Undiagnosed Diabetes May Affect 3.8% of Adults

BY DOUG BRUNK

The prevalence of elevated hemoglobin A_{1c} levels in adults without a history of diabetes is 3.8%, based on an analysis of data from the National Health and Nutrition Examination Survey.

This indication of a significant prevalence of undiagnosed diabetes was seen in an evaluation of data from 15,934 men and women aged 20 years and older. All had HbA_{1c} measured during their participation in NHANES 1999-2006. Elevated HbA_{1c} was defined as a level higher than 6%, and normal fasting glucose was defined as a level below 100 mg/dL.

The 3.8% overall prevalence of elevated HbA_{1c} levels seen in this population translates into 7.1 million American adults. About 90% of the individuals with high HbA_{1c} values also had fasting glucose levels that were 100 mg/dL or higher.

Elevated HbA_{1c} values were significantly associated with male sex, advanced age, nonwhite race/ethnicity, hypercholesterolemia, a high body mass index, and a low level of education. The associations remained even for study participants with elevated HbA_{1c} levels and normal fasting glucose values, according to Elizabeth Selvin, Ph.D., of the department of epidemiology at the Johns Hopkins University, Baltimore, and her associates.

Non-Hispanic blacks had higher rates of elevated HbA_{1c} values, compared with other ethnic groups; however, the explanation for this association remains unclear. "Further research should be conducted to determine whether this disparity stems from racial differences in postprandial glycemia or from racial differences in the tendency of hemoglobin to undergo glycosylation," the researchers stated (Diabetes Care 2009;32:828-33).

Dr. Selvin and her associates acknowledged the study's limitations, including its cross-sectional design and the fact that only one measurement of fasting glucose was taken. (The American Diabetes Association recommends repeating an elevated fasting glucose result.)

HbA_{1c} values have been proposed for the screening and diagnosis of diabetes. The advantages of using HbA_{1c} rather than glucose measures include the test's widespread availability and the fact that patients do not need to fast, as well as the "high repeatability of the measurement and the high specificity of elevated values," the researchers wrote.

Although it "seems reasonable to adopt a single elevated A_{1c} value as being diagnostic for diabetes … the real test of utility for A_{1c} as a screening or diagnostic test of diabetes is its association with long-term clinical outcomes in an initially nondiabetic population specifically in comparison with fasting glucose levels," they said.

The study was supported by grants from the National Institutes of Health/National Institute of Diabetes and Digestive and Kidney Diseases.

The authors disclosed no conflicts. ■

Part D 'Doughnut Hole' Affects Quarter of Diabetic Patients

BY ROBERT FINN

LONG BEACH, CALIF. — About one-quarter of diabetes patients receiving Medicare Part D drug benefits enter the coverage gap—the so-called "doughnut hole"—that comes after using $2,250 in medications during a single year.

Although some of these patients have supplemental drug coverage that pays for medications in the gap, many do not. Of diabetic patients with no supplemental coverage, 22% report forgoing medications after entering the coverage gap, and 12% report going without food or withholding rent payment to pay for their drugs, Dr. Carol M. Mangione reported at a meeting on diabetes sponsored by the Centers for Disease Control and Prevention.

"Papers in the literature have shown that cost-related nonadherence can lead to increased hospitalizations and mortality with diabetes," said Dr. Mangione of the University of California, Los Angeles. She discussed several studies she and her colleagues conducted using data from surveys of Medicare Part D beneficiaries enrolled in freestanding or managed care–based plans in eight states during 2006. Two of the studies focused on patients aged older than 65 years with evidence of diabetes, and a third included all Medicare Part D patients enrolled in those plans.

In all, 22%-29% of the patients with diabetes entered the gap, and having a coverage gap was associated with a 4%-7% reduction in total drug costs. This is explained at least partly by nonadherence. Beneficiaries who entered the gap were 17% less adherent with respect to their oral diabetes medications than were non-gap beneficiaries.

"Some patients have no coverage in the gap, others have generic-only coverage, and some people have full coverage," Dr. Mangione said.

Having generic-only gap coverage helped somewhat. Significantly fewer patients with such coverage, 17%, reported nonadherence due to cost, than the 22% with no gap coverage, but the difference in those who reported going without food or not paying rent between those with and without generic-only gap coverage was not significant, at 10% and 12%, respectively. In contrast, only 1% of the patients with full gap coverage reported nonadherence due to cost, and 1% reported going without food or rent.

Patients also engaged in "rational" approaches to contain costs, said Dr. Mangione. Fifty percent of the patients with no gap coverage and 54% of the patients with generic-only gap coverage used mail-order pharmacies because of costs. In contrast, only 9% of patients with full gap coverage used mail-order pharmacies.

In the third study, the investigators asked whether an earlier switch to generic medications could reduce expenditures enough to keep patients out of the gap. This analysis included all patients who entered the gap during 2006 (with and without diabetes) from one for-profit plan.

The investigators found that 87% of patients enrolled in freestanding Part D plans and 78% of patients enrolled in managed care Part D plans had at least one possible cost-saving therapeutic substitution.

If generics had been substituted for brand-name drugs, the average patient in a freestanding plan would have saved $377; the average patient in a managed care plan would have saved $293 in the pregap period.

Dr. Mangione disclosed no conflicts of interest related to her presentation. ■

Lower Copays May Improve Adherence Among Diabetics

BY ROBERT FINN

LONG BEACH, CALIF. — Modest reductions in medication copayments can encourage patients with diabetes to fill their prescriptions and use their drugs, according to researchers at the University of Michigan.

As part of the Michigan Healthy Communities Initiative, the university chose to test a concept called "value-based benefit design." According to this concept, cost sharing is based not just on the acquisition cost of medication, but also on the likelihood of benefit, Dr. William Herman explained at a diabetes meeting sponsored by the Centers for Disease Control and Prevention. The greater the benefit to the patient, the lower would be his or her copayment.

Use of more expensive tier 2 medications actually decreased from 30% to 15% of all claims.

DR. HERMAN

"Value-based benefit design provides a financial incentive, therefore, to targeted patients to use therapies from which they are most likely to benefit," said Dr. Herman of the university, in Ann Arbor.

To test this concept, 1,777 university employees and dependents with diabetes were identified and offered copayment reductions on antihyperglycemics, antihypertensives, antihyperlipidemics, and antidepressants.

The price of tier 1 generic medications was reduced 100%, from $7 to zero; the price of tier 2 preferred brand medications was reduced 50%, from $14 to $7; and the price of tier 3 nonpreferred brand medications was reduced 25%, from $24 to $18.

As a control group, investigators identified 3,273 patients with diabetes from the same health plan but with employers other than the University of Michigan. These patients were not offered this reduction in copayments.

Over a 2-year period, patients in the intervention group filled significantly more prescriptions in all medication groups than did those in the control group. For example, there was a 3% absolute increase in filled metformin prescriptions and a 5% absolute increase in filled statin prescriptions.

The investigators measured adherence using a metric called the medication possession ratio (MPR), defined as the amount of medication filled divided by the amount needed to fill to take as prescribed.

Investigators saw a statistically significant 7% absolute increase in MPR for ACE inhibitors and angiotensin II receptor blockers. There was also a 4% absolute increase in the MPR for statins, but that did not reach statistical significance. There were no significant changes in MPR for metformin or SSRIs.

The investigators were concerned that reductions in copayments across the board might encourage use of the more expensive tier 2 and tier 3 medications, but that did not happen. Use of tier 2 medications actually decreased from about 30% to about 15% of all claims, while the use of generic medications increased from 65% to 80%.

In all, the health system granted copayment relief for 86,655 claims, at a cost of $869,767 over 2 years. Antihypertensives represented 36% of this, antihyperglycemics represented 35%, antihyperlipidemics 19%, and antidepressants 10%.

Almost three-quarters (74%) of the copayment relief went for tier 1 medications; 21% went to tier 2 and 5% to tier 3.

"We concluded that value-based benefit design is a useful adjunct to interventions designed to increase patient initiation of and adherence to evidence-based medications," Dr. Herman said.

Dr. Herman did not report any conflicts of interest related to his presentation. Dr. Herman is the Stefan S. Fajans/GlaxoSmithKline Professor of Diabetes at the University of Michigan. ■