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Is there a role for generic antiretroviral drugs in the United States?

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The high cost of antiretroviral drugs has limited access to treatment for some HIV-infected patients in the United States and strained public resources. With the introduction of much cheaper generic versions of some of these agents, and with more to come in the next few years, the need increases to define the role of generic antiretroviral drugs in patient management.

Although not curative, antiretroviral drugs have dramatically improved the survival and quality of life of HIV-infected patients in the USA. Antiretroviral drugs are able to reduce the viral load, ideally to undetectable levels, which typically results in substantive increases in the CD4 T cell count. Higher CD4 T cell counts in turn reduce or eliminate the risk for opportunistic infections.

The first antiretroviral drug, zidovudine, received US FDA approval in 1987. Since then, more than 30 additional antiretroviral medications have received approval as of January 2014, including seven formulated as a fixed combination of two or more active agents. The large number of drug choices has provided effective drug regimens for most patients, even those harboring drug-resistant strains of HIV, and allowed reductions in the pill burden to as few as one pill per day. Certain older antiretroviral drugs with unsatisfactory toxicity profiles are rarely utilized or are no longer manufactured. Guidelines for antiretroviral drug management of patients in the USA are prepared and regularly updated by panels of experts in the field [1,2].

Antiretroviral regimens recommended as first-line therapy typically consist of the fixed combination of the two nucleoside agents, tenofovir and emtricitabine (the brand name of the combination drug is Truvada), if the infecting strain of HIV is susceptible [1], plus a potent third drug from another antiretroviral class [1,2]. In the USA, neither tenofovir

nor emtricitabine is available as a generic drug, nor are any of the recommended third drugs from other classes. As of 1 January 2014, however, at least six individual antiretroviral drugs are off patent protection and available in generic formulations (e.g., zidovudine, lamivudine and abacavir) in the USA; in addition, the fixed combination of zidovudine plus lamivudine (with the brand name of Combivir) is also available as a generic preparation [1]. Utilization of generic antiretroviral agents has enabled thousands of patients in resource-limited regions such as sub-Saharan Africa to receive these beneficial treatments as part of the President's Emergency Plan for AIDS Relief and has saved hundreds of millions of dollars [3]. However, there has been little discussion of where generic formulations might be used in clinical management of US patients, the potential economic benefits of substituting these drugs in place of other currently recommended first-line therapies or whether they deserve prioritization.

To address some of these issues, we obtained the costs of selected generic and nongeneric antiretroviral drugs based on a January 2014 survey of New York City pharmacies from three national chains (TABLE 1). The regimen of generic zidovudine plus generic lamivudine purchased as individual drugs was much less expensive than Truvada. Compared with the cost per year of Truvada, the savings to a patient paying out of pocket for the regimen of generic

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Table 1. Pharmacy charges for selected generic and brand name nucleoside antiretroviral drugs for the treatment of adult patients with HIV infection in January 2014.

Pharmacy chain	Annual costs of generic nucleoside drugs	Annual cost of least expensive generic two nucleoside regimen [†]	Annual cost of Truvada (tenofovir plus emtricitabine)*
A	Zidovudine – US\$3588.48 Lamivudine – US\$4436.50 Abacavir – US\$6101.53 Zidovudine fixed combination with lamivudine – US\$9865.94	US\$8024.98	US\$17,208.60
B	Zidovudine – US\$2214.24 Lamivudine – US\$4379.92 Abacavir – US\$7299.96 Zidovudine fixed combination with lamivudine – US\$9515.53	US\$6594.16	US\$19,224.64
C	Zidovudine – US\$4014.92 Lamivudine – US\$4513.76 Abacavir – US\$6363.11 Zidovudine fixed combination with lamivudine – US\$9197.98	US\$8528.68	US\$20,026.43

Annual costs refers to a 365 day supply of medication.

[†]Generic zidovudine plus generic lamivudine as individual drugs was the least expensive option.

*Truvada was less expensive than the cost of tenofovir plus emtricitabine given as separate drugs, with an annual cost differential of US\$1468.41 for pharmacy chain A, US\$3272.75 for pharmacy chain B and US\$1131.39 for pharmacy chain C.

zidovudine plus generic lamivudine as individual drugs varied from US\$9183.62 to US\$12,630.48 per year depending on the pharmacy chosen to fill the prescriptions. The price individual patients pay is, of course, much more complex than the findings of our survey would imply and depends on the insurance policies and prescription plans if the patient is insured, including features such as copayments, deductibles and maximum expenditures allowed. The cost of these drugs for larger purchasing groups is also complex and highly dependent on negotiated rates. A wholesale price list for the cost of antiretroviral drugs in January 2014 in the USA was included in the May 2014 revision of one of the antiretroviral treatment guidelines [1].

Lamivudine is available as a generic drug, whereas emtricitabine is not, but there are few, if any, substantive differences between these drugs in adverse effect profile. Although evidence indicates that antiretroviral regimens that include tenofovir plus emtricitabine are more likely to lead to undetectable levels of HIV than regimens that include other nucleoside antiretroviral drugs [4], this has not been found in all studies [1], and regardless of the overall study findings, for many patients, alternative nucleoside drug regimens would be expected to produce the same outcome. On the other hand, use of currently available generics poses challenges such as the need to take more pills per day and at different times. For example, a disadvantage of the nucleoside drug zidovudine is that unlike tenofovir, it must be taken twice daily. A disadvantage of the generic abacavir plus generic lamivudine drug regimen is the absence of a

generic formulation in which the two drugs are combined. Such issues may negatively impact compliance and thereby potentially reduce viral suppression and increase the chance for drug resistance to develop. Nevertheless, it should also be emphasized that high drug costs *per se*, regardless of the simplicity or convenience of the drug regimen, may negatively impact compliance and lead to more frequent drug discontinuation [1].

There is no one-size-fits-all approach for the role of generic antiretroviral drugs in the management of patients with HIV infection in the USA. Nevertheless, there is already the potential for sizable cost savings by utilizing regimens that include generic nucleoside antiretroviral drugs for selected patients, with even greater savings anticipated in the future as drugs from other antiretroviral classes come off patent protection [5]. Consequently, there should be greater emphasis on discussing the role of generic agents, both by expert committees and by individual health care providers with their patients who are facing their particular economic challenges.

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