



## New York City's Initiatives on Diabetes and HIV/AIDS: Implications for Patient Care, Public Health, and Medical Professionalism

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Two recent New York City Department of Health and Mental Hygiene initiatives expanded the mission and scope of public health, with implications for both New York and the nation.

The programs target diabetes and HIV/AIDS for greater systemic and expanded reporting, surveillance, and intervention. These initiatives do not balance heightened surveillance and intervention with the provision of meaningful safeguards or resources for prevention and treatment. The programs intrude on the doctor-patient relationship and may alienate the

very patients and health professionals they aim to serve.

Better models are available to achieve their intended goals. These initiatives should be reconsidered so that such an expansion of public health authority in New York City does not become part of a national trend. (*Am J Public Health*. 2008;98:XXX-XXX. doi:10.2105/AJPH.2007.121152)

### IN 2005, THE NEW YORK CITY

Department of Health and Mental Hygiene (DOHMH) adopted a more expansive approach to

critical health care problems, raising fundamental questions about the mission and scope of public health programs, not only in New York but also in the nation. Public health agendas have expanded in the aftermath of the terrorist attacks of September 11, 2001. National funding has swelled in an effort to anticipate and counter potential bioterrorism.<sup>1</sup> So too, more attention is being devoted to naturally occurring global health diseases, including West Nile virus and avian flu. The invigoration of

public health in the United States, perhaps long overdue, may well be encouraging officials to enlarge the scope of their concerns and broaden their powers. However, new initiatives should simultaneously be effective, protective of individual liberty and privacy, and respectful of the relationship between patients and medical professionals.<sup>2</sup> It is no exaggeration to say that public health policy is at a crossroads and that the events in New York may be a harbinger of a national trend.



We focus here on 2 New York City initiatives that target diabetes and HIV/AIDS for greater systematic and expanded reporting, surveillance, and intervention. Although it is not unusual for expansions in public health mandates to meet resistance, and surveillance often precedes intervention, new policies may be essential to address changed circumstances.<sup>3</sup> Almost every public health intervention carries a potential risk to individual privacy rights and civil liberties. However, these 2 initiatives are novel in the ways they intrude on the doctor–patient relationship.

Despite many differences, diabetes and HIV/AIDS share considerable similarities: both are considered preventable, treatments are expensive and difficult to manage, patient stigma and discrimination persist, and the diseases disproportionately affect low-income groups and racial and ethnic minorities.

Regarding diabetes, laboratories in New York City as of January 15, 2006, have been required to report to the DOHMH all blood sugar (A1C) test results, provided those laboratories have electronic reporting capabilities.<sup>4</sup> A novel pilot intervention program also is planned for the South Bronx. In this program, DOHMH officials will contact physicians whose patients have A1C test results of more than 9%; in certain cases, officials plan to directly contact the patients.<sup>5,6</sup> Unlike the laws for HIV/AIDS that were established in the 1980s to protect privacy and reduce discrimination, there are no such precedents in

diabetes or other noncommunicable diseases. For HIV/AIDS, the DOHMH proposes significant changes to the state's public health law; these changes would eliminate the written informed consent requirement and abbreviate the pretest counseling provisions in current HIV testing and counseling safeguards.<sup>7</sup> After the DOHMH issued its proposals, the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) issued similar guidelines that called for routine screening for HIV and the complete elimination of consent and counseling procedures.<sup>8–10</sup> It is critical to note that the privacy rule of the Health Insurance Portability and Accountability Act (HIPAA) explicitly does not preempt state public health laws related to monitoring, surveillance, and intervention. Public health law has traditionally been regulated on a state-by-state basis.<sup>11</sup> Most state public health law contains stringent confidentiality safeguards, particularly mandatory reporting and surveillance rules.<sup>12,13</sup>

Noting the increases in cases of type 2 diabetes and HIV infection, particularly among low-income racial and ethnic minorities, the DOHMH has labeled both diseases “epidemics.” Although an epidemic is defined epidemiologically as “the occurrence of more cases of disease than would normally be expected in a specific place or group of people over a given period of time,”<sup>14</sup> the more general use of the term raises the specter of an acute, contagious

disease that spreads rapidly through a population.<sup>15</sup> Labeling a disease an epidemic may be a useful strategy for raising public awareness; indeed, the term has been widely used in recent years for obesity and depression. But the language of epidemic also implicitly justifies an expansion of public health authority. Before it is used to legitimate heightened surveillance and intervention, public health officials should acknowledge a “concomitant duty” to provide resources for prevention and treatment of disease and to implement meaningful safeguards that protect patients from undue exposure to risk and harm.<sup>16,17</sup>

Public health officials, including DOHMH Commissioner Thomas Frieden, have often expressed frustration at the failure of the health care system to address preventable and treatable diseases such as HIV and diabetes, but the most effective and fair response is seldom increased government surveillance and weakening of patient protections. Rather, the underlying social, environmental, and economic factors that contribute to disease must be confronted, and the doctor–patient relationship must be reinforced with resources that enhance treatment, communication, and trust. In the zeal to ameliorate pressing health problems, public health measures may alienate the very communities and health professionals they aim to serve and reduce a willingness to seek or to provide health care services.

## DIABETES

### Rising Diabetes Rates and the Plan to Address Them

Diabetes is the fourth leading cause of death in New York City. More than 500 000 adults (approximately 9% of the overall population) have been diagnosed with diabetes in New York City, and more than 25% of people may have undiagnosed diabetes or have elevated glucose levels indicating a prediabetic condition.<sup>18</sup> The demographics of diabetes have shifted such that racial and ethnic minorities and people in poverty are disproportionately affected. On the basis of New York City's Health and Nutrition Examination Survey (NYC HANES), which collected data from 2000 people, and the *Vital Statistics 2005* report, the prevalence of diabetes and death from the disease among Asians, Blacks, and Hispanics was significantly higher than it was among Whites.<sup>18,19</sup> Most diabetics are served only by their primary care physicians and not through a team-based model of care, although most providers agree that the latter is more effective. By all accounts, New York City's health system is ill equipped to handle the burgeoning number of diabetes cases, and the economic burden of the disease is substantial.

To address these problems, the DOHMH established a mandatory A1C registry and implemented a pilot intervention project. With the establishment of the A1C registry, laboratories are required to report the A1C levels of all patients tested to the DOHMH, and the results are



then linked to the patient's name, date of birth, physical address, and physician's contact information.<sup>20</sup> The DOHMH states that data from the registry will enable it to "plan programs, measure outcomes of diabetes care and direct more efficient interventions to health care institutions, health care providers and people with diabetes" for diabetics in treatment.<sup>20(p2)</sup> In amending the city's health code to establish the registry, the DOHMH stated that all test data would be kept confidential and that insurers, licensure organizations, and employers would not have access to this information. Inclusion in the registry is mandatory—neither patients nor physicians can opt out.<sup>21</sup>

The DOHMH intends to use the registry to implement a pilot intervention project in the South Bronx, which has the highest level of newly reported diabetes cases in the city. The DOHMH will compile for physicians in the region a quarterly roster of all their patients' A1C levels. If their levels are greater than 9%, the DOHMH will send patients a letter advising them of their high glucose level along with educational and resource materials. Although aspects of this proposal remain in flux, the DOHMH has stated that the letterhead will be from the patient's physician or medical practice and the return address on the envelope will be from the DOHMH. Unlike the registry, physicians and patients will be able to opt out of the intervention program; however, patients will not be aware of their ability to opt out until they

have received their first mailing from the DOHMH.

### Patients' Avoiding Care

The proposals, however well intentioned, may trigger unintended consequences.<sup>22</sup> Although the DOHMH sees a duty to intervene for a population that is economically and medically vulnerable, this same population—as the target of the pilot intervention—is especially concerned about the risk of stigma, discrimination, and a "blame-the-victim" approach to the disease.<sup>23,24</sup> Thus, the plan to directly inform patients that they are not adequately managing their disease may backfire. Such patients may be angered or frightened by a letter from a public health official who has no direct relationship to them. Further, telling patients that their A1C levels are too high may be interpreted as faulting them for the disease, and when patients feel inadequate for not properly caring for themselves, they may be even less likely to seek medical assistance.<sup>25–28</sup> Both the decision to send a letter and the letter's contents may jeopardize the care of these diabetes patients.

In addition, fearful that the government and other institutions will take action against them, patients may opt to avoid care. This is not an idle concern. Studies by the California Health-Care Foundation in 1999 and again in 2005 found that racial and ethnic minorities avoided care, fearing that insurers, employers, the government, and others might use their health information to limit or deny

certain benefits or services.<sup>29–31</sup> A lengthy historical record buttresses these contemporary surveys. The public health response in the early 20th century to tuberculosis and typhoid set off a department "seek" and a patient "hide" dynamic that had less-than-optimal results for everyone.<sup>32–36</sup> A pilot intervention in the South Bronx could racialize diabetes and drive away from care the groups most in need of treatment and services.

### Physicians' Shunning the Difficult Patient

The DOHMH registry and intervention efforts may be seen by physicians as unfairly blaming them for the test results of their patients. If A1C levels are not at 9% or below, then physicians as well as their patients may appear to be at fault. Physicians may interpret such a notification from the health department as an indicator of substandard care, especially at a time when "pay for performance" and other quality measures are being instituted. An intervention project based on such standards and notifications is likely to make some doctors reluctant to treat difficult diabetes cases.<sup>37,38</sup> If patients may be driven to avoid seeking care, doctors may be driven to avoid giving care. In effect, surveillance and intervention in "problem" cases may foster a mutually antagonist relationship between doctors and patients, undermining the relationship most essential to quality care.

Physicians will be further dismayed by the DOHMH plan because it casts too wide a net in

its effort to monitor people with type 2 diabetes. The registry does not distinguish different underlying conditions among those with high A1C levels. It does not differentiate between type 1 and type 2 diabetics; nor are people with conditions other than diabetes, such as cystic fibrosis or cancer, identified. Thus, physicians treating patients with elevated A1C levels caused by other conditions will be subject to DOHMH intervention, which may further erode trust and confidence in public health officials.

### Limits of the Initiative

Finally, but by no means least important, the DOHMH initiative offers no increased resources for diabetes treatment or services. This is a reporting and notification program with no enhancement of facilities or programs. The registry and pilot intervention do not include a guarantee of access to care along the lines of what currently exists for people with HIV/AIDS. The registry will neither identify nor address the needs of people who lack any access to health care—given that the laboratory results of only those receiving care will be reported to the DOHMH—nor will it bring additional treatment and services to those already in care.

Public health surveillance and intervention in the doctor-patient relationship are not substitutes for resources aimed at prevention and better management of diabetes. The DOHMH recognizes the need for a more systemic approach and has



hired a new coordinator of food policy, organized free family fitness programs, created a project to address fitness and nutrition in public schools, and urged convenience store owners to stock low-fat milk and fresh produce. However, the DOHMH does not have the resources to ensure diabetes patients complete access to health care, to make clinical judgments on behalf of physicians, or to manage patient treatment.<sup>39–46</sup> But this fact has not prompted it to rethink the registry and pilot programs.

Curiously, there is a far better model for improving the care of diabetes already operating in New York City. The Health and Hospitals Corporation (HHC), which oversees the city's public hospital system, has put in place a registry and care coordination system that includes its own diabetes registry for use by health care workers in its 11 facilities.<sup>47–50</sup> As of October 2006, the registry was tracking 50 000 diabetic patients, with data on patients' blood sugar, blood pressure, and cholesterol levels, all of which are available to HHC doctors, nurses, medical assistants, and nutritionists. The HHC registry is aimed at enabling diabetes management teams to better coordinate care for their patients; it operates within the health care profession, not as an external public health intervention. HHC's program is a more appropriate model for diabetes treatment and were other providers to adopt such a system, the DOHMH initiative might prove unnecessary.

## HIV/AIDS

### HIV/AIDS and the Plan to Address it

Similar to diabetes, AIDS disproportionately affects racial and ethnic minorities and people living in poverty. In 2005, of the people in New York City who had progressed to full-blown AIDS at point of diagnosis, 85% were Black and Latino; Latinas and Blacks accounted for 92.9% of all women diagnosed with HIV. People newly diagnosed with HIV are more likely to be male, young, and Black or Latino (81.2%).<sup>51</sup> The death rates from AIDS are 6 times higher among Black males than among White males and 9 times higher among Black females than among White females.<sup>52</sup>

The centerpiece of the DOHMH's efforts to combat this greater incidence of infections in low-income communities of color and the concomitant lack of early HIV testing and diagnosis in these communities is to offer HIV tests as a routine part of care. To accomplish this goal, the department has sought (1) to eliminate the requirement that informed consent for an HIV test be in writing, allowing the consent and pretest counseling process to be given orally (for non-rapid testing), and (2) to remove the pretest counseling requirement that people be informed of the risks of discrimination and of the legal protections available to them.<sup>53</sup>

The DOHMH proposed to add language to the pretest counseling and consent process related to the treatments available,

the voluntary nature of the test, and the confidentiality of the test.<sup>53</sup> For HIV-negative patients, the DOHMH has sought to eliminate the posttest counseling requirement that includes information about the risk of "discrimination problems" that may result from a positive diagnosis. (Earlier versions of the DOHMH proposal would have authorized direct monitoring and intervention by public health officials of HIV-positive patients and their physicians to ensure compliance with treatment—which would have been unique in the country. Following vigorous opposition, the DOHMH withdrew these plans.<sup>54,55</sup>)

The DOHMH initiative continues to be the focus of attention. A number of HIV-testing bills are currently being debated in the New York State Legislature. Richard Gottfried, chair of the State Assembly Health Committee, introduced a bill in June 2007 that called for the "universal offer" of HIV testing. It would waive specific consent for HIV testing in favor of general medical consent and would follow an opt-out model.<sup>56</sup> The state assembly passed the bill shortly after its introduction, but it is not currently scheduled for consideration in the senate.

### Written Informed Consent Is Not a Barrier to Routine HIV Testing

We fully support making the offer of an HIV test a routine part of care. Currently, physicians use their discretion to decide who should be tested for HIV,

basing their decision on risk factors such as drug use and sexual orientation and behavior. So too, many patients do not seek testing because they are unaware of the risk, are in denial, or are afraid of the result. By dispensing with this risk-based testing model, the stigma and psychological discomfort many patients experience will be reduced. Further, physicians would no longer be forced to make assumptions about who might be at risk for HIV, thereby overriding misconceptions and biases that inhibit more widespread and effective HIV testing, detection, treatment, and prevention.

The DOHMH, however, insists that the written consent and counseling currently in place is too complex, costly, and burdensome, arguing that providers and their patients must engage in extensive face-to-face time, 45 minutes on average. In fact, written informed consent does not present a barrier to making widespread testing a reality. The process serves critical functions for patients, health care providers, and the community.<sup>57</sup>

Again, the New York HHC's policies and practices are instructive. A recent HIV-testing initiative that it undertook demonstrates that more-widespread testing can go forward with the written informed consent process in place, without sacrificing patient care or autonomy. The HHC expanded testing beyond its HIV and prenatal clinics, employing rapid HIV tests in all of its acute care centers and 6 of its diagnostic centers and increasing testing capacity in its



emergency departments, outpatient clinics, and other health care settings.

The HHC streamlined pretest counseling so that patients waiting to have their blood drawn would, in some cases, watch a video explaining HIV, the testing process, the meaning of the results, and providing transmission and prevention information. Through New York State Department of Health HIV forms, patients were asked if they wanted to be tested for HIV and then asked to sign the consent form. Using these methods, the HHC in 2006 increased HIV testing by 63% from the previous year.<sup>58,59</sup> HHC's approach and success is not idiosyncratic. Kaiser Permanente, the second largest provider of HIV care in the United States, routinely offers HIV tests while maintaining counseling and informed consent.<sup>60</sup>

### Value of Written Consent and Informing Patients of Risks and Options

Informed consent is a process, not a form. The current written informed consent and counseling procedures for HIV testing deliver crucial information. Counseling leads to positive behavior changes, such as engaging in practices to prevent HIV transmission. Informed consent and pretest counseling give health care providers the opportunity to educate patients about the social and legal risks of testing, as well as the benefits of testing, treatment, and prevention for both HIV-positive and HIV-negative patients.<sup>61</sup>

Making people aware of the risks of testing positive for HIV enables them to make better, fully informed choices about whether and how to be tested and gives them the opportunity to take precautions to limit the disclosure of their diagnosis.<sup>62</sup> Armed with information about privacy and discrimination, a person may opt to be tested anonymously. In New York City, all 11 of the DOHMH clinics (located in all 5 boroughs) offer both confidential and anonymous testing.<sup>63</sup> People may also choose to use home testing kits, pay for the test out of pocket to avoid submission of a claim, or talk with a doctor about limiting disclosure of the test results to family members or other providers. Indeed, patients are more likely to adhere to prescribed treatment plans if they trust their doctors and if their doctors are more forthcoming about medical risks and treatments.<sup>64,65</sup>

The safeguards implemented for those most heavily affected by HIV/AIDS in the 1980s—White, gay men—should be sustained, because the demographics of the disease have shifted to marginalized groups that are especially vulnerable to discrimination in employment and housing and to stigma in their families and communities. Regrettably, the discrimination and social stigma that informed the enactment of the law persists, although current treatment for HIV is much improved over what was available 18 years ago when New York's HIV testing and confidentiality law was adopted.<sup>66–71</sup>

A 2006 survey in Los Angeles County found that some health care providers (i.e., personnel in skilled nursing facilities [56%], obstetricians [47%], and plastic and cosmetic surgeons [26%]) continue to deny treatment to patients with HIV.<sup>72</sup> A number of states prohibit the licensing of people with HIV in professions such as barbering, massage therapy, home health care, and nursing. The Job Corps, Peace Corps, Federal Aviation Administration, and all branches of the military continue to exclude or restrict the employment or licensing of people with HIV. Twenty-seven states, not including New York, have laws that criminalize the sexual conduct of those who have tested positive for HIV, most imposing prison terms regardless of the consent of the parties, whether prophylaxis was used, or whether transmission occurred.<sup>73</sup>

For the informed consent process to be most effective, meaningful, and protective, a patient's written acknowledgment of consent is vital. Oral assent is not an effective substitute for written consent. The physical act of signing a document leaves less room for ambiguity and inference and is tangible evidence of a person's intent and understanding. Claims that the current consent and counseling safeguards are overly burdensome are not supported by existing data. The DOHMH cannot justify weakening existing protections when the data support the efficacy of maintaining current safeguards while making the offer of an HIV test a routine standard of care.

## CONCLUSION

In their zeal to take action to stem the rising cases of diabetes and HIV infection in New York City, public health officials have devised initiatives that are more invasive than remedial, that are not tailored to achieve their intended goals, and that are likely to further alienate the people most in need of comprehensive prevention, diagnosis and treatment programs. To paraphrase a popular slogan, we urge that their actions not become an instance of “as New York goes, so goes the nation.” ■

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No human participants were involved in the research reported in this manuscript.

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