School of Public Health
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Forum for Collaborative HIV Research

The Use of Generic Antiretrovirals for Treatment of HIV in the United States
A Project of the Forum for Collaborative HIV Research

With a number of first-line regimen drug patents expiring in the next few years, the availability of generic antiretrovirals (ARVs) will be an unprecedented occurrence in the history of the treatment of HIV infection. Recent modeling studies have suggested that a 3-pill, generic-based regimen (two generics, one branded) has the potential for significant price reductions.[1] However, patients and providers have expressed concerns about potential consequences including: 1) increased pill burden, 2) decreased treatment adherence, and 3) the perceived quality of generic drugs. In most branches of medicine patent expirations and the use of generic regimens has become standard practice, however as the current US HIV treatment guidelines lack sufficient data to make evidence-based recommendations, the role of generics for treatment of HIV in the US is still unclear.

Beginning in 2014, the Patient Protection and Affordable Care Act (ACA) will expand coverage for many people living with HIV (PLWH) through Medicaid expansion and/or enrollment in private coverage. At present, only 37% of PLWH are in regular care and a majority of those in care rely on Medicaid, Medicare and/or support through the Ryan White HIV/AIDS program. In combination with state expenditures, Medicaid represents the largest public financing source for HIV care; prescription drug therapy representing the largest treatment service for PLWH. With drug expenditures and demand continuing to grow, we want to take advantage of this unique opportunity to discuss the potential clinical and fiscal impacts of generic antiretrovirals.

The Forum and its partners, HIVMA and ACRIA, plan to organize a one- or two-day roundtable to identify and discuss issues that will or may need to be addressed as generic ARVs continue to become available. Using its unique approach, the Forum can bring together key stakeholders from academia, community groups, clinicians, industry, and government to address the myriad questions and issues the ACA will raise.

Topics under consideration:

Payers

- What guidance and data are needed for payers regarding the utility of generics in HIV treatment in the US?
- What are the implications for PLWH residing in states that choose not to participate in Medicaid expansion?
- Copayments for branded drugs are often covered by their manufacturers' copayment assistance programs. As generic manufacturers often do not have copayment assistance programs, will payers employ copays for generic drugs?
- As more PLWH become eligible and enroll in Medicaid and/or private insurance, what are the implications for state formularies?

- What data are needed to support reinvestment of savings from potential lower drug costs into HIV/AIDS treatment and/or prevention programs? What mechanisms and checks will be needed to monitor and audit this investment to ensure it is used as planned?

Patients (subpopulations)

- What impact will the use of generics have on treatment decisions and outcomes in disproportionately affected populations, such as racial/ethnic and sexual minorities or those otherwise marginalized in the epidemic?
- What, if any, individual-level tradeoffs (*e.g.*, a decrease in Quality Adjusted Life Years [QALYs] or reduced length of life) are acceptable for societal benefit?
- How might increased out-of-pocket costs negatively impact treatment choices, treatment adherence or even care-seeking, and if so which patient sub-populations are most impacted?

Providers

- How can providers be best informed about the appropriate use of generics for their patients?
- One pill per day has been a major advance in treatment of HIV. How will providers deal with the potentially increased complexity of treatment regimens?

Research

- What are the implications of cost-effectiveness and comparative effectiveness research?
- What data are needed to support the use of one pill per day *vs*. three pill per day?
- What are the advantages and disadvantages for the use of generics in treatment regimens?
- What unique, but vital, research questions should be addressed as this natural experiment proceeds to determine the type and level of impact upon treatment adherence, HIV care-seeking, and HIV care?

1. Walensky RP, Sax PE, Nakamura YM, et al. Economic savings versus health losses: the cost-effectiveness of generic antiretroviral therapy in the United States. Ann Intern Med 2013;158:84-92.

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