PUBLIC HEALTH

Diabetes and Disease Surveillance

Where should the line be drawn between good public health practice and government intrusion?

Amy L. Fairchild

If New York City comes to serve as a model, public health surveillance in the United States will take on a radical new form, entailing a reconfiguration of the relation between public health and medicine. Recent events raise questions about the relations between privacy and public health and the obligations and limits of the state in clinical disease management.

In July 2005, New York City Health Commissioner Thomas Frieden described diabetes as "the only major health problem in this country that's getting worse and getting worse quickly" (*1*). To make an impact on the epidemic, the New York City health department put forward a bold proposal for electronic laboratory-based reporting of hemoglobin A1C tests for all city residents (*2*). Commissioner Frieden explained that it was essential for health officials to gain a view of the problem that would facilitate improvements in care and public savings. But more than conventional surveillance was involved. According to the health department, 31% of diabetic patients in commercial managed care and 42% in Medicaid Managed Care in New York State have an A1C of greater than 9%, indicative of poor control. Yet only 10% of people with diabetes are aware of their A1C levels (*3*). The health department thus proposed to use its authority to contact both doctors and patients when A1C levels suggested the need to review the clinical picture or to modify the course of treatment. Although it acknowledged that the proposed surveillance and intervention measure represented an unprecedented step, the department underscored its legal mandate to prevent and control chronic, as well as communicable, disease, citing cancer, dementia, and congenital malformations registries as providing established precedents for diabetes surveillance (*3*).

Never has a government initiated ongoing, systematic diabetes surveillance for an entire population (*4*), although there have been voluntary efforts based on the use of surveys or administrative data, like billing records, to assess prevalence levels. In Israel, for example, a state-funded health service network serving more than a million members uses an internal diabetes registry and computer monitoring system to track patient health status and care (*5*). Sweden's voluntary National Diabetes Registry draws data from participating primary health care and hospital outpatient clinics that have gained the informed consent of eligible patients (*6*). Efforts are being made to construct diabetes registries across Canada and Europe (*7*, *8*). Registries have been pilot tested in the United States (*9*).

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The author is at the Center for the History and Ethics of Public Health, Mailman School of Public Health, Columbia University, New York, NY 10502, USA. E-mail: alf4@columbia.edu

Although the New York surveillance effort will cover the entire city, the disease management intervention will be piloted first in the South Bronx, a poor, largely African-American and Hispanic-American community with particularly high rates of diabetes. Thus, the measure is also groundbreaking in that public health is responding to what it has taken to be a moral duty to meet the needs of and, indeed, empower populations that have been inadequately served by the existing health care system.

The Surveillance Initiative and Debate

As the city health department began to develop its surveillance scheme, officials consulted with organizations such as the Centers for Disease Control and Prevention, the American Diabetes Association (ADA), major New York City hospitals, clinicians, and patients with diabetes. Remarkably, the county, state, and national medical associations were not consulted. Privacy advocates were also not included in the early discussion.

In response to patient concerns about stigma and discrimination, Frieden argued that the privacy protections for the registry would be "stronger even than [those that] are in place for communicable disease reporting." Confidentiality provisions, the department asserted, would explicitly prohibit data sharing "to make it more difficult for persons with diabetes to obtain or renew a driver's license, health insurance, life insurance, etc." (*3*). Indeed, health officials assured the public that data would not be released to other parties other than the patient's physician.

The leadership of the ADA was quite receptive to surveillance, some viewing it as crucial for patients on the margins of the health care system—those who had no ongoing relationship with health practitioners. The organization, however, ultimately yielded to concerns of their membership and resolved that it could support A1C surveillance only if patients gave their informed consent.

Citizen objections to the surveillance proposal voiced at a public hearing in August 2005 were based on privacy and autonomy concerns. A medical privacy attorney, who explained that she also managed a chronic health condition, commented, "To me diabetes is a very private matter that would become a public matter." One diabetic expressed his "desire as a private citizen to keep my personal medical information private between my physician and myself and nobody else" (*3*).

The proposed incursion on privacy was unacceptable to such opponents because diabetes posed no communicable risk. One patient who testified against the proposal stressed "that as a diabetic I am not a threat to the City's public health, nor do I wish to be treated as one" (*3*). This was echoed by the American Clinical Laboratory Association, which objected that the measure placed burdens on laboratories in the absence of a clear public health "danger" (*10*). One attorney representing health care groups concerned with medical privacy asked, "What gives New York City the right to take my private information from me without my consent and usurp it as their own? Do I pose a bioterrorist threat? No. Is there some type of infectious disease threat? No. Is

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there an imminent threat that I will harm someone else? No." (*3*).

Absent the possibility of harm to others, the proposed system was characterized as an unwarranted intrusion into the domain of medicine. As did other ideologically libertarian organizations, the Association of American Physicians and Surgeons objected to lab-based A1C reporting as a "blatant invasion of patient privacy that will cause many patients to avoid testing and treatment." It saw the plan as "replacing individualized medical care with population-based medicine for patients having one of our nation's most significant chronic diseases" (*11*).

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Diabetes registration could, argued opponents, only open the door to greater intrusions and drive people away from health care. One patient flatly rejected what he called a "Big Brother approach to diabetes management" (*3*). He shared the concerns of another citizen who asked, "Are you going to demand what I can and can't eat?" (*12*). Only informed consent could mitigate such fears.

Against the claims of the individual were counterpoised those of the common good. That diabetes control, in particular, had been identified as a priority area for quality improvement both in the United States and internationally was reflected in the roster of physicians who advocated for laboratory-based A1C reporting at the public hearing. A mantra of the testimony from the quality improvement community was "what you don't measure you can't improve." Informed consent requirements, supporters agreed, would result in a "grossly inaccurate undercount" of cases and undo the effort (*3*).

Remarkably, none of the other privacy advocates and organizations that had been so engaged in debates about surveillance during the past two decades of heightened concerns spawned by the AIDS epidemic, the federal Privacy Rule, and bioterrorism appeared at the public hearing or made any comment on diabetes surveillance. More surprising was the degree to which physicians—who have been the most ardent opponents of public health reporting efforts for more than a century, particularly when they have involved any kind of interference with patients or their treatment—failed to object. The Medical Society of the State of New York, while noting the new regime, offered no comment on it (*13*). The New York County Medical Society, like the American Medical Association, was unaware of the measure even after it received the imprimatur of law.

The lack of physician involvement may be explained by the routine experience of third-party oversight with the rise of managed care. Whether they bristle at the requirements or not, doctors now view as unremarkable the need to seek prior approval for or review of their clinical decisions. Outside of the private sector, Medicaid and Medicare and other publicly funded health-care initiatives have given birth to governmental agencies that have treated the kind of surveillance involved in quality assurance and improvement as central to the fulfillment of a fiduciary responsibility to taxpayers.

Despite the absence of broad-based opposition, the little that initially arose caused the health department to modify its initial proposal. Although universal laboratory-based A1C would remain mandatory, patients would be given the right to opt out of clinical supervision and intervention on the part of the health department.

Privacy, Social Justice, and the Future

The opening debate over diabetes surveillance and intervention was limited—the health department received fewer than 50 oral and written comments—and appeared to have been brought to a conclusion when the New York City Board of Health unanimously approved the surveillance measure in December 2005. Yet as the pilot clinical intervention program is implemented in the Bronx with the intent of eventually rolling it out to the city as a whole, many issues revolving around how patient privacy and autonomy might limit the uses of surveillance data remain to be resolved. They have been thrown into bold relief by an emergent, fractious debate over proposals to extend the new surveillance paradigm to HIV, where Commissioner Frieden has argued that, by monitoring patient viral loads and drug resistance, the city can ensure that patients receive appropriate treatment (*14*). Some members of the New York City Council, as part of its deliberations over the health department's budget for fiscal year 2007, pressed for the health department to adopt an informed consent model (*15*). The American Civil Liberties Union is currently strategizing about how to weigh in on both the developments in diabetes and HIV surveillance. The time is thus right for an explicit discussion of the relations between public health surveillance, the claims of privacy, and the duty of public health to protect the interests of the most vulnerable.

Public health policy-makers must consider whether diabetes surveillance can really achieve all that it promises. But as important, and ultimately more vexing, are the underlying philosophical and political issues: We must distinguish paternalism in its most pejorative sense of overriding the judgment of individuals about their own health care from the commitment to providing for the most vulnerable in society who do not enjoy the benefit of a consistent, reliable relationship to a single provider or group of practitioners. Viewed from one vantage point, paternalism amounts to an unwarranted denial of privacy and choice; viewed from another, it holds the prospect of enhancing access to appropriate care, representing a commitment to social justice (*16*).

What distinguishes hard paternalism from its softer counterpart is the role of coercion. Despite the bristling rhetoric of those who would oppose diabetes surveillance—and, indeed, of city officials like Mayor Michael Bloomberg who have called for "the forceful application of law … as the principal instrument of our public health policy"—no one would be forced to undergo treatment or lifestyle change. If city officials hold true to their commitment to moving forward with such measures only when "democratically debated and approved," surveillance can promote empowerment (*17*).

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