Commentary: A Legal Perspective on Diabetes Surveillance—Privacy and the Police Power

MICHELLE M. MELLO and LAWRENCE O. GOSTIN

Harvard University; Georgetown University

THE NEW YORK CITY A1C REGISTRY (NYCAR) PROGRAM IS an unusual and groundbreaking extension of the reach of public health law. It marks the first time that the government has mandated name-based reporting of a chronic, noninfectious disease not caused by an environmental toxin and where the data are given to patients and physicians. Although the program has generated deep social controversy, remarkably it has not been challenged in court. Nonetheless, the law offers a useful lens through which to consider the program's justification and legitimacy. In this commentary to the article in this issue by Chamany and colleagues (2009), we examine the state's powers and responsibilities; patients' rights to privacy and security of personal data; and physicians' "privacy" rights.

Police Powers and Paternalism

Scholars sometime argue that diabetes surveillance represents a constitutionally impermissible exercise of the police power: the state's power to act to protect the public's health, welfare, safety, or morals. The claim is that the police power extends only to policies designed to prevent individuals from harming others (the "harm principle") and not to protect a person from harming himself or herself (paternalism) (Mariner 2007). This claim is difficult to support, however, in light of the persistence of

Address correspondence to: Michelle M. Mello, Department of Health Policy and Administration, Harvard School of Public Health, 677 Huntington Avenue, Boston, MA 02115 (email: mmello@hsph.harvard.edu).

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named reporting and data registries for cancer, lead poisoning, Lyme disease, workplace exposures, and prescriptions for controlled substances.

Legal challenges to public health reporting requirements typically fail (*United States v. Westinghouse Electric Corp.*, 638 F.2d 570 [3d Cir. 1980]; *Whalen v. Roe*, 429 U.S. 589 [1977]), as do challenges to other types of “paternalistic” public health laws, such as motorcycle helmet laws. Courts explicitly hold that such interventions are within the police power, ruling that the state has a legitimate interest in avoiding the social and economic costs associated with health risk behaviors (see *Simon v. Sargent*, 346 F. Supp. 277, 279 [D. Mass. 1972]). When viewed from a population-based perspective, helping vulnerable people monitor their health status and take measures to reduce risk is well within the government’s power.

Privacy and Security of Personally Identifiable Patient Information

Surveillance systems that collect personally identifiable information, of course, can invade a sphere of personal privacy. The U.S. Supreme Court has recognized a limited constitutionally protected interest in health information privacy (see *Whalen v. Roe*, 429 U.S. 589 [1977]). The judiciary grants public health agencies considerable discretion to use identifiable data for the public good, provided that they have a legitimate objective and maintain personal data in a private and secure manner. Specifically, courts weigh several factors (see *United States v. Westinghouse Electric Corp.*, 638 F.2d 570 [3d Cir. 1980]):

1. *What type of information is being requested, and how much harm could occur if confidentiality were breached?* In the NYCAR program, the reported information should be considered quite sensitive, owing to the potential for stigma and discrimination in insurance and employment if persons are identified as having poorly controlled hemoglobin A1C. Consequently, privacy and security safeguards are essential.

2. *How much damage would be done to the relationship in which the information was generated if confidentiality were breached?* The relationship of concern in the case of NYCAR is that of physician and patient. It seems unlikely that this relationship would be seriously jeopardized by a confidentiality breach in the NYCAR database because physicians are not involved in reporting the information. Instead, the city and/or

laboratories, not physicians, would receive blame for any data security lapses. Moreover, the high levels of voluntary provider participation in NYCAR's Bronx pilot project and the many ways in which the program involves partnerships between health officials and providers belie the image of the government dictating to physicians how they should render care.

3. *How adequate are the safeguards against privacy breaches?* Chamany and colleagues describe a range of privacy and security safeguards that serve as credible and successful bulwarks against breaches. Furthermore, public health agencies have a long track record of holding health report data secure, with few historical examples of breaches (Lee and Gostin 2009).

4. *What is the government's need for access to the information, and is there a statutory mandate, public policy, or strong public interest favoring access to the information?* These questions lie at the heart of the controversy over NYCAR. Few people question the legitimacy of infectious disease surveillance, but many challenge the government's authority to mandate reporting when the risk behavior does not directly threaten the health of others. Chamany and colleagues convincingly demonstrate that the health department can and will use these data to benefit patients (e.g., through behavioral counseling, treatment, and disease management) and to allow the agency to monitor and analyze disease and health care utilization patterns. From a population-based perspective, the state has a compelling interest in controlling the staggering human, social, and economic burdens of diabetes, particularly among the most vulnerable patients.

Overall, as long as adequate data safeguards are maintained, NYCAR's minimal intrusion into patients' privacy seems more than justified by the potential value of the registry information.

Physicians' "Privacy" Rights

Courts have been even less inclined to find that health care professionals have a legally protected interest in privacy. For example, the judiciary has declined to find a protected privacy interest in a physician's practice-pattern information that is distinct from their patients' privacy rights. Recent litigation over the sale of prescription information including physician identifiers to prescription drug information intermediaries

indicates that the courts distinguish “professional information” about physician practice patterns from personal data about patients (see *IMS Health, Inc. v. Ayotte*, 490 F. Supp. 2d 163 [D.N.H. 2007]; *IMS Health Care Corp. v. Rowe*, 532 F. Supp. 2d 153 [D. Me. 2007]). Information about the proportion of a physician’s patients who have elevated hemoglobin A1C levels would likely be classified as “professional.”

Social Harms of Diabetes Surveillance

The social controversy surrounding NYCAR often centers on privacy, particularly the patient’s right to control personal information but also the physician’s rights. Civil libertarians express concerns about possible “floodgates effects,” fearing that the policy “will cause other databases of sensitive patient information or disease registries to be seriously contemplated in the future” (Santora 2005, p. B5). Certainly, if the health department does not safeguard hemoglobin A1C information, patients could be subjected to embarrassment and stigma and possibly even blamed for their condition. Fearing unauthorized disclosure, patients could avoid seeking care (Goldman et al. 2008). Physicians also might be held responsible for a patient’s failure to follow medical advice or be penalized in pay-for-performance schemes (Goldman et al. 2008; Krent et al. 2008).

These social harms would be serious, but they do raise empirical questions: Are surveillance data wrongly disclosed to employers, family, or others outside the health system? Does diabetes surveillance deter individuals from seeking care? Are physicians inappropriately compromised by their role in the program? Chamany and colleagues’ report of the program’s experience to date gives no indication that such problems have occurred.

The Effectiveness of Diabetes Surveillance

Ultimately, to maintain the program’s legitimacy, the New York City Department of Health and Mental Hygiene should provide some assurance that NYCAR is having an impact on New Yorkers’ health. Whether the system will be effective in promoting clinical follow-up and behavioral change is an open question. Vermont’s provider-based diabetes

registry, on which NYCAR is modeled, has had positive effects on test ordering (MacLean, Littenberg, and Gagnon 2006), but many studies evaluating electronic registries, clinician reminders, facilitated relay of clinical information to physicians, and patient education strategies have not found significant improvements in glycemic control (Shojania et al. 2006). Because New Yorkers may opt out of receiving test results, it is possible that those most in need of controlling their diabetes may not be helped.

Given these empirical challenges, it is heartening to learn of the NYCAR leaders' detailed plans to conduct timely, rigorous, and comprehensive program evaluations. The range of assessments under way or planned and the level of expertise engaged to carry out these programs are extraordinary. The law generally does not require public health officials to make a very strong empirical showing to defend their exercises of the police power. Public opinion, however, may require more.

Government's Responsibility for Ensuring the Public's Health

What is the government's responsibility to help create the conditions for the public's health? New York's most vulnerable citizens are suffering from a growing burden of chronic disease caused by diet, smoking, and a sedentary lifestyle. Certainly the state must treat individual civil liberties with care, but arguably it also has a responsibility to lower morbidity and prevent premature mortality among New Yorkers. Rather than maintaining passive in the face of a growing crisis, the department has demonstrated its commitment to gathering and using data to reduce the burden of diabetes. Although it is too early to assess the program's effectiveness, its design and politically brave commitment to act boldly to serve the needs of the city's most vulnerable citizens are promising.

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