by developing a sophisticated supply chain management system to anticipate demand. In addition, over time the FDA has lowered the costs it charges foreign drug companies to test their generics.

"We are now providing HIV medications for more than 3 million people, hopefully 4 million soon, and are buying them for the least cost possible," Carpenter said.

Carpenter and Dr. Kenneth Mayer, a professor at Harvard Medical School and adjunct professor of epidemiology at Brown, are co-authors on the paper.

PEPfAR is now facing the challenge that many people have HIV infections that are resistant to the first-line and second-line antiretroviral drugs available as generics. PEPfAR has not yet approved and gained access to many of the drugs that make up a second and third line of antiviral defense in a generic form.

"I don't know how long that's going to take, but I do know that Ambassador Goosby is working very hard to achieve that end," Carpenter said.

For other major global health efforts, Carpenter said, what PEPfAR's experience has to teach will vary based on the disease at hand.

But Venkatesh said studying PEPFAR's history with generics does have value for the future, even in new efforts that might target non-communicable diseases such as diabetes or obesity.

"One piece of this puzzle is having a regulatory framework in place early on to allow for efficient and transparent procurement of generic drugs," Venkatesh said. "This requires the U.S. government, the Food and Drug Administration, the World Health Organization, generic drug manufacturers in the developing world, as well as the multinational pharmaceutical companies to all be on the same page, at least at some level."

It's apparently not easy to do that, but when it happens, as PEPfAR shows, it can save and prolong millions of lives.

Provided by Brown University