Patient Privacy Is at Stake

Diabetics *from page 1*

gram. So having the assistance of public health officials to help engage them in treatment is important," he noted in an interview.

"Public health has to be viewed beyond the traditional confines of infectious disease, and just as we would expect the health department to intervene in an epidemic of an infectious disease like influenza or some other epidemic, diabetes has become this type of epidemic in New York City, and in fact is responsible for more morbidity and mortality than many infectious diseases."

"Hopefully, [this]will become a model for the rest of the country," he said.

New York City is the quintessential place for waging such a public health–led war on diabetes. According to surveys, the prevalence of self-reported diabetes shot up from 3.9% in 1993 to 9% in 2003, or to 530,000 people. And if one factors in those not yet diagnosed, the number of New Yorkers with diabetes is closer to 750,000, according to Dr. Silver.

"Most practices can't tell you who their diabetes patients are and how they're doing unless they have a very well organized electronic health record. There have been a number of studies showing that just to know who diabetes patients are and monitoring how they are doing can be a really helpful step in efforts to improve quality. This will give us an important intervention to provide support to practitioners," she added.

But some physicians don't seem to want the help. "If the test shows an undesirable result, what are doctors going to do about it?" said Dr. Jane Orient, executive director of the Association of American Physicians and Surgeons, Tucson, Ariz. "A lot of this is out of my hands; a patient may say, 'I've got better things to do. I'm not going to test my blood six times a day.' Or 'I know I need to lose weight, but I'm not going to do it.' For a lot of diabetics, it's not possible to control them because it depends so much on patient behavior."

Others think that the program is a good idea. "This should significantly help in the improvement of diabetes control, both for patients and clinicians," Dr. Allan Rosenfield, dean of the Mailman School of Public Health at Columbia University, New York, wrote in a letter to the health department. "I think this is an important step forward."

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Dr. Steven Safyer, chief medical officer of Montefiore Medical Center, New York, agreed. "The need is urgent," he said in a letter. "Montefiore wholeheartedly supports putting in the hands of the health department the information it needs to help patients and clinicians better manage this devastating chronic disease."

One issue that is foremost for many people is confidentiality, since the database is not anonymous. "I'm concerned about the government having information about their status as chronic disease patients in an electronic format, which could lead to discrimination if it gets out," Dr. Orient said. And the likelihood of the information getting inadvertently released is high, since it's not secure, she said.

Dr. Silver disagreed:

"We've been collecting confidential data on sensitive issues for 100 years without any significant breaches of confidentiality," she said. "While we recognize these can be legitimate concerns, we feel the potential benefit in light of the epidemic condition outweighs any risk to privacy."

Patients will be able to opt out of the intervention phase of the program, but not out of the data collection phase, Dr. Silver said. The opt-out opportunity will come when the patient first receives the letter about the test results; the opt-out will remain available after that.

Although concerns about privacy are important, Dr. Calman said the issue is one that is manageable. "It's not a 'domino theory' where if you give the health department access to the patient's hemoglobin A_{1c}, the entire record will become available soon."

Dr. Paul Jellinger, immediate past president of the American College of Endocrinology, said privacy issues are always a concern for diabetes patients.

New York officials "need to take great care in making certain that the individual's privacy is protected because once one loses that protection, being branded a poorly controlled or uncontrolled diabetic can have significant ramifications, insurance-wise or employment-wise," said Dr. Jellinger, who is also professor of medicine on the voluntary faculty of the University of Miami and in practice at the Center for Diabetes and Endocrine Care in Hollywood, Fla.

But as long as the privacy issues are properly managed, "the idea of tracking diabetics is a good one," he continued. Dr. Jellinger noted that a 39-state study done by the American Association of Clinical Endocrinologists found that 67% of patients had hemoglobin A_{1c} levels greater than 6.5%, the organization's recommended target for good control of diabetes. "I like the idea that someone is going to monitor patients because it brings home the finding of the study that a lot of people are not aware they aren't reaching the goal," he said.

The thing that will really make the difference, though, is the intervention piece, Dr. Jellinger said.

"Giving patients a gentle nudge or pestering them—that's not the way to do it. The nature of the intervention needs to be effective; it has to be something meaningful. It needs to be more time with a physician, funding for diabetes education, and counseling by a dietician," Dr. Jellinger said. He suggested that the city consider setting up clinics for diabetes patients to get this kind of help.

Dr. Silver said that the city is still designing the interventions, which will start in the second year of the program. (The first year will just involve collecting and analyzing the data.) As a model, the city is looking at the Vermont Diabetes Information System, "which uses a voluntary reporting system combined with automated feedback to physicians," she explained.

"It generates a quarterly report to physicians on all their patients with diabetes and classifies them on how they're doing. It also provides information to patients, which goes out under the physician's name."

Dr. Silver emphasized that the Vermont program "goes out in a way to support care to patients, and not interfere [with the physician-patient relationship]." For instance, patients overdue for an A_{1c} test get a letter from the system on behalf of their doctors. The city is also studying "more robust" disease management to support the people who are doing the worst, she said.

The city hopes to have a pilot intervention program up and running by next year, according to Dr. Silver. The pilot will probably be done in South Bronx, which has a diabetes prevalence of 18% among adults, she said. ■

Rosiglitazone Tied to Macular Edema, FDA Warns

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

The Food and Drug Administration and GlaxoSmithKline are notifying physicians of the possibility of new onset or worsening diabetic macular edema associated with drugs containing rosiglitazone.

In a "Dear Health Care Provider" letter posted on the FDA's Medwatch Web site, the drug company said it has received "very rare" postmarketing reports of the disorder. Bernadette King, director of product communications for the company, said the reports were less than 1 in 10,000 people taking the drug.

Ms. King said the connection between the drug and the disorder is unclear. "We don't know if the macular edema is due to the drug, or due to the disease process. But we wanted to make physicians aware of these symptoms." She said that GlaxoSmithKline has already added new safety information and a precaution in both prescribing and patient information leaflets.

Most patients who experienced macular edema also reported concurrent peripheral edema, the drug company noted. In some cases, the macular edema resolved or improved following discontinuation of the drug; in one case, the edema resolved after dose reduction.

The letter didn't give any advice about changing doses or avoiding rosiglitazone in patients with diabetic retinopathy, which often occurs along with macular edema, or in patients with risk factors for macular edema.

In Canada, however, GlaxoSmithKline and Health Canada have recommended discontinuing the drug and consulting an ophthalmologist in patients who report visual deterioration while on rosiglitazone.

A "Dear Health Care Provider" letter, distributed in late 2005 to Canadian physicians, warns that rosiglitazone "should be used with caution in patients with pre-existing diagnosis of macular edema or diabetic retinopathy." The letter also mentions that new safety information will soon be included in the drug's leaflet.

"We are working with our other global markets to see how we can best alert prescribers to this information," Ms. King said.

A search of PubMed identified just one published report of rosiglitazone being associated with diabetic macular edema. A 37-year-old man with type 1 diabetes, who had been taking the drug for 3 years, reported a sudden decrease in visual acuity 1 month after his dose was increased from 2 mg/day to 8 mg/day. Bilateral macular edema was present, as was peripheral edema. Three weeks after the rosiglitazone dosage was decreased to 2 mg/day, his visual acuity had improved to baseline, and the macular edema had resolved (Arch. Ophthalmol. 2005;123:1273-5).

The report's author, Dr. Michael Colucciello, an ophthalmologist in Moorestown, N.J., warned physicians prescribing rosiglitazone and other thiazolidinediones to be aware of the possibility of decreased vision associated with the development of macular edema. "Caution should be exercised when thiazolidinediones are used in those [patients] with nephropathy or congestive heart failure," he wrote. "Options for the management of rosiglitazone- or thiazolidinedione-induced macular edema with vision loss include dose reduction and discontinuation." ■

Combined Tx Best for Obesity

Group lifestyle modification should be prescribed along with weight-loss medication to obese patients trying to lose weight, said Thomas A. Wadden, Ph.D., of the University of Pennsylvania in Philadelphia, and his colleagues.

In a 1-year trial, 55 patients were randomized to sibutramine (Meridia) alone. Another 55 were treated with lifestyle modification alone, attending sessions weekly until week 18, then twice a month thereafter, as well as completing daily food logs. Also, 60 patients received both treatments, and 54 received sibutramine and eight brief therapy sessions with a primary care provider who examined their daily food logs (N. Engl. J. Med. 2005;353:2111-20).

At 1 year, subjects who received combined therapy lost a mean of 12.1 kg, significantly more than the other groups.

The sibutramine plus brief therapy group lost 7.5 kg, the lifestyle modification group lost 6.7 kg, and those taking only sibutramine lost 5.0 kg, the investigators said.

—Kevin Foley