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Increasing Knowledge of HIV Infection Status through Opt-Out Testing

Opt-Out HIV Testing

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Abstract The diagnosis of HIV infection is the point of entry for treatment and prevention services, yet many infected persons in both developed and developing countries remain undiagnosed. To reduce the number of undiagnosed infections, a variety of expanded testing policies have been recommended, including opt-out testing. This testing model assumes that in populations of increased HIV prevalence, voluntary testing should be offered to all patients seen in healthcare settings and performed unless patients specifically decline. While this approach raises ethical issues concerning "voluntariness", access to care, and stigma, the potential benefits of opt-out testing far outweigh its potential adverse effects.

Keywords HIV · Diagnosis · Bioethics

Introduction

In this article, I will outline the case for expanded testing for infection with the human immunodeficiency virus (HIV) as a key strategy for controlling the HIV/AIDS epidemic. I first briefly describe the history of HIV testing policies in the United States, with a focus on recommendations made by the United States Centers for Disease Control and Prevention (CDC), and then examine testing policies in sub-Saharan Africa and in the United Kingdom. In particular, I discuss the "opt-out" approach to HIV testing and the ethical questions that it raises.

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A Brief History of HIV Testing

In 1985, only 2 years after the discovery of HIV, the U.S. Food and Drug Administration licensed a test to detect antibodies to the virus. The first use of the test was to screen donated blood and plasma to prevent HIV infection in transfusion recipients and persons with hemophilia (Centers for Disease Control 1985). Because of a concern that individuals wishing to know their infection status might seek testing in blood banks, "alternative test sites" were established with provision for confidential or anonymous—that is, with no name identifiers—testing.

Initially, there was strong opposition to the use of the test outside blood and plasma collection settings. This opposition, which came primarily from gay rights advocacy groups, was based on the belief that little benefit and much harm could come from testing. No treatment was available for HIV, and persons at highest risk for infection in the United States, men

who have sex with men (MSM), already faced discrimination. Further, the ability of public health agencies to keep test results confidential was questioned. The slogan of the anti-test movement was "No test is best".

In the medical community, these concerns about testing formed the basis of what has been called "AIDS exceptionalism" (Bayer and Fairchild 2006). Whereas consent for routine diagnostic testing was considered to be part of general consent for medical care, specific written informed consent with pre- and post-test counseling was required for HIV testing. In addition, the language of the consent forms often served to discourage testing by emphasizing the negative consequences of a positive test result. The additional requirements of the testing procedure and the negative messages about the test served to discourage providers from offering the test and patients from accepting it.

Attitudes and policies regarding HIV testing remained relatively static for most of the next decade. In 1994, however, a clinical trial showed that the risk of mother-to-child HIV transmission could be reduced by about two-thirds by treating infected pregnant women with zidovudine (Connor et al. 1994). As summarized by Bayer and Fairchild (2006), this finding led several U.S. medical organizations to endorse expanded HIV testing of pregnant women by relaxing some of the most stringent testing requirements. By 2001, the U.S. Public Health Service had recommended that all pregnant women in the United States be tested for HIV infection as a routine part of prenatal care (Centers for Disease Control and Prevention 2001a). Further, either oral or written consent were considered acceptable, and women had the right to refuse testing.

The case for changing testing policy more generally was strengthened later in the 1990s with the increasing availability of highly active antiretroviral therapy, a combination of drugs which dramatically increased the survival of HIV-infected patients. To take advantage of this therapeutic advance, persons needed to know if they were infected. Yet, additional CDC guidelines published in 2001 continued to advocate risk-based testing; that is, they recommended that the offer of testing to persons other than pregnant women should be based upon a judgment of their clinical or behavioral risk for infection (Centers for Disease Control and Prevention 2001b). An underlying assumption of the guidelines was that providers would either know or be able to ascertain if their clients were MSM, had injected drugs, or had multiple heterosexual partners.

Because an estimated 25% of HIV-infected persons in the United States were thought to be undiagnosed, CDC recommendations published in 2003 advocated HIV testing "as part of routine medical care on the same voluntary basis as other diagnostic and screening tests" (Centers for Disease Control and Prevention 2003). Further, pre-test prevention counseling was no longer required. It was not until 2006, however, that CDC modified the guideline for routine screening by recommending an opt-out approach, which was noted to result in higher testing rates in pregnant women than other approaches (Centers for Disease Control and Prevention 2006). Additional support for this modification came from studies showing that high-risk sexual behavior tends to decrease in persons after they become aware of their HIV infection (Marks et al. 2005).

Opt-Out Testing

The opt-out approach, based on the CDC guideline, meant that patients would be told that HIV testing would be done unless the patient declined. Consent was still required, but it could be obtained either orally or in writing, and no separate consent form for HIV testing was recommended. Prevention counseling was no longer required as part of the testing procedure. The guidelines summarized in Table 1 would apply in all settings unless the prevalence of undiagnosed HIV infection was known to be <0.1%. Once infected persons were diagnosed, they would be referred for appropriate clinical and prevention services.

Because of the much higher prevalence of HIV and the much lower awareness of infection status (estimated to be no more than 10–20%), expanding HIV testing through an opt-out approach could be expected to have a much bigger impact in sub-Saharan Africa than in the United States. Increasing the rate of diagnosis of HIV infection in this region has taken on special importance at a time when major initiatives are leading to the rollout of antiretroviral therapy (ART) in developing countries. By the end of 2007, about 3 million individuals living in low- and middle-

Table 1 HIV Screening guidelines for the United States

- Opt-out HIV screening is recommended for patients in all healthcare settings
- People at high risk for HIV infection should be screened for HIV at least annually
- Separate written consent for HIV testing is not required; general consent for medical care should be considered sufficient to encompass consent for HIV testing
- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings.

Adapted from "Revised recommendations for HIV testing of adults, adolescents, and pregnant women in health-care settings" (Centers for Disease Control and Prevention 2006).

income countries were receiving ART (WHO, UNAIDS, & UNICEF 2008).

Among sub-Saharan Africa countries, Botswana, a country with one of the highest rates of HIV infection in the world, took the lead in recommending routine opt-out HIV testing for all patients accessing medical care (Weiser et al. 2006). Subsequently, the World Health Organization and the Joint United Nations Programme on AIDS published guidelines which also recommended provider-initiated, opt-out HIV testing for all adults and adolescents seen in health care facilities of countries with "generalized epidemics" (defined as an HIV prevalence of >1% in pregnant women) (WHO & UAIDS 2007). A more targeted testing approach was recommended in countries with concentrated and low-level epidemics.

Although an estimated one-third of HIV-infected persons in the U.K. remain undiagnosed (Health Protection Agency 2006), the approach to testing in the U.K. has been somewhat cautious. Opt-out testing is recommended for routine use only in genitourinary medicine clinics and for pregnant women attending antenatal care. My colleagues and I put forward a case to examine the feasibility of expanding opt-out testing in medical facilities that are known to serve people at increased risk for infection (Hamill et al. 2007). In the U.K., those groups would particularly include MSM and recent immigrants from sub-Saharan Africa. The Chief Medical Officer and the Chief Nursing Officer of the U.K. subsequently issued a "Dear Colleague" letter in which they pointed out that late diagnoses accounted for at least 35% of HIV-related deaths in the U.K. The letter concluded with the request to "Please offer your patients an HIV test if they may have been exposed to HIV infection and recommend to them that they should accept testing" (Donaldson and Beasley 2007).

Ethical Concerns

Given the increasing momentum towards making opt-out HIV testing the standard of practice in many medical settings, what are the arguments against it? One key ethical issue concerns the "voluntariness" of opt-out testing (Rennie and Behets 2006). Although all formal recommendations for opt-out testing emphasize the right of patients to decline the test, some patients will almost certainly not understand that they will be tested or believe that they must accept the test offer (Gostin 2008). Weiser et al. conducted a population-based survey in Botswana following the introduction of national opt-out testing (2006). Although 81% of respondents were in favor of the new testing policy, 68% felt that they could not refuse the test.

Another important testing issue concerns access to care. As previously noted, one of the main drivers towards expanded testing in recent years has been expanded access to ART. Yet despite rapid progress in expanding HIV treatment programs, only about 31% of persons needing treatment in low- and middle-income countries were receiving it by the end of 2007 (WHO, UNAIDS, & UNICEF 2008). Diagnosing HIV infection without being able to provide care creates a serious ethical problem. A more subtle aspect of this problem exists in the U.K, where testing Africans would likely detect previously undiagnosed infection. However, some of these persons may be illegal immigrants or failed asylum seekers and are not entitled to free HIV therapy under the National Health Service.

Although the stigma related to HIV infection has gradually decreased over time, it still exists; and expanding HIV testing may subject newly diagnosed persons to this stigma. In particular, HIV-infected

women in low-income countries may experience gender-based discrimination and violence (Rennie and Behets 2006). As noted by Gostin, however, universal HIV testing may also be less stigmatizing than risk-based testing because it does not single out particular individuals or members of particular groups (e.g., MSM) for testing (Gostin 2008).

While all of the aforementioned issues deserve careful consideration in any decision regarding the implementation of an opt-out testing model, the benefits of this approach for most persons far outweigh the risks. Most importantly, modern treatment for HIV saves lives. During the pre-treatment era, almost all HIV-infected persons died as a result of their infection. Median survival from the time of infection to death ranged from about 8–12 years, depending on the age of the individual (Collaborative Group on AIDS Incubation and HIV Survival 2000). With treatment, the excess mortality in infected persons is reduced by more than 90% (Bhaskaran et al. 2008). However, the benefits of treatment for HIV-infected persons cannot be realized unless their infection is diagnosed.

Beyond benefits to the infected individual, early diagnosis and treatment may also serve to reduce HIV transmission. As noted previously, once individuals become aware of their infection, they tend to reduce their high-risk sexual activities. Successful treatment also reduces the concentration of HIV in blood and genital secretions, thus reducing infectiousness. Authors from the WHO have recently suggested that the global impact of HIV/AIDS could be substantially reduced through universal voluntary HIV testing and immediate treatment in countries with generalized epidemics (Granich et al. 2009). If this approach were adopted, the opt-out strategy would certainly facilitate the necessary expansion of HIV testing.

Conclusion

Ethical issues deserve careful attention in any program designed to expand HIV testing using the opt-out approach. No matter how carefully planned, however, at least some persons will likely be adversely affected by such programs. Nonetheless, that the potential benefits of this approach far outweigh it potential adverse effects. In my view, failure to identify someone whose life is at risk because of undiagnosed HIV infection can no longer be seen as ethical.

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