

A Human Rights Approach to Routine Provider-Initiated HIV Testing

Rahul Rajkumar*

INTRODUCTION

This Article describes the ethical, legal and public health implications of routine HIV testing—that is, testing such that individuals receive a routine offer of an HIV test whenever they come into contact with the health care system. In recent months, the consensus in favor of voluntary testing has yielded to a debate over whether efforts to curb the spread of HIV and to treat individual patients themselves would benefit from health care providers initiating testing.

This Article first describes the history of HIV testing policy in the United States and internationally. It outlines the arguments in favor of routine provider-initiated testing and responds to objections that have been raised in the literature. Finally, it describes a proposal for an ethical routine testing regime that is consistent with human rights principles as well as U.S. and international statutes and case law on testing. This Article also proposes model legislation that addresses the issues of counseling, confidentiality, and informed consent in the context of routine-offer HIV testing.

HIV, the virus that causes AIDS, has spread to every region of the world.¹ There are now nearly forty million people living with HIV. In 2006 alone, some 4.3 million people became infected with HIV and nearly three million people died of AIDS.² AIDS is a leading cause of adult death in many developing countries.³

As a result of HIV/AIDS, average life expectancy in some African countries, which had been rising consistently over the past fifty years, has fallen by twenty years or more.⁴ AIDS also continues to devastate the civil societies and economies of poor nations. The disease has orphaned an estimated twelve million children in sub-Saharan Africa and has decimated the ranks of teachers, health

* The author is a physician in the Department of Internal Medicine at Brigham and Women's Hospital in Boston, Massachusetts. I am deeply grateful to my advisors, Kaveh Khoshnood and Robert Burt, for their support and critical insights. I also thank the many individuals who have guided me along the way by reading and responding to drafts: Nancy Angoff, Robert Levine, Elizabeth Claus, Amy Kapczynski, James Silk, Tyler Crone, Mary Hahn, and Kiran Ghia.

1. UNAIDS, 2006 AIDS EPIDEMIC UPDATE 1-2 (2006).

2. *Id.*

3. *Id.*

4. UNAIDS, 2004 REPORT ON THE GLOBAL AIDS EPIDEMIC 43 fig.13 (2004).

care workers, and civil servants.⁵ A 2003 study by the World Bank predicts that South Africa—the nation with the largest number of AIDS cases, with a prevalence that may be as high as 26.5% of the adult population—will face “complete economic collapse” within three generations if the country does not take effective measures to combat AIDS.⁶ By any objective measure—lives lost, children orphaned or GDP growth unrealized—the AIDS epidemic has been and continues to be a global catastrophe.

A crucial—but so far uncelebrated—strategy to curb the spread of AIDS is expanding HIV testing such that all individuals receive a routine offer of an HIV test whenever they come into contact with the health care system. This Article argues in favor of routine provider-initiated testing. Specifically, I argue that the benefits of routine provider-initiated HIV testing, both for individual patients and for the public health, weigh heavily in favor of shifting to routine testing, provided that certain conditions are met. Routine testing must be coupled with a promise of antiretroviral (ARV) treatment for those who test positive and meet the clinical criteria for treatment. Moreover, routine testing must be coupled with a guarantee of confidentiality and a rigorous standard for informed consent. If these conditions are met, it is possible to design a fair, equitable, and non-coercive testing regime that protects the human rights principles of autonomy, confidentiality, and voluntariness.

I. BACKGROUND AND LIMITATIONS

A. The Consequences of Untreated HIV Infection

HIV specifically targets CD4+ T-cells, a type of white blood cell that helps to organize and coordinate the body’s immune response against infections. HIV weakens the body’s immune system until it can no longer resist infections, leaving it vulnerable to many types of pneumonia, diarrhea, tumors, and other illnesses that would pose no threat to uninfected individuals. The opportunistic infections common among AIDS patients are known as “AIDS defining illnesses.”⁷

A patient’s “CD4+ count”—the number of CD4+ T-cells per unit of blood—is a useful measure of disease progression in HIV infection. A normal adult has a CD4+ count of 500 to 1500 cells per cubic millimeter of blood. AIDS is defined as a CD4+ count of less than 200, or a CD4+ count higher than 200 if the

5. *Id.* at 61.

6. WORLD BANK, THE LONG-RUN ECONOMIC COSTS OF AIDS: THEORY AND APPLICATION TO SOUTH AFRICA 3 (C. Bell et. al. eds., 2003), available at http://www1.worldbank.org/hiv_aids/docs/BeDeGe_BP_total2.pdf; Press Release, Sibani Mngadi, Spokesperson, S. Afr. Minister of Health, HIV Prevalence in South Africa (July 3, 2003), available at <http://www.doh.gov.za/docs/pr/2003/pr0703.html>.

7. *Id.*

individual has an AIDS defining illness.⁸ The length of time between infection with HIV and progression to AIDS varies considerably among individuals. However, most HIV-infected individuals will develop AIDS, and all of these individuals will die without treatment. The average life expectancy for an untreated HIV-infected patient between the age of twenty-five and thirty-four is approximately ten years.⁹

B. The Possibility of Mass-Scale Treatment

The arrival of Highly Active ARV Therapy (HAART) in 1996 radically altered the natural progression of HIV infection in the United States and in Europe.¹⁰ HAART is a combination of several ARV drugs that is used to treat HIV by inhibiting different parts of the life cycle of HIV. HAART is responsible for a decrease in the incidence of AIDS, opportunistic infections, and AIDS-related mortality by 60% to 80% in the United States.¹¹ The number of deaths attributed to AIDS in the United States decreased from 48,371 in 1995,¹² to 16,316 in 2005, according to a review of data from death certificates by the CDC.¹³ Other studies have demonstrated that a patient's probability of surviving for at least twenty-four months following a clinical diagnosis of AIDS based on a CD4+ count of less than 200 cells per cubic millimeter of blood increases dramatically with HAART.¹⁴ It is important to note that many of the deaths reported in these studies occurred in patients who had already developed clinical AIDS before they had access to HAART.¹⁵ The weight of the clinical and

8. Kenneth G. Castro et al., *1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults*, MORBIDITY & MORTALITY WKLY. REP., Dec. 18, 1992, at RR-17, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm>.

9. Collaborative Group on AIDS Incubation and HIV Survival, *Time from HIV-1 Seroconversion to AIDS and Death Before Widespread Use of Highly-Active ARV Therapy: A Collaborative Re-Analysis*, 355 LANCET 1131, 1134 tbl.2 (2000); see generally George W. Rutherford et al., *Course of HIV-1 Infection in a Cohort of Homosexual and Bisexual Men: An 11 Year Follow Up Study*, 301 BMJ 1183 (1990) (describing the natural history of HIV infection in an eleven-year follow up study of a cohort of homosexual and bisexual men).

10. See A. Mocroft et al., *Decline in the AIDS and Death Rates in the EuroSIDA Study: An Observational Study*, 362 LANCET 22, 24-27 (2003).

11. John G. Bartlett, *The Stages and Natural History of HIV Infection*, [Version 15.1] UpToDate ¶ 4 (Aug. 11, 2006).

12. Ctrs. for Disease Control & Prevention, 9 HIV-AIDS SURVEILLANCE REP. 1, 20 (1997), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/pdf/hivsur92.pdf>.

13. Ctrs. for Disease Control & Prevention, 17 HIV-AIDS SURVEILLANCE REP. 1 (2005), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/reports/2005report/pdf/2005SurveillanceReport.pdf>.

14. See, e.g., Matthias Egger et al., *Prognosis of HIV-1 Infected Patients Starting HAART: A Collaborative Analysis of Prospective Studies*, 360 LANCET 119 (2002) (summarizing data on improved survival with the advent of HAART).

15. *Id.*

scientific evidence suggests that clinical AIDS can be averted altogether in HIV-infected individuals if they begin ARV treatment early and are followed closely enough.¹⁶

Until recently, it appeared that the citizens of resource-poor countries in Africa, Asia, and Latin America would not see the benefits of ARV therapy. During the early stages of the treatment era, many international donors and public health authorities constructed a dichotomy between prevention and treatment, and withheld treatment from poorer populations in favor of prevention-only strategies to combat the AIDS epidemic. Particular notions about Africans and other inhabitants of less developed countries, their perceived inability to comply with complicated treatment regimens, and the literature on cost-effectiveness all fueled this approach to confronting the epidemic. The weight of criticism from treatment activists and the governments of poor countries during the late 1990s largely eroded this dichotomy between prevention and treatment in the public discourse on the AIDS pandemic.

While the provision of adequate treatment for millions of HIV-positive individuals in poor countries is still far from reality, there now appears to be a greater political commitment to treat HIV in resource-poor countries. This political commitment has been justified in both moral and economic terms. There is an overwhelming need to prolong millions of productive lives in developing countries so as to prevent economic collapse, keep families intact, and prevent millions of children from being orphaned. ARV agents both lower viral load, which reduces HIV transmission, and reduce maternal-to-child transmission of HIV. Expanded access to treatment will improve the morale and performance of health care workers. Treatment will lessen AIDS-related stigma and mobilize communities to develop more effective AIDS policies.

Western governments have committed significant resources to attempt to treat HIV in the developing world. In 2003, the World Health Organization (WHO) publicly declared that it would pursue an approach to AIDS control that combines treatment and prevention, and committed to treating three million people in developing nations with ARV therapy by the end of 2005.¹⁷ In January

16. See generally Felipe Garcia et al., *Long-Term CD4+ T-Cell Response to Highly Active ARV Therapy According to Baseline CD4+ T-Cell Count*, 36 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 702 (2004) (describing the results of an observational study of the long term CD4+ cell response to HAART); Roy M. Gulick et al., *Six-Year Follow-Up of HIV-1-Infected Adults in a Clinical Trial of ARV Therapy with Indinavir, Zidovudine, and Lamivudine*, 17 AIDS 2345 (2003) (reporting the results of a randomized trial finding that ARV therapy with indinavir, zidovudine, and lamivudine suppressed HIV viremia and produced continued CD4 cell increases in a majority of subjects for six years); Gilbert R. Kaufmann et al., *CD4 T-Lymphocyte Recovery in Individuals with Advanced HIV-1 Infection Receiving Potent ARV Therapy for 4 Years: The Swiss HIV Cohort Study*, 163 ARCHIVES INTERNAL MED. 2187 (2003) (reporting the results of a longitudinal cohort study of CD4+ counts in Swiss subjects receiving HAART).

17. Lawrence K. Altman, *W.H.O. Declaring Crisis, Plans a Big Push With AIDS Drugs*, N.Y. TIMES, Sept. 22, 2003, at A5.

of 2003, the United States signaled a major shift in its thinking on the global AIDS pandemic when President Bush pledged to spend \$15 billion over five years to treat HIV in the most afflicted nations of Africa and the Caribbean.¹⁸ Whatever the reasoning behind them, these massive treatment initiatives all depend on identifying HIV-positive individuals, and therefore they depend on an equally massive effort to expand access to testing for HIV.

C. HIV Testing and Treatment

During the early days of the global AIDS epidemic, there was a broad international consensus that all HIV testing should be not only confidential, accompanied by counseling, and based on informed consent, but also that health care providers should only test individuals on a voluntary basis.¹⁹ This consensus emerged during a period when there was no treatment for HIV. Recognizing that HIV-positive individuals faced considerable stigma and discrimination, it was reasoned that the potential costs of a positive test result for an individual might outweigh the benefit to the individual.

ARV therapy for HIV has fundamentally changed this calculus, as some public health authorities now view the lack of widespread HIV testing in the general population as a barrier to treatment. Twenty-five percent of the nearly one million HIV-positive individuals in the United States are thought to be unaware of their status.²⁰ As a result, the consensus behind the strict commitment to voluntary testing has steadily eroded. According to one author writing in a prominent medical journal, "Increasingly, the challenge for the health care community is not how to prevent progression of HIV disease in a person with known infection, but, rather, is how to identify persons who are unknowingly infected with HIV."²¹ At the same time, there has been significant opposition to routine provider-initiated testing from the human rights community. Some have argued that routine-offer testing compromises human rights principles and is potentially coercive and paternalistic—and, rather than expanding testing programs, we should instead aim to create a "climate in which people *want* to know their HIV status and *trust* health care providers to provide them both that information and concomitant support."²²

18. George W. Bush, Pres. of the U.S., 2003 State of the Union Address (Jan. 28, 2003).

19. Renslow D. Sherer, *Physician Use of the HIV Antibody Test: The Need for Consent, Counseling, Confidentiality, and Caution*, 259 JAMA 264, 264-65 (1988).

20. Patricia L. Fleming et al., Abstract, HIV Prevalence in the United States, 2000, Program and Abstracts of the 9th Conference on Retroviruses and Opportunistic Infections (Feb. 25, 2002), available at <http://www.retroconference.org/2002/abstract/13996.htm>.

21. Curt G. Beckwith et al., *It Is Time To Implement Routine, Not Risk-Based, HIV Testing*, 40 CLINICAL INFECTIOUS DISEASES 1037, 1039 (2005).

22. Mary Crewe & Frans Viljoen, *Routine HIV Testing: A Challenge to Human Rights* 17 (Feb. 14, 2005) (unpublished manuscript, on file with author).

This Article argues in favor of a policy of routine provider-initiated testing—coupled with the promise of ARV treatment for those who test positive and meet clinical criteria for treatment. Specifically, I argue that we should not think of legal and ethical concerns as barriers to expanded testing. Rather, these considerations will assist us in creating a fair, equitable, and non-coercive testing regime that will more fully realize the end goal of testing itself: bringing more individuals into treatment programs. The legal and ethical considerations of informed consent, confidentiality, and voluntariness can all work to reinforce public health goals, as people who understand testing and who are given a sense of agency over their own health care are more likely to act on a positive HIV test result.

D. Limitations of This Article

This Article is limited in at least two significant ways. As I have described, in the early years of the AIDS epidemic, policy makers constructed a dichotomy between rich countries and poor countries. As a result, treatment was available for those who were fortunate enough to live in Europe or North America, but denied to those who were unfortunate enough to live in Africa or South Asia. This Article deliberately avoids creating a new dichotomy between settings where routine testing may be “culturally feasible” and settings in which it may be “culturally infeasible.” Rather, it attempts to develop an argument for routine testing, based on certain conditions that must be met, that can be generalized across settings. Given that the impact of HIV/AIDS promises to be so profoundly catastrophic in resource-poor settings such as Africa and South Asia, it is especially important that these regions move toward routine provider-initiated testing coupled with treatment. However, there are relatively few studies of the uptake, impact, and consequences of routine testing in resource-poor settings. This Article relies mainly on data from the United States to substantiate most of its empirical claims.

Second, while cultural considerations should not impact the decision to implement routine testing—just as they should not impact the decision to provide ARV treatment—such considerations may significantly impact the manner in which routine testing is implemented. To the extent that culture is relevant, other technical considerations are relevant too. For example, how often should tests be offered and what specific type of HIV test should be used? These questions are beyond the scope of this Article. My purpose is only to set out the case for routine testing, to address the arguments against routine testing and, finally, to describe the requirements for a testing regime that is consistent with human rights principles.

II. A BRIEF HISTORY OF HIV TESTING POLICY

Before discussing the history of HIV testing policy, it is useful to clarify the

terminology used in this Article, as this is a source of considerable confusion in both the medical and legal literature. Voluntary counseling and testing (VCT), the dominant testing paradigm in both the United States and in most resource-poor settings, describes a system in which health care providers make testing available but do not offer an HIV test to patients routinely.²³ Rather, individuals must consciously seek out an HIV test. This mode of testing is also referred to as patient-initiated or opt-in testing.

At the other extreme, mandatory testing describes a type of screening, either for certain groups of patients or for patients in the general population, in which the patients themselves are required to submit to testing either by law or as a condition for receiving health care services. Examples of mandatory testing programs include those initiated by the Government of Zambia for all new military recruits in that country as a condition for military service,²⁴ or those implemented in New York and Connecticut for all newborn children whose mothers were not tested for HIV during pregnancy.²⁵

Routine testing differs from both of the above models in that health care providers themselves may initiate a discussion on HIV testing with individuals who come into contact with the health care system. Under this model, the health care provider offers the patient a choice between proceeding with an HIV test and opting out of a test. This mode of testing, also referred to as provider-initiated, opt-out, or routine voluntary testing, is the norm for several subgroups in the United States: pregnant women, patients presenting at sexually-transmitted disease clinics, and other patients in high HIV prevalence areas.²⁶ Routine testing is “voluntary” in the sense that individuals must give informed consent before being tested; they are protected by guarantees of confidentiality and counseling; and they remain free to refuse testing. So as to avoid confusion, this paper will use the term “routine provider-initiated testing” or “routine testing” to refer to this mode of testing.²⁷

23. PHILLIP NIEBURG ET AL., CTR. FOR STRATEGIC & INT’L STUDIES, EXPANDED HIV TESTING 5-6 (2005) [hereinafter CSIS REPORT], available at <http://usinfo.state.gov/gi/img/assets/5096/expandedhivtesting.pdf>.

24. Zarina Geloo, *Zambia in a Quagmire over AIDS Testing*, MAIL & GUARDIAN (Johannesburg), Sept. 16, 2004.

25. Ctrs. for Disease Control & Prevention, *HIV Testing Among Pregnant Women—United States and Canada, 1998-2001*, 51 MORBIDITY & MORTALITY WKLY. REP. 1013, 1014-15 (2002).

26. Beckwith et al., *supra* note 21, at 1038.

27. Yet another testing modality, distinct from the routine testing proposal presented in this Article, would be required routine testing, which is similar to the “required request” laws that are in place in at least forty-two U.S. states and require hospitals to have procedures to tell families about organ donation. American Heart Association, Organ Donation, <http://www.americanheart.org/presenter.jhtml?identifier=4697> (last visited May 3, 2007). Currently, HIV testing strategy is implemented through guidelines promulgated by “expert” bodies such as the CDC and the WHO. Because there is still much to understand about the practical aspects of routine testing for HIV, I opt in this Article against recommending required routine testing. Rather, routine testing should be coupled with a program for systematic data gathering—

It is important to note that many authors conflate the terms mandatory and routine provider-initiated testing. Consider, for example, this excerpt from a 1989 article in the *Villanova Law Review*: “This article argues that routine testing of patients entering a health care institution is of little benefit in protecting health care workers. Furthermore, testing of blood without the consent of the patient greatly compromises the patient’s rights and is neither legally nor morally defensible.”²⁸ The author uses the term routine testing but directs his argument against mandatory testing. Routine testing does not mean testing without a patient’s consent—it only means that the health care provider, rather than the patient, may initiate a conversation on testing.

Lastly, all of the above testing modalities—voluntary, mandatory, and routine provider-initiated—describe HIV screening strategies either for the general population or for certain subgroups of individuals. This is distinct from diagnostic HIV testing, which describes a situation in which a patient presents to a health care facility with symptoms of HIV infection. In such cases, it is widely expected that HIV testing can and should become a routine part of a patient’s diagnostic evaluation. Diagnostic HIV testing is not at issue in this Article.

Because all of the testing modalities described above permit diagnostic testing for individuals who exhibit the symptoms of HIV infection, any shift to routine testing will have implications primarily for asymptomatic individuals. This Article recommends a policy shift toward routine testing for asymptomatic individuals in the general population whenever they come into contact with the health care system. This includes but is not limited to routine clinic visits, prenatal care, visitations to hospital emergency departments, and hospital admissions.

A. HIV Testing During the Early Years of the Epidemic

In June 1987, then Vice President George H.W. Bush delivered a speech in which he discussed making HIV testing routine.²⁹ He was booed during the speech, which was felt by many AIDS activists and civil rights groups to reflect an insensitive response to the epidemic.³⁰ The Reagan-Bush administration scuttled the idea and, soon thereafter, state and local governments passed laws that recognized the special nature of HIV testing. These laws required patients to sign separate and extraordinarily detailed informed consent documents before they could be tested for HIV.³¹

and the testing policy must remain agile enough to respond to the results of this information.

28. Barry R. Furrow, *AIDS and the Health care Provider: The Argument for Voluntary HIV Testing*, 34 VILL. L. REV. 823, 828 (1989).

29. Marlene Cimon & Harry Nelson, *Bush Is Booed As He Defends AIDS Proposals*, L.A. TIMES, June 2, 1987, at 1.

30. Mark D. Wagner, *Back to Basics: Making HIV Testing Routine*, 9 IAPAC MONTHLY 187, 187 (2003).

31. *Id.*

The rationale behind voluntary HIV testing with detailed informed consent was rooted in the idea that a diagnosis of HIV infection is somehow exceptional. Unlike a diagnosis for diabetes or hypertension, a diagnosis of HIV was surrounded by an aura of stigma, discrimination, and fear. During the early years of the AIDS epidemic, a positive test result could result not only in psychological and emotional hardship, but financial, occupational, and legal hardship as well—and there were few available treatment options.³² Further, it was thought that routine—and potentially coercive—testing without the possibility of treatment would not aid prevention efforts in that it would only drive HIV-positive individuals away from the health care system. It is useful to consider a few examples that reflect the enormous potential cost of HIV testing to individuals.

As Ronald Bayer describes in *Private Acts, Social Consequences: AIDS and the Politics of Public Health*, HIV-positive individuals and AIDS patients suffered from overt discrimination in employment, housing, obtaining health insurance, and accessing health care services.³³ A representative for National Gay Rights Advocates explained his fears to a *Los Angeles Times* reporter in 1987: “All those who test positive are going to get their insurance canceled and go on Medicaid, possibly lose their jobs, their apartment.”³⁴

One 1988 survey reported that between one in four and one in five people in the United States “believe that those with AIDS should be excluded from working with them, attending school with their children, and living in their neighborhoods.”³⁵ Internationally, many countries officially outlawed people with HIV or members of high-risk social groups like commercial sex workers and homosexuals.³⁶ As Barry Furrow suggests in his article, the U.S. public merged its fears of the AIDS epidemic with negative attitudes toward high-risk groups such as homosexuals.³⁷ Violence against homosexuals in the United States escalated from 4946 incidents in 1986, to 7008 incidents in 1987.³⁸

This report by a physician, excerpted from an article published in 1988 in the *Journal of the American Medical Association*, describes some of these effects:

In 1985, I was the primary physician for a young man whose life was ruined by the inappropriate disclosure of a positive human immunodeficiency virus (HIV)-antibody test. A physician ordered the test without consent and notified

32. See David J. Casarett & John D. Lantos, *Have We Treated AIDS Too Well? Rationing and the Future of AIDS Exceptionalism*, 128 ANNALS INTERNAL MED. 756, 756-59 (1998).

33. RONALD BAYER, *PRIVATE ACTS, SOCIAL CONSEQUENCES: AIDS AND THE POLITICS OF PUBLIC HEALTH* 101-36 (1989).

34. Lynn Simross, *AIDS, Politics: Seeking a Safe Stand*, L.A. TIMES, June 3, 1987, at 1.

35. Robert J. Blendon & Karen Donelan, *Discrimination Against People With AIDS: The Public's Perspective*, 19 NEW ENG. J. MED. 1022, 1026 (1988); see also Furrow, *supra* note 28, at 830 (describing the reasons that policy makers initially favored a policy of voluntary testing for HIV).

36. LAURIE GARRETT, *THE COMING PLAGUE* 457-77 (1994).

37. Furrow, *supra* note 28, at 830.

38. Blendon & Donelan, *supra* note 35, at 1023.

the local health department of the positive result. The health department notified the individual's employer and he was promptly fired. These events became common knowledge at his workplace and in his rural Midwestern town and he was shunned. His landlord asked him to move. Ten days after testing, the life he had known for the past ten years was permanently ruined and he left town. With the loss of his job came loss of health insurance and insurability; he has been unable to obtain health or life insurance since then.³⁹

Moreover, during the early years of the epidemic, some physicians and health care workers themselves reinforced these fears by calling for mandatory HIV testing of patients as a condition for receiving medical services. While these calls were soundly rejected by policy makers, there is evidence that at least some hospitals implemented de facto mandatory testing programs. One study published in the *Journal of the American Medical Association* in 1988 concluded that about 80% of HIV tests carried out in a hospital in Minnesota were performed without justification or patient consent.⁴⁰

A full accounting of the sufferings of HIV-positive individuals during the early years of the AIDS epidemic is beyond the scope of this Article. It should suffice to say that HIV-positive individuals held a well-founded fear of discrimination, prejudice, and violence—and it was in the context of this social environment that policy makers chose to emphasize voluntary counseling and testing for HIV.

B. A Shifting Paradigm

In a 1993 article in the *South African Journal on Human Rights*, Australian High Court Judge Michael Kirby described the “AIDS paradox,” which encapsulates the basic rationale for voluntary testing:

[O]ne of the most effective laws we can offer to combat the spread of HIV . . . is the protection of persons living with AIDS, and those about them, from discrimination. This is a paradox because the community expects laws to protect the uninfected from the infected. Yet, at least at this stage of this epidemic, we must protect the infected too.⁴¹

According to this view, voluntary testing is necessary not only because it protects HIV-positive individuals, but also because protecting HIV-positive individuals itself is the most effective strategy to combat the AIDS epidemic.

This is not an uncontroversial assertion. The traditional public health approach to combating an epidemic necessarily involves widespread routine

39. Sherer, *supra* note 19, at 264.

40. Keith Henry et al., *Analysis of the Use of HIV Antibody Testing in a Minnesota Hospital*, 259 JAMA 229, 231 tbl.5 (1988).

41. Michael Kirby, *AIDS and the Law*, 9 S. AFR. J. ON HUM. RTS. 1, 3-4 (1993).

testing to protect the uninfected from the infected.⁴² In the case of HIV testing policy, these two goals—protecting HIV-positive individuals and protecting HIV-negative individuals—can be in tension with one another. Those concerned with protecting HIV-positive individuals focus on the costs of HIV testing to individuals and adopt the defensive model of voluntary testing. In contrast, the impulse of many public health experts to prioritize protecting HIV-negative individuals may lead them to favor a more standard public health approach of routine provider-initiated testing, even if this means accepting the dangers attendant with this approach. Because the proponents of voluntary testing have thus far prevailed in policy debates over HIV testing, the goal of protecting HIV-negative individuals through expanded testing and counseling has, in the view of some public health experts, been subordinated to the goal of protecting HIV-positive individuals.

However, even in these early debates, some proponents of voluntary testing recognized that, if a treatment or a vaccine for HIV were developed, the balance between these two priorities might shift in favor of expanded routine provider-initiated testing.⁴³ With the availability of ARV treatment for HIV, this now appears to be happening. The most recent UNAIDS/WHO guidelines on HIV testing published in June 2004 nominally support voluntary testing.⁴⁴ This has unfortunately contributed greatly to the confusion between voluntary and routine-provider initiated testing, as these guidelines also call for an expansion of routine testing for patients in sexually transmitted disease clinics, pregnant women, and in clinical settings where HIV is prevalent and ARV therapy is available.⁴⁵ The last part of this statement essentially calls for a shift to routine provider-initiated testing for individuals in the general population, provided that testing is coupled with treatment.

These changes mirror statements that the WHO has published more recently. For example, the 2004 guidelines themselves include the following introductory statement:

In many low and middle income countries, the primary model for HIV testing has been the provision of client-initiated voluntary counselling and testing services. Increasingly, provider-initiated approaches in clinical settings are being promoted, i.e. health care providers routinely initiating an offer of HIV testing in a context in which the provision of, or referral to, effective prevention and treatment services is assured. To reach people in need of treatment, tens of millions of tests will have to be conducted among those who may have been

42. See Chandler Burr, *The AIDS Exception: Privacy vs. Public Health*, ATLANTIC MONTHLY, June 1997, at 57-67 (arguing that a new public health approach to HIV/AIDS is required).

43. See, e.g., David Miller et al., *HTLV-III: Should Testing Ever be Routine?*, 292 BMJ 941, 943 (1986).

44. UNAIDS/WHO Policy Statement on HIV Testing 1, June 2004, [hereinafter UNAIDS/WHO] available at http://data.unaids.org/una-docs/hivtestingpolicy_en.pdf.

45. *Id.*

exposed to HIV.⁴⁶

Another unpublished WHO policy document describes a positive HIV test as “a sick patient’s gateway to health” as opposed to something to be feared.⁴⁷ Most recently, Kevin De Cock, Director of the WHO Department of HIV/AIDS, made the following statement at the Sixteenth International AIDS Conference in Toronto:

Only ten percent of people living with HIV in the world are aware of their HIV status. That’s appalling. We have to scale up the traditional ways of knowledge, in other words voluntary counseling and testing . . . we need innovative ways of doing it. We will talk about provider-initiated testing and counseling.⁴⁸

On the same day, the WHO and UNAIDS Secretariat released a joint statement on HIV testing and counseling—as of this writing, the most current WHO/UNAIDS public statement on HIV testing. The statement notes that uptake from voluntary counseling and testing has been inadequate and calls for a “more diverse range of approaches” to increase knowledge of HIV status—including both “client-initiated” and “provider-initiated” testing, depending on the prevalence of HIV in a particular setting and other local conditions.⁴⁹ Further, in June 2006, the WHO and UNAIDS Secretariat initiated a consultative process to develop guidance on provider-initiated HIV testing and counseling in health care settings. This process included an international meeting of experts, government representatives, and non-governmental organizations.⁵⁰ As of February 2007, the WHO has circulated draft guidelines for comment. It is unclear when the WHO will issue formal guidelines in final form.

Other international organizations involved in HIV care such as the Global HIV Prevention Working Group⁵¹ and the Global Business Coalition on HIV/AIDS⁵² are also encouraging a shift toward expanded testing. In parallel, several countries have begun to revise their laws and guidelines on HIV testing in favor of expanded testing. In 2004, Botswana introduced a routine provider-initiated testing program in which all patients are tested for HIV during doctors’

46. *Id.* (emphasis omitted).

47. David Miller et al., World Health Org., *The Gateway to Treatment: An Increased Role for Provider-Initiated Testing and Counseling in Resource-Poor Settings* 4 (Oct. 2004) (unpublished manuscript, on file with author).

48. Isabel Parenthoen, WHO Calls for Massive Increase in Global AIDS Tests, *AGENCE FRANCE-PRESSE*, Aug. 15, 2006.

49. Joint Statement, WHO and UNAIDS Secretariat Statement on HIV Testing and Counselling, Aug. 14, 2006, *available at* http://www.who.int/hiv/toronto2006/WHO-UNAIDS_statement_TC_081406_dh.pdf.

50. *Id.*

51. GLOBAL HIV PREVENTION WORKING GROUP, *HIV PREVENTION IN THE ERA OF EXPANDED TREATMENT ACCESS* (2004), *available at* <http://www.kff.org/hivaids/upload/HIV-Prevention-in-the-Era-of-Expanded-Treatment-Access.pdf>.

52. Richard Holbrooke & Richard Furman, Op-Ed., *A Global Battle’s Missing Weapon*, N.Y. TIMES, Feb. 10, 2004, at A25.

visits unless they opt out.⁵³ This policy was adopted in recognition of the fact that uptake of voluntary testing in sub-Saharan Africa is troublingly low, and it aims to reduce HIV-related stigma by administering the HIV test like any other routine medical test. In November 2005, Lesotho launched a program with a goal of informing every person in the country of his or her HIV status. The program calls for door-to-door “confidential and voluntary HIV testing and counseling with an aim to reach all households in Lesotho by the end of 2007.”⁵⁴ Similar initiatives are being considered in Malawi and Zambia, to name just two countries.⁵⁵

Perhaps most significantly, in September 2006, the CDC released revised guidelines on HIV testing that called for routine HIV testing for the general U.S. population:

In all health-care settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years. Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.⁵⁶

The earlier guidelines, published in 2001, recommended routine testing only where the prevalence of HIV infection is greater than 1% of the adult population as well as for individuals with increased behavioral and clinical risks for HIV infection, regardless of the prevalence of HIV.⁵⁷ The revised 2006 guidelines also differ from the prior recommendations in the following respects: 1) A patient may be screened for HIV after being notified, unless he or she specifically declines; 2) Specific signed consent for HIV testing is not required (a general consent to medical care suffices); 3) Individuals at high risk for HIV should be screened annually; 4) Prevention counseling is not required as a part of HIV screening programs in all health-care settings—though, it is encouraged for persons at high risk for HIV in settings such as STD clinics.

These policy statements represent the beginning—not the end—of a policy debate that has already begun to take place in state legislatures and ministries of

53. Sheri D. Weiser et al., *Routine HIV Testing in Botswana*, 3 PLOS MED e261 (2006).

54. World Health Org., Lesotho Launches Groundbreaking HIV Campaign on World AIDS Day, Nov. 30, 2005, <http://www.who.int/mediacentre/news/releases/2005/pr64/en/index.html>.

55. CSIS REPORT, *supra* note 23, at 4.

56. Ctrs. for Disease Control & Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings*, 55 MORBIDITY & MORTALITY WKLY. REP. 1, 7 (2006).

57. *Id.*; see also Judith A. Aberg et al., *Primary Care Guidelines for the Management of Persons Infected with Human Immunodeficiency Virus*, 39 CLINICAL INFECTIOUS DISEASE 609 (2004) (describing similar guidelines promulgated by the Infectious Diseases Society of America that call for routine testing in areas where the prevalence of HIV infection is greater than 1%).

health around the world. A number of human rights advocates have swiftly criticized this move toward routine provider-initiated testing. In response to Kevin De Cock's comments at the 2006 AIDS Conference, Mary Robinson, former president of Ireland and patron of the International Community of Women Living with HIV/AIDS, had this to say: "Scaling up HIV testing isn't a simple matter, and especially for women, and HIV-positive women know this very well."⁵⁸ Similarly, Joe Amon, director of HIV-AIDS programs at Human Rights Watch, voiced concern:

The testing creates a moment when there can either be trust and a relationship with health-care provision or it can be a moment when people are turned away or they don't want to come back. And that's why it's critical that there be counseling and there be an opportunity to build a relationship for chronic disease care over the long term.⁵⁹

At the same time, several U.S. states are now debating proposals to align their laws on HIV testing with the CDC's revised recommendations. The New York State Assembly is currently considering a proposal by Dr. Thomas Freiden, the Health Commissioner of New York City, to change a 1988 state law that requires physicians to obtain specific written consent for an HIV test and conduct lengthy pre-test counseling. Freiden's proposal would give doctors the option of obtaining oral consent, simplify pre-test counseling, and strengthen post-test counseling.⁶⁰ The New York Civil Liberties Union and several physician activists have criticized this proposal.⁶¹

Despite this debate, there is clearly a new momentum toward routine provider-initiated testing. One interpretation of these events is that science is finally winning over politics. According to this view "activists and civil libertarians" have tied the hands of public health experts for years with misplaced concerns over privacy rights and discrimination.⁶² Now that treatment for HIV has fundamentally changed the cost-benefit calculus for individuals, it is possible to shift to a more standard public health approach to combating the spread of HIV.⁶³ This Article does not share this view, though it does argue in favor of routine provider-initiated testing. The history of the AIDS epidemic demonstrates that the concerns of the activists and civil libertarians are neither misplaced nor merely political. They were well founded. The challenge now is to craft a public

58. Sheryl Ubelacker, *HIV Testing can have Severe Consequences, Especially for Women: Robinson*, CANADIAN PRESS, Aug. 16, 2006, available at <http://www.cbc.ca/cp/health/060816/x081624.html> (internal quotation marks omitted).

59. *Id.*

60. Sewell Chan, *Rifts Emerge on Push To End Written Consent for H.I.V. Tests*, N.Y. TIMES, Dec. 25, 2006, at B1.

61. *Id.*

62. Wagner, *supra* note 30, at 2.

63. *Id.*

health approach to fighting AIDS, one that includes routine provider-initiated testing, but also safeguards the rights of individual patients.

III. THE CASE FOR ROUTINE PROVIDER-INITIATED HIV TESTING

There are at least six broad arguments in favor of routine provider-initiated HIV testing. First, whereas during the early days of the AIDS pandemic testing exposed individuals to potential stigma while offering them scant benefit, the availability of life-saving treatment for HIV infection has fundamentally altered this balance. Where treatment is available, individual patients now stand to benefit from routine testing. Second, at the national and international levels, the slow uptake of voluntary testing is inhibiting the roll-out of HIV treatment programs. Third, the slow uptake of voluntary testing is impeding HIV prevention efforts. Individuals need to “know their status” in order to take steps to prevent spreading the virus. Fourth, routine-offer testing is the norm for most other treatable diseases for which there are straightforward tests. Promoting “AIDS exceptionalism” actually perpetuates the stigma, denial, and fear associated with HIV. Fifth, a recent series of studies have demonstrated that routine HIV testing is cost-effective. Testing is not only better for individuals and for combating the AIDS pandemic, but it is also a comparatively good value for society. Sixth, while opponents of expanded testing often cite human rights principles for support,⁶⁴ one can argue that principles of international human rights law, such as the right to health, actually favor routine provider-initiated testing. That is, we should not take extraordinary measures to safeguard autonomy at the expense of patients’ health or well-being. I will address each of these arguments in turn.

A. Individual patients now stand to benefit from routine testing

1. Treatment for HIV

A positive HIV test result in the pre-treatment era conferred little benefit to patients. The only rationale that those in favor of routine testing could offer was that it represented the most effective prevention strategy. According to this argument, which was eventually rejected by guideline-writing authorities, the benefit of these prevention efforts to society outweighed the imposition on the individual.

With the advent of treatment, the potential benefit of an HIV test to an individual patient has increased relative to the potential harm. ARV therapy can result in improvements in CD4+ counts and HIV viral loads that have been

64. Crewe & Viljoen, *supra* note 22, at 1.

sustained over four to five years in observational studies.⁶⁵ Though long-term clinical data is not yet available, it appears possible that individuals can maintain their health on ARV therapy indefinitely. In the United States alone, the use of ARV therapy has resulted in a decrease in HIV mortality rates from 20 to 30 deaths per 100 person-years to 8.4 to 8.8 deaths per 100 person-years.⁶⁶

In this context, testing is important because health care providers often do not recognize infected individuals during the quiescent phase of HIV infection.⁶⁷ HIV positive individuals are more commonly identified when they present with opportunistic infections or other clinical symptoms. As one study in the *Archives of Internal Medicine* described, the years during which individuals unknowingly carry HIV “represent therapeutic opportunities lost.”⁶⁸ Routine provider-initiated testing is likely to identify substantial numbers of asymptomatic individuals who would qualify for treatment under current guidelines—as many as 740 for every 10,000 individuals tested, according to one study.⁶⁹

A number of observational studies suggest that starting ARV therapy early diminishes the incidence of opportunistic infections and allows individuals to sustain normal CD4+ levels—sparing them the morbidity and mortality associated with such infections.⁷⁰ It is important to note that these observational studies are not definitive. The case for routine testing would be greatly strengthened by evidence from a randomized prospective trial showing that identifying HIV-positive patients at an earlier stage of infection, who might not qualify for treatment under current clinical guidelines, nonetheless confers a benefit in the form of increased survival.

The results of the ongoing Strategies for Management of Anti-Retroviral

65. Garcia et al., *supra* note 16, at 704-08.

66. Richard D. Moore & Richard E. Chaisson, *Natural History of HIV Infection in the Era of Combination Antiretroviral Therapy*, 13 AIDS 1933, 1936-37 (1999); see also Frank J. Palella Jr. et al., *Declining Morbidity and Mortality Among Patients with Advanced Human Immunodeficiency Virus Infection*, 338 NEW ENG. J. MED. 853 (1998) (describing the decline in mortality attributable to AIDS after the advent of ARV).

67. Cf. Jeffrey H. Samet et al., *Trillion Virion Delay: Time from Testing Positive for HIV to Presentation for Primary Care*, 158 ARCHIVES INTERNAL MED. 734 (1998) (concluding that “patients with positive HIV test results often delay for more than a year before establishing primary medical care”); Barbara J. Turner et al., *Delayed Medical Care after Diagnosis in a US National Probability Sample of Persons Infected with Human Immunodeficiency Virus*, 160 ARCHIVES INTERNAL MED. 2614 (2000) (identifying health care and patient factors that are associated with delayed medical care for HIV).

68. Rochelle Walensky et al., *Identifying Undiagnosed Human Immunodeficiency Virus*, 162 ARCHIVES INTERNAL MED. 887, 890 (2002).

69. This figure varies depending on the population prevalence of HIV. Seven hundred and forty represents the upper limit of an estimate based on a population prevalence of 15%. Roger Chou et al., *Screening for HIV: A Review of the Evidence for the U.S. Preventive Services Task Force*, 143 ANNALS INTERNAL MED. 55, 62 (2005).

70. See, e.g., Bruno Ledergerber et al., *AIDS-Related Opportunistic Illnesses Occurring After Initiation of Potent Antiretroviral Therapy: The Swiss HIV Cohort Study*, 282 JAMA 2220, 2221-24 (1999).

Therapy (SMART) trial may resolve this issue. The trial was designed to analyze whether it is better to use ARV medicines continuously to maintain the viral load as low as possible or to delay therapy until the CD4+ count is higher.⁷¹ Participants in the trial were assigned at random to viral suppression therapy, in which ARV therapy was taken on an ongoing basis to suppress viral load, or drug conservation therapy, in which ARV therapy was started only after the participant's CD4+ count dropped below 250 cells per milliliter of blood.⁷² However, enrollment in the trial was stopped on January 11, 2006, after a periodic interim analysis of the trial data showed that participants receiving drug conservation therapy had twice the risk of disease progression (defined as the development of clinical AIDS or death). Moreover, participants in the drug conservation arm were also found to have a higher rate of major complications such as cardiovascular, kidney, and liver disease.⁷³ These results, when combined with those from observational studies, strongly suggest that individual patients can improve their own chance of survival by learning that they are infected sooner rather than later and by initiating ARV therapy earlier.

By extension, routine testing is also likely to produce substantial reductions in HIV-related mortality at the population level. A recent systematic review of the empirical evidence on HIV testing for the U.S. Preventive Services Task Force considered outcomes of counseling and one-time screening for HIV infection after three years in a hypothetical cohort of 10,000 asymptomatic adults. Where the population prevalence of HIV is one percent, routine testing was projected to prevent between two and twenty-eight cases of clinical progression or death over three years. Where the population prevalence of HIV is between 5% and 15%—as it is in some sub-Saharan African nations—routine testing was projected to prevent between 24 and 410 cases of clinical progression or death over three years, assuming that treatment is available.⁷⁴

2. Other Developments That May Mitigate the Harm to Individuals of HIV Testing

As I have already described, HIV testing has been associated in the past with a number of harms. However, since the early days of the epidemic, there have been a number of developments in addition to the clear benefits of treatment that may mitigate some of these harms.

First, some opponents of testing point out that false-positive test results may

71. Press Release, Nat'l Inst. of Health, A Large International HIV/AIDS Study Comparing Two Strategies for Management of Anti-Retroviral Therapy (The SMART Study) (Jan. 18, 2006), available at <http://www3.niaid.nih.gov/news/newsreleases/2006/smartqa06.htm>.

72. *Id.*

73. Press Release, Nat'l Inst. of Health, International HIV/AIDS Trial Finds Continuous Antiretroviral Therapy Superior to Episodic Therapy (Jan. 18, 2006), available at <http://www.nih.gov/news/pr/jan2006/niad-18.htm>.

74. Chou et al., *supra* note 69, at 57-58, 62.

produce unnecessary anxiety and emotional distress.⁷⁵ False negative results could provide false reassurance if individuals take such results as a license to engage in high-risk behavior.⁷⁶ Advances in the science of HIV testing now make both false-positive and false-negative test results extremely rare. The current HIV testing protocol of an enzyme-linked immunosorbent assay (EIA) followed by a confirmatory Western Blot analysis has a sensitivity (the proportion of people with disease who have a positive test result) and specificity (the proportion of people without disease who have a negative test result) that approaches 100%.⁷⁷ Newly developed rapid test kits can deliver final negative results and preliminary positive results within one hour of testing.

Second, opponents of testing argue that true-positive test results are associated with even more serious harms. These include fears of rejection or abandonment by partners, verbal abuse, physical assault, loss of a job, social ostracization, emotional and psychological distress, and an increased risk of suicide.⁷⁸ However, evolving legal norms may mitigate many of these harms, further altering the harm-benefit equation for individuals. Since the 1980s, a number of U.S. states have enacted anti-discrimination laws to protect HIV-positive individuals and marginalized groups.⁷⁹ HIV-positive individuals in the United States qualify for protection under certain provisions of the Americans with Disabilities Act.⁸⁰ Internationally, the WHO convened some 150 nations to sign a document that calls for a "human rights approach" to HIV/AIDS and for compassion and solidarity with people living with HIV.⁸¹ These nations recognize that the protection of human rights is a necessary element of a worldwide public-health response to the AIDS pandemic. In theory, at least, this should force public accountability on the part of governments and international organizations for their actions toward HIV-positive individuals.

Evolving social norms, which are more nebulous and therefore more difficult to describe, also appear to be shifting. One marker of these evolving social norms is the U.S. Supreme Court's 2003 decision in *Lawrence v. Texas*,⁸² which struck down a Texas anti-sodomy law. The Court struck down its earlier

75. *Id.* at 57-58.

76. *Id.*

77. Beckwith et al., *supra* note 21, at 1039.

78. Chou et al., *supra* note 69, at 57-58.

79. See generally Paul Barron et al., *State Statutes Dealing With HIV and AIDS: A Comprehensive State-by-State Summary (2004 Edition)*, 13 L. & SEXUALITY 1 (2004).

80. George J. Annas, *Protecting Patients from Discrimination: The Americans with Disabilities Act and HIV Infection*, 339 NEW ENG. J. MED. 1255, 1255-56 (1998).

81. World Health Org., World Health Assembly, Avoidance of Discrimination Against HIV-Infected Persons and Persons with AIDS, pmbl., Resolution WHA 41.24 (May 13, 1988); World Health Org., World Health Assembly, Global Strategy for the Prevention and Control of AIDS, Resolution WHA 40.26 (May 15, 1987).

82. *Lawrence v. Texas*, 539 U.S. 558 (2003).

1986 decision, *Bowers v. Hardwick*,⁸³ which had upheld a state law banning homosexual sex. Justice Sandra Day O'Connor, who cast a critical vote in *Lawrence* remarked in a recent collection of essays, "rare indeed is the legal victory—in the court or legislature—that is not the careful byproduct of an emerging social consensus."⁸⁴ Pamela Karlan, a law professor at Stanford University who filed an amicus curiae brief in the case, notes that during the seventeen years between *Bowers* and *Lawrence*, the justices' were influenced by a growing familiarity with gays.⁸⁵ That is, being "gay" became relatively normalized and, therefore, discriminatory laws based on the nonconforming behavior of a minority—though "normal"—group became untenable.

It is difficult to state quantitatively how this legal and social evolution will impact individuals who receive a routine offer for an HIV test—and there will be vast differences depending on where the person lives. Still, according to a 1999 study published in the *American Journal of Public Health* based on a telephone survey of 1300 U.S. adults, negative feelings toward people living with AIDS among respondents decreased by at least 8% annually between 1991 and 1999.⁸⁶ Similarly, the proportion of respondents who said that they would avoid a coworker with AIDS, and that they would have their own children avoid a schoolmate with AIDS, declined significantly between 1991 and 1999.⁸⁷ In 1991, 45% of respondents said that they would avoid shopping at a grocery store whose owner had AIDS. By 1999, this proportion had dropped to approximately 29%.⁸⁸ Another study published in 2000 by the CDC, also based on a telephone survey, concluded that most U.S. adults—approximately 80%—do not hold stigmatizing views about persons with HIV infection or AIDS. Moreover, stigmatizing attitudes about HIV were associated with misinformation about HIV transmission—suggesting that increased education about HIV may result in lower levels of stigmatizing beliefs about HIV-positive individuals.⁸⁹

More recent population studies in the United States have found that HIV-negative and HIV-positive individuals appear to have similar rates of intimate partner violence when controlled for other high-risk behaviors.⁹⁰ At least two

83. *Bowers v. Hardwick*. 478 U.S. 186 (1986).

84. Linda Greenhouse, *The Supreme Court: The Justices; Context and the Court*, N.Y. TIMES, June 25, 2003, at A1.

85. Wagner, *supra* note 30, at 6.

86. Gregory M. Herek et al., *HIV-Related Stigma and Knowledge in the United States: Prevalence and Trends, 1991-1999*, 92 AM. J. PUB. HEALTH 371, 371 (2002).

87. *Id.* at 373.

88. *Id.*

89. Ctrs. for Disease Control & Prevention, *HIV-Related Knowledge and Stigma-U.S., 2000*, 49 MORBIDITY & MORTALITY WKLY. REP. 1062, 1062-64 (2000).

90. Chou et al., *supra* note 69, at 58; see Linda J. Koenig & Jan Moore, *Women, Violence, and HIV: A Critical Evaluation with Implications for HIV Services*, 4 MATERNAL CHILD HEALTH J. 103 (2000) (concluding, based on a literature review, that violence is not statistically increased among HIV-infected women compared to demographically and behaviorally similar uninfected women); David Vlahov et al., *Violence Among Women with or at Risk for HIV Infection*, 2 AIDS & BEHAV.

observational studies have shown that HIV-positive individuals had a rate of partnership dissolution that was no higher than that of HIV-negative individuals.⁹¹

Unfortunately, most questions related to the harms associated with a positive HIV-test result—including the risk of suicide,⁹² the incidence of individual cases of discrimination, and emotional distress—have not been studied systematically since the beginning of the treatment era. Nevertheless, while there is not enough evidence to state this quantitatively, and while there is undoubtedly still much progress to be made, the situation for HIV-positive individuals is not what it was twenty years ago. Further, as I will argue later, routine provider-initiated testing may actually work to de-stigmatize HIV infection. When coupled with the potentially lifesaving benefit of treatment, which can be stated quantitatively and would in and of itself support an argument for routine testing, these evolving legal and social norms bolster the case for routine provider-initiated testing.

B. The Slow Uptake of Voluntary Testing Is an Obstacle to National and International HIV Treatment Programs

Closely related to the argument that individual patients now stand to benefit from routine testing is the argument that certain disadvantaged groups, especially poor minorities and women, and indeed whole societies will also benefit from expanded routine testing. While there is an emerging political commitment to treat HIV positive individuals in both rich and poor countries, the slow uptake of voluntary counseling and testing is inhibiting the roll-out of treatment programs. Zimbabwe, for example, missed the WHO's "3 by 5" target of providing 120,000 HIV/AIDS patients with treatment by the end of 2005. While the exact number of individuals receiving treatment is not yet known, only 17,500 people were receiving treatment for HIV as of August 2005. According to Owen Mugurungi, head of the tuberculosis and AIDS unit in Zimbabwe's Ministry of Health and Child Welfare, insufficient uptake in Zimbabwe's voluntary HIV testing program was one of many factors that contributed to the country missing its treatment target.⁹³ It now appears likely that most of the countries targeted by the WHO

53 (1998) (finding that both physical abuse and sexual abuse were similarly common among both HIV-seropositive (66.4%, 45.7%) and HIV-seronegative women (69.2%, 48.8%), respectively); see also Mardge Cohen et al., *Domestic Violence and Childhood Sexual Abuse in HIV-Infected Women and Women at Risk for HIV*, 90 AM. J. PUBLIC HEALTH 560, 560 (2000) (finding that HIV-positive and HIV-negative individuals have similar rates of intimate partner violence).

91. Tamara Hoxworth et al., *Changes in Partnerships and HIV Risk Behaviors after Partner Notification*, 30 SEXUALLY TRANSMITTED DISEASES 83, 86 (2003); Patricia J. Kissinger et al., *Partner Notification for HIV and Syphilis: Effects on Sexual Behaviors and Relationship Stability*, 30 SEXUALLY TRANSMITTED DISEASES 75, 78-79 (2003).

92. Chou et al., *supra* note 69, at 58.

93. *Zimbabwe Has Missed World Health Organization "3 by 5" Target*, LIFE SCI. WKLY., Jan. 3, 2006, at 801.

have missed their treatment targets.⁹⁴ In short, voluntary counseling and testing does not work at the population level because it does not allow public health authorities to identify cases of HIV with enough frequency and reliability to administer a viable large-scale treatment program.

1. Routine Testing Results in an Increased Uptake in Testing and in Fewer Missed Diagnoses

Botswana's experience with voluntary counseling and testing provides a vivid example of the need to rethink testing strategy at the population level. Botswana, despite having the highest per capita GNP in sub-Saharan Africa and a relatively impressive health infrastructure, has an estimated HIV prevalence of 35%. As a result, life expectancy at birth in this small nation of 1.7 million people has fallen from sixty-five years in 1990-1995 to thirty-nine years in 2004—a decline so severe that it threatens Botswana with complete economic collapse.⁹⁵ The government of Botswana, led by President Festus Mogae, has responded to this national crisis with one of the most assertive AIDS campaigns in Africa. Botswana budgeted \$198 million dollars for AIDS treatment and prevention in 2004-2005, including \$60 million of its own money. This program undertook to treat some 20% of the country's HIV-positive individuals, possibly as much as 4% of the total population of Botswana, with ARV therapy.⁹⁶

Since only a small percent of the population of Botswana had been tested for HIV as of 2002, the first major obstacle the government faced was identifying which 4% of the population required treatment.⁹⁷ Individuals in this 4% would qualify for treatment under current clinical guidelines but would otherwise be indistinguishable from uninfected individuals even based on a thorough medical exam. Facing this enormous challenge, the Government of Botswana increased the number of voluntary testing centers. However, by early 2003, only 28% of the country's citizens in the most populous districts knew their HIV status and only 10,000 people were receiving treatment. This was far below the government's target.⁹⁸

In late 2003, the Government of Botswana sponsored a public discussion on its HIV testing strategy and held a consultative meeting with experts from UNAIDS and the CDC. The outcome of this discussion was a decision to shift course by adopting a country-wide program of routine provider-initiated HIV testing. Under this program, patients in Botswana are offered an HIV test whenever they have contact with their health care system. Though individuals

94. WHO Likely To Miss "3 by 5" AIDS Drug Target, REUTERS, June 29, 2005.

95. UNITED NATIONS, THE IMPACT OF AIDS 17 (2004), available at http://www.un.org/esa/population/publications/AIDSimpact/5_CHAP_II.pdf.

96. CSIS REPORT, *supra* note 23, at 8.

97. Weiser et al., *supra* note 53.

98. CSIS REPORT, *supra* note 23, at 9.

remain free to opt out of testing, the default position has changed such that all individuals are tested unless they specifically decline to be tested.⁹⁹

There is insufficient data to evaluate Botswana's routine testing program since it was put into place in January 2004. However, some 28,000 people are now receiving ARV treatment in Botswana¹⁰⁰ and the percentage of women receiving an HIV test in antenatal clinics in one city for which data is available has risen from 75% to 90%.¹⁰¹ As of this writing, few adverse consequences of this program have been publicly reported in the medical or legal literature or in the English-language press—and those reports that have been published have been limited to describing confusion among health care workers as to when to offer an HIV test, increased stress on the country's health infrastructure, and bottlenecks in laboratory logistics.¹⁰²

Data from four U.S. studies in settings with an HIV prevalence of greater than one percent support these basic conclusions from Botswana. All four studies demonstrated an increased yield in testing and two retrospective studies indicated a lower rate of missed diagnosis after the implementation of routine provider-initiated testing.¹⁰³ The most recent of these studies implemented a routine testing program for admitted patients at a Boston teaching hospital and compared the results of this program with a fifteen-month historical control period. The study found that patients admitted during the study program period were 3.4 times more likely to undergo HIV testing. Patients who would not have undergone testing had the program not been implemented had an HIV prevalence of 3.8%. This would mean that routine testing could detect 19 undiagnosed cases of HIV in a hospital with 500 medical admissions per month—this as compared with a detection rate of 1.3 undiagnosed cases for targeted testing.¹⁰⁴

Similarly, a 2003 study in the United Kingdom published in the *British Medical Journal*, also found that switching from voluntary to routine provider-initiated testing resulted in an increased uptake in HIV testing from 35% of patients to 65% of patients examined in the clinical center.¹⁰⁵ These findings are further verified by data from the antenatal testing context, where routine testing is the norm in most countries. The CDC published a study in 2002 which found that antenatal testing rates for pregnant women are much higher in states that use an opt-out approach as opposed to an opt-in approach.¹⁰⁶

99. *Id.*

100. *Id.*

101. Khumo Seipone et al., *Introduction of Routine HIV Testing in Prenatal Care*, 53 MORBIDITY & MORTALITY WKLY. REP. 1083, 1083-84 (2004).

102. CSIS REPORT, *supra* note 23, at 9-10

103. See Chou et al., *supra* note 69, at 57.

104. Rochelle P. Wallensky et al., *Identifying Undiagnosed HIV: The Yield of Routine, Voluntary Inpatient Testing*, 162 ARCHIVES INTERNAL MED. 887, 889-91 (2002).

105. Belinda Stanley, *Uptake of HIV Screening in Genitourinary Medicine After Change to "Opt-Out" Consent*, 326 BMJ 1174, 1174 (2003).

106. Ctrs. for Disease Control & Prevention, *HIV Testing Among Pregnant Women—United*

2. The Disparate Impact of Voluntary Testing on the Poor and Uneducated

While there is a relative lack of data on the population level impact of voluntary versus routine HIV testing in poor countries, data from the United States, which is available, supports the contention that national voluntary testing programs are insufficiently sensitive to patterns and trends in HIV prevalence. One 2002 study, which used data from the 1998 National Health Interview Survey, found that 66% of the 32,440 U.S. adults surveyed had not been tested for HIV.¹⁰⁷ More alarmingly, however, the study found that potential barriers to seeking HIV testing included age, ethnicity, educational level, marital status, gender, and region of residence.¹⁰⁸ Certain subpopulations are more likely to seek testing than others. Perhaps unsurprisingly, those without insurance and those without higher education are less likely to seek testing.¹⁰⁹

If these findings can be generalized, they would necessarily mean that the poor and less educated will have a lower testing rate, and therefore less access to potentially life-saving treatment, even though the policy of voluntary testing was ostensibly developed to protect the poor and less educated. It is not a coincidence that AIDS afflicts certain populations, namely poorer populations, more than others.¹¹⁰ The shortcomings of voluntary testing, which track other traditional indices of access to information such as poverty and illiteracy, are more likely to shortchange the very people that voluntary testing was meant to protect.

3. Targeting High-Risk Groups Is Not a Viable Testing Strategy

Some countries have adopted so called “risk-based” HIV testing, a blend of voluntary testing and routine testing for the general population. Risk-based testing is essentially routine provider-initiated testing for certain subgroups that are thought to be at high risk for HIV infection—or in clinical settings that are thought to have a high HIV prevalence. Voluntary testing remains the norm for the rest of the general population. This Article argues that risk-based testing, the status quo testing policy in the United States, is no more viable than voluntary testing as a testing strategy because it too prevents the identification of a large number of cases of HIV.

There are at least three reasons that risk-based HIV testing fails in practice in

States and Canada, 1998-2001, 51 MORBIDITY & MORTALITY WKLY. REP. 1013, 1013-16 (2002).

107. Joseph N. Inungu, *Potential Barriers to Seeking HIV Testing Among Adults in the U.S.: Data from the 1998 National Health Interview Survey*, 16 AIDS PATIENT CARE & STDs 293, 297 (2002).

108. *Id.*

109. There are some exceptions to this general finding. Some poor subpopulations are more likely to be tested. One example would be injection drug users, who have higher testing rates, as they are often targeting by HIV prevention programs. Robert Heimer et al., *Assessment of HIV Testing of Urban Injection Drug Users*, 97 AM. J. PUB. HEALTH 110 (2007).

110. *Id.*

the United States, the country for which the best data is available. First, while a substantial percentage of Americans report high-risk behaviors,¹¹¹ high-risk behaviors often remain undetected in health care settings.¹¹² Second, even when detected, high-risk behaviors often fail to lead to testing.¹¹³ Third, a large number of HIV-infected individuals report no risk factors for infection. According to one U.S. study of 1.2 million individuals identified at federally funded testing sites, between 20% and 26% of HIV-positive individuals reported no risk factors for infection.¹¹⁴ Other smaller studies have placed this figure between 7% and 51%.¹¹⁵

In short, strategies that are based on risk, or based on the prevalence of HIV in a certain subpopulation, are impractical because they rely on risk assessment either by health care providers or by patients themselves, both of which are inherently inaccurate.¹¹⁶ Multiple studies in the United States have attempted to devise risk-based or prevalence-based criteria for HIV testing. These studies report a rate of missed diagnosis of HIV that ranges from 7% to 74%.¹¹⁷ Even 7% is an unacceptably high number for a fatal illness that is otherwise treatable.

Moreover, even if epidemiologic science could devise criteria for risk-based testing that could eliminate missed diagnoses altogether, most of the legal and ethical issues associated with routine provider-initiated testing would still remain. Risk-based testing only shifts the negative burden of widespread HIV testing from the general population to a more specific subpopulation.

C. The Low Testing Rate Associated with Voluntary Testing Is an Obstacle to HIV Prevention

The slow uptake and low testing rates associated with voluntary testing does not just impede treatment, but also impedes efforts to prevent the spread of HIV. This is an argument advanced most visibly and forcefully by Richard Holbrooke, former U.S. Ambassador to the United Nations and the President of the Global Business Coalition on HIV/AIDS. Holbrooke noted in an op-ed essay that the number of people infected with HIV has increased every day since the first

111. For example, one telephone survey of 33,913 U.S. residents found that 11% of respondents reported having multiple sexual partners within the past year. P. Owens et al., *Prevalence of Risk Behaviors for HIV Infection Among Adults*, 50 MORBIDITY & MORTALITY WKLY. REP. 262, 262 (2001).

112. Daniel Klein et al., *Review of Medical Encounters 5 Years Before a Diagnosis of HIV-1 Infection*, 32 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 143, 143 (2002).

113. Rebecca V. Liddicoat et al., *Assessing Missed Opportunities for HIV Testing in Medical Settings*, 19 J. GEN. INTERNAL MED. 349, 352-53 (2004).

114. Thomas A. Peterman et al., *Opportunities for Targeting Publicly Funded Human Immunodeficiency Virus Counseling and Testing*, 12 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES & RETROVIROLOGY 69 (1996).

115. Chou et al., *supra* note 69, at 57.

116. Beckwith et al., *supra* note 21, at 1038.

117. Chou et al., *supra* note 69, at 57.

World AIDS Day.¹¹⁸ While action on many fronts is necessary to combat the spread of AIDS, the world community has been silent on testing and detection. Holbrooke writes,

Because of legitimate concerns about confidentiality and the risk of stigmatization, testing has always been voluntary, and it has been systematically played down as an important component of the effort . . . [this] means that 90 percent of the roughly 12,000 people around the world who will be infected today—just today!—will not know it until roughly 2013. That's plenty of time for them to spread it further, infecting others, who will also spread it, and so on. No wonder we are losing the war against AIDS: In no other epidemic in modern history has detection been so downgraded.¹¹⁹

Holbrooke further argues that more people must be made aware of their HIV status, as this knowledge changes people's behavior. That is, many who learn that they are HIV-positive act on the information they receive from HIV testing to behave more carefully, preventing the further spread of the virus.

Holbrooke preempts the charge of medical paternalism by casting his argument as one for empowering patients by providing them with more information. Routine provider-initiated testing is part of a larger package of information dissemination that strengthens the ability of individuals to take measures to protect themselves and their families. I will address each of Holbrooke's arguments in turn.

1. The Relationship Between Access to Information and Testing Rates

I have already reviewed the evidence that routine provider-initiated testing leads to a greater uptake of testing in the general population. A related finding is that individuals in high-risk groups—individuals with multiple sexual partners and homosexual men—are more likely to be tested for HIV than individuals in the general population.¹²⁰ As the authors of one such study note, this suggests that increased HIV testing in high-risk populations results from a reasoned decision making process on the part of individuals and their health care providers.¹²¹ That is, high-risk groups are the subjects of targeted information and education campaigns, and increased information leads to testing. This finding, when joined with the studies from the above Section on the impact of provider-initiated testing and the disparate negative impact of voluntary testing on the poor and less educated, suggests that a lack of access explains—at least in part—the low testing rates associated with voluntary testing. This would support

118. Richard Holbrooke, *AIDS: The Strategy Is Wrong*, WASH. POST, Nov. 29, 2005, at A21.

119. *Id.*

120. See, e.g., Christine McGarrigle et al., *Investigating the Relationship Between HIV Testing and Risk Behaviour in Britain*, 19 AIDS 77, 83 (2005).

121. *Id.* at 83.

Holbrooke's argument that a lack of information or knowledge regarding HIV explains the low percentage of individuals who know their HIV status.

2. The Relationship Between Expanded Testing and Reduced HIV Transmission

While Holbrooke claims that knowledge of one's HIV status leads to changes in high-risk behavior, the reality appears to be somewhat more complicated. Because all studies must involve, as a matter of research ethics, interventions such as counseling or treatment, no studies have examined whether simply learning of one's HIV status leads to a change in behavior. However, it is possible to examine the effects of treatment and counseling on high-risk behavior.

One recent meta-analysis of twenty-five studies published in the *Journal of the American Medical Association* found that there was neither an association between receiving ARV therapy and having unprotected sex, nor an association between having an undetectable viral load and having unprotected sex.¹²² However, among both HIV-positive and HIV-negative individuals, the study found that having unprotected sex was associated with having optimistic beliefs about HIV treatment.¹²³ This suggests that treatment in and of itself does not lead to an increase or decrease in high-risk behavior—rather, changes in behavior appear to be mediated through counseling and education.¹²⁴

The data on the effects of testing and counseling on sexual risk behavior gives some reason for cautious optimism about the power of testing to aid prevention efforts. Three systematic reviews of the literature found that testing, together with counseling, was effective in reducing sexual risk behavior among those who tested positive for HIV and among serodiscordant heterosexual couples (couples with one HIV-infected partner).¹²⁵ While the counseling methods used vary significantly across these studies, some of the studies included in these analyses found that more intensive counseling was associated with greater reductions in risky behavior. However, while testing positive for HIV appears to lead to reductions in risky behavior, it also appears that testing negative for HIV either has no effect on risky behavior or may actually increase risky behavior.¹²⁶

Independent of its effect on sexual risk behavior, expanded testing may reduce transmission through mechanisms that are more difficult to study. The example of Botswana, discussed above, suggests that stimulating a public

122. Nicole Crepaz et al., *Highly Active Antiretroviral Therapy and Sexual Risk Behavior*, 292 JAMA 224, 231-34 (2004).

123. *Id.*

124. *Id.*

125. Chou et al., *supra* note 69, at 59.

126. *Id.* at 59-60.

dialogue on testing may itself lead to greater social awareness and decreased transmission of HIV. Botswana's efforts to increase testing are only one part of the country's larger campaign to implement a community-based educational program.¹²⁷ Also, when coupled with treatment, HIV testing will decrease the viral load in the general population.¹²⁸ This will aid prevention efforts as it will decrease overall transmission rates.

The lack of studies that analyze how all of these factors—risk behavior, counseling, and viral load—fit together to impact overall HIV transmission rates represents a major gap in the public health literature. Only one study has followed the effect of a national testing and treatment campaign on the evolution of an HIV epidemic. This study, conducted in Taiwan between 1997 and 2002, analyzed national HIV surveillance data and estimated the HIV transmission rate by using a statistical projection. The study found that expanded testing, coupled with providing free ARV therapy to all HIV-infected citizens, was associated with a 53% decrease in the HIV transmission rate.¹²⁹ While this is certainly an area for further study, there is at least reason to be hopeful that routine provider-initiated testing can help to slow the spread of HIV.

*D. Routine Testing May Work To Reduce the Stigma and
Fear Associated with HIV*

Because routine testing is the norm for most other treatable diseases for which there are straightforward tests, creating a system of rules and procedures for AIDS—that is, promoting “AIDS exceptionalism”—may actually perpetuate the stigma, denial, and fear associated with HIV. This is a controversial argument; and, indeed, some opponents of routine testing have argued that expanded testing will not necessarily reduce HIV-related stigma.¹³⁰ At best, the argument that routine testing will lessen stigma represents an optimistic hope, not an assertion that is well established by existing evidence.

However, there are at least a few reasons to be optimistic that expanded testing may dilute stigma. First, as I have already noted, testing rates have risen dramatically in settings where routine testing has been attempted. It is important to note that even in situations where testing is routine, testing is still voluntary. That is, individuals can still decline to be tested. This suggests that an increasing number of individuals are at least willing to accept HIV testing. The alternative explanation, that this dramatic rise in testing rates can be explained by

127. Weiser et al., *supra* note 53.

128. See Thomas C. Quinn, *Viral Load and Heterosexual Transmission of Human Immunodeficiency Virus Type 1*, 342 NEW ENG. J. MED. 921, 923-26 (2000).

129. Chi-Tai Fang et al., *Decreased HIV Transmission After a Policy of Providing Free Access to Highly Active Antiretroviral Therapy in Taiwan*, 190 J. INFECTIOUS DISEASES 879, 881-83 (2004).

130. Crewe & Viljoen, *supra* note 22, at 10.

widespread coercion, is unlikely. Some studies suggest that patients are generally accepting of routine testing and may even prefer routine testing.¹³¹

Second, the example of Botswana suggests that downgrading HIV to a “manageable disease” has contributed to changes in deeply rooted perceptions of the moral stature of AIDS patients. Botswana’s routine testing program has resulted in a dramatic uptake in testing at the same time as it has stimulated a public dialogue on HIV and the possibility of treatment. Though the effects of this program are still being studied, there have been no reports of adverse consequences. Indeed, the President of Botswana had his blood drawn for an HIV test and admitted publicly that he was concerned that he could be infected.¹³²

Third, the principle of voluntary testing, though developed in response to HIV-associated stigma, does nothing by itself to preempt such stigma. Because nearly everyone with HIV who does not receive will develop clinical AIDS with its attendant body marks—skin lesions and wasting, to name two—the best that can be said of a policy that leaves most individuals ignorant of their HIV status is that it merely postpones stigma. Testing coupled with treatment, on the other hand, has the power to prevent individuals from developing the physically distinguishing characteristics of HIV infection.

Despite these reasons for optimism, subjecting individuals to HIV-associated stigma remains a very real concern for any routine testing program. For this reason, it is essential that even under a routine testing paradigm individuals retain control over the time and place of HIV testing and, as I will argue, over any subsequent disclosure of test results to others. As this Article argues, it is possible to advance the goal of expanded access to testing and treatment while at the same time advancing the goal of protecting individual rights. In fact, as I will argue in the final section of this paper, these twin goals can be mutually reinforcing.

E. Routine Provider-Initiated HIV Testing Is Cost-Effective

Until recently there have been few studies that have examined the cost-effectiveness of routine testing for HIV in the era of ARV treatment. In 2005, however, several papers were published that examined this issue for specific target populations. One study of pregnant women in Chicago found that universal screening for this population would both decrease the number of HIV-infected newborns and save money when compared to a voluntary testing strategy, where population prevalence of HIV was .21% or higher.¹³³ Another modeling study

131. Angela B. Hutchinson et al., *Understanding the Patient’s Perspective on Rapid and Routine HIV Testing in an Inner-City Urgent Care Center*, 16 AIDS EDUC. & PREVENTION 101 (2004).

132. CSIS REPORT, *supra* note 23, at 10.

133. Lilly Cheng Immergluck et al., *Cost Effectiveness of Universal Compared With Voluntary Screening for Human Immunodeficiency Virus Among Pregnant Women in Chicago*, PEDIATRICS

applied to inpatients at U.S. hospitals found that screening is cost-effective assuming a prevalence of 1% (the threshold, according to the recommendations of the CDC, for routine testing). As a point of reference, the prevalence of HIV in the U.S. general population is approximately 0.10%.¹³⁴ Although this is less than the minimum prevalence for which these studies found that routine testing would be cost-effective, they support the argument that routine testing is desirable in high-prevalence areas.

Most notably, the authors of two landmark papers in the *New England Journal of Medicine* conducted a modeling analysis to estimate the cost of one-time screening in the U.S. general population. These two papers found the cost to be \$38,000 and \$41,736 respectively per quality-adjusted life-year gained—estimates calculated using a prevalence of 1%.¹³⁵ Both of these estimates are lower than the commonly cited \$50,000 threshold for cost-effective care—a threshold that is derived from the per capita GDP of the United States.

One of these studies also estimated that routine one-time screening would reduce the annual HIV transmission rate by more than 20%. When this consideration is included in the analysis, the cost of screening in a population with a prevalence of 1% fell to \$15,078 per quality-adjusted life year. Moreover, the study found that when decreased transmission was included in the analysis, the cost of routine screening does not cross the \$50,000 threshold until the prevalence of HIV falls below 0.05%.¹³⁶

These studies did not include in their analysis several of the secondary benefits of routine testing—for example, averting the productivity loss caused by HIV infection and the effect of expanded testing on combating other sexually transmitted diseases. As the accompanying editorial in the *New England Journal of Medicine* notes, the most provocative implication of these studies is that expanded testing could, if combined with a partially effective vaccine, reduce the person-to-person transmissibility below the threshold of one new infection per infected person. If achieved, this would lead to the end the AIDS epidemic.¹³⁷ All of these secondary benefits could potentially lower the cost of HIV testing below the figures put forth by these two studies.

It should be noted that these two studies do have some moderate limitations. The estimates for the costs associated with counseling and testing may exceed those assumed, as different settings may have different operational difficulties.

April 2000, at E54.

134. Samuel A. Bozzette, *Routine Screening for HIV Infection—Timely and Cost-Effective*, 352 NEW ENG. J. MED. 620, 620 (2005).

135. A. David Paltiel et al., *Expanded Screening for HIV in the United States—An Analysis of Cost-Effectiveness*, 352 NEW ENG. J. MED. 586, 586 (2005); Gillian D. Sanders et al., *Cost-Effectiveness of Screening for HIV in the Era of Highly Active Antiretroviral Therapy*, 352 NEW ENG. J. MED. 570, 570 (2005).

136. Sanders et al., *supra* note 135, at 577.

137. Bozzette, *supra* note 134, at 586-87.

The increased need for pre-test and post-test counseling may divert health care workers from other activities, further increasing costs. Lastly, these modeling studies used variables that are specific to the United States.¹³⁸ It is unclear what these findings would mean for testing in resource-poor settings. However, given that treatment and testing are cheaper, and that prevalence is higher, in these settings—and that these are essentially the two main determinants of cost-effectiveness—it may be even more cost-effective to begin routine screening in poor countries.

Despite their limitations, these studies present solid evidence that routine provider-initiated testing is cost-effective in the U.S. context. They suggest that routine testing is likely cost-effective in resource poor settings as well. As I have argued, routine testing benefits individuals by giving them an opportunity to receive life-saving treatment and society at large by offering a powerful tool for combating the AIDS epidemic. While the finding that routine testing is cost-effective may not carry the moral force of these arguments, it does demonstrate that routine testing represents a comparatively good value for society.

F. Routine Provider-Initiated Testing Is Consistent with Human Rights Principles

1. Social and Economic Rights: The Right to Health

Perhaps the strongest charge leveled against routine testing proposals is that they are inconsistent with the principle of autonomy, the idea that individuals have a right to make choices free from coercion based on their own values and beliefs.¹³⁹ The principle of autonomy has at least two sources in U.S. law. Courts in almost all U.S. jurisdictions have recognized the existence of a common law right to be free from nonconsensual bodily invasion. Further, in *Cruzan v. Missouri*, the U.S. Supreme Court affirmed that there is a constitutional Substantive Due Process right to make decisions of critical importance to one's own destiny.¹⁴⁰

The autonomy principle is also strongly rooted in international law. Both Articles 1 and 3 of the Universal Declaration of Human Rights as well as Article 10 of the International Covenant on Civil and Political Rights recognize the "inherent dignity of the human person."¹⁴¹ Article 17 recognizes that "No one

138. *Id.*

139. Crewe & Viljoen, *supra* note 22, at 9.

140. The Court also held that Missouri could limit the exercise of this right for persons found to be incompetent. *See Cruzan v. Director, Mo. Dept. of Health*, 497 U.S. 261 (1990).

141. International Covenant on Civil and Political Rights, pmbl., art. 10, adopted Dec. 16, 1966, 999 U.N.T.S. 171 (entered into force Mar. 23, 1976) [hereinafter ICCPR]; *see* Universal Declaration of Human Rights, arts. 1, 3, G.A. Res. 217A(III), at 71, U.N. Doc A/810 (Dec. 12, 1948) [hereinafter UDHR].

shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honour and reputation.”¹⁴² This foundational idea—that individuals should have control over what is done to their own bodies—protects patients in at least two ways. In many countries, including the United States, it gives patients a cause of action if they have suffered a harm due to an unwanted bodily invasion.¹⁴³ More importantly, this idea has developed into the legal doctrine of informed consent, which allows patients to prevent unwanted bodily invasions by refusing care.

Critics of routine testing argue that routine testing contravenes the principle of autonomy and use human rights principles to justify a policy of voluntary testing. However, this Article argues that one can use human rights principles to justify routine provider-initiated testing.

First, the autonomy principle contains more than the simple right to decline medical care. Respect for autonomy involves not only refraining from coercion, but it also involves ensuring the necessary conditions for exercising free choice. Especially as it is expressed in the doctrine of informed consent, autonomy also includes a right to a certain package of information. This is, after all, what separates *informed* consent from mere consent. Indeed, the main issue of contention in many judicial opinions on informed consent is the issue of materiality, or what information is material to a patient’s decision to undergo a given therapy or procedure.¹⁴⁴ The argument for routine-offer testing is essentially an argument for giving patients more information. By giving patients more information to make informed decisions about their health, routine testing may potentially enhance individual autonomy.

Second, even independent of the autonomy principle, the letter and the substance of international human rights law can be interpreted to support routine provider-initiated HIV testing. Simply put, the principle of autonomy and the right to be free from coercion must be supplemented and augmented by other equally important human rights principles. One such principle is the right to health, which is expressed in several international human rights documents, including Article 25 of the Universal Declaration of Human Rights,¹⁴⁵ Article 12 of the International Covenant on Economic, Social and Cultural Rights,¹⁴⁶ Article

142. *Id.*

143. *See, e.g.,* *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972) (defining the physician’s duty to disclose as including information that is material to a patient’s decision if “a reasonable person, in what the physician knows or should know to be the patient’s position, would be likely to attach significance to the [information] in deciding whether or not to forgo the proposed therapy”).

144. 464 F.2d 772, 787; *see also* *Culbertson v. Mernitz*, 602 N.E.2d 98, 102-04 (Ind. 1992) (holding that expert testimony from a physician is required to establish the professional standard of care in an action for negligence based on physician’s failure to obtain informed consent).

145. UDHR, *supra* note 141, art. 25.

146. International Covenant on Economic, Social and Cultural Rights, art. 12, adopted Dec. 16, 1966, 993 U.N.T.S. 3 (entered into force Jan. 3, 1976).

24 of the Convention on the Rights of the Child,¹⁴⁷ and Article 16 of the African Charter on Human and Peoples' Rights.¹⁴⁸ Several national constitutions also recognize the right to health, including Article 47 of the Constitutional Law of the Republic of Angola,¹⁴⁹ Section 27 of the Constitution of the Republic of South Africa,¹⁵⁰ Article 30 of the Republic of Malawi,¹⁵¹ and Article 21 of the Republic of India.¹⁵²

As David Patterson of the Canadian HIV/AIDS Legal Network notes, historically human rights discourse in Western countries has tended to privilege civil and political rights over social and economic rights.¹⁵³ This is most apparent in the human rights community's focus on discrimination against people living with HIV/AIDS, which reflects the concern with individual rights that is characteristic of American civil libertarianism. However, this narrow formulation of "human rights," which has drawn criticism from some practitioners in developing countries,¹⁵⁴ fails to address the human rights imperative to ensure the right to health of HIV positive individuals by giving them access to treatment.¹⁵⁵

Few issues other than HIV testing better illustrate the tension that can exist between civil and political rights, and social and economic rights. One could imagine a regime justifying mandatory testing by invoking social and economic human rights principles—that is, by arguing that the public health imperative presented by HIV/AIDS overrides the autonomy principle.¹⁵⁶ On the other hand, the current policy of voluntary testing privileges civil and political rights at great expense in terms of public health and the right to health of individuals. As this paper has already argued, expanded testing coupled with treatment comes with potentially enormous benefits both for individuals and for society. To the extent that the autonomy principle may be in tension with the right to health, HIV testing policies should not take extraordinary measures to safeguard autonomy at

147. Convention on the Rights of the Child, art. 24, G.A. Res. 25, 44th Sess., Annex, Agenda Item 108, at 170, U.N. Doc. A/RES/44/25 (1989).

148. African Charter on Human and Peoples' Rights, art. 16, adopted June 27, 1981, 1520 U.N.T.S. 217 (entered into force Oct. 21, 1986).

149. CONST. ANGL. part 2, art. 47 (1992).

150. S. AFR. CONST. 1996, sec. 27.

151. CONST. OF THE REP. OF MALAWI chap. 4, art. 30 (1994).

152. INDIA CONST. arts. 21 and 14. Article 21 provides for the "right to life." Article 14 provides for the "right to equality." The Indian Supreme Court has interpreted these two provisions as guaranteeing a right to health.

153. David Patterson & Leslie London, *International Law, Human Rights and HIV/AIDS*, 80 BULLETIN WORLD HEALTH ORG. 964, 965 (2002).

154. Kevin De Cock et al., *Shadow on the Continent: Public Health and HIV/AIDS in Africa in the 21st Century*, 360 LANCET 67, 67 (2002).

155. Patterson & London, *supra* note 153, at 966.

156. One example of this would be Cuba's mandatory quarantine policy for people with HIV infection. Ronald Bayer & Cheryl Heaton, *Controlling AIDS in Cuba: The Logic of Quarantine*, 320 NEW ENG. J. MED. 1022 (1989).

the expense of the health or well-being of the public.

2. *The Human Rights Consequences of a Policy of Voluntary Testing*

While it is possible that a routine testing may erode individual autonomy—a possibility that I will consider in the following Subsection—it is also possible that the failure to make HIV testing routine may itself lead to a non-recognition of the right of individuals to know their HIV status. As a result, individuals who *voluntarily* seek an HIV test may be denied a test.

Few courts have actually considered the issue of whether individuals have a right to an HIV test. In the United States, this question has been considered only in the context of whether prisoners have a right to HIV testing on demand. The U.S. Supreme Court's Eighth Amendment jurisprudence requires prison officials to provide prisoners with adequate medical care. Under the analysis provided by the Court in *Estelle v. Gamble*, "adequate" is defined according to a community standard.¹⁵⁷ To demonstrate that the denial of a particular form of medical care violates the Eighth Amendment, *Estelle* requires evidence that (1) there was deliberate indifference on the part of prison officials and (2) that the prisoner's medical needs were serious.¹⁵⁸

Only one case has applied *Estelle* to a situation where an HIV test was denied. In *Doe v. Wigginton*, the Sixth Circuit considered the case of an inmate in the Kentucky State Reformatory in 1989, who requested an HIV test. His request was denied by a nurse because he did not meet the testing criteria established by Kentucky's medical regulations for correctional facilities. These regulations specifically stated that no routine testing would be performed, but that a physician could order a test if an inmate has physical symptoms of HIV infection or a presumptive history of exposure.¹⁵⁹ The inmate in question was transferred to another facility two years later, where he was tested for HIV and found to be positive. By the time of his diagnosis, his immune function had already declined.¹⁶⁰ The Sixth Circuit held that the prison officials were not deliberately indifferent to the possibility that the inmate had been infected with the HIV virus.¹⁶¹ In its reasoning, the court relied heavily on the fact that HIV testing was not routine in the community and that Kentucky's regulations on HIV testing, therefore, were reasonable.¹⁶² If routine testing had been the norm in the community, this likely would have satisfied the constitutional standard for an Eighth Amendment violation. In essence, the court treated HIV testing, because it was not routine in the community, as if it was unnecessary or extraordinary

157. *Estelle v. Gamble*, 429 U.S. 97, 103 (1976).

158. *Id.* at 104.

159. *Doe v. Wigginton*, 21 F.3d 733, 733-35 (6th Cir. 1994).

160. *Id.*

161. *Id.* at 738.

162. *Id.*

medical care.

Even in countries that recognize a right to health, courts are hesitant to recognize a self-standing and independent positive right for individuals to claim some basic minimum package of medical care, often preferring instead to review government actions for reasonableness. The South African Constitutional Court, for example, has twice been asked to enforce the right to health under Article 27 of the South African Constitution. In the first case, *Soobramoney v. Minister of Health*, the court considered whether a forty-one-year-old man with chronic renal failure, who required lifelong dialysis to survive but did not qualify for dialysis at his local medical facility, could require the health department to provide a sufficient number of machines to offer dialysis to everyone whose life could be saved through such treatment. The court noted that the right to health is limited by “available resources” and that the courts should not interfere with decisions that are rational and made “in good faith by the political organs and medical authorities whose responsibility it is to deal with such matters.”¹⁶³ In *TAC v. Minister of Health*, the court considered whether the government’s refusal to allow doctors to use the ARV drug nevirapine, which was freely available in South Africa, was reasonable in light of the drug’s ability to reduce the risk of mother to child transmission of HIV—and whether the South African government’s delay in introducing a comprehensive plan to reduce mother to child transmission of HIV was reasonable. The court ruled that the government’s actions were unreasonable, but implied that individuals had no self-standing right to claim a minimum package of medical care.¹⁶⁴

It is not so difficult to imagine governments or public health authorities denying HIV testing to individuals by citing resource constraints. If HIV testing remains a voluntary medical test as opposed to a routine medical test, courts may interpret the denial of an HIV test on demand as reasonable—just as the Sixth Circuit did in *Wigginton*. This could potentially mean that many individuals seeking an HIV test would be denied access to a test by their health care system.

3. *Balancing Individual Autonomy and the “Right to Know”*

In truth, one can use human rights principles to justify either a voluntary or a routine-offer testing policy. It simply depends on whether one chooses to emphasize civil and political rights or social and economic rights. This Article takes the view that it is inconsistent with the right to health not to offer individuals a test for a treatable disease—that, if there is a right to health, it follows as a corollary that there must also be a right to comprehensive HIV care, of which HIV testing is a necessary component. By offering an HIV test to an individual, a health care worker helps that individual realize this right.

163. *Soobramoney v Minister of Health (KwaZulu-Natal)* 1997 (12) BCLR 1696 (CC) 1706 (S. Afr.).

164. *TAC v Minister of Health* 2001 (4) BCLR 356 (T), 2001 SACLRL 123 (S. Afr.).

However, the right to health in the context of HIV testing, if taken to its extreme, can easily become an argument for paternalism. As some proponents of mandatory testing argue, avoiding the greatest human rights violation of all, premature and avoidable death, requires abandoning the autonomy principle. Kevin De Cock has asserted that the “failure to prevent HIV transmission constitutes an infringement of human rights that hampers Africa’s human and social development.”¹⁶⁵ De Cock creates a dichotomy between the human rights principles of autonomy and the right to health. In his view, human rights advocates deter HIV testing by demanding specialized informed consent and confidentiality procedures. Because this Article argues in favor of coupling expanded testing with expanded protection for individual rights, it argues for a balance between individual autonomy and the right to health implicated by HIV testing.

Equally problematic is the way in which the WHO has chosen to frame this issue—that is, in terms of the individual’s “right to know” their HIV status. Consider this excerpt from a 2003 WHO policy paper: “People have a right to know their HIV status, and testing and counseling should be widely accessible through innovative, ethical and practical models of delivery.”¹⁶⁶ Another 2004 policy paper described “the right to seek, receive and impart information . . . as a fundamental human right.”¹⁶⁷

While this paper agrees with the claim that people have a right to know their HIV status, this formulation taken alone is potentially problematic given the current politics of HIV testing. Richard Holbrooke, for example, chose to weigh the autonomy principle against the “right to know”: “[Knowledge of HIV status] changes people’s behavior; many who learn that they are HIV positive behave more carefully, and they can act on the information to save themselves and their family members. Isn’t this the most important human right of all?”¹⁶⁸ This statement implies that the civil and political rights of individuals, as expressed in the autonomy principle, are somehow less important than the “right to know.” Segolame Ramothlwa, operations manager for Botswana’s national treatment program, expressed this idea more directly while responding to concerns that Botswana’s decision to start routine testing would compromise patients’ rights: “I think the first right of a human being is to be alive. All other rights are secondary.”¹⁶⁹ One need only traverse a short logical distance from this statement to construe the “right to know” as implying that the state has a duty to inform individuals of their HIV status, even if they do not want to be informed of it.

165. De Cock et al., *supra* note 154, at 71.

166. WORLD HEALTH ORG., THE RIGHT TO KNOW: NEW APPROACHES TO HIV TESTING AND COUNSELING (2003).

167. Miller et al., *supra* note 47, at 3; UDHR, *supra* note 141, art. 19; ICCPR, *supra* note 141, art. 19.2; Convention on the Rights of the Child, *supra* note 147, arts. 13, 17, 24.

168. Holbrooke, *supra* note 118.

169. *Botswana’s AIDS Program Confronts Stigma, Fear*, ASSOCIATED PRESS, Jan. 5, 2005.

It is important, while recognizing the “right to know” or the right to have a test offered by a health care worker, to clarify the accompanying responsibilities of governments, public health authorities, and health care workers. Asserting a “right to know,” disconnected from a duty to protect individual rights, invites violations of individual autonomy in the name of social and economic rights. This is both inadvisable and unnecessary. More preferable would be a strategy of expanded routine provider-initiated testing that includes expanded protection for autonomy and confidentiality. This strategy, which unifies principles of civil and political rights with principles of social and economic rights, is discussed further in the proposal for expanded protections for individual rights in the final Part of this Article.

IV. THE CASE AGAINST ROUTINE PROVIDER-INITIATED HIV TESTING

The case against routine testing can be summarized as follows: routine-offer testing is potentially coercive and paternalistic and compromises important human rights principles. According to this argument, national health care systems should instead aim to create a climate in which people want to know their HIV status and trust health care providers to provide them with information and support. Opponents of routine testing have raised at least six specific objections to routine testing proposals. While I will discuss each in turn, these objections can be grouped into three categories. The first two reflect a fundamental misunderstanding of proposals for routine-offer testing: that routine testing will be packaged with a streamlining of informed consent procedure; and that those who test positive under routine testing may not receive treatment. The second two arguments challenge proposals for routine-offer testing on the basis of currently available evidence: that routine testing may hamper prevention efforts and that routine testing is not necessary for rational patient management. Finally, two of the objections raised by opponents of routine testing—that routine testing will result in mandatory testing via a slippery slope and that routine testing will lead to a greater number of involuntary disclosures of HIV status—are serious concerns that require a more thoughtful response.

A. The Danger of Streamlined Informed Consent

Opponents of routine testing, who fear that patient consent is unlikely to be fully informed in routine testing situations, make two claims. First, proposals for routine testing are often packaged with proposals that call for a streamlining of counseling and informed consent protocols.¹⁷⁰ Second, as a result of this streamlining of informed consent, patients will receive less information.¹⁷¹

170. See Can. HIV/AIDS Legal Network, *Human Rights and HIV/AIDS in the Context of 3 by 5: Time for New Directions?*, 9 CAN. HIV/AIDS POL’Y & L. REV., August 2004, at 10.

171. Crewe & Viljoen, *supra* note 22, at 6.

The second claim is simply untrue. Routine testing would mean that the *average* patient would receive more information about HIV testing than under voluntary testing, because under voluntary testing patients who do not seek an HIV test receive no information. Even if the first claim were entirely true—that routine testing will be packaged with a relaxation of informed consent requirements—only a small percentage of individuals would receive less information than they would in a voluntary testing regime, because so few individuals actually volunteer to be tested.

In any case, the first claim is only partially true. A 1999 Institute of Medicine panel issued a report that recommended routine prenatal HIV testing and also concluded that pre-test counseling and specific written consent requirements deterred providers from offering HIV testing to pregnant women. According to the panel, many health care providers reported that they lacked sufficient time to offer testing and counseling.¹⁷² Michigan, which required routine testing for pregnant women, found that only 55% of women actually received an offer of an HIV test.¹⁷³ Other than the Institute of Medicine, few routine testing proposals promulgated by major public health agencies actually call for a streamlining of informed consent procedure. The 2004 guidelines on HIV testing published jointly by the WHO and UNAIDS discuss improved protections for individual rights quite prominently in the first section of a three page document:

[T]he cornerstones of HIV testing scale-up must include improved protection from stigma and discrimination as well as assured access to integrated prevention, treatment and care services. The conditions under which people undergo HIV testing must be anchored in a human rights approach which protects their human rights and pays due respect to ethical principles.¹⁷⁴

Similarly, the CDC guidelines for HIV testing include specific and stringent procedures for confidentiality and for obtaining informed consent before an HIV test.¹⁷⁵

Some individual authors have called for a streamlining of informed consent requirements for HIV testing. Richard Holbrooke, as noted earlier, has done this indirectly in suggesting that the rights to life and health outweigh the principles of autonomy and privacy. Though he has made no direct statement on this issue, his earlier position favoring mandatory testing for individuals participating in U.N. peacekeeping forces suggests that he might be amenable to relaxing informed consent requirements in the context of routine testing.¹⁷⁶

172. REDUCING THE ODDS: PREVENTING PERINATAL TRANSMISSION OF HIV IN THE U.S. 85 (Michael A. Stoto & Marie C. McCormick eds., 1999).

173. *Id.* at 78-79.

174. UNAIDS/WHO, *supra* note 44, at 1.

175. See Ctrs. for Disease Control & Prevention, *supra* note 56, at 7.

176. See UN-AIDS: UNAIDS Says HIV Testing Must Be Voluntary for UN Troops, AGENCY

Kevin De Cock published two widely cited papers in *The Lancet* in which he called for routine testing as well as for a “serostatus approach” to HIV—that is, an approach based on widespread routine testing in which individuals learn their status, disclose it to their partners and seek medical care.¹⁷⁷ However, De Cock also argues that routine testing should not require specific consent or pre-test counseling: “Awareness of HIV/AIDS is now high in Africa, and evidence that more extensive pre-test counseling is necessary for HIV than for other diseases is lacking.”¹⁷⁸

De Cock is essentially arguing for a default policy of testing without pre-test counseling, unless an individual specifically elects to decline testing, with post-test counseling for those infected with HIV. This Article agrees with the idea that HIV should be treated more like other diseases only in the limited sense that health care providers should make a routine offer of a test to their patients. However, rather than relax informed consent requirements for HIV testing, this Article instead proposes specialized informed consent, confidentiality, and counseling procedures for HIV.

The apparent differences among the positions of De Cock, the WHO, the CDC, and this Article mirror a larger controversy in informed consent. As Peter Schuck has written, there is an informed consent gap between the ideal of informed consent represented in legal doctrine, and the actual practice of informed consent by physicians.¹⁷⁹ At the poles of this gap are idealists, mostly judges and legal ethicists who want an expansive and subjective conception of a physician’s duty to disclose, and realists, primarily physicians who question whether patients want exhaustive information and whether fully informed consent is worth its costs.

One might describe De Cock as a realist who believes that the idealized form of consent required for HIV testing is overly burdensome in that it has a detrimental effect on health care delivery. Both De Cock and the Institute of Medicine (in the specific context of prenatal testing) suggest that extensive and specialized pre-test counseling may not be necessary. While this Article argues otherwise, it is important not to overstate the scope of this disagreement. Everyone agrees that patients should receive some information before testing and should be free to decline testing. The real debate is about how much information they should receive—not whether to jettison informed consent altogether. To the extent that there is disagreement, the major public health agencies have favored a specific and rigorous informed consent requirement for HIV testing.

This Article agrees with this majority position. A shift from voluntary to

FRANCE-PRESSE, July 17, 2000, available at <http://www.aegis.com/news/afp/2000/AF0007E2.html>.

177. Kevin M. De Cock et al., *A Serostatus-Based Approach to HIV/AIDS Prevention and Care in Africa*, 362 LANCET 1847, 1847 (2003).

178. De Cock, *supra* note 154, at 69.

179. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994).

routine testing need not mark a broader systemic shift in the culture of our approach to the HIV/AIDS pandemic, nor a move away from prevention strategies based on education and behavior change toward strategies that emphasize testing exclusively. Routine provider-initiated testing does not imply that we must abandon the key principles of autonomy, confidentiality, and informed consent. Quite the contrary, human rights aims and public health aims can be mutually reinforcing. In order to further public health aims, patients must become engaged in preventive and treatment programs. This requires voluntary long-term cooperation.

B. Individuals Who Test Positive May Not Receive Treatment

Some critics of routine testing have pointed out that there is no guarantee that those who are tested and are found to require ARV treatment will receive treatment. Treatment remains unavailable for most HIV-positive individuals in the world. Therefore, one cannot assume that the proposed tradeoff—"universal treatment in exchange for a reduction in individual rights—even exists."¹⁸⁰ Notwithstanding the contention that routine testing does not necessarily result in a reduction in individual rights, this statement is entirely true. As one critic has accurately described, treatment programs in most developing countries are site-based, not universal. Especially in rural areas, some individuals may have no conceivable access to treatment.¹⁸¹

Without access to treatment, the strongest arguments for testing, which are rooted in the benefit to the individual being tested, do not hold up. What is left of the case for routine testing depends on the idea that it may aid prevention efforts: that individuals need to "know their status" in order to take steps to prevent spreading the virus, as Richard Holbrooke has argued.¹⁸² This is essentially similar to the situation that existed before the ARV era, during which governments and public health agencies made testing strictly voluntary.

Because testing without treatment may yield more harm than benefit for individuals, this Article takes the stand that routine testing should be strictly coupled with a promise of access to treatment. Where treatment is not a possibility, the status quo policy of voluntary testing should be maintained. This is the same position adopted by the WHO and UNAIDS in their 2004 guidelines on HIV testing.¹⁸³

C. Routine Testing May Impede Prevention Efforts

While I have suggested that routine testing is likely to aid prevention efforts,

180. Crewe & Viljoen, *supra* note 22, at 11.

181. *Id.*

182. Holbrooke & Furman, *supra* note 52, at A25.

183. UNAIDS/WHO, *supra* note 44, at 2.

some critics argue that routine testing may actually impede prevention. According to this argument, routine testing may lead to some individuals being tested against their will. Some number of individuals, out of fear and distrust engendered by this forced medical treatment, may avoid medical care altogether.¹⁸⁴ As a corollary to this argument, critics also suggest that people who are at risk for HIV, and who are therefore more likely to fear HIV-associated stigma, may make the decision to opt out of testing while those at lower risk may submit to testing unnecessarily.

While there is a dearth of empirical evidence on this issue, the little evidence that is available suggests that routine testing does not adversely impact overall health care utilization. Botswana, one of the few countries for which data is available, implemented routine testing for pregnant women in 2004. The CDC Global AIDS Program conducted a study of four selected clinics in Francistown, Botswana's second largest city. Data on prenatal care-attendance, HIV test acceptance, and receipt of test results were collected for four months before the implementation of routine testing and then for four months afterward. A median of 114 women per month began prenatal care during the initial four months; a median of 130 women per month began prenatal care during the three months after the implementation of routine testing. The study concluded that routine testing did not lead to reductions in the number of women attending prenatal care. Moreover, approximately 90% of women opted to have an HIV test—a finding that suggests that testing not only had no impact on health care utilization but also that testing was well accepted by patients.¹⁸⁵ Botswana has since extended routine testing to individuals in the general population. While comprehensive national data is not yet available, no adverse consequences of this program have been reported to date.¹⁸⁶

It also appears unlikely that those who are at high risk of becoming infected with HIV are more likely to decline testing and thereby thwart much of the purpose of routine testing. Several studies have found that higher acceptance rates for HIV testing are associated with the individual's perception of HIV risk and acknowledgement of risk behaviors. Conversely, low prevalence settings are associated with lower acceptance rates for testing.¹⁸⁷

As I have already described, it is at least a very real possibility that routine testing will bolster HIV prevention efforts. Testing may bring about reductions in sexual risk behavior, though the evidence on this issue remains equivocal. Expanded testing is also likely to reduce transmission through other mechanisms: by stimulating a greater social awareness of HIV and, when coupled with

184. Bozzette, *supra* note 134, at 621; Crewe & Viljoen, *supra* note 22, at 11.

185. Ctrs. for Disease Control & Prevention, *Introduction of Routine HIV Testing in Prenatal Care—Botswana, 2004*, 53 MORBIDITY & MORTALITY WKLY. REP. 1083 (2004), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5346a2.htm>.

186. CSIS REPORT, *supra* note 23, at 9.

187. Chou et al., *supra* note 69, at 58.

treatment, by decreasing viral loads and transmissibility.¹⁸⁸

D. Routine Testing Is Not Necessary for Rational Patient Management

Opponents of routine testing argue that diagnosing HIV is not necessary to ensure rational patient management where treatment is not available.¹⁸⁹ This paper concedes that for individuals who have no access to ARV treatment the harms associated with routine testing may outweigh the benefits. However, where treatment is available, this statement is simply untrue.

A recent review article found that between 12% and 43% of patients already had full-blown AIDS—that is, a CD4+ count of less than 200 cells per cubic millimeter of blood—at the time they were diagnosed with HIV infection.¹⁹⁰ Even 12%, which represents the lower end of this range, is alarmingly high. Two studies in particular, conducted in Boston and in San Francisco, found that on initial presentation for HIV-related medical care, 37% and 29% of patients respectively had a CD4+ count of less than 200 cells per cubic millimeter of blood.¹⁹¹ According to a 2001 report by the CDC, 39% of individuals who received a diagnosis of HIV infection in the United States developed AIDS within a year of receiving their diagnosis.¹⁹² As high as the rate of late presentations is in the United States, one could reasonably expect it to be even higher in resource-poor settings, where the number of individuals who know their status is far lower.¹⁹³

As I have described earlier, a number of observational studies show that starting treatment early diminishes the incidence of opportunistic infections and allows individuals to sustain normal CD4+ levels, sparing them the morbidity and mortality associated with such infections.¹⁹⁴ Initiating therapy earlier leads to a higher likelihood of suppressing viral replication, improving immunity, and reducing drug-related adverse events.¹⁹⁵ Conversely, it appears that interventions are less effective in persons with advanced immune deficiency.¹⁹⁶

188. See *supra* Section III.C.

189. Crewe & Viljoen, *supra* note 22, at 17.

190. Chou et al., *supra* note 69, at 58.

191. Mitchell H. Katz et al., *CD4 Lymphocyte Count As an Indicator of Delay in Seeking Human Immunodeficiency Virus-Related Treatment*, 152 ARCHIVES INTERNAL MED. 1501, 1501 (1992) (describing San Francisco study); Samet et al., *supra* note 67, at 737 tbl.2 (describing Boston study).

192. CTRS. FOR DISEASE CONTROL & PREVENTION, HIV/AIDS SURVEILLANCE REPORT (2002).

193. Miller et al., *supra* note 47, at 2.

194. Ledergerber et al., *supra* note 70, at 2220.

195. Scott D. Holmberg et al., *The Case for Earlier Treatment of HIV Infection*, 39 CLINICAL INFECTIOUS DISEASES 1699, 1700 (2004).

196. Egger et al., *supra* note 14, at 119.

E. Routine Testing Will Lead to Mandatory Testing via a Slippery Slope

Perhaps the core argument offered against routine testing is that it is inherently coercive. As one critic describes, it is unrealistic to expect already overburdened health care workers to provide meaningful counseling and consent. Once these safeguards are “diluted,” individuals will be coerced into testing.¹⁹⁷ That is, routine-offer testing will necessarily lead to mandatory testing for the general population, which is universally rejected by public health experts and multilateral bodies and would be tantamount to outing HIV-positive individuals.¹⁹⁸

Indeed, some articles in the medical literature suggest that doctors should re-offer tests to those who initially refuse. One 2005 study published in *AIDS Patient Care & STDs*, for example, concluded from a survey of prenatal care providers that the percent of providers reporting universal testing among their patients was associated with the degree to which they encouraged testing.¹⁹⁹ The authors implicitly recommend that health care providers strongly encourage testing and persist in offering testing to women who have initially refused.²⁰⁰ This language, which stops short of suggesting coercion, nevertheless suggests that a fine line separates coercion from persuasion.

The same critic of routine testing quoted above echoes this idea: “Part of the problem with most health services is that they are disempowering, paternalistic and authoritarian. They tend to infantilise people by reducing their power and claiming to know what is best for them.”²⁰¹ Notwithstanding the sweeping generalization about patient-provider interaction it contains, this statement does convey a valid criticism in that it is representative of the way that many critics feel about the practice of informed consent in health care. This Article offers three interrelated arguments in response.

First, to the extent that there is slippage between routine testing with informed consent and coercion, I have already argued that a utilitarian end justifies this risk. The potential benefits to the individual and to society are high and, if routine testing is part of a package of protections for individual rights, the risk of coercion can be minimized. Moreover, the risk of slippage between voluntary consent and coercion exists throughout medicine. The real question

197. Crewe & Viljoen, *supra* note 22, at 18.

198. Mandatory testing is a much closer question in limited cases involving select populations—pregnant women, public employees—and has survived constitutional scrutiny in the United States in cases that are specific to these groups. See Dorian L. Eden, *Is It Constitutional and Will It Be Effective? An Analysis of Mandatory HIV Testing of Pregnant Women*, 11 HEALTH MATRIX 659 (2001); Kellie E. Lagitch, *Mandatory HIV Testing: An Orwellian Proposition*, 72 ST. JOHN’S L. REV. 103 (1998).

199. John E. Anderson et al., *Achieving Universal HIV Screening in Prenatal Care in the United States: Provider Persistence Pays Off*, 19 AIDS PATIENT CARE & STDs 247, 251 (2005).

200. *Id.*

201. Crewe & Viljoen, *supra* note 22, at 18.

raised by the danger of coercion is whether there is any rational reason for treating HIV testing differently from any other type of diagnostic testing. With all other types of diagnostic testing, it is assumed that a utilitarian end justifies the risk of coercion. That is, while ordinary people lack sufficient knowledge to seek out diagnostic tests that may improve their longevity on their own, they can decide on the basis of information presented to them whether or not to undergo a particular diagnostic test. Hence, all other diagnostic testing in medicine is initiated by health care providers or “routinely offered.” This Article has argued that the twin possibilities of HIV treatment and prevention lead to a utilitarian calculus for HIV testing that resembles that which is used to justify all other types of diagnostic testing.

Second, even the current voluntary approach to HIV testing concedes some risk—albeit a lower risk—of slippage into coercion. For example, the WHO, the International Labor Organization (ILO) and several countries have actively promoted a “Know Your Status” campaign whose main goal is to persuade more individuals to seek an HIV test.²⁰² As part of this campaign, the WHO and the ILO created a pamphlet, presumably for dissemination by health care providers, entitled “Know Your Status. HIV Testing and Counseling: The Gateway to Wellness.”²⁰³ Inherent in these persuasive materials is a claim that public health authorities know what is best for certain individuals. The main difference between this form of persuasion and that in routine testing is that in the latter setting a health care provider would actually verbalize an offer of a test, as opposed to merely offering a patient literature about a test.

Third, slippage between routine testing with informed consent and coercion is not inevitable. Because the danger of coercion—and the fact that many patients feel overborne by their doctors—is not itself a justification for making all medical care patient-initiated, it is more useful to ask whether there are other remedies for this danger than denying medical care altogether. One such remedy, which I will describe in more detail in the final Part of this Article, is to create a more robust standard for informed consent in routine HIV testing that unites the goals of expanding access to testing and protecting individual rights.

F. Routine Testing Will Lead to Involuntary Disclosures of HIV Status

The right to privacy is closely related to concerns about autonomy and informed consent, and is the other core human rights issue implicated by routine testing. Critics of routine testing argue that routine testing is disempowering because it may lead to a greater number of involuntary disclosures of HIV

202. Press Release, World Health Org., ILO and WHO Co-developing Guidelines on Workplaces and HIV/AIDS (Mar. 14, 2005), available at <http://www.who.int/3by5/news44/en/>.

203. Int'l Labor Org., Know Your Status: HIV Testing and Counseling: The Gateway to Wellness (Mar. 14, 2005), available at <http://www.ilo.org/public/english/protection/trav/aids/publ/kys-en.pdf>.

status.²⁰⁴ Involuntary disclosure—whether due to mandatory partner notification laws or other breaches of confidentiality—will put some people at risk of social stigmatization and even of physical danger. This, in turn, amplifies the danger associated with the possibility of routine testing slipping into coercion.

Moreover, women are more likely to face the dangers associated with involuntary disclosures of HIV status, since they are more likely to have contact with the health care system, mostly notably through antenatal care.²⁰⁵ Women also often face spousal abuse when they are known or are suspected to be HIV positive.²⁰⁶ Moreover, as has been widely documented, cultural norms and laws on property, inheritance, and divorce in many countries provide a foundation of inequality on which this violence thrives. This inequality limits the choices that women have and prevents them from leaving abusive relationships.²⁰⁷ One study of 245 women in Tanzania, who were followed for three months after HIV testing, found that younger (less than thirty years old) women who were HIV-positive were ten times more likely than younger HIV-negative women to report partner violence.²⁰⁸ Another qualitative study of women in the Dominican Republic by Human Rights Watch found that,

regardless of the actual source of the infection, many women who test positive for HIV are subject to ostracism, violence, or abandonment by spouses, long-term partners, or families. In the Dominican Republic, moreover, cultural norms dictate that women—but not necessarily men—should be faithful and that a woman is ultimately responsible even for her spouse's infidelity.²⁰⁹

In the United States, there have been reports of women being physically and verbally abused after revealing their HIV status.²¹⁰

204. Crewe & Viljoen, *supra* note 22, at 16.

205. *Id.*

206. HUMAN RIGHTS WATCH, JUST DIE QUIETLY: DOMESTIC VIOLENCE AND WOMEN'S VULNERABILITY TO HIV IN UGANDA 28-29 (2003).

207. See HUMAN RIGHTS WATCH, DOUBLE STANDARDS: WOMEN'S PROPERTY RIGHTS VIOLATIONS IN KENYA 30 (2003).

208. Suzanne Maman et al., *HIV-Positive Women Report More Lifetime Partner Violence: Findings from a Voluntary Counseling and Testing Clinic in Dar es Salaam, Tanzania*, 92 AM. J. PUB. HEALTH 1331 (2002). The women in this study reported violence over their entire lifetimes—that is, both before and after their HIV tests. As a result, this study does not directly support the contention that a positive diagnosis of HIV results in partner violence. Rather, the study identifies violence as a risk factor for HIV infection.

209. HUMAN RIGHTS WATCH, A TEST OF INEQUALITY: DISCRIMINATION AGAINST WOMEN LIVING WITH HIV IN THE DOMINICAN REPUBLIC 2 (2004), available at <http://hrw.org/reports/2004/dr0704/>.

210. See, e.g., Richard L. North & Karen H. Rothenberg, *Partner Notification and the Threat of Domestic Violence Against Women with HIV Infection*, 329 NEW ENG. J. MED. 1194 (1993); Karen H. Rothenberg et al., *Domestic Violence and Partner Notification: Implications for Treatment and Counseling of Women with HIV*, 50 J. AM. MED. WOMEN'S ASS'N 87 (2005); Karen H. Rothenberg & Stephen J. Paskey, *The Risk of Domestic Violence and Women with HIV Infection: Implications for Partner Notification, Public Policy, and the Law*, 85 AM. J. PUB. HEALTH 1569 (1995); Leslie E. Wolf et al., *Legal Barriers to Implementing Recommendations for Universal, Routine Prenatal HIV*

1. A Guarantee of Confidentiality

In light of these findings, this Article argues that routine testing must be linked to a guarantee of confidentiality. This position echoes the strong presumption in international human rights law in favor of policies that respect the right to privacy through confidentiality and informed consent. The right to privacy is protected by Article 17 of the International Covenant on Civil and Political Rights, Article 11 of the American Convention on Human Rights, Article 8 of the European Convention on Human Rights, and Article 16 of the U.N. Convention on the Rights of the Child.²¹¹ State laws in the United States by and large reflect this presumption in favor of privacy for HIV test results. Thirty-two states have adopted laws that specifically protect the confidentiality of HIV test results. Of these states, only six permit disclosure to a test subject's spouse without consent. Three additional states permit disclosure to a spouse, a sexual partner, or needle-sharing partners, with two of these three requiring that the test subject be notified first.²¹² Some scholars have argued that certain personal information—presumably including such sensitive information as the results of an HIV test—is constitutionally protected, subject to a balancing test regarding the individual's privacy right against the interests of the state.²¹³

It is important to note that this guarantee of confidentiality would not preclude systematic voluntary partner notification, provided that such notification is based on the same rigorous standard of informed consent that I propose in the final section of this paper. Both the CDC and UNAIDS have published guidelines that support providing voluntary partner notification services to those who test positive for HIV.²¹⁴ The UNAIDS guidelines also support creating provisions for exceptional cases where voluntary partner notification is not possible. Suggested provisions include establishing a panel of experts to provide advice to health care providers on the ethics of partner notification, or requiring health care providers to consult with another professional before notifying an HIV-positive patient's sexual partners. The guidelines emphasize that health care

Testing, 32 J. L. MED. & ETHICS 137, 138 (2004); Sally Zierler et al., *Violence Victimization After HIV Infection in a US Probability Sample of Adult Patients in Primary Care*, 90 AM. J. PUB. HEALTH 208, 208 (2000).

211. See Ctr. for Reproductive Rights, *Safe and Legal Abortion Is a Woman's Human Right* 5 (2004), available at http://www.crlp.org/pdf/pub_bp_safeandlegal.pdf.

212. Wolf et al., *supra* note 210, at 142.

213. See generally Roger Doughty, Comment, *The Confidentiality of HIV-Related Information: Responding to the Resurgence of Public Health Interventions in the AIDS Epidemic*, 82 CAL. L. REV. 111, 148-154 (1994) (reviewing the constitutional status of HIV-related personal information).

214. UNAIDS/WHO, *supra* note 44, at 1; UNAIDS, HANDBOOK FOR LEGISLATORS ON HIV/AIDS, LAW AND HUMAN RIGHTS 45 (1999); Ctrs. for Disease Control & Prevention, *Advancing HIV Prevention: New Strategies for a Changing Epidemic—United States 2003*, 52 MORBIDITY & MORTALITY WKLY. REP. 329, 329-30 (2003).

professionals should not be required to notify patients' sexual partners.²¹⁵ Moreover, the American Civil Liberties Union (ACLU), which has taken a strong stand against mandatory partner notification, endorses public health programs that help people with HIV notify their partners, provided that these services are voluntary, non-coercive, and confidential.²¹⁶

The remaining question is whether third-party notification is ever permissible without an individual's consent. International codes of medical ethics generally require that physicians maintain complete loyalty to their patients. The World Medical Association Declaration of Geneva calls on physicians to pledge that "the health of [their] patient[s] shall be [their] first consideration."²¹⁷ The World Medical Association International Code of Medical Ethics states that "a physician shall owe his/her patients complete loyalty and all the scientific resources available to him/her."²¹⁸ In reality, physicians are often called upon to maintain a "dual loyalty"—a simultaneous obligation to a patient and to a third party (an individual, an organization, or the state)—in many of the tasks they perform or preside over: forensic psychiatry, vaccination, organ donation, employment evaluation, and, in the context of the "war on terror," participating in the interrogation of prisoners.²¹⁹ In the case of partner notification for HIV, the question is whether physicians have a simultaneous duty to warn third parties of the danger of HIV infection and to take action that may prevent the spread of HIV. I have already argued that a utilitarian calculus justifies the danger that some individuals may be tested without their consent; a similar utilitarian argument could be used to justify partner notification.

There are at least two reasons to recommend a policy that forbids partner notification without consent. First, as I have already argued, there is a strong presumption in both U.S. law as well as in international human rights law in favor of privacy. Second, as a matter of public health policy, the utilitarian calculus probably cuts against partner notification without consent. Prevention strategies based on testing in the general population require widespread cooperation—and there are several reasons to believe that this cooperation is dependent upon the promise of confidentiality. Many patients fear partner notification because they believe it will lead to domestic violence.²²⁰ As I have already described, involuntary partner notification can put individuals in physical danger. Moreover, some means of transmitting HIV implicate activity that is illegal in many jurisdictions. Injection drug use is a felony in all fifty U.S. states,

215. UNAIDS, *supra* note 214, at 45.

216. AM. CIVIL LIBERTIES UNION, HIV PARTNER NOTIFICATION: WHY COERCION WON'T WORK 6 (1998).

217. WORLD MED. ASS'N, INTERNATIONAL CODE OF MEDICAL ETHICS: DECLARATION OF GENEVA (1949), available at <http://www.wma.net/e/policy/c8.htm>.

218. WORLD MED. ASS'N, INTERNATIONAL CODE OF MEDICAL ETHICS: DUTIES OF PHYSICIANS TO PATIENTS (1949), available at <http://www.wma.net/e/policy/c8.htm>.

219. PHYSICIANS FOR HUMAN RIGHTS, DUAL LOYALTY AND HUMAN RIGHTS 1 (2003).

220. AM. CIVIL LIBERTIES UNION, *supra* note 216, at 7.

and homosexual intercourse remains illegal in many countries.²²¹ Without a strict promise of confidentiality, HIV testing may result in a de facto admission of criminal activity.²²²

Moreover, there is some evidence in the public health literature that involuntary partner notification is ineffective as a public health strategy for controlling the spread of sexually transmitted diseases when there is a considerable delay before sexual partners can be contacted.²²³ This is a hallmark characteristic of HIV infection. Most importantly, there are no community-based comparison studies that demonstrate a reduction in the incidence or prevalence of a sexually transmitted disease based on an intervention strategy including involuntary partner notification.²²⁴

This is quite different from voluntary partner notification programs, which have been studied to a limited extent. According to the results of one program reported by the San Francisco Department of Public Health in the *San Francisco Chronicle*, a voluntary partner notification program was able to notify 112 partners of 136 clients newly diagnosed with HIV. The program detected ten new cases of HIV.²²⁵

As a practical matter, part of the reason to favor a policy of voluntary partner notification is that in addition to the need to ensure cooperation in order for a testing strategy to work, health care providers would be hard pressed to enforce a notification policy without the cooperation of the individuals involved, regardless of what the law holds. An individual can simply choose to withhold information about his or her sexual or needle-sharing partners. Few health care providers would be in a position to question the accuracy of these information disclosures.²²⁶ For example, one study reported the results of a partner notification program in North Carolina, a state where the failure of an HIV-positive individual to notify his or her sexual partners is a misdemeanor punishable by incarceration and a fine. The study found that only 7% of study participants succeeded initially in notifying their partners of their HIV status. Even after the participants were given assistance, 66% of partners could not be found.²²⁷

221. *Id.*

222. *Id.*

223. *Id.* at 5.

224. *Id.* See generally Ronald Bayer & Kathleen E. Toomey, *HIV Prevention and the Two Faces of Partner Notification*, 82 AM. J. PUB. HEALTH 1158, 1158-63 (1992); Frances M. Cohen et al., *The Role and Effectiveness of Partner Notification in STD Control: A Review*, 72 GENITOURINARY MED. 247, 247-52 (1996).

225. Sabin Russell, *Dreaded Call Becomes Words To Live By—Notifying Partners of HIV-Positive People: An Important Weapon in the Fight Against AIDS*, S.F. CHRON., Jan. 9, 2006, at A1.

226. See Bayer & Toomey, *supra* note 224 (describing the practical difficulties involved in enforcing a mandatory partner notification policy for HIV).

227. Suzanne E. Landis et al., *Results of a Randomized Trial of Partner Notification in Cases of*

Moreover, partner notification is an extremely sensitive task that requires the skill of highly trained social workers and health care providers. As one social worker in San Francisco put it, "it takes a special kind of person to do this job."²²⁸ Partner notification must involve extensive counseling, and different strategies will be appropriate for different situations. For example, interventions to prevent domestic violence may be necessary in many cases. Mandatory notification threatens to create a blanket policy that will not be able to accommodate the range of situations that health care providers may encounter.

The fact that so few people are offered voluntary partner notification services suggests that any discussion of involuntary partner notification is simply premature. If voluntary partner notification proves to be a viable public health strategy, and if the voluntariness principle is actually found to be limiting, then it may be necessary to revisit the possibility of creating limited exceptions for extreme cases where voluntary notification is not possible. As I have already discussed, the human rights guidelines published by UNAIDS already favor creating such exceptions.

2. Other Interventions To Mitigate the Danger of Involuntary Disclosure

In addition to a legally enforceable guarantee of confidentiality, a policy of routine testing should be coupled with other "structural" interventions to prevent involuntary disclosures and to protect HIV-positive individuals from abuse. One such change might be to implement anonymous testing, wherein health care providers would not be able to associate any particular set of test results with any individual patient.²²⁹ Forty-five U.S. states offer anonymous testing as an option, and several studies have demonstrated that anonymous testing results in increased testing rates.²³⁰ However, anonymous testing places the burden for follow up on the individual patient and therefore comes with several drawbacks: more patients may be lost in follow up; some may not receive referrals for treatment and care; and many will likely not receive post-test counseling. Much of the benefit of expanded testing—in terms of guiding individuals into treatment programs and stemming the spread of HIV through behavior modification—may be lost as a result. Other structural interventions to reduce the risk of involuntary

HIV Infection in North Carolina, 326 NEW ENG. J. MED. 101 (1992).

228. Russell, *supra* note 225.

229. This is different from confidential testing, in which the health care provider can identify a test result with a particular patient.

230. KAISER FAMILY FOUND., HIV/AIDS POLICY FACT SHEET (2005), available at <http://www.kff.org/hivaids/upload/updated-fact-sheet-HIV-Testing-in-the-United-States.pdf>; Laura J. Fehrs et al., *Trial of Anonymous Versus Confidential HIV Testing*, 1988, 2 LANCET 379, 380-81 (1998); Iruce Hertz-Picciotto, *HIV Test-Seeking Before and After the Restriction of Anonymous Testing in North Carolina*, 86 AM. J. PUB. HEALTH 1446, 1448-49 (1996); Douglas Hirano et al., *Anonymous HIV Testing: The Impact of Availability on Demand in Arizona*, 84 AM. J. PUB. HEALTH 2008, 2009-10 (1994).

disclosures could include requiring training in confidential testing procedures for health care workers, similar to HIPAA training in the United States, or creating a cause of action for individuals whose right of privacy has been violated. Other interventions may mitigate the dangers of involuntary disclosures after they have occurred. These include, but are not limited to creating emergency help lines for patients, providing safe shelters for battered women, and training law enforcement and social workers in handling AIDS-related violence.²³¹ Longer-term structural interventions, which are beyond the scope of this Article, but critical nonetheless, might include school and community-based awareness programs and reform of inequitable laws on property, inheritance, and divorce.

Routine testing must be implemented as a part of a larger package of interventions that address HIV-related stigma and empower individuals. The human rights approach to testing that this paper proposes would expand testing at the same time as it implements this larger package of interventions and, as I describe in the final Part, safeguards both autonomy and confidentiality.

V. A PROPOSED FRAMEWORK FOR AN ETHICAL ROUTINE TESTING PROGRAM

I have already argued that any shift toward routine testing must be linked to a guarantee of confidentiality, informed consent and, should the individual meet the appropriate clinical criteria, ARV treatment. States must not prioritize routine-offer testing above their obligation to protect those who test positive from discrimination and violence. More than this, policies that promote informed decisions and that protect individual patients will benefit the public's health, as all of the positive benefits of expanded testing, including treatment and the possibility of behavior modification, depend on the cooperation of individuals.²³² More specifically, what are the components of an ethical HIV testing program? I will use the last Part of this Article to present one particular legislative model for addressing the issues of informed consent, counseling, and confidentiality in the context of routine-offer HIV testing. The model legislation to which I refer appears as Appendix 1 and was prepared by myself in cooperation with the Human Rights and Democratization in Africa Programme at the University of Pretoria and the Allard K. Lowenstein International Human Rights Clinic at Yale Law School. I will describe each section of this model legislation in turn.

231. Joanne Csete et al., Letter, *Opt-Out Testing for HIV in Africa: A Caution*, 363 LANCET, 493, 494 (2004).

232. Wolf et al., *supra* note 210, at 144.

*A. Informed Consent**1. The Scope of the Informed Consent Disclosure*

With the exception of some inherited genetic disorders, the test for HIV is the only diagnostic test in the United States that requires specific consent, as opposed to general consent to medical care. A majority of U.S. states and territories require specific consent for HIV testing.²³³ The Model Legislation on Testing and Counseling for HIV/AIDS does not disturb this majority rule. It requires specific consent for HIV testing. Sixteen states require written consent, though nearly all of these states permit oral consent if written consent is not possible.²³⁴ This model legislation requires written consent, unless written consent is not possible.

In order for a patient's consent to be meaningful, the health care provider must give the patient all information that would be material to her decision about whether to be tested before the test is administered. This is, not coincidentally, the main question debated among jurists and medical ethicists with regard to informed consent. That is, how much information does a health care provider have to disclose in order to make consent "informed consent?" Different institutions and jurisdictions have interpreted the materiality requirement in different ways. This model legislation provides a non-exhaustive list of information and considerations that must be discussed with the patient before the patient's consent can be considered informed and voluntary. This list is based on guidelines promulgated by the WHO,²³⁵ the South African *Department of Health Draft National Policy on Testing for HIV*,²³⁶ the United Kingdom General Medical Council statement on informed consent,²³⁷ as well as a survey of case law and statutes from the U.S. states.

The June 2004 guidelines published jointly by UNAIDS and WHO outline the information that must be disclosed to the patient in order to obtain his or her informed consent prior to testing for HIV. At a minimum, the guidelines require that the informed consent disclosure must include information on the clinical benefit and the prevention benefits of testing; the right to refuse; the follow-up services that will be offered in the event of a positive test result; and the importance of anticipating the need to inform anyone at ongoing risk who would otherwise not suspect they were being exposed to HIV infection.²³⁸ It is

233. See also, Barron et al., *supra* note 80; Wolf et al., *supra* note 210, at 141-42.

234. Wolf et al., *supra* note 210, at 141.

235. UNAIDS/WHO, *supra* note 44, at 3.

236. S. AFR. DEP'T. OF HEALTH, DRAFT NATIONAL POLICY ON TESTING FOR HIV (1990), available at <http://www.doh.gov.za/aids/docs/policy.html>.

237. U.K. GEN. MED. COUNCIL, SEEKING PATIENTS' CONSENT: THE ETHICAL CONSIDERATIONS (1998), available at <http://www.gmc-uk.org/guidance/current/library/consent.asp>.

238. UNAIDS/WHO, *supra* note 44, at 3.

important to emphasize that these guidelines describe a *minimum* requirement. In the context of HIV, even the expansive informed consent disclosure they describe may not adequately safeguard the interests of an individual patient.

Rather than rely on an ambiguous legal standard, this model legislation clearly and specifically defines the required scope of the health care provider's informed consent disclosure. However, the listed points of information are not meant to be exhaustive—courts and national health authorities would remain free to expand the scope of the informed consent disclosure even further as our understanding of HIV/AIDS evolves.

The 2002 South African *Draft National Policy on Testing for HIV*, though not formally enacted into law, provides a useful benchmark for defining the scope of the informed consent disclosure: "In the context of HIV/AIDS, testing with informed consent implies that the individual understands what the test is, why it is necessary and the benefits, risks, alternatives and possible social implications of the outcome."²³⁹

According to the South African Department of Health, the patient should also be given the following specific information:

- What an HIV test is, the purpose of the test;
- The meaning of both a positive and negative result, including the practical implications such as medical treatment and care, sexual relations, psycho-social implications, etc;
- Assessment of personal risk of HIV infection;
- Safer sex and strategies to reduce risk;
- Coping with a positive test result, including whom to tell and identifying needs and support services; and
- An opportunity for decision making about taking the HIV test.²⁴⁰

Other national authorities have set out even more specific guidelines for defining the scope of the informed consent disclosure. The United Kingdom General Medical Council offered the following detailed advice to physicians in a 1998 statement on informed consent:

The information which patients want or ought to know, before deciding whether to consent to treatment or an investigation, may include:

- details of the diagnosis, and prognosis, and the likely prognosis if the condition is left untreated;
- uncertainties about the diagnosis including options for further investigation prior to treatment;
- options for treatment or management of the condition, including the option not to treat;
- the purpose of a proposed investigation or treatment; details of the procedures or therapies involved, including subsidiary treatment such

239. S. AFR. DEP'T. OF HEALTH, *supra* note 236, at 3.

240. *Id.*

as methods of pain relief; how the patient should prepare for the procedure; and details of what the patient might experience during or after the procedure including common and serious side effects;

- for each option, explanations of the likely benefits and the probabilities of success; and discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by, or necessitated by, the treatment;
- advice about whether a proposed treatment is experimental;
- how and when the patient's condition and any side effects will be monitored or re-assessed;
- the name of the doctor who will have overall responsibility for the treatment and, where appropriate, names of the senior members of his or her team;
- whether doctors in training will be involved, and the extent to which students may be involved in an investigation or treatment;
- a reminder that patients can change their minds about a decision at any time;
- a reminder that patients have a right to seek a second opinion;
- where applicable, details of costs or charges which the patient may have to meet.²⁴¹

In the United States, two competing standards for interpreting the materiality requirement exist. The "patient centered" standard for defining the physician's duty to disclose maintains that information is material to a patient's decision if "a reasonable person, in what the physician knows or should know to be the patient's position, would likely attach significance to the [information] in deciding whether or not to forgo the proposed therapy."²⁴² The majority of U.S. jurisdictions apply the "physician centered" standard, which requires health care providers to disclose information based on the prevailing practice among similarly situated professionals.²⁴³ This standard is somewhat ambiguous, as it is open to interpretation by courts and professional associations. This model legislation opts instead to define the scope of the informed consent disclosure more specifically.

Additionally, I have also incorporated the most expansive set of specific information as defined by HIV testing-specific state statutes in the United States. Twenty-two U.S. states specify information that must be conveyed to patients during pre-test counseling as part of the informed consent process. This information includes: how test results may be used; the risks and benefits of testing; the nature of HIV/AIDS; information on prevention measures; the voluntary nature of the test; the right to refuse testing; the requirement of written consent; information on the confidentiality of test results; circumstances, if any,

241. U.K. GEN. MED. COUNCIL, *supra* note 237, at 2.

242. *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972).

243. *See, e.g., Culbertson v. Mernitz*, 602 N.E.2d 98, 102-04 (Ind. 1992).

under which confidentiality may be overridden; the availability of treatment; and the effect of testing on the patient's ability to receive further services.²⁴⁴

2. Limited Situations in Which Individuals May Be Tested Without Their Consent

This model legislation defines four specific situations in which HIV testing may be permissible without a patient's informed consent. These circumstances are the only exceptions, and they are meant to be strictly construed.

The provision allowing for anonymous research testing will allow for important fact-gathering about the spread of HIV and AIDS. In order to ensure the privacy of the donors, all identifying information about the donors must be separated from the sample. Such research testing must be in accordance with national legal and ethical guidelines regarding research testing.²⁴⁵ The language for this provision draws primarily from the South African *Draft National Policy on Testing for HIV*.

Another provision allows for testing without consent when a health care worker has experienced an occupational exposure. In these cases, HIV testing of the source patient may be necessary so that, in the event that the source patient is HIV positive, the health care worker can take steps to lower her risk of infection by taking HIV prophylaxis. This provision is borrowed with slight modification from the South African *Draft National Policy on Testing for HIV*, which allows testing without informed consent after an occupational exposure, but only after informing the source patient that the result may be disclosed, and only if the source person has declined to give her informed consent or is unable to do so.²⁴⁶ The *American Medical Association Code of Ethics* similarly provides that "when a health care provider is at risk for HIV infection because of the occurrence of puncture injury or mucosal contact with potentially infected bodily fluids, it is acceptable to test the patient for HIV infection even if the patient refuses consent."²⁴⁷

The model legislation also provides an exception to informed consent for life-threatening situations and emergencies. In a recent commentary in the *Journal of the American Medical Association*, bioethicist Scott Halpern outlined three reasons why HIV testing should be permitted without consent for critically ill patients. First, such testing may improve the quality of their care. Prompt ARV therapy may effectively treat such conditions as HIV dementia, progressive multifocal leukoencephalopathy, respiratory failure, and fever of unknown origin. Second, because most patients in one of these situations would likely

244. Wolf et al., *supra* note 210, at 141.

245. S. AFR. DEP'T OF HEALTH, *supra* note 236.

246. *Id.*

247. AM. MED. ASS'N, AMA CODE OF ETHICS E-2.23 (1994), available at <http://www.ama-assn.org/ama/pub/category/print/8463.html>.

choose to be tested if they were competent, allowing testing may respect the autonomy of those who cannot voice their preferences. Finally, closely tracking the arguments I have laid out in this Article, Halpern argues that HIV should no longer be treated as an exceptional disease—policies on HIV testing should be brought into line with general medical practice.²⁴⁸

Among U.S. states, twenty-six states do not specify any exceptions to informed consent laws for HIV testing. Thirteen states permit testing without the patient's specific consent whenever a physician expects that the test result would improve the patient's immediate medical care, provided that the patient has already provided general consent to care. Both the American Medical Association and the British General Medical Council endorse this position.²⁴⁹ Six states permit such testing only in emergency or life-threatening situations. Eight states permit testing if the patient's legal guardian or next-of-kin provides surrogate consent.²⁵⁰ This model legislation takes the view that allowing an exception to specific informed consent based on the medical opinion of a physician is too permissive a standard. Instead, it permits an exception for life-threatening and emergency situations and, for other situations, the possibility of proxy consent whenever a physician expects that the test result would improve the patient's immediate medical care. The person giving proxy consent must be legally permitted to give consent for the patient in question. In accordance with common law and statutory provisions, this may include, but is not limited to, a parent or guardian of a child below the age of consent, individuals designated by law to consent for individuals with mental illness, or an individual designated by the patient to exercise durable power of attorney for the patient.²⁵¹

B. Counseling

There is little evidence to suggest that simply supplying patients with information about a specific test, therapy or procedure actually helps patients to understand this information unless this disclosure is accompanied by interactive counseling by the health care provider.²⁵² A number of empirical studies have

248. Scott D. Halpern, *HIV Testing Without Consent in Critically Ill Patients*, 294 JAMA 734, 736 (2005).

249. AM. MED. ASS'N, HIV TESTING, H-20.920 (2005); GEN. MED. COUNCIL, SERIOUS COMMUNICABLE DISEASES (1997).

250. Halpern, *supra* note 248, at 735.

251. See Dom W. Brock, *Children's Competence for Health care Decision-making*, in CHILDREN AND HEALTH CARE: MORAL AND SOCIAL ISSUES 181-212 (Loretta M. Kopelman & John C. Moskop eds., 1989); Nancy M.P. King & Alan W. Cross, *Children As Decision Makers: Guidelines for Pediatricians*, 115 J. PEDIATRICS 10 (1989).

252. A number of studies have demonstrated that written informed consent forms often contain unreadable jargon. A 2003 study in *The American Journal of Medicine* surveyed Institutional Review Board (IRB) forms used for consent in human research at sixty-one U.S. medical schools. The study found that the average Flesch-Kincaid score for these forms was 10.6 (the Flesch-Kincaid scale assigns a score based on the minimum grade level required to understand a particular

presented alarming findings on the gap between informed consent disclosures and patient understanding, and these studies suggest that health care providers must work harder to ensure that patients understand the risks involved with medical tests, therapies or procedures.²⁵³ However, there is strong evidence that interactive counseling and spending more time with patients are both independently effective ways of improving patients' understanding of informed consent disclosures.²⁵⁴ Informed consent should be an interactive process—not simply a signature on a pre-prepared form.

Counseling is especially important in the context of HIV testing because a positive result involves a serious medical condition and may result in severe social stigmatization, discrimination, and emotional and psychological stress. In the 1996 South African case of *C v. Minister of Correctional Services*, the court emphasized the need for counseling:

It is axiomatic that there can only be consent if the person appreciates and understands what the object and purpose of the test is, what an HIV positive test is, what an HIV positive result entails and what the probability of AIDS occurring thereafter is. Evidence was led in this case on the need for informed consent before the HIV test is performed. . . . Because of the devastation which a positive result entails, the norm so developed contains as a requirement counseling both pre- and post-testing, the latter in the event of a positive result.²⁵⁵

As the court recognized, the issue of informed consent is closely related to the issue of counseling. Most medical tests, therapies, and procedures are accompanied by pre-test counseling, if for no other reason, to obtain informed consent. However, because of the unique social implications associated with a positive HIV test result, as well as the physical devastation which HIV may cause if left untreated, counseling assumes an added importance. In the context of HIV, both pre-test and post-test support and services are crucial.

This model legislation implements the guidelines for HIV pre-test

text). This exceeded the average of the published standards of these IRBs by 2.8 grade levels. Michael K. Paasche-Orlow & Frederick L. Brancati, *Assessment of Medical School Institutional Review Board Policies Regarding Compensation of Subjects for Research-Related Injury*, 118 AM. J. MED. 175, 175(2005).

253. One analysis of a cross-section of patients receiving experimental therapies in cancer trials showed that 30% of participants believed they were receiving a treatment that had already been proven to be the best treatment for their cancer. Steven Joffe et al., *Quality of Informed Consent in Cancer Clinical Trials*, 358 LANCET 1772, 1772 (2001). In another study assessing the use of beta-blocker drugs to prolong the lives of people who have suffered from a heart attack, 43% of research participants did not know that they were being assigned randomly to receive beta-blocker treatment or a placebo. John M. Howard et al., *How Informed is Informed Consent?*, 2 CONTROLLED CLINICAL TRIALS 287, 292 (1981).

254. See James Flory & Ezekiel Emanuel, *Interventions To Improve Research Participants' Understanding in Informed Consent for Research*, 292 JAMA 1593, 1599 (2004).

255. *C v Minister of Correctional Services* 1996 (4) SA 292 (T) at 301 (S. Afr.).

counseling published by the CDC. All patients who request or are offered an HIV test should receive the following information in addition to the informed consent disclosure, even if they decline to be tested:

- Information regarding the HIV test and its benefits and consequences;
- Risks for transmission and how HIV can be prevented, including but not limited to: a) descriptions or demonstrations of how to use condoms correctly; b) information regarding risk-free and safer sex options; c) descriptions regarding the effectiveness of using clean needles, syringes, cotton, water, and other drug paraphernalia;
- The importance of obtaining test results and explicit procedures for doing so;
- The meaning of the test results in explicit, understandable language;
- Where to obtain further information or, if applicable, HIV prevention counseling;
- Where to obtain other services;
- Information regarding other sexually transmitted and bloodborne diseases;
- Where applicable, information regarding drug treatment.²⁵⁶

In addition to obtaining informed consent during pre-test counseling, the health care provider should offer HIV prevention counseling. That is, the health care provider should help the patient identify specific behaviors that put her at risk for acquiring or transmitting HIV and should help her understand how to reduce this risk.²⁵⁷ A number of empirical studies have demonstrated that ongoing counseling and testing is negatively associated with high-risk sexual behavior.²⁵⁸ This underscores the need to recognize pre-test counseling as more than simply an opportunity to obtain informed consent. Pre-test counseling can also be an effective public health intervention. Because women are at particular risk for domestic violence, and because they are more likely to be tested, this model legislation also requires a domestic violence screening and referral to appropriate counseling as part of pre-test counseling.

This legislation also draws on the detailed post-test counseling guidelines described in the South African *Department of Health Draft National Policy on Testing for HIV*²⁵⁹ and the *World Health Organization Testing and Counseling Toolkit*.²⁶⁰ Post-test counseling should provide appropriate information about the

256. CTRS. FOR DISEASE CONTROL & PREVENTION, REVISED GUIDELINES FOR HIV COUNSELING, TESTING, AND REFERRAL AND REVISED RECOMMENDATIONS FOR HIV SCREENING OF PREGNANT WOMEN 13-14 (2001).

257. *Id.*

258. See, e.g., P. Sangani et al., *Population-Based Interventions for Reducing Sexually Transmitted Infections, Including HIV Infection*, COCHRANE DATABASE OF SYSTEMATIC REVIEWS CD001220 (2001).

259. See S. AFR. DEP'T OF HEALTH, *supra* note 236.

260. See WORLD HEALTH ORG., TESTING AND COUNSELING TOOLKIT (2004), available at

test result and its implications, referral to care, support, and treatment.²⁶¹

State law among U.S. states is not as useful in guiding counseling requirements, as most of these laws appear to fall short of the guidelines published by the above authorities. Only eleven states address counseling in their HIV testing statutes: Georgia, Hawaii, Illinois, Maine, Maryland, Michigan, Montana, New York, North Carolina, Pennsylvania, and Rhode Island. Seven of these states require pre-test counseling, whereas four only require physicians to make an offer of pre-test counseling. Two states, Maine and Maryland, require that counseling be face-to-face. Two states, North Carolina and Rhode Island, imply that counseling must be oral.²⁶²

C. Confidentiality

I have already argued that, because an assurance of confidentiality is necessary to encourage persons at high risk of contracting HIV to undergo testing, consent to disseminate information about the HIV status of individuals should be required in all cases. HIV-positive individuals, especially women, who are more likely to be tested for HIV, face a well-founded fear of partner abuse, stigma and discrimination. Therefore, though health care workers should counsel patients to inform their partners of their HIV status, health care workers are specifically prohibited from informing a partner, employer, family member, or any other third party of a patient's HIV status unless the patient explicitly authorizes it. Similarly, children should be allowed to obtain confidential HIV/AIDS testing and treatment without parental consent. This model legislation defines a limited and specific exception to this rule for emergencies.

However, courts have recognized that in certain situations the health care worker's duty to maintain confidentiality may conflict with their duty to protect third parties from imminent danger. In the United States, for example, state courts have held that a doctor has a duty to warn third parties of the foreseeable dangerous conduct of her patient.²⁶³ The case most often cited in support of this proposition is *Tarasoff v. Regents of the University of California*, in which a therapist whose patient threatened to kill a woman with whom he had been romantically involved neglected to warn that woman that she was in any danger. The court held that the therapist had a duty to use reasonable care to protect the intended victim against the danger threatened by the patient.²⁶⁴ Other nations have also held that the doctor-patient relationship imposes on a doctor the duty to use reasonable care to protect other individuals from danger that might result

<http://who.arvkit.net/tc/en/contentdetail.jsp>.

261. *Id.*

262. Wolf et al., *supra* note 210, at 140.

263. See, e.g., *Tarasoff v. Regents of Univ. of Cal.*, 551 P.2d 334 (Cal. 1976).

264. *Id.* at 339-41.

from a patient's illness.²⁶⁵ However, it is unclear whether courts are willing to extend this line of cases to include a doctor's duty to warn an HIV-positive individual's sexual partner that he or she may be in danger of being infected with HIV. The hypothetical situation evoked by a routine HIV test would be strictly analogous to that in *Tarasoff* if an individual announced his intention to purposefully infect his sexual partner with HIV through unprotected intercourse. This is obviously an unlikely scenario. In reality, HIV-positive individuals may or may not disclose her sexual contacts; they may take precautions on their own; and even unprotected sex may or may not result in the transmission of HIV.

There is also another line of state court cases in the United States that holds that a physician has a duty to exercise reasonable care to warn members of a patient's family if the patient has a contagious disease and if they are likely to have contact with the patient.²⁶⁶ However, these cases, which concern diseases like typhoid, smallpox, and tuberculosis, predate much of the understanding about disease prevention gleaned from the modern science of public health. The public health interest in maintaining confidentiality, so that more people will submit to testing, is high. Moreover, it is unclear that mandatory partner notification is necessary or even useful. For these reasons, and because of the importance of protecting confidentiality, this model legislation does not impose a "duty to warn" on health care workers. Instead, it takes the position that the health care workers have a duty to counsel their patients on the advantages and consequences of disclosing his or her HIV status to their partners.

CONCLUSION

Not all of the necessary elements of an ethical testing program can be encapsulated in a piece of model legislation. It is necessary to distinguish between substantive protections that such a program might include and the process through which it should be enacted. The process of enacting a routine testing program should include representation by civil society—including groups of people living with AIDS; women, who are more likely to be tested for HIV; and disenfranchised minorities, who may view a program of routine testing more suspiciously. This will allow policy makers to include input from the communities most at risk into their decision-making process on testing policies. This will also allow policy makers to adapt the general human rights principles discussed in this paper to the cultural context in which they operate. For example, the Government of Botswana sponsored an extensive public discussion as well as

265. See, e.g., *Jansen van Vuuren & Another NNO v Kruger* 1993 (4) SA 842 (A) (S. Afr.); J.S. Talbot, *The Conflict Between a Doctor's Duty To Warn a Patient's Sexual Partner that the Patient has AIDS and a Doctor's Duty To Maintain Patient Confidentiality*, 45 WASH. & LEE L. REV. 355, (1988).

266. *Davis v. Rodman*, 227 S.W. 612 (Ark. 1921); *Hoffman v. Blackmon*, 241 So. 2d 752 (Fla. Dist. Ct. App. 1970); *Jones v. Stanko*, 160 N.E. 456 (Ohio 1928).

a series of consultative meetings with civil society groups and international experts before unveiling its routine testing program in 2003.²⁶⁷ This consultative process likely had some role in the widespread acceptance of routine testing in Botswana.²⁶⁸

Further, any shift to routine testing should also be accompanied by a commitment to operational research and systematic data gathering to understand better the impact of routine testing on treatment, stigma, and prevention efforts. Many unanswered questions about routine testing remain. What is the precise impact of routine-offer testing on testing rates? How much information must be conveyed—and in what format—for consent to be truly informed? Do patients experience routine-offer testing as coercion? How much and what type of counseling is required to affect risk behavior for HIV? Do the answers to these questions vary across different cultures and settings? These are just a few of the questions that we should ask in defining a research agenda to inform future policy debates about HIV testing.

I have argued that access to HIV treatment—and the benefits to the individual and to the public health that come with the promise of treatment—require us to rethink our approach to HIV testing. Where treatment is available, a human rights approach to HIV requires that health care providers routinely offer HIV tests to their patients. This proposed shift in policy need not signify a broader shift in the culture of our approach to the HIV/AIDS pandemic away from education and toward coercion. I have argued that HIV testing should be brought into line with general medical practice only in the sense that testing should be offered to individuals. However, a human rights approach to routine testing also requires that health care providers not abandon the principles of autonomy and privacy. To this end, I have argued that routine testing should be accompanied by a commitment to use specialized informed consent, counseling, and confidentiality procedures.

This commitment to scale up HIV testing in conjunction with a scaling up of protections for individual rights will require a significant expenditure of resources, most notably in the form of the time that health care workers will have to spend training in and complying with these procedures. This is a potentially significant issue—and one that is beyond the scope of this paper. However cost alone should not dissuade policy makers from adopting a human rights approach to routine testing for HIV. Those who insist that expanding HIV testing will require a curtailment of protections for individuals insist on a false dichotomy between protecting civil and political rights and guaranteeing the right to health.

Only a few years ago, few thought that mass-scale treatment for HIV was possible in poor countries—ARV drug prices were too high; health systems in

267. CSIS REPORT, *supra* note 23, at 9.

268. Seipone et al., *supra* note 101, at 1083.

poor countries lacked sufficient manpower to administer complicated drug regimens; and it was thought that individuals in poor countries would not be able to adhere to complicated dosing regimens. Treatment activists prevailed in changing the world's thinking on HIV treatment because they worked to change every constraint that their critics believed to be binding. As a result, prices have been lowered, health care workers are being trained, and several studies have shown that individuals in poor countries do adhere to dosing regimens for ARV treatment, perhaps better than their counterparts in rich countries.²⁶⁹ Similarly, shifting to routine testing in a way that preserves and enhances protections on individual rights will require new thinking, new understanding, and new resources.

269. D. Coetzee et al., *Promoting Adherence to ARV Therapy: The Experience from a Primary Care Setting in Khayelitsha, South Africa*, 18 AIDS S27, S30-31 (2004); S. Koenig et al., *Scaling-Up HIV Treatment Programmes in Resource-Limited Settings: The Rural Haiti Experience*, 18 AIDS S21, S25 (2004); I. Lanièce et al., *Adherence to HAART and Its Principal Determinants in a Cohort of Senegalese Adults*, 17 AIDS S103, S107 (2003); M. Nemes et al., *ARV Therapy Adherence in Brazil*, 18 AIDS S15, S12 (2004).

APPENDIX 1

Model Legislation on Testing Counseling for HIV/AIDS

Preamble

Recognizing that testing for human immunodeficiency virus (HIV) infection implicates serious medical, legal, ethical, economic, social, and psychological issues;

Recognizing that HIV infection is life-threatening;

Recognizing that HIV causes AIDS;

Recognizing that HIV is treatable;

Recognizing that individuals have a right to health, which includes a right to know their HIV status;

Understanding that individuals may face significant discrimination and social stigmatization based on their HIV status;

Respecting the right to life, the guarantees of freedom and security of the person, and the right to privacy and dignity, as protected by the International Covenant on Civil and Political Rights;²⁷⁰

Recognizing the goals of expanding testing, decreasing HIV-related stigma, increasing the reach of treatment programs and empowering people living with HIV to improve their health;

The following provisions of legislation are hereby proposed:

Definitions

Acquired Immunodeficiency Syndrome (AIDS): The advanced stage of HIV disease during which the patient displays the signs and symptoms of severe immune deficiency, and the patient's body loses its ability to resist infections. Defined by the presence of an AIDS-defining opportunist infection or a CD4 T-lymphocyte count of less than 200/micro-liter.²⁷¹

Epidemiology: The study of the distribution of diseases in society, and the application of this information for the prevention and control of disease.

Epidemiological Purposes: The testing for HIV in order to obtain information

270. ICCPR, *supra* note 141, arts. 6, 9, 10, 17.

271. Castro et al., *supra* note 8.

regarding the distribution of HIV infection within society.

Full Informed Consent Disclosure: Disclosure of material information prior to obtaining patient's consent to testing, as provided for in Article 1.

Human Immunodeficiency Virus (HIV): The virus that causes AIDS.

HIV Testing: The obtaining of a bodily sample for the specific purpose of performing a medical test or a number of medical tests to determine the HIV status of a person.

Proxy Consent: Consent by a person legally permitted to give consent for another individual. This may include, but is not limited to: a parent or guardian of a child below the age of consent; individuals designated by law to consent for individuals with mental illness; and an individual exercising durable power of attorney for a patient.

Occupational Exposure: An exposure to HIV that carries the risk of infection and that occurs during the course of an individual's occupational activities (an accident such as a needle-stick injury, in which a health care worker has been exposed to a patient's blood.)

Article 1:

Right To Refuse Testing And The Right To Informed Consent

(a) Except for the limited provisions contained in Article 4:

(1) All individuals have a right to refuse to be tested.

(2) All individuals have a right to informed consent.

(b) Informed consent requires that the individual voluntarily agrees to be tested. Informed consent also requires that the individual giving consent does so without any element of coercion and that the individual is equally free to grant or withhold consent. Testing with informed consent means that the individual understands information related to the test. This information must be disclosed by the health care provider prior to testing and should include, at minimum, the following non-exhaustive points of information:

(1) The patient's right to refuse testing;

(2) A reminder that patients can change their minds about a decision at any time;

(3) A reminder that patients have a right to seek a second opinion;

(4) Confidentiality procedures;

(5) What the test is;

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- (6) Why the test is necessary;
- (7) Risks of testing;
- (8) Benefits of testing;
- (9) Alternatives to testing;
- (10) Possible social implications of a positive test result;
- (11) Follow up services that will be offered;
- (12) The availability of treatment for HIV in that particular location and the likelihood of receiving treatment if the test result is positive;
- (13) Options for treatment or management of the condition - including the option not to treat;
- (14) For each treatment option – including the option to forgo all treatment – explanations of the likely benefits and the probabilities of success, and a discussion of any serious or frequently occurring risks, and of any lifestyle changes which may be caused by or necessitated by the treatment;
- (15) The name of the health care provider who will have overall responsibility for follow up care;
- (16) Details of costs or charges which the patient may have to meet; and
- (17) The importance of informing anyone at ongoing risk of infection if the test result is positive.

Article 2:

Requirements for Ensuring Testing Occurs with a Patient's Voluntary and Informed Consent

- (a) HIV testing must always be conducted with the informed consent of the individual being tested, except in the limited set of circumstances outlined in Article 4.
- (b) The patient's consent must be obtained by the health care provider in writing except where this is impossible.
- (c) Where applicable, a patient's refusal to be tested should be documented in writing.
- (d) HIV testing must always be accompanied by pre-test counseling and post-test counseling. Counseling should include, at a minimum, the information included in Article 1.

Article 3:

Circumstances Under Which HIV Testing May Be Conducted with Informed Consent

- (a) Subject to the provisions of this Statute, HIV testing may only be conducted under the following circumstances and with the informed consent of the patient:
 - (1) Upon individual request;
 - (2) Upon the recommendation of a health care provider; and

(3) As part of the screening protocol for blood products or organ donations, provided that such testing is conducted in accordance with the statutory provisions on blood donations.

(b) Where a patient presents to a health care provider with recognizable symptoms that are specific to HIV/AIDS, but no facilities exist for HIV testing, the health care provider must provide pre-test counseling and then refer the patient to a facility that offers HIV testing.

Article 4:

Limited Circumstances Under Which HIV Testing May Be Conducted Without Informed Consent

(a) Notwithstanding the provisions in Article 1, testing for HIV without informed consent may be conducted under the following strictly limited circumstances:

(1) When an existing blood or tissue sample is being used in an anonymous testing protocol for epidemiological purposes. Further, such testing must be conducted in accordance with national legal and ethical guidelines regarding research testing, unless such national guidelines are contrary to the provisions of this legislation. The identity of the donor will be kept anonymous and will not be included in any records involving the sample.

(2) When a health care worker has experienced an occupational exposure, HIV testing of the source patient may be conducted without informed consent, but only after informing the source patient that the result may be disclosed to relevant medical personnel and the exposed health care worker, and only if: 1) the source person has declined to give his/her informed consent; or 2) the source person is unable to give informed consent and no proxy consent is available. In all such cases, the source patient must receive an offer of pre-test and post-test counseling.

(3) When an individual is unable to consent to an HIV test due to their incapacity or age, and a physician expects that the test result would improve the patient's immediate medical care, another person with legal guardianship of the incapacitated individual may offer proxy consent.

(4) In emergency or life-threatening situations.

(b) These circumstances are the only exceptions to the requirement of informed consent and shall be strictly and narrowly construed.

Article 5:

Right To Pre-Test And Post-Test Counseling

Pre-Test Counseling

(a) All individuals have a right to pre-test counseling before receiving an HIV test. Pre-test counseling shall be offered to an individual before an HIV test by a suitably trained person (a doctor, nurse, trained social worker, psychologist, or

trained HIV counselor) with the purpose of offering information, gaining consent and ensuring that the individual has sufficient information to make an informed decision about having an HIV test. This session must include a full informed consent disclosure, as defined by Article 1 of this statute. During the pre-test counseling session the individual patient should be given an opportunity to make a decision, free from any element of pressure or coercion, as to whether or not he/she wishes to be tested for HIV.

Regardless of whether the individual refuses testing, pre-test counseling should also include discussions on the following:

- (1) An assessment of personal risk of HIV infection;
- (2) Safer sex and strategies to reduce risk.
- (3) A domestic violence screening with referral to appropriate counseling, if necessary;
- (4) This list shall not be construed as limiting or exhaustive.

Post-Test Counseling

(b) All individuals have a right to post-test counseling after receiving an HIV test. Post-test counseling shall be provided by a suitably trained person (a doctor, nurse, trained social worker, psychologist or trained HIV counselor) to a patient when he/she receives his/her HIV test result. Post-test counseling must involve two or more sessions. These sessions should include:

- (1) An opportunity for the patient to provide feedback;
- (2) Interpretation of the test results;

If the result is negative:

- (3) Counseling on strategies for risk reduction; and
- (4) Counseling on the possibility that the patient may be in the “window period,” during which HIV antibodies are not yet detectable, but during which the patient may still be infectious.

If the result is positive:

- (5) Immediate emotional counseling, as necessary;
- (6) Counseling on the personal, family and social implications;
- (7) Reasonable assistance in coping with difficulties that the patient may foresee;
- (8) Counseling on the patient’s responsibilities to sexual partners;
- (9) An assessment of immediate needs and social support identification;
- (10) A schedule for follow up supportive counseling; and
- (11) Arrangements for follow-up medical care.
- (12) This list shall not be construed as limiting or exhaustive.

*Article 6:
Confidentiality*

- (a) No health care provider shall disclose any information concerning the result of an HIV test or any related assessment of a patient to any other person except with the written consent of that patient.
- (b) Where the written consent of a patient cannot be procured for the purposes of section (a) in an emergency, the consent of the following persons shall suffice:
 - (1) If the patient is a minor, the written consent of a parent or legal guardian of that child; or
 - (2) If the patient is unable to give written consent, with the oral consent of the patient or with the written consent of the person with the power of attorney for that patient.
- (c) Any consent for disclosure required under section A above must be accompanied by pre-consent and post-consent counseling, which must, at a minimum, facilitate an understanding of the nature and purpose of the consent to disclose, the advantages and disadvantages of the consent, and the effect of the consent upon the patient.
- (d) A person's HIV test result may be disclosed without their consent only if the information is used for statistical or other purposes that could not reasonably be expected to lead to the identification of the person to whom it relates.
- (e) The results of an HIV test shall not be discoverable in any civil, criminal, or administrative proceeding, except with the written consent of the patient involved.
- (f) A medical practitioner has a duty to encourage the patient to disclose his or her HIV status to his or her sexual partner(s) and counsel the patient on issues and consequences related to such disclosure.

*Article 7:
Interpretation*

- (a) In all instances, this statute shall be interpreted to ensure respect for rights to privacy, dignity, bodily integrity, and autonomy.

*Article 8:
Enforcement*

- (a) This statute shall not be construed as interfering with an individual's rights as guaranteed by any other statute, constitutional provision, or international legal instrument.
- (b) Under this legislation, individuals possess a private right of action for the violation of their rights as specified above, by any individual, acting within the scope of his or her professional capacity.

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- (c) All requirements and provisions specified in this legislation are subject to review by national courts.
- (d) In addressing alleged violations of the provisions of this legislation, national courts have the authority to grant remedies in the form of injunctive relief, damages, attorney's fees, and any further awards deemed appropriate by the court.

