

GAO

Report to the Chairman, Committee on
Veterans' Affairs, House of
Representatives

April 2002

VA HEALTH CARE

Implementation of Prescribing Guideline for Atypical Antipsychotic Drugs Generally Sound



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Abbreviations

CATIE	Clinical Antipsychotic Trials of Intervention Effectiveness
GAO	United States General Accounting Office
NAMI	The National Alliance for the Mentally Ill
PORT	Patient Outcomes Research Team
TMAP	Texas Medication Algorithm Project
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



United States General Accounting Office
Washington, D.C. 20548

April 29, 2002

The Honorable Christopher H. Smith
Chairman
Committee on Veterans' Affairs
House of Representatives

Dear Mr. Chairman:

The Department of Veterans Affairs (VA) provides health care services to veterans who have been diagnosed with psychosis—primarily schizophrenia, a disorder that can substantially limit their ability to care for themselves, secure employment, and maintain relationships. These veterans also have a high risk of premature death, including suicide. For many of them, effective treatment, especially antipsychotic drug therapy, has reduced the severity of their illnesses and increased their ability to function in society. In fiscal year 2000, VA spent \$1.1 billion to provide psychiatric care for almost 200,000 veterans with psychosis. Of this amount, \$123 million was spent on antipsychotic drugs. In fiscal year 2001, the amount for antipsychotic drugs jumped 29 percent to \$158 million—or 7 percent of VA's total drug costs.

Since 1989, new antipsychotic drugs have been approved in the United States. These new “atypical” drugs are effective and much less likely to cause involuntary body and facial movements, tremors, and contractions associated with the traditional drugs for schizophrenics. However, atypical antipsychotic drugs are expensive, and the cost differences among them can vary significantly. All atypical antipsychotic drugs are on VA's national formulary,¹ except the newest, which is available through nonformulary approval processes. To ensure that veterans with mental disorders receive the most appropriate yet cost-effective drug, VA issued a guideline in July 2001 for prescribing atypical antipsychotic drugs for newly diagnosed patients or for patients not responding favorably to their current medication. According to VA officials, the guideline was needed to better manage the cost associated with atypical antipsychotic drugs and the effect of the drug companies' marketing of these drugs to physicians. However,

¹Formularies are lists of medications that health care organizations encourage or require their providers to use when they write prescriptions for patients. Physicians are generally free to prescribe any drug on VA's formulary.

the guideline emphasizes that clinical factors rather than cost ultimately determine physicians' prescribing decisions.

You asked us to review whether this guideline may result in restricted access to the more costly atypical antipsychotic drugs and, in turn, adversely affect the quality of care for veterans. To address these concerns, you asked us to determine (1) if VA's clinical guideline for prescribing atypical antipsychotic drugs is consistent with medical community practices for managing serious mental illnesses and (2) whether implementation of the guideline is consistent with its intent to ensure that prescribing decisions are ultimately based on physicians' clinical judgment.

To conduct our work, we interviewed or obtained documents from VA officials responsible for developing the guideline, representatives from federal agencies responsible for mental health issues, professional medical organizations, mental health advocacy groups, private mental health care providers, private pharmacy benefits management companies, and state Medicaid or mental health departments in California, Florida, Georgia, Massachusetts, and Texas. Also, we obtained and reviewed four clinical guidelines for antipsychotic drug use that are widely accepted by public and private health systems. Further, we contacted pharmacists in each of VA's 22 Veterans Integrated Service Networks (VISN) and visited or contacted 14 facilities in 8 of them to determine whether the guideline was being used.² We also surveyed VA psychiatrists about how the guideline affected their prescribing practices. In addition, we reviewed VA antipsychotic drug utilization data for each VISN and its medical facilities. (For more information on our methodology, see appendix I.) We conducted our work from September 2001 through April 2002 in accordance with generally accepted government auditing standards.

Results in Brief

VA's guideline for prescribing atypical antipsychotic drugs is sound and consistent with published clinical practice guidelines commonly used by public and private health care systems. VA's prescribing guideline, like other practice guidelines, recommends that physicians use their best clinical judgment, based on clinical circumstances and patients' needs,

²In January 2002, VA announced the merger of networks 13 and 14 into a single organization known as network 23. We report on these two networks separately because at the time of our survey they were operating as individual networks.

when choosing among the atypical drugs. VA's prescribing guideline also includes a cost factor, stating that if no clinical reason exists to prescribe one atypical antipsychotic drug over another, physicians should begin treatment with one of the less expensive atypical drugs on VA's formulary. Almost all of the public and private sector psychiatric experts we interviewed agree that VA's use of cost as a factor to prioritize atypical antipsychotic drugs is reasonable, appropriate, and consistent with providing quality and cost-effective medical care.

Most VISNs and facilities use VA's prescribing guideline and have implemented it in various ways, including supplementing its distribution with group discussions. However, facilities within five VISNs have additional policies and procedures for prescribing atypical antipsychotic drugs. While these procedures help manage pharmaceutical cost, they also have the potential to result in more weight given to cost than clinical judgment which is not consistent with the prescribing guideline. For example, our survey indicates that the vast majority of VA psychiatrists—91 percent—report they are able to prescribe the atypical antipsychotic drugs that are best for their patients, but 9 percent report not feeling free to do so. These psychiatrists are concentrated in VISNs where one or more facilities have additional procedures.

We are recommending that VA monitor implementation of the guideline by VISNs and facilities to ensure that facilities' policies and procedures conform to the intent of the guideline by not restricting physicians from prescribing atypical antipsychotic drugs on VA's formulary. In commenting on a draft of this report, VA concurred with our recommendation.

Background

Over the past several decades, the introduction of two types of drugs—traditional and atypical antipsychotic drugs—for treating schizophrenia, and in some cases, bipolar disorder, have enabled physicians to better manage their patients' mental illnesses, resulting in a better quality of life for many veterans. Because schizophrenia severely impairs thinking, language, perception, mood, and behavior, schizophrenics often withdraw from society and retreat into a world of delusions, hallucinations, and fantasies. With drug treatment, approximately 60 to 70 percent of schizophrenics experience either complete remission or only mild symptoms of the disease; the remaining 30 to 40 percent continue to experience psychotic symptoms. Most patients with schizophrenia are maintained on antipsychotic drugs throughout their lives since symptoms return in over 70 percent of stable patients who stop taking their drugs.

Bipolar disorder, also known as manic-depressive illness, is characterized by extreme and unpredictable mood swings, ranging from high excitement or euphoria—where the patient is energetic and confident—to despair or deep depression, where the patient may feel sad, helpless, apathetic, angry, or suicidal. As with schizophrenia, bipolar disorder can impair a patient’s ability to function. To control bipolar episodes, physicians often prescribe mood-stabilizing drugs, but in cases where these drugs are not effective, physicians may prescribe antipsychotic drugs on a short-term basis. The introduction of traditional and atypical antipsychotic drugs has also helped facilitate a shift in treatment settings for adults with severe mental illness, both in the VA system and in the general medical community, from expensive inpatient care in hospitals to less costly outpatient care in community-based treatment facilities.

Traditional antipsychotic drugs were first introduced in the 1950s. While these drugs are effective in treating psychosis, they can often cause severe side effects, such as involuntary body and facial movements, tremors, and contractions. For example, after 5 years of taking traditional drugs, patients have a 32 percent chance of developing a sometimes irreversible movement disorder, and after 25 years, they have a 68 percent chance. The Food and Drug Administration first approved atypical antipsychotic drugs in 1989, and five are currently available for use. (See table 1.) They are considered as effective as traditional drugs in treating psychosis, but they are much less likely to cause the severe involuntary movements associated with the traditional drugs. While atypical drugs also have side effects—some of which can be serious—most occur with less severity than the side effects associated with traditional drugs. The side effects vary among the atypical drugs and include sedation, sexual dysfunction, cardiac problems, and sudden drops in blood pressure. Additional side effects are weight gain and elevated cholesterol that could lead to heart disease and diabetes.³ Various studies and psychiatrists we interviewed have concluded that because the side effects are reduced, patients are more likely to stay on their drug therapy and have fewer relapses of psychosis when taking atypical antipsychotic drugs.

³Clozapine can also cause a life-threatening blood disorder. The manufacturer’s prescribing information recommends prescribing it only to patients who fail therapy on at least two other antipsychotic medications and states that patients taking it are required to have weekly blood tests for the first 6 months and every other week thereafter.

Table 1: Atypical Antipsychotic Drugs

Drug name (brand name)	Year approved
Clozapine (Clozaril)	1989
Risperidone (Risperdal)	1993
Olanzapine (Zyprexa)	1996
Quetiapine (Seroquel)	1997
Ziprasidone (Geodon)	2001

Source: Food and Drug Administration.

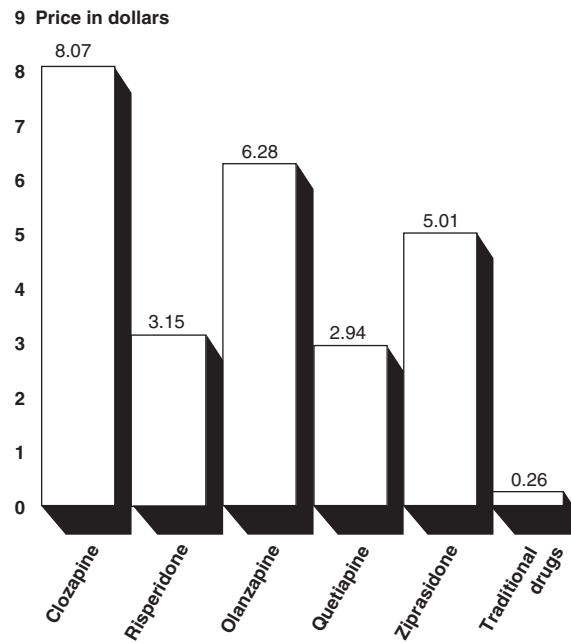
Over the last few years, the number of prescriptions for atypical antipsychotic drugs has increased dramatically in VA. In fiscal year 1999, 62 percent of all antipsychotic drug prescriptions were for atypical drugs; by fiscal year 2001, more than 80 percent were for atypical drugs.

Antipsychotic drugs—both traditional and atypical—are VA’s third most expensive class of drugs.⁴ In fiscal year 2001, VA filled more than 1.5 million 30-day antipsychotic prescriptions for more than 176,000 patients at a cost of \$158 million, accounting for 7 percent of its total pharmacy budget.⁵ Overall, atypical antipsychotic drugs are more costly than traditional antipsychotic drugs. For VA, the average daily cost of atypical drugs is about 17 times higher than the average daily cost of traditional drugs. However, the average daily cost among atypical drugs varies. In fiscal year 2001, clozapine cost about \$8 a day per patient, while quetiapine cost less than \$3 a day. (See fig. 1.)

⁴The most expensive class of drugs in VA is antilipemic (blood cholesterol lowering drugs) and the second most expensive class is antidepressants.

⁵To count prescriptions, VA standardized them in 30-day units. For example, a prescription that covered drugs for 90 days would be counted as three 30-day prescriptions.

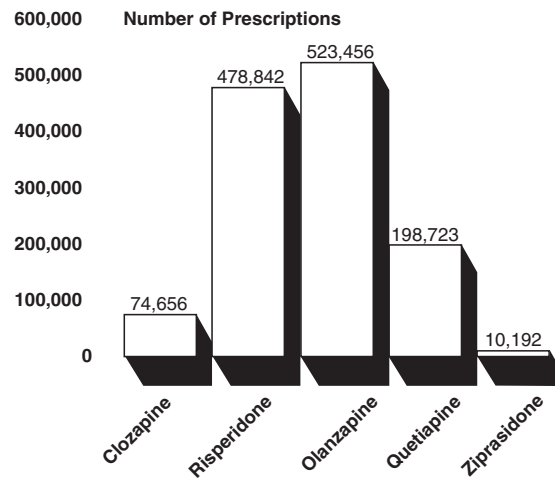
Figure 1: Average Daily Cost per Patient for Antipsychotic Drugs, Fiscal Year 2001



Source: VA Pharmacy Benefits Management.

In 2001, 30-day prescriptions were written for all five atypical antipsychotic drugs, with olanzapine and risperidone prescribed most often to veterans. (See fig. 2.)

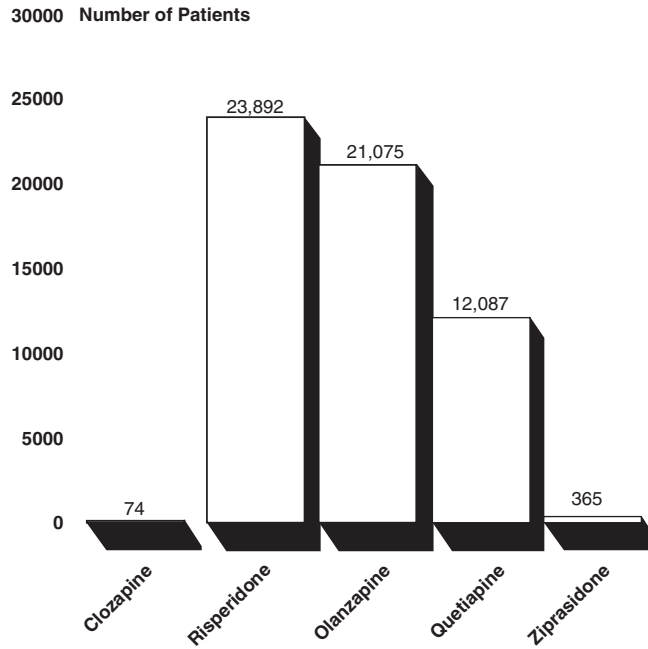
Figure 2: Number of VA 30-day Prescriptions for the Five Atypical Drugs in 2001



Source: VA Pharmacy Benefits Management.

In 2001, most patients began treatment on risperidone, olanzapine, or quetiapine. (See fig. 3.)

Figure 3: Number of Patients Beginning Treatment on Each Atypical Antipsychotic Drug in 2001



Note: Patients were considered to have begun treatment on an atypical antipsychotic drug if they had not received a prescription for that drug since October 1998.

Source: VA Pharmacy Benefits Management.

Choosing which atypical antipsychotic drug to prescribe for patients can be difficult. Experts have concluded that the scientific evidence is not sufficient to favor any one of the atypical drugs.⁶ Each has been proven effective in clinical trials, but effectiveness appears to depend on the particular patient. A panel of academic researchers reviewed available scientific evidence in 1999 and concluded that the three most widely used atypicals—risperidone, quetiapine, and olanzapine—are comparable in efficacy, safety, and patient tolerability.⁷ The Cochrane Collaboration, an organization that systematically reviews randomized clinical medical trials, reviewed the evidence comparing two of the atypical drugs, risperidone and olanzapine.⁸ It concluded that little evidence exists to suggest choosing one drug over the other. Three internal VA panels in the last 3 years agreed that none of the three most widely used atypical drugs could be judged better than the others.

Studies conducted by drug manufacturers have been inconclusive in comparing atypical drugs. The studies often were too short in duration to draw conclusions about the drugs' long-term effects. In addition, many studies excluded substance abusers and those who were violent and uncooperative—a significant problem in determining effectiveness because many schizophrenics meet these criteria.

The National Institute of Mental Health has recently funded a \$42 million study that will compare the five atypical antipsychotic drugs available today to each other and to a traditional antipsychotic drug. This study, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE), will examine 1,800 schizophrenic patients, including patients with substance abuse and other medical problems. Four VA facilities are among the 53 medical facilities participating in CATIE. One of the objectives of the CATIE study is to identify specific patient profiles for each drug in order to guide physicians in selecting the best atypical drug for their patients. The study's results are expected to be available by 2006.

⁶Evidence suggests that clozapine is more effective—particularly for schizophrenics who do not respond to traditional drugs. However, clozapine is associated with a risk of life-threatening blood disorder. Ziprasidone was not included in most reviews of scientific evidence because the FDA had not yet approved it when they were completed.

⁷Miller et al. 1999. The Texas Medication Algorithm Project (TMAP) Schizophrenia Algorithms. *Journal of Clinical Psychiatry*. Vol. 60, no. 10, pp. 649-657.

⁸Gilbody et al. 2002. Risperidone versus other atypical antipsychotic medication for schizophrenia (Cochrane Review). *The Cochrane Library*, issue 1.

VA physicians are generally free to prescribe any drug on the formulary. VISNs and facilities can place restrictions on some drugs that require close monitoring to ensure appropriate use, but these restrictions cannot be based solely on cost. Usually psychiatrists are the practitioners that prescribe atypical drugs for psychotic patients, although some facilities allow other types of physicians to write refill prescriptions or to prescribe these drugs for nonpsychotic patients with dementia or diseases such as Parkinson's and Alzheimer's. VA policy requires that all drugs on the formulary be available at each VA pharmacy. VA further requires its 22 VISNs to establish approval processes for prescribers to obtain drugs not listed on their formularies. In addition, to provide flexibility in meeting local patient needs, VA allows VISNs to add drugs to network formularies to supplement the national formulary.⁹ Pharmacy and Therapeutics committees in each VISN, consisting of physicians, pharmacists, and other health care professionals are usually responsible for selecting these additional drugs.

According to VA's Pharmacy Benefits Management Strategic Health Care Group's Medical Advisory Panel officials,¹⁰ VA chose not to limit the number of atypical drugs available on the formulary because such limits potentially restrict physicians' ability to prescribe the most appropriate drug for their patients. Four of the five atypical antipsychotic drugs—olanzapine, risperidone, quetiapine, and clozapine—are listed on VA's national formulary. The fifth, ziprasidone, which the Food and Drug Administration approved in 2001, is not listed on the national formulary, but is available through local nonformulary approval processes. VA generally does not place drugs on the formulary until they have been on the market at least 1 year.

To educate physicians about the increasing importance and cost of atypical antipsychotics and to provide uniform information in the face of increasing pharmaceutical industry marketing to VA psychiatrists, VA issued the guideline for prescribing atypical antipsychotics to supplement VA's overall treatment guidelines for managing patients with psychosis. In addition to discussing appropriate drug therapy, the overall treatment guidelines include sections on the evaluation, diagnosis, and social rehabilitation of

⁹U.S. General Accounting Office, *VA Drug Formulary: Better Oversight Is Required, but Veterans Are Getting Needed Drugs*, [GAO-01-183](#) (Washington, D.C.: Jan. 29, 2001), p. 3.

¹⁰The panel consists of 11 VA and 1 Department of Defense practicing physicians, from multiple specialties, including psychiatry.

patients with psychoses. The overall treatment guidelines currently recommend that psychiatrists treating patients with psychosis either prescribe moderate doses of traditional antipsychotic drugs or prescribe atypical antipsychotic drugs. VA is currently revising the guidelines for managing patients with psychosis, including recommending atypical drugs before traditional drugs for these patients.

While the National Alliance for the Mentally Ill (NAMI) and the National Mental Health Association stated that physicians could consider cost when prescribing antipsychotic drugs, each has voiced concerns that some local VA officials might use the guideline more stringently to cut costs—either by restricting physician access to more expensive atypical drugs for new patients or by switching stable patients to the less expensive atypical drugs. Officials from the American Psychiatric Association and the National Association of VA Physicians and Dentists have expressed similar concerns.

VA Prescribing Guideline for Atypical Antipsychotic Drugs Is Sound

VA's guideline for prescribing atypical antipsychotic drugs is consistent with published clinical practice guidelines commonly used by public and private health care systems. Like most other practice guidelines, VA's guideline recommends that physicians use their best medical judgment, based on clinical circumstances and patients' needs, when choosing among the atypical drugs. VA's prescribing guideline also recommends that physicians use cost as a factor in deciding which atypical antipsychotic to prescribe when no clinical reason exists to choose one drug over another—a practice most of the public and private sector psychiatric experts we interviewed agreed is reasonable, appropriate, and consistent with providing quality cost-effective medical care.

VA's Prescribing Guideline Is Consistent with Commonly Used Clinical Guidelines

VA's prescribing guideline, which supplements its broader psychosis treatment guidelines, is similar to the four clinical guidelines most widely accepted by public and private health systems—the Texas Medication Algorithm Project (TMAP); The Expert Consensus Guideline Series: Treatment of Schizophrenia; The Schizophrenia Patient Outcomes Research Team (PORT); and the American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. (See table 2.) Like VA's guideline, each suggests that therapy be based on physicians' assessment of patient needs and is not intended to interfere with clinical judgment.

Table 2: Guidelines for Antipsychotic Drug Use When Clinical Judgment Does Not Indicate a Particular Drug

Guideline	Patient(s)	First line of drug treatment	Effective date
VA Guideline for Atypical Antipsychotic Use	<ul style="list-style-type: none"> • New psychosis patients • Patients having problems with traditional drugs 	Prescribe risperidone or quetiapine--the two less expensive atypical antipsychotics--if no patient-specific issue suggests another drug. Next, prescribe olanzapine.	2001
Texas Medication Algorithm Project	<ul style="list-style-type: none"> • New schizophrenia patients • Patients who have failed treatment with traditional drugs 	Prescribe olanzapine, quetiapine, and risperidone, in any order.	1999
The Expert Consensus Guideline Series: Treatment of Schizophrenia	<ul style="list-style-type: none"> • Schizophrenia patients 	Prescribe olanzapine, quetiapine, and risperidone, in any order.	1999
The Schizophrenia Patient Outcomes Research Team	<ul style="list-style-type: none"> • Schizophrenia patients 	Prescribe antipsychotic medications other than clozapine.	1998
American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia	<ul style="list-style-type: none"> • Schizophrenia patients 	Prescribe traditional antipsychotic medications or risperidone; other atypical antipsychotics may also be appropriate.	1997

Source: GAO review of private and public sector clinical guidelines.

VA's prescribing guideline aims to assist physicians in selecting from its national formulary the most cost-effective atypical antipsychotic drugs for their patients without interfering with their clinical judgment. VA's prescribing guideline for atypical antipsychotic drugs is reprinted in appendix II. For information on how the guideline was developed, see appendix III. Specifically, VA's guideline states that

- the guideline is to be used only for new patients or for patients not responding favorably to traditional medications,
- therapy is ultimately based on physicians' assessment of patient needs and the guidelines are not intended to interfere with clinical judgment, and
- because no consensus exists in scientific literature to support that one atypical antipsychotic drug is superior to another, physicians should begin treatment with one of the less expensive atypical antipsychotic drugs on VA's national formulary if there are no patient specific reasons to prescribe one drug over another.

For cases where no clinical reason exists to prescribe one atypical drug over another, VA's guideline includes an algorithm showing the suggested treatment order for prescribing the four atypical antipsychotic drugs on VA's formulary. The guideline's algorithm recommends that physicians first prescribe risperidone or quetiapine, in either order, to patients with a first episode of psychosis or patients with chronic psychosis who have relapsed. The algorithm lists olanzapine as the next drug that physicians should try, and clozapine as the last drug. The guideline's treatment order reflects VA's prices of the drugs—risperidone and quetiapine are significantly less expensive than olanzapine. Clozapine is not only the most expensive drug, but it is seldom used because of its risk of causing a life-threatening blood disorder. Because ziprasidone has only recently received Food and Drug Administration approval, it is not included on VA's national formulary, and it is not included in the algorithm. However, the guideline states that it may be considered for patients with intolerance or a poor response to the other atypical drugs.

In the preface to its algorithm VA's prescribing guideline discusses the importance of cost-effective high quality care. According to officials responsible for developing the TMAP and PORT guidelines, their guidelines did not include cost because they were meant to be broad and apply to a wide variety of organizations. Nevertheless, some health care systems that use these guidelines also consider cost. For example, the Texas Department of Mental Health and Mental Retardation has a supplemental policy that recommends using the less expensive atypical antipsychotics before other atypicals when appropriate. It asks its physicians to choose the least expensive of the three drugs recommended by TMAP for new patients when their clinical judgment does not indicate the use of one atypical drug over another. The Massachusetts Medicaid behavioral health program has a similar approach. It follows the PORT guidelines, and in 1999 issued a memorandum with additional guidance and a cost-effectiveness study to its psychiatrists pointing out that risperidone was less expensive and just as effective as olanzapine for new patients. The memorandum and study were issued to highlight the importance of using cost as a factor in deciding which drug to prescribe.

Experts Acknowledge That Using Cost as a Factor Is Reasonable and Appropriate

Because available scientific evidence and expert opinion suggest that all atypical drugs are appropriate treatment for psychosis, incorporating cost into VA's prescribing guideline is reasonable, appropriate, and consistent with providing cost-effective health care. The Institute of Medicine¹¹ has concluded that when no marginal therapeutic benefit is expected from more expensive drugs, guideline developers may reasonably recommend less expensive drugs.¹²

Almost all of the psychiatric experts we interviewed—including those in charge of TMAP and PORT—said that asking physicians to consider drug cost as a factor when prescribing atypical antipsychotic drugs is reasonable, appropriate, and consistent with providing cost-effective quality medical care to patients. Psychiatrists from the National Institute of Mental Health, which funds antipsychotic drug research, also agreed that it was appropriate for psychiatrists to consider less expensive atypical drugs. The co-chairman of VA's Committee on Care of Severely Chronically Mentally Ill Veterans¹³ stated that the VA guideline represents quality medical care because no scientific evidence exists to recommend one drug over another and because physicians make the final prescribing decisions based on their medical judgment.

State mental health officials from California, Georgia, and Florida—states that do not use cost to rank medications—recognize the importance of considering costs when choosing among them. For example, the medical director of Georgia's Division of Mental Health, Mental Retardation and Substance Abuse stated that in the face of recent state budget cuts of 2.5 to 5 percent, the state may consider adopting guidelines similar to VA's that include cost as a factor. While neither Florida nor California officials suggest that physicians should use atypical drugs in any particular order,

¹¹The Institute of Medicine is an associated organization of the National Academy of Sciences. Its mission is to advance and disseminate scientific knowledge to improve human health.

¹²Committee on Clinical Practice Guidelines, Division of Health Care Services, Institute of Medicine, *Guidelines for Clinical Practice: From Development to Use* (Washington, D.C.: National Academy Press, 1992), pp. 145-146.

¹³This committee was established in 1996 by statute to assess VA's ability to effectively treat severely mentally ill veterans. Annually, the committee issues a report containing data on the care provided to seriously mentally ill veterans.

state health officials agreed that cost could be a factor in prescribing these drugs.

Guideline Generally Implemented as Intended, but Some Facility Policies Conflict with It by Overemphasizing Cost

Most VISNs use VA's prescribing guideline. The policies and procedures for implementing the guideline vary as some facilities have added a requirement for prescribing atypical antipsychotic drugs. This additional requirement calls for pharmacists or senior psychiatrists to review prescriptions for one of the atypical antipsychotic drugs and to confer with the prescribing psychiatrist on the appropriateness of the prescription. The vast majority of psychiatrists who responded to our survey reported they are free to prescribe the atypical antipsychotic drugs consistent with their best clinical judgment. However, we identified some facility policies and procedures that conflict with the intent of VA's prescribing guideline, which asks physicians to consider cost only if there is no clear clinical choice for one drug over another.

Most VISNs Use VA's Prescribing Guideline

We contacted the formulary leaders at each VISN and had further discussions with psychiatrists and pharmacists in selected VISNs to determine if the prescribing guideline was being used. Eighteen of the formulary leaders reported that their VISNs use VA's prescribing guideline. Two other formulary leaders reported that their VISNs were using different guidelines—one VISN modified the guideline to include ziprasidone in the algorithm and the other VISN developed a guideline that does not suggest a treatment order or use cost as a determining factor under any circumstances. The remaining two formulary leaders stated that their VISNs do not use guidelines for prescribing atypical antipsychotic drugs.

In implementing VA's prescribing guideline, some VISNs simply distributed the guideline to facilities for use, and some facilities combined guideline distribution with group discussions on the costs of atypical antipsychotic drugs. Officials from one VISN distributed the guideline to its facilities along with pocket-sized cards for each psychiatrist showing the prices and doses for every antipsychotic drug. Despite the fact that most VISNs use the guideline, not all psychiatrists told us they were aware of it. Specifically, in our survey we asked psychiatrists if they had seen or been briefed on the prescribing guideline. Of those responding, 66 percent reported that they had, 11 percent reported that they were unsure, and 23 percent reported that they had not.

In addition, formulary leaders, psychiatrists, and pharmacists in five VISNs told us that several facilities require physicians to follow additional policies and procedures for prescribing atypical antipsychotic drugs. (See table 3.) Some of them also told us that the need to manage cost is the primary reason for implementing additional prescribing procedures for atypical antipsychotic drugs at their facilities.

Table 3: Guidelines and Procedures Used by VISNs for Prescribing Atypical Antipsychotic Drugs

VISN (location)	Use VA's prescribing guideline	Use VISN specific guidelines	Use other or additional procedures at one or more facilities
1 (Boston)	✓		
2 (Albany)			✓
3 (Bronx)	✓		✓
4 (Pittsburgh)			
5 (Baltimore)	✓		
6 (Durham)	✓		
7 (Atlanta)	✓		
8 (Bay Pines)	✓		✓
9 (Nashville)	✓		
10 (Cincinnati)	✓		
11 (Ann Arbor)	✓		
12 (Chicago)	✓		
13 (Minneapolis)	✓		
14 (Omaha)	✓		
15 (Kansas City)	✓		
16 (Jackson)		✓ ^a	
17 (Dallas)	✓		
18 (Phoenix)		✓ ^b	✓
19 (Denver)	✓		
20 (Portland)	✓		
21 (San Francisco)	✓		
22 (Long Beach)	✓		✓

^aVISN guidelines do not distinguish among the atypical antipsychotic drugs, except for clozapine.

^bVISN modified VA's prescribing guideline to include ziprasidone in the algorithm.

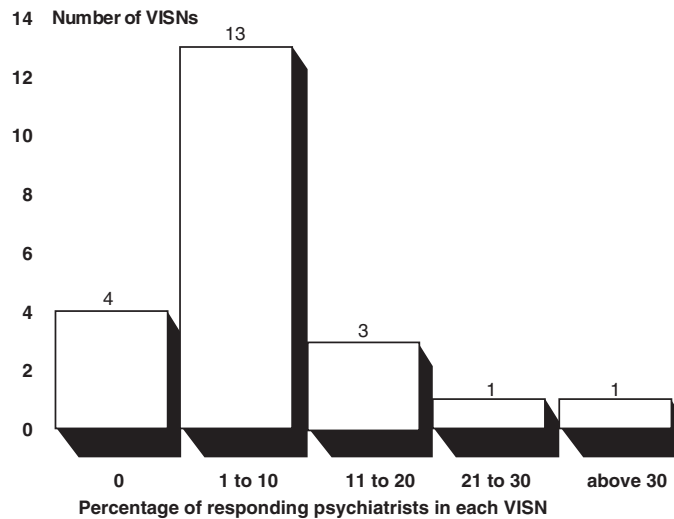
Source: GAO Interviews with VA Officials.

Intent of Prescribing Guideline Generally Followed, but Cost-Containment Procedures Could Conflict with It

Since VA issued the prescribing guideline, it has reiterated its policy that the guideline not interfere with physicians' clinical judgment. Most psychiatrists we interviewed agree that the intent of VA's policy is being followed. The vast majority of the psychiatrists who responded to our survey—91 percent—indicated that they have been able to prescribe the atypical antipsychotic drugs that are best for their patients.

Nevertheless, a number of psychiatrists—9 percent of those who responded to our survey—reported they did not feel free to prescribe the antipsychotic drug of their choice. These psychiatrists are generally concentrated in a few VISNs. For example, in VISN 22, 33 percent of responding psychiatrists reported that they did not feel free to prescribe the atypical antipsychotic drug that they believed was best for some of their patients, and in VISN 18, the rate was 22 percent. Three other VISNs had rates of more than 10 percent. Conversely, four VISNs had no psychiatrists who felt they could not exercise their clinical judgment in prescribing these drugs. (See fig. 4.) (See appendix IV for additional survey information for each VISN.)

Figure 4: Percentage of Responding Psychiatrists in Each VISN Who Reported That They Did Not Feel Free To Prescribe the Atypical Antipsychotic Drug of Their Choice



Source: GAO survey of VA psychiatrists.

Our survey showed that several VISNs with one or more facilities that have additional prescribing requirements for atypical antipsychotic drugs also had relatively high percentages of psychiatrists who reported they were not always free to prescribe the most appropriate atypical drug. For example, VISN 22—which had the highest percentage of physicians who reported they were not free to prescribe the drug of their choice—has four facilities that require pharmacists to review prescriptions for olanzapine.

Psychiatrists' concerns may be related to cost control procedures at some facilities that have limited access to atypical antipsychotic drugs—practices which conflict with the prescribing guideline. For example, the Miami VA Medical Center no longer requires physicians to first select among the traditional antipsychotic drugs before prescribing any atypical drugs, but it does require that psychiatrists prescribe risperidone and quetiapine before prescribing olanzapine. The chief pharmacist at the center told us that this policy was implemented to control cost. This policy conflicts with the prescribing guideline, because cost has greater weight than physicians' clinical judgment. Furthermore, VA psychiatrists at other facilities reported that their managers exerted pressure to prescribe the lower cost atypical drugs. One psychiatrist stated that facility administrators pushed for prescribing less expensive atypical drugs, even though the psychiatrist's evaluation of some patients indicated that these drugs would be less effective than the more costly atypical drug olanzapine. In addition, 31 of the 876 psychiatrists that we included in our survey analysis reported that they believed prescribing high-cost atypical antipsychotic drugs could affect their performance ratings.

About 22 percent of the psychiatrists who responded to our survey reported that they are required to follow additional VISN or facility procedures for prescribing olanzapine. While these procedures help the facility manage pharmaceutical use, they have the potential to overemphasize cost-containment if they put pressure on physicians to prescribe the less expensive drugs. Examples where this could happen are discussed below.

-
- In VA's Greater Los Angeles Healthcare System, Los Angeles, California, part of VISN 22, all psychiatrists provide written justifications for olanzapine prescriptions, which are reviewed by pharmacists or senior psychiatrists. For routine requests—such as those for VA patients who are already stable on olanzapine or patients who did not respond favorably to other atypical antipsychotic drugs—the pharmacist fills the prescription. For nonroutine requests—such as those for new patients who have not previously taken atypical antipsychotic drugs—the pharmacist forwards the request and written justification to a senior psychiatrist who reviews them and may discuss recommended treatment options with the prescribing physician.¹⁴ In the 4 months after the prescribing guideline was implemented, 11 percent of all olanzapine requests were denied as part of its cost containment procedures. However, according to a member of the facility's Pharmacy and Therapeutics Committee, the facility may eliminate these cost-control measures entirely as a result of a January 2002 notice from the Under Secretary for Health that discusses VA policy when treating patients with psychosis.
 - The VA San Diego Healthcare System, San Diego, California, part of VISN 22, also regulates olanzapine use, but it does not require prescribing physicians to provide written justification. Instead, pharmacists trained in the use of drugs to treat mental illness are required to review all prescriptions for olanzapine and discuss treatment options with prescribing physicians, recommending the lower cost risperidone or quetiapine first for patients who have not tried them. For cases where the psychiatrist does not agree with the pharmacist's recommendation, the case is forwarded to the chief psychiatrist or the facility's pharmacy and therapeutics committee for final approval or denial.
 - The Carl T. Hayden VA Medical Center, Phoenix, Arizona, part of VISN 18, requires clinical pharmacists to review prescriptions for olanzapine for patients who have not tried less expensive atypical drugs and to discuss with the prescribing physician the clinical reason for choosing one drug over another. The pharmacist may recommend risperidone and quetiapine; however, if the psychiatrist disagrees with the recommendation, the prescription is referred to the chief psychiatrist

¹⁴The Greater Los Angeles Healthcare System implemented this policy for nonroutine requests when it implemented VA's prescribing guideline.

for review. If the matter is still not resolved, another psychiatrist will review the case. If the original prescribing psychiatrist still disagrees with the recommendation, the matter is referred to and decided by the facility's chief of medicine. In addition, psychiatrists have been asked to examine their cases of veterans who are currently on olanzapine to determine if these veterans could be switched to a less expensive atypical drug. If this practice results in switching, using cost to justify changing the drugs of patients would not be consistent with the intent of VA's prescribing guideline.

In July 2001, the Secretary of Veterans Affairs testified before the Senate Committee on Veterans' Affairs that physicians are free to prescribe any medication on the VA formulary, consistent with VA policy that formulary drugs cannot be restricted based solely on cost.¹⁵ At the same time, the Deputy Under Secretary for Health asked VISN directors to ensure that none of their facilities' policies or procedures restrict physician access to the atypical drugs. Further, the Assistant Deputy Under Secretary for Health stated that the clinical judgment of each veteran's individual psychiatrist should determine which atypical antipsychotic drug to prescribe. Also, the conference report on VA's fiscal year 2002 appropriations directed the Secretary of Veterans Affairs to communicate to physicians existing VA policy that physicians are to use their best clinical judgment when choosing atypical antipsychotic drugs.¹⁶ In response, VA's Under Secretary for Health issued a notice on January 16, 2002, reiterating the conference report's message.

Conclusions

Atypical antipsychotic drugs are essential to providing quality mental health care; however, they vary significantly in cost. To educate physicians on the effectiveness of atypical antipsychotic drugs and their costs, VA implemented a prescribing guideline, based on scientific evidence and expert consensus. This guideline is consistent with widely accepted guidelines in other public and private health care systems. If properly implemented, it would result in both quality and cost-effective mental health care, and providing it to VA physicians is appropriate.

¹⁵Veterans Health Administration Directive 2001-044, sec. 3f, July 24, 2001.

¹⁶H.R. Rep. No. 107-272, at 56 (2001).

In managing pharmacy costs, one of the major challenges facing managers at VA facilities is the high cost of atypical antipsychotic drugs. Consultations between prescribing physicians, senior psychiatrists, and pharmacists on the appropriate use of atypical drugs—including asking physicians to explain their drug choices and to consider using an alternative less expensive atypical drug—could be effective ways to help manage the cost of drugs as well as to educate physicians on the clinical aspects of each drug. Such consultations provide vital information for consideration by physicians when choosing the most appropriate drugs for their patients with psychosis, and nationally the vast majority of psychiatrists report that their clinical judgment, not cost factors, determines which atypical drugs they prescribe. However, procedures at a few facilities have limited or could restrict access to certain atypical antipsychotic drugs on VA's national formulary because of cost considerations. Such procedures are contrary to VA's prescribing guideline for atypical antipsychotic drugs.

Recommendation for Executive Action

To ensure that the atypical antipsychotic prescribing guideline is implemented consistent with VA intent, we recommend that the Secretary of Veterans Affairs direct the Under Secretary for Health to monitor implementation of the guideline by VISNs and facilities. In doing so, the Secretary should ensure that facility policies and procedures conform to the intent of the guideline and allow physicians to prescribe the most appropriate atypical antipsychotic drugs for their patients.

Agency Comments and Our Evaluation

VA provided written comments on a draft of this report, which are reprinted in appendix V. VA concurred with our recommendation that the prescribing guideline be implemented consistently throughout the VA health care system. VA also stated that the Veterans Health Administration (VHA) will continue to coordinate with VISN clinical managers to ensure the intent of the guideline is understood by all involved and appropriately implemented systemwide. VA also stated that VHA would continue to routinely monitor prescribing patterns of atypical antipsychotic drugs through its national drug utilization database in order to identify and address any outliers in drug usage that might become apparent. However, we found that while VHA was periodically reviewing atypical antipsychotic drug utilization mainly at the national and VISN levels, it had no formal plan to systematically review the data to monitor compliance with the guideline at the facility level. Thus, we caution VA from relying too heavily on

national and VISN data. Doing so might not detect individual facility policies that could restrict access to the more costly atypical antipsychotic drugs.

We are sending copies of this report to the Secretary of Veterans Affairs; appropriate congressional committees; and other interested parties. We will also make copies available to others upon request. If you have any questions on matters discussed in this report, please contact me at (202) 512-7101. Another contact and key contributors are listed in appendix VI.

Sincerely yours,

A handwritten signature in black ink that reads "Cynthia Bascetta". The signature is written in a cursive, flowing style.

Cynthia A. Bascetta
Director, Health Care—Veterans’
Health and Benefits Issues

Scope and Methodology

To determine how the Department of Veterans Affairs (VA) developed its prescribing guideline, and what it expected to accomplish with it, we interviewed and obtained relevant documentation from the officials who developed the guideline, including officials from VA's Pharmacy Benefits Management Strategic Healthcare Group, its Medical Advisory Panel, the Mental Health Strategic Healthcare Group, and the Office of Quality and Performance. We also spoke with VA's Assistant Deputy Under Secretary for Health, obtained records of internal VA communication concerning the guideline, and reviewed testimony from senior VA officials.

To determine the clinical guidelines for atypical antipsychotic drugs that are commonly used and accepted by the general medical community, and to compare VA's prescribing guideline on atypical antipsychotic drugs to these guidelines, we interviewed officials and obtained documentation from several organizations, including the

- Institute of Medicine,
- Department of Health and Human Services' National Institute of Mental Health, Substance Abuse and Mental Health Services Administration, and Centers for Medicare and Medicaid Services, and
- National Association of State Mental Health Program Directors.

We compared VA's guideline with the four most commonly used guidelines—The Texas Medication Algorithm Project; The Expert Consensus Guideline Series: Treatment of Schizophrenia; The Schizophrenia Patient Outcomes Research Team; and the American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia—and interviewed officials from the Texas Medication Algorithm Project and the Schizophrenia Patient Outcomes Research Team. We also interviewed experts on the use of atypical antipsychotic drugs.

To determine commonly used policies for prescribing atypical antipsychotic drugs, we interviewed officials from private mental health care delivery systems, pharmacy benefits management companies, and the Department of Defense. For geographical dispersion, we selected and obtained information from five states' Medicaid or mental health departments in California, Florida, Georgia, Massachusetts, and Texas. To determine the nature and extent of the guideline's implementation in VA's Veterans Integrated Service Networks (VISN), we interviewed each VISN

formulary leader. Formulary leaders are the liaisons between VISN management and VA officials responsible for managing the national formulary.

We visited or contacted the following 14 VA facilities chosen in part because of their procedures for prescribing atypical antipsychotic drugs:

VISN 1 – Edith Nourse Rogers Memorial Veterans Hospital, Bedford, Massachusetts; and Providence VA Medical Center, Providence, Rhode Island.

VISN 2 - Canandaigua VA Medical Center, Canandaigua, New York; Samuel S. Stratton VA Medical Center, Albany, New York; and VA Healthcare Network Upstate New York at Syracuse, Syracuse, New York.

VISN 7 - Atlanta VA Medical Center, Decatur, Georgia.

VISN 8 – James A. Haley Veterans Hospital, Tampa, Florida; and Miami VA Medical Center, Miami, Florida.

VISN 11 – VA Ann Arbor Healthcare System, Ann Arbor, Michigan; and John D. Dingell VA Medical Center, Detroit, Michigan.

VISN 18 – Carl T. Hayden VA Medical Center, Phoenix, Arizona.

VISN 20 – VA Puget Sound Health Care System, Seattle, Washington.

VISN 22 - VA Greater Los Angeles Healthcare System, Los Angeles, California; and VA San Diego Healthcare System, San Diego, California.

To determine local policies and practices on atypical antipsychotic drug usage at the 14 facilities that we visited or contacted, including how the guideline was implemented, we interviewed pharmacy leadership, mental health leadership, or individual psychiatrists and we collected relevant documents.

To assess the effect of these guidelines and other atypical antipsychotic drug policies and procedures on psychiatrists throughout the VA system, we surveyed VA psychiatrists. Using electronic mail, we distributed an internet-based survey to VA's entire November 2001 reported population of 1,723 psychiatrists. Of these psychiatrists, 903 or approximately 52 percent

responded. Response rates by VISN ranged from 33 percent to nearly 72 percent. However, for analysis purposes, we included only the 876 psychiatrists who prescribed an atypical antipsychotic drug in the 12 months prior to the mailing of our survey in November 2001.

We took steps to determine if psychiatrists who reported they lacked freedom to prescribe the more costly atypical antipsychotic drugs were more likely to respond to our survey than were psychiatrists who reported they had such freedom. For each VISN, we compared the response rate from its psychiatrists with their responses to the survey question “When, in your clinical judgment, a more costly atypical antipsychotic drug is warranted, do you feel free to prescribe the more costly drug?” We found no indication that psychiatrists’ answers to the question were related to their VISN’s response rate. In addition, we conducted telephone interviews on a random sample of 29 nonrespondents. We asked them the same question—if they felt free to prescribe the more costly atypical antipsychotic drugs. Their responses to this question were similar to those from psychiatrists who responded to the survey. Based on these results, we have no reason to believe that psychiatrists who felt restricted in their prescribing practices were over-represented in our survey results and therefore, our results are generalizable to the entire population.

To help identify problems with guideline implementation, we interviewed officials or reviewed documents from two large mental health advocacy groups—the National Alliance for the Mentally Ill and the National Mental Health Association. We also interviewed officials from the National Association of VA Physicians and Dentists and VA’s Committee on the Care of Severely Chronically Mentally Ill Veterans. In addition, we reviewed correspondence from the American Psychiatric Association regarding VA’s prescribing guideline.

VA Prescribing Guideline for Atypical Antipsychotic Use

Department of Veterans Affairs Pharmacy Benefits Management, Medical Advisory Panel,
and Mental Health Strategic Healthcare Group
Guideline for Atypical Antipsychotic Use

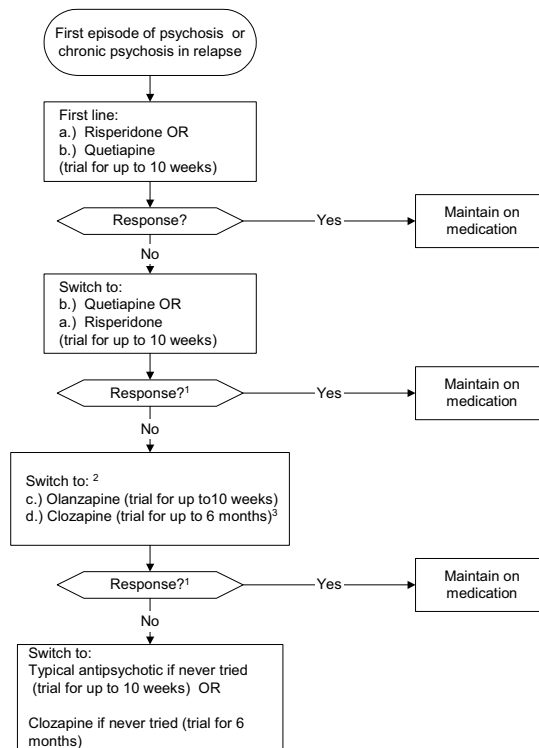
Selection of therapy for individual patients is ultimately based on physicians' assessment of clinical circumstances and patient needs. At the same time, prudent policy requires appropriate husbanding of resources to VA to meet the needs of all our veteran patients. These guidelines are not intended to interfere with clinical judgment. Rather, they are intended to assist practitioners in providing cost effective, consistent, high quality care. The following recommendations are dynamic and will be revised, as new clinical data become available.

Consensus Goals:

- 1) Prioritize the use of atypical antipsychotic medication for new antipsychotic medication starts and for patients not responding to or having problematic side effects on typical antipsychotic medication.
- 2) Though differences in the clinical effectiveness and pharmaco-economic profile of the atypicals have been suggested by some studies, there is no consensus in the literature to support one being globally superior to another; therefore, once the physician determines there are no patient specific issues, begin therapy with an effective, less expensive agent. At the present time, this would lead to the preference of quetiapine and risperidone over olanzapine.
- 3) Utilize current local approaches of clinical assessment to determine response to medication and whether medication changes are indicated. Such assessments should include the presence and severity of positive and negative symptoms, AIMS score, tremor, weight and GAF.
- 4) For patients currently on olanzapine, consider a trial of risperidone or quetiapine in the face of relapse or significant/ problematic weight gain or other side effects.

Suggested dosage range for treating psychosis*	
risperidone	2 -6 mg
quetiapine	250 - 800mg
olanzapine	5 -20mg
clozapine	200 - 600mg

*may need to adjust for age, co-morbidities, and other factors



¹ Consider a trial of haloperidol or fluphenazine decanoate for patients non-adherent to therapy.

² Ziprasidone may be considered in patients with significant intolerance or poor response while taking another atypical antipsychotic. The place of ziprasidone in the guideline will become better defined as more safety and efficacy data become available. **See ziprasidone non-formulary criteria for use at www.vapbm.org**

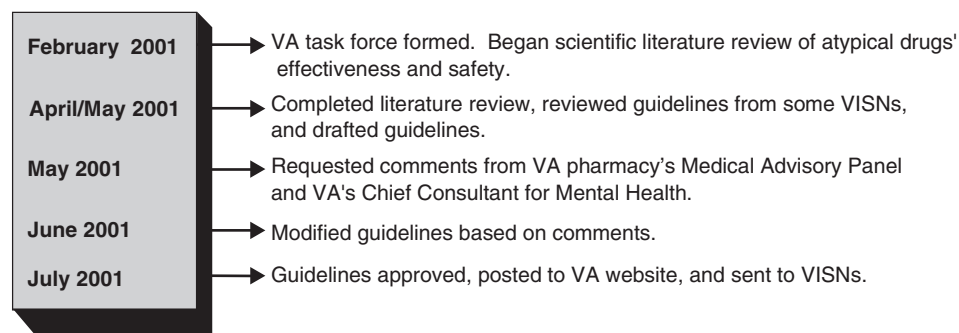
³ Patient eligible for clozapine trial - suboptimal response or adverse events to 2 or more antipsychotics

Source: VA.

Process VA Used to Develop Its Prescribing Guideline for Atypical Antipsychotic Drugs

In February 2001, VA's Pharmacy Benefits Management Strategic Healthcare Group's Medical Advisory Panel formed a task force of two VA psychiatrists and two VA pharmacists to develop a guideline for prescribing atypical antipsychotic drugs. According to the panel, such a guideline would help physicians prescribe them appropriately and cost effectively. The task members were selected based on their mental health clinical expertise and diverse skills. See figure 5 for the timeline and process of the task force.

Figure 5: Timeline of Task Force



The task force reviewed scientific literature on the effectiveness, including side effects, of the atypical antipsychotic drugs and examined existing VISN guidance on prescribing these drugs.¹⁷ Based on these reviews, the task force drafted the guideline for prescribing atypical drugs. The draft guideline was then reviewed and modified by the Medical Advisory Panel and VA mental health officials. VISN pharmacy leaders and the Medical Advisory Panel approved the guideline. In July 2001, VA Pharmacy Benefits Management posted the guideline to its web site and sent it to the VISNs. In the past, VA Pharmacy Benefits Management has used the same process to develop several similar guidelines for prescribing other classes of drugs. The Institute of Medicine, in a recent report on VA's national formulary, commended VA for these previous pharmacy-specific guidelines, stating that they were based on current scientific and clinical research data and its

¹⁷The task force reviewed literature on olanzapine, risperidone, quetiapine, and ziprasidone. Clozapine was excluded from the review because of its life-threatening side effects.

Appendix III
Process VA Used to Develop Its Prescribing
Guideline for Atypical Antipsychotic Drugs

recommendations were consistent with recommendations of other leading medical organizations.¹⁸

VA's commissioning of a task force of health care professionals to review medical literature and develop a guideline based on that literature is an accepted practice. For example, the Department of Defense and the American Psychiatric Association developed clinical practice guidelines this way. Supplementing the literature with input from medical experts, as VA did, is also consistent with accepted medical practice. An Institute of Medicine report on developing clinical guidelines strongly urges that processes for developing and revising guidelines be firmly based on scientific evidence and expert clinical judgment.¹⁹ Most other published guidelines for atypical antipsychotic drugs were developed using some combination of evidence from scientific literature and experts' judgments.

¹⁸VA Pharmacy Formulary Analysis Committee, Division of Health Care Services, Institute of Medicine, *Description and Analysis of the VA National Formulary* (Washington, D.C.: National Academy Press, 2000), pp. 194-195.

¹⁹Institute of Medicine, *Guidelines for Clinical Practice: From Development to Use*, p. 18.

Results from GAO Survey of VA Psychiatrists

VISN (location)	Percentage answering "Yes"				Percentage answering "No"
	Question #1	Question #2 olanzapine	Question #2 quetiapine	Question #2 risperidone	
1 (Boston)	51	5	5	2	0
2 (Albany)	73	71	9	4	9
3 (Bronx)	72	54	2	2	10
4 (Pittsburgh)	73	8	8	4	4
5 (Baltimore)	68	14	0	0	5
6 (Durham)	69	7	7	3	4
7 (Atlanta)	76	15	10	6	4
8 (Bay Pines)	74	12	5	5	13
9 (Nashville)	66	23	12	9	18
10 (Cincinnati)	76	12	6	6	6
11 (Ann Arbor)	79	31	13	7	8
12 (Chicago)	78	8	0	0	0
13 (Minneapolis)	61	0	0	0	0
14 (Omaha)	47	6	0	0	0
15 (Kansas City)	58	15	16	3	13
16 (Jackson)	72	15	7	7	8
17 (Dallas)	70	20	17	17	3
18 (Phoenix)	49	41	50	36	22
19 (Denver)	68	0	3	0	4
20 (Portland)	64	9	17	8	10
21 (San Francisco)	44	10	8	7	7
22 (Long Beach)	65	76	9	4	33
VA total	66	22	10	6	9

Questions

1. Prior to receiving GAO's email notifying you of this survey, had you been briefed on or provided a copy of these guidelines?
2. When prescribing _____, do psychiatrists at your facility have to follow procedures not required for most other drugs, such as obtaining approval, providing justification, or some other procedure?

-
3. When, in your clinical judgment, a more costly atypical antipsychotic drug is warranted, do you feel free to prescribe the more costly drug?

Comments from the Department of Veterans Affairs



THE SECRETARY OF VETERANS AFFAIRS

WASHINGTON

April 17, 2002

Ms. Cynthia A. Bascetta
Director, Health Care Team
U. S. General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Ms. Bascetta:

This is in response to the General Accounting Office's (GAO) draft report, **VETERANS HEALTH CARE: Implementation of Prescribing Guidelines for Atypical Antipsychotic Drugs Generally Sound** (GAO-02-579). Your conclusion that the Department of Veterans Affairs (VA) guideline for prescribing atypical antipsychotic drugs is sound and consistent with published clinical practice guidelines that public and private health care systems commonly use confirms our own confidence in the guidance.

VA concurs with your recommendation that the atypical antipsychotic prescribing guideline should be implemented consistently throughout the Department's health care system. The Veterans Health Administration (VHA) will distribute copies of the GAO report to all VISNs for review and, if needed, they will take follow-up action, particularly in instances where the application of additional prescription approval procedures might lead to perceptions of restricted prescribing freedom. GAO is also aware that VHA routinely monitors atypical antipsychotic prescribing patterns across the system through our national drug utilization database in order to identify and address any outliers in drug usage that might become apparent.

VHA program offices will continue to coordinate with the VISN clinical managers to ensure the intent of the prescribing guideline for atypical antipsychotic drugs is understood by all involved clinicians and appropriately implemented systemwide.

Thank you for the opportunity to comment on your draft report.

Sincerely yours,

Handwritten signature of Anthony J. Principi in cursive script.
Anthony J. Principi

GAO Contact and Staff Acknowledgments

GAO Contact

Michael T. Blair Jr., (404) 679-1944

**Staff
Acknowledgments**

In addition to the contact named above, Cherie M. Starck, Beverly J. Brooks-Hall, William R. Simerl, Michael Tropauer, Karen M. Sloan, Deborah L. Edwards, and Susan Lawes made key contributions to this report.

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