



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Atypical Antipsychotic Medications and Diabetes Screening and Management

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Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) evaluated the effectiveness of diabetes screening, monitoring, and treatment for mental health patients between the ages of 35 and 50 who received atypical antipsychotic medications at Veterans Health Administration (VHA) facilities. Atypical antipsychotic medications have a mode of action that leads to fewer side effects compared with older antipsychotic medications, but they place patients at increased risk for the development of Type 2 diabetes.

We evaluated whether clinicians screened mental health patients between the ages of 35 and 50 who received atypical antipsychotic medications for early diabetes detection. We also determined how effectively clinicians monitored and managed diabetes for mental health patients in this age group receiving these medications. We chose this population because patients receiving atypical antipsychotic medications, especially patients below the age of 40, may represent an under recognized group at risk for the development of Type 2 diabetes. We conducted the evaluations during 48 Combined Assessment Program reviews from January 1–December 31, 2006.

To improve patient outcomes we recommended that:

- VHA clinicians implement and document weight reduction strategies for obese and overweight patients between the ages of 35 and 50 who are prescribed atypical antipsychotic medications.
- VHA clinicians improve treatment and documentation of interventions for elevated fasting blood glucose levels for patients between the ages of 35 and 50 who are prescribed atypical antipsychotic medications.
- VHA clinicians implement interventions to maintain blood pressures less than 140/90 for younger patients without diabetes who are prescribed atypical antipsychotic medications.
- VHA clinicians strive to achieve target blood glucose levels for younger patients with diabetes who are prescribed atypical antipsychotic medications that are reasonable for their patients, are consistent with VA/DoD clinical practice guidelines, and can be safely achieved.



DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Under Secretary for Health, Department of Veterans Affairs (10)

SUBJECT: Healthcare Inspection – Atypical Antipsychotic Medications and Diabetes Screening and Management

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) evaluated the effectiveness of diabetes screening, monitoring, and treatment for mental health patients who received atypical antipsychotic medications¹ at Veterans Health Administration (VHA) facilities. Although we recognize that literature supports that VHA provides high-quality diabetic care in its general patient population,^{2, 3} we evaluated whether clinicians screened mental health patients between the ages of 35 and 50 years who received atypical antipsychotic medications for early diabetes detection. We also determined how effectively clinicians monitored and managed diabetes for mental health patients in this age group receiving these medications.

Background

The World Health Organization (WHO) estimates that more than 180 million people worldwide have diabetes and projects that this number is likely to double by 2030. WHO also estimates that in 2005 1.1 million people died from diabetes. Almost half of diabetes related deaths occurred in people under the age of 70 years, and WHO projects that deaths due to diabetes will increase by more than 50 percent in the next 10 years without urgent action.⁴ Because of its chronic nature and the severity of its complications, diabetes is a costly disease for the affected individuals, the individuals' families, and for healthcare systems.

¹ Atypical antipsychotic medications have a mode of action that leads to fewer side effects compared with older antipsychotic medications known as "typical antipsychotics."

² Asch, Steven M., M.D., MPH; McGlynn, Elizabeth A., PhD; Hogan, Mary M., PhD et al. *Comparison of Quality of Care for Patients in the Veterans Health Administration and patients in a National Sample*. *Annals of Internal Medicine*, Vol. 141:12 938-945

³ *Diabetes Management for Today's Pharmacist*, December 2004, p.8

⁴ <http://www.who.int/mediacentre/factsheets/fs312/en/>

As early as the mid 1960's, associations between diabetes and conventional antipsychotic medications were reported; but the risk of diabetes increased with the use of atypical antipsychotic drugs. These newer drugs, with lower extrapyramidal symptoms (EPS),⁵ are increasingly replacing conventional therapies. Patients receiving atypical antipsychotic medications, especially patients below the age of 40,⁶ may represent an under recognized group of those at high risk for the development of Type 2 diabetes.⁷ The mechanism(s) responsible for the increased risk are unclear but may relate to increased weight gain, elevated leptin levels, (a weight related hormone), and the development of insulin resistance.

A study published in 2002⁸ reported that when the effects of age were controlled, patients who received atypical antipsychotic medications were 9 percent more likely to have diabetes than those who received conventional antipsychotic medications and that the prevalence of diabetes was significantly increased.

The American Diabetes Association (ADA), the American Psychiatric Association, and the North American Association for the Study of Obesity, in conjunction with the Consensus Development Conference on antipsychotic drugs, obesity, and diabetes held in 2004,⁹ proposed a monitoring protocol. Recommendations included regular monitoring as well as the following baseline screening measures:

- Personal and family history of obesity, diabetes, dyslipidemia,¹⁰ hypertension (HTN), or cardiovascular disease (CVD).
- Weight and height for body mass index (BMI) calculation.
- Waist circumference.
- Blood pressure.
- Fasting blood glucose (FBG).
- Fasting lipid profile.¹¹

⁵ A neurological side effect of antipsychotic medication. EPS can occur within the first few days or weeks of treatment, or it can appear after months and years of antipsychotic medication use. EPS can cause a variety of symptoms, such as involuntary movements, tremors and rigidity, body restlessness, muscle contractions, and changes in breathing and heart rate.

⁶ Diabetes Care 26:1597-1605, 2003.

⁷ In the past, Type 2 diabetes was also known as adult onset diabetes, type II or non-insulin dependent diabetes. Type 2 diabetes occurs when insulin that the body produces is less efficient at moving sugar out of the bloodstream as opposed to Type 1, where the body does not produce insulin.

⁸ Sernyak, Michael J., M.D., Leslie, Douglas L., M.D., Alarcon, Renato D., et al *Association of Diabetes Mellitus With Use of Atypical Neuroleptics in the Treatment of Schizophrenia*. Am J Psychiatry 159:561-566 April 2002.

⁹ Diabetes Care 2004; 27:596-601

¹⁰ An abnormal amount of lipids (cholesterol) in the blood.

¹¹ A lipid panel or lipid profile commonly includes laboratory tests for blood levels of triglycerides, total cholesterol, high density lipoprotein (HDL-C or good cholesterol), and low density lipoprotein (LDL-C or bad cholesterol). The panel of tests is used to evaluate coronary heart disease risk.

VA/DoD (Department of Defense) clinical practice guidelines (CPG) for the management of diabetes suggest that:

- Hemoglobin A1c (HbA1c) levels, which is an indicator of blood glucose levels over time, should be less than 9 percent for all patients to avoid symptoms of hyperglycemia. The ADA and VA/DoD CPG both recommend that levels should be below 7 percent for optimum outcomes for patients who have little or no microvascular complications,¹² and who have a life expectancy of greater than 15 years.
- Cholesterol levels, specifically low-density lipoprotein cholesterol (LDL-C), should be less than 120 milligrams per deciliter (mg/dL).
- Blood pressures should be maintained at less than, or equal to, 140/90 millimeters of mercury (mmHg).

VHA CPGs for the screening of patients at risk for the development of diabetes suggest that clinicians obtain FBG levels every 1 to 3 years.

Scope and Methodology

We conducted the evaluations during 48 Combined Assessment Program reviews from January 1–December 31, 2006. The reviews included analyses of national, Veterans Integrated Service Network (VISN), and facility endocrine performance measure scores for blood pressure, LDL-C, and HbA1c. We reviewed the medical records of mental health patients aged 35 to 50 years that were prescribed atypical antipsychotic medications and diagnosed with diabetes for evidence of blood pressure, LDL-C, and HbA1c management and control. In addition, we evaluated diabetes screening for mental health patients aged 35 to 50 years at risk for development of the disease because they were prescribed atypical antipsychotic medications.

We conducted interviews with clinical staff at each facility. Included are the results of 589 medical record reviews conducted at the 48 facilities. We selected the patients from lists provided to us from each of the facilities. The patients had active prescriptions for one or more atypical antipsychotic medications,¹³ and their pharmacy profiles reflected that the patients were prescribed the medications for longer than 90 days. All patients included in the review results were between the ages of 35 and 50 years (average age 45.5 years). We reviewed medical records to determine that:

- Clinicians appropriately screened patients taking atypical antipsychotic medications that were not diagnosed with diabetes in the following areas:

¹² Injury or disease involving any small blood vessels in the body. For instance, the smallest vessels in the kidney, called glomeruli, may become abnormally thick but weak, and therefore bleed, leak protein, and slow the flow of blood through the kidney.

¹³ Atypical antipsychotic medications include: aripiprazole, clozapine, olanzapine, quetiapine, risperidone, and ziprasidone.

- Weight measurement
 - FBG performed every 1–3 years
 - Risk factors
 - Blood pressure
- Clinicians monitored and managed patients taking atypical antipsychotic medications diagnosed with diabetes in the following areas:
 - Weight measurement
 - LDL-C
 - HbA1c
 - Risk factors
 - Blood pressure

Additionally, we reviewed medical records for documentation of weight monitoring and management.

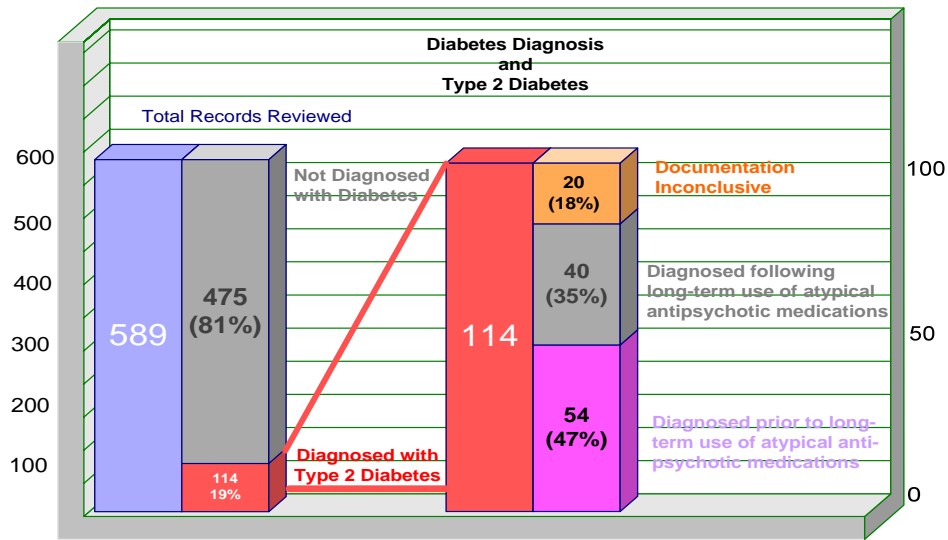
We conducted the inspection in accordance with the *Quality Standards for Inspections* published by the President’s Council on Integrity and Efficiency.

Findings

The medical records indicated that 456 (77 percent) of the 589 mental health patients reviewed received their primary care in traditional primary care clinics, and 103 (18 percent) of the patients received their primary care in a mental health setting. We were unable to determine where the remaining 30 (5 percent) of the patients received primary care.

As depicted in the chart on the following page, 589 records were reviewed. We determined that 475 (81 percent) of the patients were not diagnosed with diabetes and the remaining 114 (19 percent) patients were diagnosed with Type 2 diabetes.

Of the patients diagnosed with diabetes, 54 (47 percent) were diagnosed prior to long-term use of atypical antipsychotic medications, and 40 (35 percent) were diagnosed following long-term use. Documentation was inconclusive for the remaining 20 (18 percent) of the patients. This information is displayed on the following page.



1. Weight Monitoring and Management

BMI is a direct calculation of body fat based on height and weight, regardless of gender.¹⁴ As a tool for body fat assessment, BMI has some limitations. For instance, BMI can overestimate body fat in the very muscular; and underestimate body fat in those who have lost muscle mass, such as the elderly. Despite these limitations, BMI is the recommended assessment of body fat in the clinical setting because it provides a more accurate measurement of total body fat compared with the assessment of body weight alone.¹⁵

Overweight and obese patients are at increased risk for several diseases, such as HTN and dyslipidemia; but are at particular risk for CVD and diabetes.¹⁶ Overweight and obesity are a major cause of preventable deaths in the United States.

We reviewed medical records for the frequency of weight measurements for all 589 patients. We also reviewed the patients' current weights and determined if clinicians instituted weight reduction interventions when appropriate.

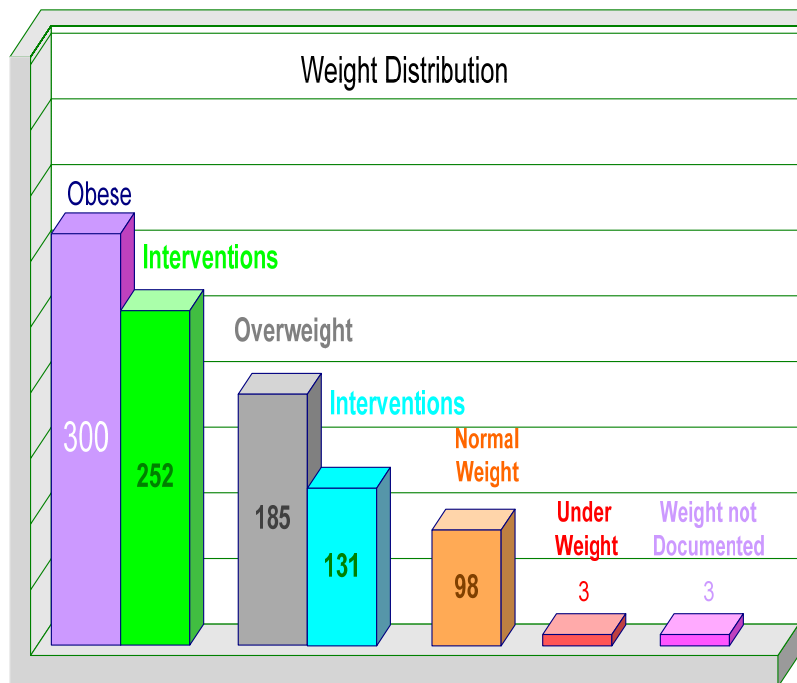
¹⁴ Though BMI reference charts are widely available, BMI is a mathematical calculation – Weight (lbs) ÷ [Height (in)]² X 703. For example, the BMI for a person who is 5 feet 7 inches tall, weighing 150 lbs is calculated as follows: 150 ÷ 67² (67 inches = 5 feet 7 inches) X 703 = 23.4 (rounded to 23). This person is of normal weight. In comparison, a person of the same height, but weighing 200 lbs has a calculated BMI of 31 (200 ÷ 67² X 703) and is considered obese.

¹⁵ http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf

¹⁶ http://www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf

We used National Heart Blood and Lung Institute (NHBLI) criteria in determining weight classification (Appendix A).

Of the 589 patients in our sample, 485 (82 percent) were classified as obese or overweight, 98 had normal weight, 3 were underweight, and we could find no documentation of weight for 3 patients. Interventions were documented in 383 (79 percent) of the records for patients who were obese or overweight. However, we could not find documentation to support that clinicians appropriately addressed weight management, such as exercise or medical nutrition therapy, for 102 (21 percent) of the patients as displayed below.



Conclusion

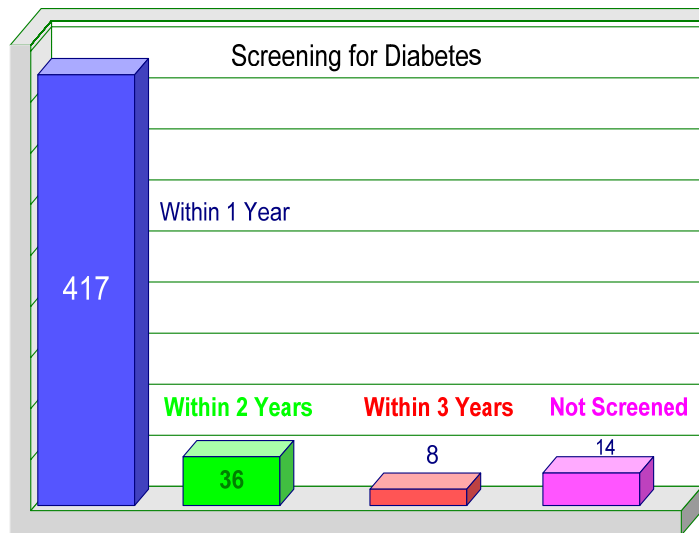
While clinicians generally monitored patients' weights, they needed to improve implementation of weight reduction and management strategies or document that strategies were discussed. Among the patients in our sample that were classified as obese or overweight, 21 percent had no documentation of diet or exercise counseling, nutrition consults, or other interventions.

2. Patients Without Diabetes

Diabetes Screening

We sought to ascertain how well VHA clinicians followed the VA/DoD CPG that recommends obtaining FBG levels every 1 to 3 years for the purpose of early disease detection.

As displayed below, our review showed that 475 patients in our sample population were not diagnosed with diabetes; and thus, were candidates for screening. Of those, 417 (88 percent) patients received FBG screening during the past year. Of the remaining patients, 36 (8 percent) received screening within the past 2 years and 8 (2 percent) received screening within the past 3 years. We found that 14 (3 percent) of the patients¹⁷ did not receive screening within the past 3 years as displayed below.



Eighty (17 percent) of the patients screened within the past 3 years had FBG levels above the normal limits for their facilities' reference range. However, clinicians documented interventions such as close monitoring, diet and exercise advice, or consults to nutrition or weight loss experts for only 39 (49 percent) of the patients.

Blood Pressure

Persistent HTN is one of the risk factors for stroke, heart attack, heart failure, and aneurysm;¹⁸ and is a leading cause of chronic kidney failure. A decrease of 6 mmHg in

¹⁷ Percentage total does not equal 100 due to decimal rounding.

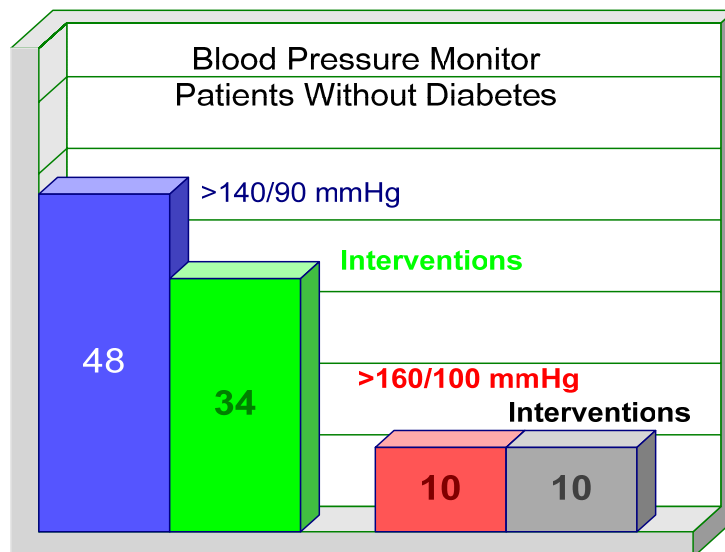
¹⁸ Localized, blood-filled dilation (bulge) of a blood vessel caused by disease or weakening of the vessel wall.

diastolic blood pressure may significantly reduce stroke by 42 percent and myocardial infarction¹⁹ by a smaller but statistically significant 14 to 16 percent.²⁰

VA/DoD CPG's define Stage 1 HTN as a systolic blood pressure (SBP) of 140–159 mmHg, or a diastolic blood pressure (DBP) of 90–99 mmHg. Stage 2 HTN is defined by the CPG's as a SBP of greater than or equal to 160 mmHg, or a DBP of greater than or equal to 100 mmHg.

We reviewed medical records to determine if the last recorded blood pressure readings for mental health patients complied with the VHA performance measure for blood pressure maintenance. According to the performance measure, clinicians should maintain blood pressures at levels that are equal to or less than 140/90 mmHg. Additionally, VHA performance measures exist for blood pressure greater than 160/100 mmHg.

We found that clinicians monitored blood pressures for 424 (89 percent) of 475 patients not diagnosed with diabetes during all, most, or some clinic visits. Our review showed that for 48 (10 percent) of 475 patients, the last recorded blood pressure was above 140/90 mmHg, possibly indicating Stage 1 HTN. Of those 48, we did not find documentation in 14 (29 percent) of the medical records to support that clinicians implemented interventions to lower blood pressures. The remaining 34 (71 percent) of the records had documentation of appropriate interventions such as change in medication, diet or exercise guidance, or a consult to a specialty clinic. Ten (2 percent) of 475 records revealed that the last recorded blood pressures were elevated beyond 160/100 mmHg, possibly indicating uncontrolled Stage 2 HTN. We found documentation to support that all 10 patients had one or more interventions as displayed below.



¹⁹ Heart attack.

²⁰ Charles H. Hennekens, MD, DrPH *Circulation*. 1998;97:1095-1102.)© 1998 American Heart Association, Inc.

Conclusions

For this sample group, we found that clinicians screened patients for diabetes within appropriate timeframes. However, documentation of interventions for elevated FBG levels needed improvement.

Clinicians monitored blood pressure at all, most, or some clinic visits for the majority of patients without diabetes (89 percent). However, interventions were lacking in 29 percent of patients with documented blood pressures of greater than 140/90 mmHg.

3. Patients with Type 2 Diabetes

Low-Density Lipoprotein Cholesterol

LDL-C, sometimes called "bad" cholesterol, tends to mix with other substances in the blood to form buildups called plaques on the inner walls of blood vessels, eventually causing atherosclerosis,²¹ heart attacks, and strokes.

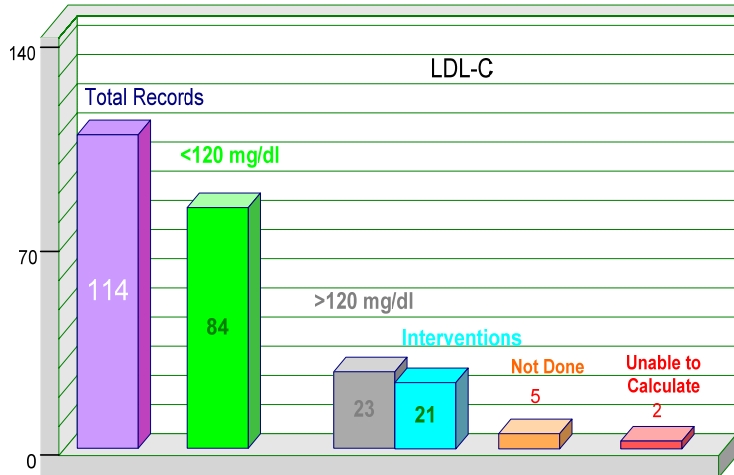
According to the ADA cholesterol guidelines, adults with diabetes who have LDL-C levels of 130 mg/dL or greater are at high risk for heart disease; those with levels of 100–129 mg/dL are at borderline risk; and those with levels below 100 mg/dL are at low risk.²²

A VHA performance measure for patients diagnosed with diabetes requires that clinicians obtain full lipid panels within the past 2 years in order to monitor cholesterol levels and cardiovascular risk. This portion of the review applied to the 114 patients diagnosed with diabetes. We found that 109 (96 percent) of the patients had lipid panels drawn within the past 2 years; however, two patients could not have their LDL-C levels calculated due to elevated triglyceride levels. Five (4 percent) of the patients in our sample of 114 did not have lipid panels drawn.

In addition, the performance measure includes tracking whether patients' last recorded LDL-C value was below 120 mg/dL. Of the 107 patients who had their LDL-C levels calculated, medical record documentation shows that 84 (79 percent) had values below 120 mg/dL; and 23 (21 percent) had values greater than 120 mg/dL. We found medical record documentation to support that clinicians implemented appropriate interventions designed to lower LDL-C levels, such as changes in lipid lowering medications, in 21 (91 percent) of 23 of the records reviewed as displayed on the following page.

²¹ Clogging, narrowing, and hardening of the body's large arteries and medium-sized blood vessels.

²² <http://www.diabetesselfmanagement.com/article.cfm?aid=436>



Blood Pressure

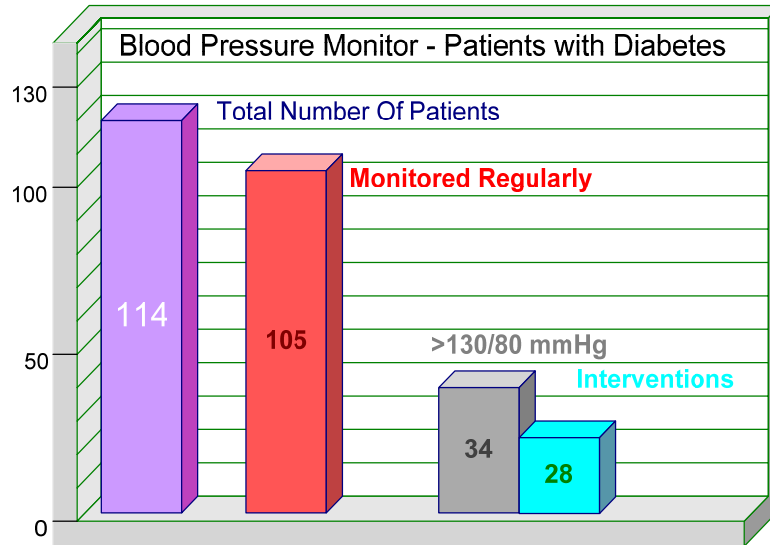
HTN affects the majority of people with diabetes, depending on the type of diabetes they have, their age, their ethnic background, and whether or not they are obese.²³ HTN is also a major risk factor for CVD and microvascular complications involving eyesight and kidney function. For those with Type 2 diabetes, HTN may be present as part of the metabolic syndrome²⁴ that is accompanied by high rates of CVD. Our review showed that, of the 114 patients in this age group with diabetes, clinicians monitored blood pressure at all, most, or some clinic visits for 105 (92 percent) of the patients.

The VHA performance measure for blood pressure control is less than or equal to 140/90 mmHg. Because some clinical trials involving individuals with diabetes have demonstrated a possible benefit of lower blood pressures, we reviewed records to ascertain if the last blood pressure reading recorded was less than or equal to 130/80 mmHg.²⁵ We found 80 (70 percent) of the medical records indicated a blood pressure reading of less than or equal to 130/80 mmHg. In addition, we found documented interventions, such as active monitoring of blood pressure or changes in medication, in 28 (82 percent) of the records of patients, whose blood pressures were greater than 130/80 mmHg as displayed on the following page.

²³ http://care.diabetesjournals.org/cgi/content/full/28/suppl_1/s4

²⁴ A combination including at least three of the following: abdominal obesity, elevated triglyceride levels, low HDL levels, hypertension, and high fasting plasma glucose levels. Metabolic syndrome is associated with an increased risk of diabetes and cardiovascular disease.

²⁵ http://care.diabetesjournals.org/cgi/content/full/28/suppl_1/s4



Hemoglobin A1c

VHA performance measures require that clinicians maintain HbA1c levels below 9 percent. However, VA/DoD CPGs add that target HbA1c levels should be below 7 percent in patients with mild or no microvascular complications of diabetes, are free of major concurrent illnesses, and have a life expectancy of 15 years or more. In addition, the American Association of Clinical Endocrinologists (AACE) clinical practice guidelines²⁶ recommend that clinicians encourage patients to achieve target HbA1c levels at or below 6.5 percent if they can safely do so without inducing clinically significant hypoglycemia.

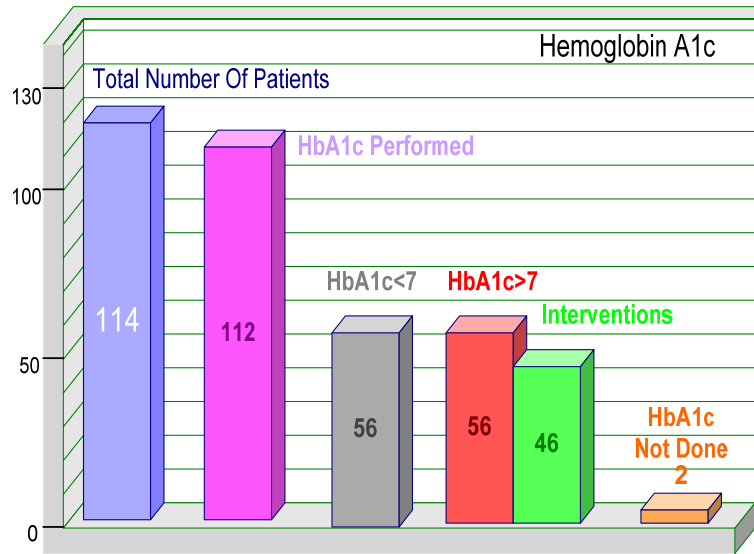
Because of the age of our patient sample (35–50 years), HbA1c levels of less than 7 could be beneficial in preventing the onset of complications of diabetes such as heart disease, kidney disease, retinopathy,²⁷ and nerve damage. We reviewed laboratory values to determine if clinicians maintained HbA1c levels below 7 percent. Of 114 patients diagnosed with diabetes, two patients (2 percent)²⁸ had no documentation of HbA1c levels having ever been obtained.

Among the remaining 112 patients, HbA1c levels were less than 7 percent in 56 (50 percent) of the patients and greater than 7 percent in 56 (50 percent) of the patients. However, of the 56 patients with HbA1c levels greater than 7 percent, the medical records of 10 (18 percent) of the patients had no documentation of interventions such as physician consultation regarding diet and exercise, change in medications, or nutrition consult, as displayed on the following page.

²⁶ Endocrine Practice Vol 13 (Suppl 1) May/June 2007

²⁷ Damage to the retina, the thin, light-sensitive inner lining in the back of the eye. This damage occurs to small blood vessels in the retina that are easily harmed by high levels of glucose in the blood.

²⁸ Actual figure 1.75 percent.



Conclusions

Clinicians provided adequate monitoring of LDL-C levels for patients with diabetes and managed those with levels above 120 mg/dL with appropriate interventions.

Clinicians monitored blood pressures for the majority of patients (92 percent) with diabetes. In addition, clinicians exceeded performance measure scores for blood pressure control in 70 percent of medical records reviewed.

To be consistent with VA/DoD guidelines clinicians needed to improve HbA1c control in this patient population. One-half of the patients with diabetes had documented HbA1c levels above the recommended VA/DoD guidelines, and 18 percent of those patients had no documented interventions.

Recommendations and Comments

We recommended that the Under Secretary for Health ensure that:

- a. VHA clinicians implement and document weight reduction strategies for obese and overweight patients between the ages of 35 and 50 who are prescribed atypical antipsychotic medications.
- b. VHA clinicians improve treatment and documentation of interventions for elevated FBG levels for patients between the ages of 35 and 50 who are prescribed atypical antipsychotic medications.

- c. VHA clinicians implement interventions to maintain blood pressures less than 140/90 mmHg for younger patients without diabetes who are prescribed atypical antipsychotic medications.
- d. VHA clinicians strive to achieve target HbA1c levels for younger patients with diabetes who are prescribed atypical antipsychotic medications that are reasonable for their patients, are consistent with VA/DoD clinical practice guidelines, and can be safely achieved.

The Under Secretary for Health agreed with the findings and recommendations and provided acceptable improvement plans. (See Appendix B, pages 16–22 for the full text of the Under Secretary’s comments.) We will follow up on the planned actions until they are completed.

(original signed by:)

JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspection

Body Mass Index Table 1

for BMI greater than 35 go to Table 2

To use the table, find the appropriate height in the left-hand column labeled Height. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.

	Normal					Overweight					Obese						
BMI	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
Height (inches)	Body Weight (pounds)																
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287

Body Mass Index Table 2

To use the table, find the appropriate height in the left-hand column labeled Height. Move across to a given weight. The number at the top of the column is the BMI at that height and weight. Pounds have been rounded off.

Obese					Extreme Obesity														
BMI	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
Height (inches)	Body Weight (pounds)																		
58	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258
59	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267
60	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276
61	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285
62	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295
63	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304
64	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314
65	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324
66	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334
67	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344
68	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354
69	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365
70	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376
71	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386
72	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397
73	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408
74	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420
75	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431
76	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443

Under Secretary for Health Comments

**Department of
Veterans Affairs**

Memorandum

Date: October 31, 2007

From: Under Secretary for Health (10)

Subject: OIG Report: **Healthcare Inspection: Atypical Antipsychotic Medications and Diabetes Screening and Management**, Project No. 2005-00680-HI-0091 (WebCIMS 389698)

To: Assistant Inspector General for Healthcare Inspections (54)

1. I have carefully reviewed your draft report, and I concur with the findings and recommendations. I am pleased with your acknowledgement of the general high-quality of diabetic care in VHA facilities. VHA works diligently to provide a consistent and high level of care for diabetic patients, and we will take the additional necessary steps to ensure that mental health patients taking atypical antipsychotic medications receive that same level of care. Ensuring that these patients receive effective diabetes screening, monitoring, and treatment is an important clinical issue, and the report cites valuable opportunities for improvement that need to be addressed.

2. In support of this goal, VHA has implemented performance measures to screen for and monitor diabetic indicators such as blood pressure, cholesterol levels, and cardiovascular risk. Your report's findings suggest that these performance measures are working since the overwhelming majority of VHA clinicians properly screened and monitored mental health patients taking atypical antipsychotic medications for diabetes. However, the report also cites that VHA clinicians inconsistently document and treat interventions for these indicators, and I agree that we can improve in this regard. As such, I will take the necessary steps to reemphasize the need for all facilities and clinicians to consistently adhere to diabetes screening, monitoring, and treatment guidance and standards as prescribed in VA/DoD Clinical Practice Guidelines - Management of Patients with Diabetes Mellitus in the Primary Care Setting.

3. I will direct the Office of Patient Care Services (PCS) to form a multidisciplinary team to study and discuss strategies to improve diabetes care for those with serious mental health conditions. The team will develop its strategies and recommendations based upon existing VA/DoD guidelines, or by consensus recommendations, and report its results for my consideration.

4. I appreciate for your willingness to mutually discuss and resolve our concerns with your initial findings and recommendations. Attached is VHA's complete plan of corrective action, which provides a summary of specific initiatives that appropriately address identified issues in the report. Thank you for the opportunity to review the draft report. If you have any questions, please contact Margaret M. Seleski, Director, Management Review Service (10B5) at (202) 565-7638.

(original signed by:)

Michael J. Kussman, MD, MS, MACP

Attachments

**Veterans Health Administration
Action Plan**

**OIG Draft Report, Healthcare Inspection: Atypical Antipsychotic
Medications and Diabetes Screening and Management in VHA
Facilities**

(Project No. 2005-00680-HI-0091)

Recommendations/ Actions	Status	Completion Date
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We recommended that the Under Secretary for Health ensures that:

Recommended Improvement Action a: VHA clinicians implement and document weight reduction strategies for obese and overweight patients between the ages of 35 and 50 who are prescribed atypical antipsychotic medications.

Concur

Through its implementation of the MOVE! Program (a comprehensive, evidence-based, clinical intervention program to treat obesity), VA clinicians can screen overweight patients, provide counseling about health risks, and offer a comprehensive patient-centered weight management program focusing on behavior, nutrition, and physical activity. On the next Chief Medical Officers conference call, the Office of Patient Care Services (PCS), in conjunction with the Deputy Under Secretary for Health for Operations and Management (DUSHOM) will reiterate the objectives of the MOVE! Program and reemphasize the need for clinicians to document patient referrals to MOVE! or other efforts that are consistent with a program of nutrition and exercise.

The PCS Office of Mental Health Services will lead a multidisciplinary team with representatives from the DUSHOM,

Medical - Surgical Services, Primary Care, the Pharmacy Benefit Management Program, the MOVE! Program, and the National Center for Health Prevention and Disease. The team will develop suggested courses of action for: 1) the consideration of factors in selecting anti-psychotic agents; 2) strategies regarding lifestyle and nutrition education for patients with serious mental health conditions and their social support networks (including families); 3) monitoring weight, blood sugar, blood pressure, and cholesterol for those with serious mental health conditions within Mental Health Care and Primary Care settings; and 4) the appropriateness of referrals for metabolic control treatment decisions.

The team will also develop strategies and recommendations based upon existing VA/DOD guidelines or otherwise by consensus recommendations, and report its results for the Under Secretary for Health's (USH) consideration by May 31, 2008. The team will hold its first organizational meeting by December 31, 2007, and communicate its progress and developments with the field through a Chief Medical Officers' conference call, and subsequently, through existing PCS communication channels.

In Process

5/31/08

Recommended Improvement Action b: VHA clinicians improve treatment and documentation of interventions for elevated FBG levels for patients between the ages of 35 and 50, who are prescribed atypical antipsychotic medications.

Concur

On the next Chief Medical Officers' conference call, PCS, in conjunction with the DUSHOM, will reiterate the need for clinicians to refer patients at risk of developing diabetes to the MOVE! Program or other efforts consistent with a program of nutrition and exercise. Clinicians will also be required to document these interventions in the patient's medical record.

The PCS Office of Mental Health Services will lead a multidisciplinary team with representatives from the DUSHOM,

Medical - Surgical Services, Primary Care, the Pharmacy Benefit Management Program, the MOVE! Program, and the National Center for Health Prevention and Disease. The team will develop suggested courses of action for: 1) the consideration of factors in selecting anti-psychotic agents; 2) strategies regarding lifestyle and nutrition education for patients with serious mental health conditions and their social support networks (including families); 3) monitoring weight, blood sugar, blood pressure, and cholesterol for those with serious mental health conditions within Mental Health Care and Primary Care settings; and 4) the appropriateness of referrals for metabolic control treatment decisions.

The team will also develop strategies and recommendations based upon existing VA/DOD guidelines, or otherwise by consensus recommendations, and report its results for USH consideration by May 31, 2008. The team will hold its first organizational meeting by December 31, 2007, and communicate its progress and developments with the field through a Chief Medical Officers' conference call, and subsequently, through existing PCS communication channels.

In Process

5/31/08

Recommended Improvement Action c: VHA clinicians implement interventions to maintain blood pressures less than 140/90 mmHg for younger patients without diabetes who are prescribed atypical antipsychotic medications.

Concur

On the next Chief Medical Officers' conference call, PCS, in conjunction with the DUSHOM, will reemphasize the need to document and implement interventions for patients with blood pressures greater than 140/90 mm/Hg. PCS will stipulate that clinicians should institute medication consistent with VHA/DOD Hypertension Guidelines if blood pressure is persistently elevated despite lifestyle and nutrition therapy.

The PCS Office of Mental Health Services will lead a multidisciplinary team with representatives from the DUSHOM, Medical - Surgical Services, Primary Care, the Pharmacy Benefit

Management Program, the MOVE! Program, and the National Center for Health Prevention and Disease. the team will develop suggested courses of action for: 1) the consideration of factors in selecting anti-psychotic agents; 2) strategies regarding lifestyle and nutrition education for patients with serious mental health conditions and their social support networks (including families); 3) monitoring weight, blood sugar, blood pressure, and cholesterol for those with serious mental health conditions within Mental Health Care and Primary Care settings; and 4) the appropriateness of referrals for metabolic control treatment decisions.

The team will also develop strategies and recommendations based upon existing VA/DOD guidelines, or otherwise by consensus recommendations, and report its results for USH consideration by May 31, 2008. The team will hold its first organizational meeting by December 31, 2007, and communicate its progress and developments with the field through a Chief Medical Officers' conference call, and subsequently, through existing PCS communication channels.

In Process

5/31/08

Recommended Improvement Action d: VHA clinicians strive to achieve target HbA1c levels for younger patients with diabetes who are prescribed atypical antipsychotic medications that are reasonable for their patients, consistent with VA/DoD clinical practice guidelines, and can be safely achieved.

Concur

On the next Chief Medical Officers' conference call, PCS, in conjunction with the DUSHOM, will reemphasize the need to document the patient's adherence to lifestyle and nutrition therapy, as well as appropriate institution/change in dosage of anti-glycemic medications. Documentation regarding the side effects of medications and patient preferences (especially for insulin) will also be required.

The PCS Office of Mental Health Services will lead a multidisciplinary team with representatives from the DUSHOM, Medical - Surgical Services, Primary Care, the Pharmacy Benefit Management Program, the MOVE! Program and the National Center for Health Prevention and Disease. The team will develop suggested courses of action for: 1) the consideration of factors in selecting anti-psychotic agents; 2) strategies regarding lifestyle and nutrition education for patients with serious mental health conditions and their social support networks (including families); 3) monitoring weight, blood sugar, blood pressure, and cholesterol for those with serious mental health conditions within Mental Health Care and Primary Care settings; and 4) the appropriateness of referrals for metabolic control treatment decisions.

The team will also develop strategies and recommendations based upon existing VA/DOD guidelines, or otherwise by consensus recommendations, and report its results for USH consideration by May 31, 2008. The team will hold its first organizational meeting by December 31, 2007, and communicate its progress and developments with the field through a Chief Medical Officers' conference call, and subsequently, through existing PCS communication channels.

In Process

5/31/08

OIG Contact and Staff Acknowledgments

OIG Contact	Jeanne Martin Boston Regional Office of Healthcare Inspections (781) 687-3187
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Acknowledgments	Shirley Carlile Bertha Clarke Charles Cook Linda DeLong Jeffrey Joppie Rayda Nadal Katherine Owens Michelle Porter Reba Ransom Jennifer Reed James Seitz Randall Snow Carol Torczon John Tryboski Susan Zarter
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