

GRAND ROUNDS

HIV Center for Clinical and Behavioral Studies

New York State Psychiatric Institute and Columbia University

“An End to Privacy: Changing the Rules on Testing and HIV Surveillance in New York”

Ronald Bayer, Ph.D., and Amy Fairchild, Ph.D.

March 9, 2006

Dr. Ronald Bayer, Professor of Sociomedical Sciences and Associate Director of the Center for the History and Ethics of Public Health at the Joseph L. Mailman School of Public Health, Columbia University, and Dr. Amy Fairchild, Assistant Professor of Sociomedical Sciences and Assistant Director of the Center, discussed the history and current policy evolution of HIV testing and surveillance in New York.

Dr. Bayer outlined the history. He noted that in 1991 he coined the term “HIV exceptionalism” to describe the distinctiveness of HIV policies reflecting the stigma, vulnerabilities, lack of treatment options, and politics, particularly related to gay men, that make HIV different from other diseases. This was illustrated in policies concerning HIV testing and named case reporting.

When HIV testing was first promoted by public health officials in mid-1985, a time treatment was not available, it was opposed by a gay community that did not see any clear benefits. Their position was that HIV testing should be done only with explicit consent after full counseling about the risks and benefits (if any), a policy quite different from standard medical practice.

But the rapidly expanding HIV epidemic and technological advances in treatment made testing more advantageous and engendered ongoing debate about policy. In 1994, clinical trial ACTG 076 demonstrated the possibility of decreasing perinatal HIV transmission by administering the AIDS drug AZT to pregnant women and newborns. Subsequent policies to test all newborns for HIV challenged pre-test counseling and informed consent requirements, since the HIV-status of each newborn’s mother is revealed by the test on her baby. The desire to offer pre-delivery drug treatment to HIV-positive mothers prompted health officials to ask providers to recommend HIV testing to every pregnant woman, a standard of care in which all are tested for HIV except those who “opt out,” that is, refuse the test, even though their HIV status still becomes known through infant testing.

After 1996, with the advent of antiretroviral therapy, the pressure increased to identify HIV-positive people and refer them for care. The attempts to routinize testing continued to loosen policy constraints.

Regarding HIV case reporting, by 1983 all states in the US had initiated reporting of AIDS cases

by name, like that for TB, STDs, cancer, and other diagnoses. By 1985, the possibility of name reporting for HIV cases was being discussed. The intent was to alert health authorities to the presence of people with a transmissible virus, to make sure they received counseling about transmission and about treatments as they became available, and to monitor prevalence trends. Confidentiality of health records was to be protected for both HIV and AIDS reporting.

However, the HIV name reporting proposal provoked fierce opposition. Opponents cited fear of discrimination in employment, housing, and insurance, and the likelihood of driving HIV-infected people underground and away from testing. Over the next fifteen years, controversy continued. Attempts to use reporting systems based on unique identifiers rather than names failed since the codes proved too complex and error-prone and did not permit adequate follow-up. Further, Ryan White funding was based on HIV surveillance. Name reporting was adopted, but opponents continued to insist that the data be used only for epidemiology purposes.

Dr. Fairchild described current discussion and changes in HIV testing and surveillance policy. In February 2005, Dr. Thomas Frieden, Commissioner, New York City Department of Health and Mental Hygiene, asked the New York State Department of Health to monitor viral loads in HIV-positive people to track drug resistant strains of the infection and determine whether patients received treatment. The threat of drug resistant HIV prompted the State to quickly amend its lab-based reporting law. In February 2006, Dr. Frieden asked for more aggressive use of HIV surveillance data and proposed more routinized HIV testing. This marks the start of a new era in disease surveillance.

Dr. Fairchild cited diabetes surveillance as the precedent for new HIV surveillance methods that depend on patient and provider feedback and combine surveillance with quality control and case management approaches. The goal is to work directly with physicians; their resistance is expected, perhaps because monitoring of clinical treatment might be perceived as threatening. While the environment for surveillance has fundamentally changed, privacy issues may serve as a limitation on state use of surveillance in the interest of public health.

In January 2005, the New York City Department of Health (DOHMH) began to frame diabetes as an epidemic. It is the third leading cause of death, is costly, and has high rates of hospitalization. Incidence of diabetes is increasing rapidly. Dr. Frieden is advocating lab reporting of A1C test results, which measure blood sugar levels. Recent test sample monitoring indicated that 31% of patients in commercial managed care and 42% in Medicaid managed care have poor control over their diabetes. Dr. Frieden suggested that the City should use the data to improve care by targeting resources and by direct intervention with patients and providers.

The City began a pilot intervention trial in the South Bronx, which the American Diabetes Association refused to support if it omitted informed consent. DOHMH said it would be too onerous to train health care workers to obtain informed consent and instead offered an opt out provision for patients who do not wish to be contacted directly, although names and test data will still be reported and the Department can still contact patients through their physicians or directly if the doctors also opt out of the

intervention.

The patients protested on grounds of privacy. Diabetes is not a communicable disease, and patients felt the intervention was unacceptably paternalistic and too much like “Big Brother;” they insisted on informed consent.

Despite these objections, in December 2005, the New York City Hemoglobin A1C Registry (NYCAR) measure was passed and became law as of January 15, 2006, providing for direct contact of patients unless an opt out form is completed. It is surprising that neither HIPAA, nor the American Medical Association, nor the American Civil Liberties Union, nor state or country medical societies, nor any other professional or privacy rights organizations weighed in with an opinion or objection.

Yet issues of patient privacy and clinical autonomy are still central to the discussion of how diabetes surveillance data may be used and to the current contentious debate about routine HIV testing and the eventual extension of seropositive surveillance to viral load and drug resistance.

The appearance of a highly virulent, multi-drug resistant strain of HIV in New York City prompted additional calls by Dr. Frieden for changes in HIV confidentiality and surveillance laws. The rationale is that many people are diagnosed with HIV and come into care only after developing AIDS, that better lymphocyte and viral load testing offer the chance for better treatment, and that African Americans and Latinos die of HIV-related illness at six times the rate of whites.

While New York State had required reporting of detectable viral load levels since 2000, the State now requires reporting of undetectable viral load test results as well as drug resistance. Both New York State and New York City want to decrease the barriers to testing and treatment. But the State seems intent on using laboratory reporting results as population-based aggregate data to better understand patterns of infection and drug resistance, and not for individual interventions as Dr. Frieden proposes.

Dr. Frieden is concerned about patients lost to care and is arguing for more aggressive intervention. He impaneled a 21-member Commission on HIV/AIDS, which included many community organization representatives. They endorsed proposed changes in lab reporting, but not use of the data for individual monitoring. Ron Johnson of the Gay Men’s Health Crisis commented that the problem for African American men is not becoming lost to the health care system, but getting into it in the first place. Housing Works is concerned about paternalism, coercion, and second guessing of doctors’ treatment decisions by health authorities. Act Up focused on the diversion of scarce prevention resources, but merely “questioned” the Commission’s endorsements. It is notable that there is opposition but no serious outrage.

Still, this new type of monitoring calls into question the appropriate relationship among surveillance, quality improvement, and case management. Many issues deserve attention: How far can health officials intrude on patient and provider management of

health care? What is the impact of cost? What are the limits of the public health mandate to supervise physicians or manage care? When should patients or providers be able to opt out? Concern for the most vulnerable, who do not necessarily have a consistent relationship with a provider, must be balanced against a concern about excessive paternalism. On one hand, health care surveillance could be linked to state police powers and, on the other, could be a tool for social justice.

Discussion:

Dr. Frieden addressed the Executive Committee of the Prevention Planning Group on March 7. He stressed aggressive monitoring of quality of care with a focus on physicians and rapid testing. He wants to know who and how many are infected. He also met with Dr. Fairchild on March 6 in discussions about the appropriate uses of data.

The role of pre-test counseling should be carefully examined. It has played an important role and should not just be discarded.

Physicians want to be independent, as they are in other disease models. However, insurance company regulation and monitoring have already compromised physician autonomy to some degree. Although physicians used to resist surveillance efforts, there is no way to know how much they will resist now. It may be very different if changes come from public health authorities rather than police power.

The goals of the NYC Commissioner are laudable. Everyone wants earlier identification of people with HIV and better care. New York City and New York State have been discussing the proposed changes for some time, and although there has been a fair amount of disagreement, the positions have evolved. New York State has considerably modified its counseling and testing policies to make testing more efficient, but it is unclear what will happen when patients are handed an HIV testing consent form in settings other than doctors' offices, like an emergency room, with no counseling. Dr. Frieden has stepped back from outright demands to change the law (Article 27-F) and does not support mandatory testing, but patients are asked to sign for general consent to test blood for any number of reasons. Specific consent for an HIV test is verbal. The opportunities for HIV prevention education are substantially reduced.

The changes really are about the end of AIDS exceptionalism. If testing is more routine it could lead to decreased stigma for people with HIV. On the other hand, it could diminish attention and resources to address the many social, economic, and other ways in which HIV still is different.

Regarding equity and social justice, there is still no universal health care system. How will better health care for more people be funded?

The opt out model is specifically designed to make it more difficult for people to say no.

Public health is not just for surveillance. It must also be concerned about the person

affected and the quality of care. Is this paternalistic? It's difficult to know where to draw the line. What is a legitimate public health concern. Should we (because of avian flu) report the death of every bird? This discussion will continue.

RELATED PUBLICATIONS:

Bayer R, Fairchild AL, "Changing the paradigm for HIV testing--the end of exceptionalism," *N Engl J Med*. 2006 Aug 17;355(7):647-9.

Bayer R, Fairchild A, "The limits of privacy: surveillance and the control of disease," *Health Care Anal*. 2002;10(1):19-35.

Fairchild AL, Bayer R, "Public health. Ethics and the conduct of public health surveillance," *Science*. 2004 Jan 30;303(5658):631-2.

NOTE: This HIV Rounds summary is a report based on notes from an oral presentation. It is not a source document for citation. Please contact the presenter(s) and peer reviewed materials for verification of data and further information.

KEYWORDS: testing, counseling, surveillance, policy, privacy, confidentiality, stigma, discrimination, law, diabetes, physicians, patients, clinical care, name reporting, newborn testing, women, quality improvement, case management, exceptionalism, prevention, treatment, paternalism, consent, opt out, drug resistance.