Economic Grand Rounds

Economic Costs of Failure to Monitor Adverse Effects of Second-Generation Antipsychotics: An Underestimated Factor

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Since 2003, the U.S. Food and Drug Administration as well as the American Diabetes Association, the American Psychiatric Association, and others have called for routine monitoring of cardiometabolic risk factors for patients of all ages prescribed second-generation antipsychotic medications. This survey of major public and private mental health treatment systems in 2010 found that adherence to such guidelines was limited. The authors describe some of the impediments to widespread monitoring of cardiometabolic risk factors among psychiatric patients taking second-generation antipsychotics and advocate for a nationwide commitment to providing the organizational and financial supports necessary to ensure systematic screening of cardiometabolic health among such patients. (Psychiatric Services 63: 202–204, 2012; doi: 10.1176/appi.ps.20120p202)

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During the past decade, an increasing body of evidence indicates that several cardiometabolic medical conditions—specifically, obesity, impaired glucose tolerance, insulin resistance or type 2 diabetes mellitus, and cardiovascular disease—are more prevalent among individuals with severe and persistent mental illnesses than among the general population (1). Second-generation antipsychotic medications are associated with disturbances in glucose and lipid homeostasis as well as with clinically significant weight gain and hypertension (2). Moreover, both first- and second-generation antipsychotics are associated with cardiac mortality (3).

In 2003 the U.S. Food and Drug Administration (FDA) required that a class warning be added to product labeling for all second-generation antipsychotics regarding the increased risk of hyperglycemia and type 2 diabetes mellitus. The warning also stated that glucose levels of patients with an established diagnosis of diabetes, risk factors for diabetes, or symptoms of hyperglycemia should be monitored (4). In 2004 the American Diabetes Association (ADA), the American Psychiatric Association (APA), and other professional associations issued a consensus statement recommending monitoring of weight, body mass index (BMI), waist circumference, and blood pressure and metabolic screening of fasting serum glucose and lipid profiles of all patients receiving second-generation antipsychotics (5).

Studies examining monitoring practices in five countries—United Kingdom, Canada, Spain, United States, and Australia—between 2000 and 2011 indicated that among patients prescribed second-generation antipsychotics, approximately 42% to 48% received routine baseline screening for cholesterol, glucose, and weight, but 70% were monitored for blood pressure and 60% for triglycerides (6). These rates did not change after the FDA warnings, the ADA-APA recommendations, or other guidelines were issued—even though the guidelines were supposed to increase monitoring activities (6). Without systematic monitoring, the only source of information about cardiometabolic health among patients taking second-generation antipsychotics is special, usually cross-sectional, studies that are based on physician surveys or analyses of existing databases—for example, Medicaid—which may significantly underestimate the incidence of cardiometabolic adverse events among those screened.

Furthermore, very few studies have attempted to provide actuarial estimates of the direct or indirect costs associated with adverse events related to the use of second-generation antipsychotics. One study conducted a cost analysis of treatment by the U.S. Department of Veterans Affairs (VA) of patients with schizophrenia who developed diabetes mellitus after three months of a stable regimen of antipsychotic therapy (7). Over a 15-month follow-up period, treatment of the patients’ diabetes accounted for an average marginal cost of $3,100. Among 4,150 children and adolescents treated with antipsychotic agents through Medicaid, patients who experienced...
incident cardiometabolic adverse events incurred 34% higher total care costs over time (about $3,500 per year) compared with the patients without such conditions (8).

Finally, Medicaid claims over a three-year period for 2,231 adults with schizophrenia who were newly prescribed second-generation antipsychotics indicated that the mean total care costs for patients with incident cardiometabolic conditions were about $1,249 higher than the costs incurred by those without such conditions. In addition, increasing numbers of patients were not being seen by a primary care physician (9). These studies indicate that the economic consequences of the adverse effects of second-generation antipsychotics are woefully underestimated.

The reintegration of psychiatry and general medicine to focus on providing optimal screening and treatment services for comorbid or incident cardiometabolic conditions to this vulnerable patient population is an important challenge for clinical psychiatry (2). Yet the multiple demands faced by health care providers reduce the likelihood that guideline-concordant recommendations will be implemented.

This study assessed the use of guideline-concordant monitoring by major public and private mental health treatment systems serving people of any age who had been prescribed antipsychotic agents. Focusing attention on this area might help promote the use of guideline-concordant monitoring by clinicians who treat patients taking second-generation antipsychotics and encourage the development of systematic procedures for widespread monitoring of the cardiometabolic health of these patients.

Interview procedures
In 2010, state mental health agencies, the VA, and clinical researchers at 14 of the nation's largest health maintenance organizations (HMOs) were contacted to ascertain their current level of implementing the ADA-APA cardiometabolic screening criteria. Qualitative interviews were conducted to assess implementation of the criteria at baseline or admission and at follow-up appointments among adult and pediatric patients who were prescribed any of the second-generation antipsychotics currently in use. [A copy of the interview protocol is available online as a data supplement to this column.]

Fifty state mental health authorities were contacted during a scheduled teleconference of the National Association of State Mental Health Program Directors. The VA was contacted through its national office of pharmacy benefits, which provided most of the information, either directly or through policy and procedure documents. HMOs were contacted by teleconference calls with representatives of the HMO Research Network (HMORN) who were knowledgeable about data being collected by HMOs about the adverse effects of antipsychotic drugs and about the resources required to implement routine monitoring and reporting of side effects.

Survey findings

State mental health agencies

Only three state mental health agencies reported that they currently implement components of cardiometabolic screening criteria at baseline, predominantly when patients are started on the antipsychotic medications in state-operated inpatient facilities. Upon discharge, patient follow-up becomes the responsibility of local treatment clinics or physicians, who are not required to routinely collect or report the follow-up results to the state mental health agency, a centralized information system, or an electronic medical or health record.

In 2010, only one state had instituted the ADA-APA cardiometabolic screening criteria at baseline and periodic follow-up, had a reporting system in place to receive the dates and results of lab tests over time for patients of all ages, and had an approved Medicaid rate for reimbursement for staff to perform the periodic screenings; however, no incidence reports had been generated. All of the state mental health agencies had notified individual providers or practitioners of the ADA-APA guidelines, but a majority did not have use of data systems or electronic or medical records that would allow the routine collection over time of new data elements about BMI and lab results or produce incidence-rate reports of positive screenings. State mental health agencies are currently struggling with fiscal and staffing cutbacks, so asking staff to take on the new duties of performing screening, adding capacity to systems for collection and reporting of new data, or developing relational databases for use by local providers might jeopardize other services deemed critical to patient care.

VA facilities

In 2007, the VA Office of the Inspector General issued a report indicating that the implementation and monitoring of the ADA-APA cardiometabolic screening criteria by the various VISNs were very inconsistent, and no national policies or procedures were in place. Two VISNs are currently pilot-testing systematic procedures for integrated screening at baseline and ongoing monitoring of cardiometabolic health. Although the VA has a nationwide electronic medical or health record that can be used to retrieve lab results for patients treated with antipsychotic medications, not all facilities have programmed it to alert psychiatric staff when the next set of fasting glucose and lipids labs are due or when a primary care physician has ordered fasting glucose and lipids labs or entered a hypertension diagnosis. Local VA hospitals and clinics are responsible for programming special alerts or summary reports to provide incidence rates for positive screening results, which increases local care costs. Because BMI and lab data may be inconsistently available over time, incidence rates have not been reported. Cost data are merged with clinical and services data only for a limited number of special analyses.

HMORN

HMORN representatives reported that there are generally no systemwide policies or procedures for implementation of cardiometabolic screening at each HMO, although individual practitioners are made aware of the ADA-APA guidelines. All HMOs have an electronic medical or health record that can be used to retrieve lab results for patients treated with antipsychotic medications, but there is no routine facility for alerting staff when the next set of fasting glucose and lipids lab
tests are due, and there is no module in the record to store height, weight, blood pressure, or waist circumference or calculate BMI. Even if the storage capacity were available, the demands for programming reports from existing data sets are already so numerous and expensive that routine reporting by each HMO of compliance with these monitoring requirements or the incidence rates for patients with positive vital or lab results would be difficult to implement. Cost data are rarely merged with clinical and services data for analysis.

Implications
Cardiovascular disease and its attendant risk factors of diabetes, obesity, and hypertension are two to three times more likely to affect adults with severe and persistent mental disorders compared with adults in the general population (1–3). Yet negative cardiometabolic consequences of use of second-generation antipsychotic medications are not inevitable. Instead, they are modifiable through a program of appropriate detection, management and treatment (2,10), and monitoring and surveillance. Such a program requires operational resources, diligent planning, and commitment.

State mental health providers generally have very limited access to integrated general medical–psychiatric clinical records or reports by primary care physicians about the medical conditions of psychiatric patients to guide clinical use of second-generation antipsychotic medications (9). In contrast, the VA and HMOs have access to both general medical and psychiatric providers and electronic medical and health records, but functional integration of general medical and mental health treatment is needed. Current fiscal cutbacks in all the treatment systems surveyed for this study severely limit the amount of time available for staff to perform cardiometabolic screening, to expand computerized databases to periodically capture and store the screening results, or to program summary reports that tabulate screening results into positive incidence rates for weight gain, change in BMI, or change in metabolic parameters, such as glucose or triglycerides levels. Current efforts to implement these administrative supports need to be continued and expanded with appropriate operational resources.

Without systematic data collection efforts or routine analyses of the incidence rates of cardiometabolic conditions and positive lab results, there is no reliable way to routinely estimate the incidence rates and costs associated with the development of cardiometabolic conditions or to adjust the care of large numbers of psychiatric patients prescribed antipsychotics. Instituting more routine monitoring, tracking, and analysis of the incidence and costs of cardiometabolic adverse events could substantially improve the health care provided to these patients and reduce the associated morbidity and mortality through better management of these conditions.

Undoubtedly, the added burden that monitoring systems place on clinical programs and individual providers must be considered in the fiscal cost-benefit equation. Yet the current economic costs of treating unchecked cardiometabolic conditions among psychiatric patients are underestimated. Without systematic detection and monitoring, there will be an even higher price to pay in substantially increased medical care costs and increased morbidity and early mortality for this patient population.

Conclusions
Instituting and further developing the administrative supports necessary to capture systematic data on cardiometabolic monitoring and to perform analyses of the incidence of cardiometabolic adverse events and their economic consequences are warranted. We believe such efforts could substantially reduce the morbidity and mortality associated with use of second-generation antipsychotics among psychiatric patients and—through better care management—improve the health care provided to these patients.

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