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Mandated Diabetes Registries Will Not Benefit Persons With Diabetes

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THIS PAST YEAR, THE New York City (NYC) Department of Health and Mental Hygiene (DOHMH) has embarked on a radical new approach to improving the care of patients with diabetes. Following the lead of a similar program in Vermont,¹ they have established a mandatory registry of diabetic patients and their hemoglobin A_{1c} (HbA_{1c}) values. Hemoglobin A_{1c} is a reliable measure of blood glucose control over the preceding 2 to 3 months.² Good glycemic control (ie, HbA_{1c} level <7.0%) is the goal patients and physicians work toward, since it has been convincingly demonstrated that good glycemic control can forestall and prevent diabetes-related complications.^{3,4} Diabetes registries have been used for many years to track and research the disease. However, this registry is different from those commonly used. In the NYC and Vermont registries, information is gathered about the patient without their explicit informed consent, using a passive opt-out procedure. We believe that this approach will be ineffective, will undermine the physician-patient relationship and the expectation of medical privacy, is ethi-

cally compromised, and could be dangerous; thus, we take the position against the establishment of such a registry.

The registry will work as follows: Due to a new law, passed in January 2006, laboratories will be required to forward HbA_{1c} results of all of their diabetes patients to the DOHMH. The DOHMH will create an HbA_{1c} (date and result) registry that includes clinician information and patient information (names, addresses, and dates of birth). It is anticipated that this will result in 1 to 2 million results per year. It is not clear if physicians will be recruited via informed consent or required to participate, but patients will be sent a letter that allows them to opt out of being contacted by the DOHMH, ie, "Submit a do-not-contact request" if they do *not* want to be contacted. If they do not reply, they are automatically eligible to be contacted, and in either case their information remains in the registry. Then, patients who have an HbA_{1c} level higher than 8% will receive a letter that alerts them to the high value and will be sent educational materials, while physicians will receive daily alerts of patients who have high HbA_{1c} levels and treatment recommendations.

The NYC public health agency certainly has the right and obligation to respond to the public health concerns about the increase in incidence of diabetes and

patients with poor blood glucose control. The problem is how to reconcile what is a laudable goal with means that intrude significantly on the patient-physician relationship, medical confidentiality, the expectation of privacy, and informed consent. How to balance these interests? We are not dealing with absolutes. The government does not have the absolute right to have all the information it wants, and individuals do not have the right to total privacy. The constitutional law concept of least restrictive alternatives may be helpful here.⁵ Under this doctrine, the government may limit individual liberty (privacy) in the face of a public health emergency so long as its intent in doing so is compelling and uses the least restrictive means available. We acknowledge that the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) does allow disclosure of protected health information to public health agencies⁶ and that DOHMH is legally entitled to this information. However, it is likely that this exclusion was made because public health authorities typically deal with communicable diseases, like human immunodeficiency virus and tuberculosis. If we were dealing with a communicable disease that poses a serious health threat to the public (the traditional concern of public health), the government's interest in obtaining

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identifiable information would be strong and compelling enough to outweigh the individual's interest in privacy. However, we are not dealing with a serious communicable disease here. This is the very first time that a disease registry has been developed for a noncommunicable disease like diabetes. While it is true that diabetes is a very serious disease and exacts a major toll on patients, families, and the health care system, we believe that this is a dangerous precedent, and it poses several risks.

WILL IT WORK?

Studies have shown that many patients are uninformed about what HbA_{1c} means and what their own values are. Harwell and colleagues⁷ found that only 24% of those in their rural sample who remembered having the HbA_{1c} test remembered the actual value, while Do and colleagues⁸ found that only 51% of their ophthalmology patients understood HbA_{1c}. Heisler and colleagues,⁹ in, to our knowledge, the only published study of HbA_{1c} awareness and outcomes, found no relationship between HbA_{1c} awareness and either behavioral self-management or diabetes self-efficacy. They concluded that^{9(p820)}

Greater patient knowledge alone does not correlate with improved glycemic control, and simply providing information more clearly is not enough to motivate patients. To enhance patients' diabetes care self-efficacy and self-management providers need to promote patients' capacity to define the problems they are facing, make informed decisions about their diabetes management, and set realistic goals and strategies to meet those goals.

Interestingly, Thomas Frieden, MD, MPH, Commissioner of Health for NYC and initiator of this registry, is quoted as saying, "Exhorting people to eat less and exercise more is totally ineffectual."^{10(p30)} We agree with Dr Frieden. We are not arguing that efforts to inform patients about HbA_{1c} are useless. However, to believe that simple HbA_{1c} knowledge and materials will affect outcomes is overly simplistic and not supported by data.

Similarly, there is no evidence that even simple registries have beneficial effects. In a study that looked at costs of care relative to implementation of several quality improvement (QI) activities, including diabetes registries, Gilmer et al¹¹ found that costs were not lower for patients listed in registries, unless those registries also indicated a patient's level of cardiovascular risk and were embedded in comprehensive QI activities. While cost is not a measure of quality, this study again speaks to the lack of evidence for the effectiveness of maintaining registries. Therefore, it probably will not work for the patients. Will it work for physicians? Again, not likely. The concern is "clinical inertia," ie, a physician's failure to intensify treatment when appropriate. The literature identifies many factors that contribute to clinical inertia, including physicians blaming patients for nonadherence to previous recommendations, faulty office systems, and time constraints.¹² It is highly unlikely, however, that the lack of knowledge of patient HbA_{1c} measurement is a cause of inertia because physicians already receive laboratory reports about their patients' HbA_{1c} values. This information is not new to them! Several studies have demonstrated that a delay or failure to intensify treatment does not relate to physician awareness of poor glycemic control.^{13,14} Also, a study of faxed physician alerts about adherence to antidepressant medications from real-time pharmacy data—thus, an intervention somewhat similar to that proposed by the DOHMH—found that such a system was "not successful."¹⁵

However, given the seriousness of diabetes, one might argue that this intervention is worth a try and it could not hurt. Advocates argue that this is merely a QI initiative and thus is not bound by the ethical concerns of research. Even if we accept this QI label, however, there are ethical standards that should apply. These include the need for "scientific validity," respect for participants (including privacy and confidentiality protections), and informed consent if the QI activity poses more than "minimal risk."¹⁶ We have argued that the scientific validity of this

registry is questionable, with evidence that it will not be efficacious. We also believe that its risks, though not physical, are more than minimal. There are significant risks associated with this opt-out registry.

POTENTIAL RISKS

One major risk is the threat to the physician-patient relationship. Confidentiality is at the core of the physician-patient relationship. The expectation of privacy and confidentiality enables patients to disclose the most intimate details of their lives for the purpose of receiving appropriate care and treatment. Patients believe their health data are confidential, and because of this belief, they place their trust in and work with their health care providers. Studies have repeatedly shown that the quality of the physician-patient relationship predicts health behavior change and outcomes.¹⁷⁻²⁰ Given that many patients will disregard or not understand the opt-out letter, a serious breach of trust could occur when patients get their first notification of having a high HbA_{1c} level. A qualitative study supports the belief that patients often are reluctant to consult their physicians, especially about sensitive topics, when concerned about confidentiality.²¹ The notification of high HbA_{1c} level from a governmental agency is likely to lead to a breach of trust that could cause patients to avoid medical visits and laboratory tests, thus fostering greater nonadherence and interfering with the physician's ability to work effectively with the patient.

A second risk relates to privacy breaches. The DOHMH has emphasized that there will be strict confidentiality and that registry information will only be released to patients and health care providers. Can patients have confidence in that statement? It is unlikely that they will. Despite HIPAA protections, a recent survey of 2000 Americans found that 67% were "somewhat" (31%) or "very" (36%) concerned about the privacy of their medical records.²² Also, even larger numbers of racial and ethnic minority consumers were concerned (73%), an important

issue given the higher incidence of diabetes in these groups. Stories abound in the popular press about databases that are “hacked” and private information distributed. In December 2006, University of California, Los Angeles, reported that a computer hacker retrieved more than 800 000 student, faculty, and staff names and social security numbers.²³ In the same survey, 24% of respondents were aware of such privacy breaches, and 66% of them said these incidents had increased their privacy concerns.²² While the consequences of this and similar incidents are still not known, we do know that there is a pervasive fear of privacy violations and their implications.

A third risk relates to potential discrimination. The DOHMH states that information will not be released to other agencies, and specifically mentions “drivers license, life insurance, and health insurance”^{24,25} as potential concerns. With this list they indicate that they know what the concerns are. Patients will be worried that the information might be used, if not now then in the future, in ways that could affect their financial and vocational security. Patients are very worried about workplace discrimination. In one study we found that more than 16% of insulin-using patients had hidden their diabetes at their workplace because of fear of negative consequences, especially fear of discrimination, despite the potential that they might need help owing to hypoglycemia.²⁶ Concerns about workplace discrimination led the American Diabetes Association (ADA) to develop a position statement on hypoglycemia and employment/licensure, which states that “any person with diabetes, whether insulin dependent or non-insulin dependent, should be eligible for any employment for which he/she is otherwise qualified.”^{27(p57)} The ADA took this stand because “discrimination in employment and licensure against people with diabetes still occurs.”^{27(p567)} At a recent ADA meeting, their representative noted that the ADA receives approximately 200 calls per month about discrimination in various

settings (eg, schools and workplaces).²⁸ It is noteworthy that the presidents of the ADA, the Endocrine Society, and the American Association of Clinical Endocrinologists have taken a stand against public reporting of individual physician-patient outcomes because of fears that such metrics might lead physicians to avoid helping diabetic patients with poor glycemic control.²⁹ Clearly, this concern is also warranted for the proposed opt-out registry, and this may be why the ADA has not yet taken a public stand on it.

CONCLUSIONS

What is the government’s interest in this registry? Yes, the incidence of diabetes is of epidemic proportions, it is a drain on public monies, and the agency is required to protect and promote the health of all New Yorkers. But what are the consequences of this registry for the individual patient? We have cited evidence suggesting that it will not work. There is a significant potential negative impact on the physician-patient relationship and consequent nonadherence. There is the possibility that information about the patient could be leaked, in spite of the intent to keep the information confidential. There is little respect for the individual patient, given the absence of informed consent. Finally, there is an infringement on the patient’s autonomy, a primary principle of medical ethics. Autonomy is the right of patients to make their own choices about medical care, a right that is especially strong when dealing with a noncommunicable disease. Even advocates of the registry describe it as relying on the “purely paternalistic assumption that patients and their physicians need state supervision . . . ,”^{30(p9)} assumptions that challenge the patient’s autonomy and reflect a lack of respect.

The registry will cost approximately \$2.3 million per year. We believe that this money should be used to institute other more effective and less intrusive methods of improving diabetes care and reducing barriers to good care, such as

addressing the significant inequities in the health care system, expanding recreational opportunities, regulating food marketing to children, and promoting healthier school and workplace policies. If a registry is to be attempted, it should certainly be an opt-in system for those who wish to participate. This mandatory registry strives toward a laudable goal but uses flawed means that raise serious ethical concerns. We believe that this registry should not be implemented.

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Rebuttal

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TRIEF AND ELLISON ARGUE against the use of registries for diabetes on the grounds that they are ineffective, undermine the physician-patient relationship, and are a violation of privacy. They present their sense that registries are "dangerous," but they give no data that registries are anything but positive for patients, their families, and communities. They are concerned primarily about the outreach programs associated with registries, which they wrongly characterize as "mandatory." In fact, public health registries have 2 major functions. The first is to measure the scope of an epidemic so that health care providers, payers, and the government can make rational policies about how to organize services, spend limited monies, and be held accountable for the well-being of the people they serve. They are correct that New York City is the only jurisdiction in the country (and to our knowledge, the

world) where this is being done with the aim of comprehensively understanding the impact of diabetes on all its victims, not just those associated with a particular provider, payer, employer, or academic researcher. Therefore, the health code mandates that laboratories (not patients, physicians, or other providers) submit data. This use of the registry has already been effective in providing better data for New York City policy makers, has little bearing on the physician-patient relationship, and poses no danger to individual patients.

The second major reason to maintain a registry is to support improved care to individual patients. Many of the great health care triumphs of the 20th century, such as the eradication of smallpox, the suppression of polio, and the recent announcement of first-ever reductions in the national burden of cancer, can be traced, in part, to the use of registries to offer services to

patients in need or at risk. Both the New York City A1C Registry and the Vermont Diabetes Information System offer patients plentiful opportunities to opt out of potentially unwanted interventions such as reminders, advice, free medications, and access to exercise facilities. Participation in these outreach programs is in no way mandated.

Where are the potential "dangerous" that motivate some to restrict knowledge in the name of privacy? If patients do not want their physicians to have the information and intelligence provided by a centralized data system in an otherwise dysfunctional and fragmented health care system, they are free to so tie their physician's hands. Likewise, they can easily exempt themselves from the support that their neighbors (acting collectively through government) offer. Physicians are also free to refuse or ignore the improvements offered and thus withhold them from their