Generic HIV treatment strategy could save nearly $1 billion annually but may be less effective

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Replacing the combination of brand-name, antiretroviral drugs currently recommended for control of HIV infection with soon-to-be-available generic medications could save the U.S. health care system almost $1 billion a year but may diminish the effectiveness of HIV treatment. A study led by Massachusetts General Hospital (MGH) investigators, appearing in the January 15 *Annals of Internal Medicine*, examines the potential impact of such a change.

"The switch from branded to generic antiretrovirals would place us in the uncomfortable position of trading some losses of both quality and quantity of life for a large potential dollar savings," says Rochelle Walensky, MD, MPH, of the MGH Medical Practice Evaluation Center, lead author of the study. "By estimating the likely magnitude of these offsetting effects now – before generic antiretrovirals actually hit the shelves – we can confront our willingness as clinicians, patients and as a society to make these difficult choices."

In 2011 the cost of antiretroviral drugs in the U.S. was around $9 billion, most of which was paid for by government sources. The currently recommended treatment for newly diagnosed patients is a single pill (Atripla) taken daily that combines three brand-name antiretrovirals: tenofovir (Viread), emtricitabine (Emtriva) and efavirenz (Sustiva). A generic form of the antiretroviral drug lamivudine, which has a similar mechanism of action to emtricitabine, became available in January 2012,

and a generic version of efavirenz is expected in the relatively near future.

Replacing two of the three branded drugs with generics could significantly reduce costs, the authors note, but such a strategy would also have disadvantages. A more complicated treatment regimen, requiring three daily pills instead of one, increases the risk that some patients will miss doses, leading to the loss of antiretroviral effectiveness called treatment failure. Laboratory studies have also found that lamivudine may be slightly less effective and more vulnerable to the development of drug-resistant viral strains than emtricitabine.

To evaluate the impact of a switch to a generic-based antiretroviral regimen, the research team used a widely used mathematical model of HIV progression to simulate the effects of a daily three-pill regimen of generic efavirenz and lamivudine plus brand-name tenofovir, compared with the current one-pill combination drug. They adopted a worst-case scenario to project the efficacy of the generic drugs and their impact on viral resistance

Their results indicated that switching all HIV-infected patients in the U.S. to the three-drug generic strategy would produce lifetime savings of $42,500 per eligible patient. In the first year alone, the nationwide savings would reach nearly $1 billion. However, the quality-adjusted loss of life expectancy could be as much as 4.5 months.

The study's senior author, Bruce Schackman, PhD, associate professor of Public Health at Weill Cornell Medical College, says, "Diverting patients from the most effective, branded treatment alternative could be made more acceptable if the savings were directed to other HIV-related needs. For example, fewer than half the state-funded AIDS Drug Assistance Programs include the effective protease-inhibitor-based treatment for hepatitis C virus (HCV), which infects up to 25 percent of HIV-infected

individuals. We calculated that, for every 15 patients switched to the generic-based regimen, one who is also infected with HCV could be treated and potentially cured of that infection."

Adds Walensky, a professor of Medicine at Harvard Medical School, "For patients who take their medications well and adhere to the medical regimen, the generic option will be a bit more complex but could be as effective as the standard regimen. But a patient who relies heavily on the simplicity of taking a single pill is more likely to suffer detrimental effects, since missing doses will increase the risk of treatment failure.

"There's no getting around the fact that savings from generics will only be realized if we deliberately route patients away from the most effective, branded treatment alternative," she stresses. "This is a trade-off that many of us will find emotionally difficult, and perhaps even ethically impossible, to recommend. All of us – consumers, providers and advocates – would be far likelier to embrace such a policy change if we knew the savings would be redirected towards other aspects of HIV medicine."

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