



# Department of Veterans Affairs Office of Inspector General

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## Healthcare Inspection

### Quality of Care Issues VA Northern Indiana Health Care System Fort Wayne, Indiana

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## Executive Summary

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to determine the validity of allegations regarding quality of care issues at the VA Northern Indiana Health Care System, Fort Wayne, IN.

A complainant alleged that there was a delay in notification of test results, diagnosis, and treatment, which may have led to multiple emergency department (ED) visits and a subsequent hospital admission. The complainant also alleged that his complaints of infection were ignored, and that a medication was prescribed that exacerbated his Myasthenia Gravis (MG), a disease that affects the connection between muscles and nerves. Additional allegations included a breach in aseptic technique during intravenous therapy and delays in access to primary care.

We substantiated that there were delays in notification of the patient's test results and the diagnosis of MG, with missed opportunities for follow-up care. We found that a neurologist was aware of abnormal test results suggestive of MG in July 2009, but he did not inform the patient until December 2009.

We substantiated that a delay in diagnosis and treatment may have led to multiple ED visits and a subsequent hospital admission. Multiple ED and primary care providers between April 2009 and December 2009 saw the patient; however, aggressive treatment for his MG was not begun until December 2009.

We substantiated that a provider prescribed an antibiotic that exacerbated the patient's MG. While there were clinical reasons for prescribing an antibiotic, given the known risk of this specific medication, a more extensive search for a safer medication or a more detailed discussion with the patient was warranted.

We did not substantiate that the patient's complaints of infection were ignored. We could neither confirm nor refute that nurses did not use aseptic technique when connecting intravenous tubing due to the lack of specificity of the allegation.

We could neither confirm nor refute significant delays in access to primary care due to the lack of specificity of the allegation. Performance measures for the primary care clinic showed that the average wait time for appointments for established patients was less than 5 days.

We recommended that an external peer review be completed for appropriateness of care.

The Veterans Integrated Service Network and System Directors concurred with the findings and recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.



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

**TO:** Director, Veterans in Partnership (10N11)

**SUBJECT:** Healthcare Inspection – Quality of Care Issues, VA Northern Indiana Health Care System, Fort Wayne, Indiana

### **Purpose**

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) received allegations regarding quality of care and delay in treatment of a patient at the Fort Wayne Campus of the VA Northern Indiana Health Care System (the system), Fort Wayne, IN. The purpose of the review was to determine whether the allegations had merit.

### **Background**

In 1995, the VA Northern Indiana Health Care System was formed by the integration of VA Medical Centers in Fort Wayne and Marion, IN. The Fort Wayne campus provides primary and secondary medical and surgical services, as well as mental health services. Neurology Service, part of the Department of Medicine, was established in March 2009. The service has one full-time neurologist and one part-time neurologist providing neurology consultations, EEG interpretation, and compensation and pension examinations. The system operates 26 hospital beds and is part of Veterans Integrated Service Network (VISN) 11.

A complainant who received his health care from the system's Ft. Wayne Campus, and was followed at VA medical centers in Prescott, AZ and Tampa, FL contacted the OIG in early June 2010, regarding the care he received from July 2009–April 2010. He sought care for facial weakness and was initially diagnosed with Bell's palsy (a neurological disorder). He was subsequently diagnosed with myasthenia gravis (MG), a disease that affects the connection between muscles and nerves. The complainant alleged that:

- He received blood testing for his facial weakness in July 2009, but was not informed of his abnormal laboratory test or correct diagnosis until December 2009.

- The delay in receiving the correct diagnosis and corresponding treatment may have led to multiple emergency department (ED) visits and a hospital admission in December 2009.
- Staff did not believe him when he complained of an infection, resulting in a hospital admission in April 2010.
- Medication was prescribed that exacerbated his neurological condition.
- Nurses did not use aseptic technique when reconnecting intravenous (IV) tubing.
- The waiting time to see a primary care provider (PCP) was up to 4 weeks.

### Bell's Palsy

Bell's palsy most commonly manifests as a sudden weakness of one side of the face. It is the most common cause of sudden facial paralysis and caused by loss of function in the nerve, which controls the muscles of the face (facial nerve). Even without treatment, symptoms often resolve within weeks to months and there is a low likelihood of recurrence. Treatment with prednisone or an antiviral medication may be prescribed to speed recovery. Often a specific cause of Bell's palsy cannot be found; however, excluding more serious causes of facial paralysis should be considered if a patient does not improve or has symptoms which differ from Bell's palsy.

### Myasthenia Gravis

MG is a disease that causes muscle fatigue and weakness. It often affects the muscles that control speech, swallowing, and eye movements, as well as muscles of the arms and legs. Antibodies against acetylcholine receptors (AChR) are produced when an abnormally functioning immune system interrupts the signals between nerves and muscles. The symptoms may vary significantly between individuals and from day to day. A severe manifestation is myasthenic crisis, which occurs when a patient's breathing muscles have weakened to the point that they have difficulty breathing and may require mechanical ventilation for adequate respiration.

MG may limit routine activities such as eating, walking, and personal hygiene. Environmental factors can worsen these functional limitations or trigger episodes, and individuals with MG are advised to avoid overexertion and temperature extremes. Certain medications are also known to worsen MG and caution should be exercised with new over-the-counter or prescription medications.

This disease is a relatively uncommon disorder with an annual incidence of five new cases per million people in the United States. This rarity makes diagnosis of MG challenging, as there are more common diseases that produce some of the same symptoms. In addition to the clinical history and physical examination, various tests are

used to confirm the diagnosis of MG, including blood tests (the AChR antibody), nerve and muscle tests, and imaging tests.

Several options are available for the treatment of MG including: medications to facilitate the signaling between muscles and nerves and suppress abnormal antibody production, plasmapheresis (blood exchange) to remove the abnormal antibodies, and removal of the thymus gland. The response to the treatment for MG can vary between individuals and trying several options may be necessary to find an effective treatment.

## Scope and Methodology

We reviewed the patient's electronic medical record (EMR), local and Veterans Health Administration (VHA) policies, and medical literature related to MG. We also reviewed quality management documents and private hospital records. We conducted a site visit on August 24–25, 2010. We interviewed quality management staff, primary care providers, the VA neurologist, an ED physician, and the Medical Service Associate Chief of Staff. We also discussed MG with experts in the field.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

## Case Summary

The patient is a male in his 60s with a past medical history of chronic obstructive pulmonary disease (COPD)<sup>1</sup> and tobacco abuse. In early April 2009, he was seen by a PCP with complaints of left facial paralysis, difficulty chewing food, and partial left eye ptosis (eyelid closure) for 2 weeks. He was diagnosed with possible left-sided Bell's palsy, placed on a tapered dose of prednisone (a synthetic corticosteroid drug used to suppress the immune system), and speech therapy was consulted.

Six days later, the speech pathologist documented a history of additional symptoms, including oral muscle fatigue, dysphagia (difficulty swallowing), and speech abnormalities when tired. Two weeks later, the patient had a follow-up visit and the PCP noted some improvement. The patient was scheduled for a return examination in 6 months.

Two months later, he was seen in the ED with complaints of acute facial weakness and difficulty speaking. He was again diagnosed with Bell's palsy, placed on valacyclovir (an antiviral medication), and given a short course of prednisone. The ED physician requested a consult for Neurology Service to see the patient for Bell's palsy.

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<sup>1</sup> Chronic obstructive pulmonary disease refers to a group of lung diseases that block airflow and breathing.

Two days later, a neurologist examined the patient and noted that the patient had daily pain consistent with migraine headaches and a history of Bell's palsy. The neurologist found that the patient showed some improvement on medication, but did not have complete recovery. The neurological exam showed "a decreased nasolabial fold on the left side."<sup>2</sup> Laboratory tests ordered at this visit included a sedimentation rate, C-reactive protein, acetylcholine receptor (AChR) antibody,<sup>3</sup> and a Lyme disease titer. The patient was asked to return to the clinic in 3–4 months. The neurologist also ordered an ear, nose, and throat (ENT) consult which was scheduled for mid-August, however, the patient cancelled the appointment.

In early September, the patient was seen in the ED at the VA Medical Center in Prescott, AZ, with complaints of left facial weakness. The neurological exam was positive for a left flat nasolabial fold and a slight left lip droop. He was diagnosed with recurrent Bell's palsy and prescribed acyclovir (antiviral medication) and prednisone; these medications helped reduce symptoms in the past.

In mid-October, the patient presented to the ED at the James Haley VA Hospital in Tampa, FL, with complaints of difficulty chewing food and a history of recurrent Bell's palsy. The neurological exam was positive for mild left eye ptosis and a slight left lip droop. He was again prescribed acyclovir and prednisone, and instructed to follow up with his PCP and neurologist in Indiana.

In mid-November, the patient had recurrent symptoms of dysphagia and ptosis, and was seen by his PCP. The PCP requested a neurology consult for within 1 week. Because the patient's symptoms were not service connected, the consult was changed to the next available appointment (which was in December), with the option to be seen at the Indianapolis VA Medical Center, if needed.

In early December, a PCP saw the patient because he had no resolution of symptoms since his previous visit to primary care. He continued to have problems with chewing, swallowing, difficulty breathing when eating, and jaw pain. The patient was encouraged to see the neurologist in 6 days, and an ENT consult was renewed.

Six days later, the patient saw the neurologist as scheduled. Since his last visit, he had received five short courses of prednisone from different ED and PCP providers, with improvement noted each time. The patient had recurrent symptoms of left-sided eye ptosis, and difficulty chewing and swallowing. The patient also reported speech changes. The neurologist informed the patient of the positive AChR antibody from July at this time, and diagnosed the patient with "possible MG,"<sup>4</sup> history of Bell's palsy, and

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<sup>2</sup> A decreased nasolabial fold is a finding that may indicate decreased function of the facial nerve and muscles.

<sup>3</sup> Patients who have detectable antibodies to the acetylcholine receptor are considered seropositive for MG.

<sup>4</sup> MG is a chronic autoimmune neuromuscular disease characterized by varying degrees of weakness of the skeletal muscles of the body.

migraine headaches. The treatment plan included a trial of Mestinon<sup>®</sup> 30 mg, 4 times daily, and a return to the clinic in 2–3 months.

A week later, the patient called the neurologist and complained of difficulty breathing and blurred vision. The patient had increased the Mestinon<sup>®</sup> to 60 mg, 4 times daily 4 days earlier. The neurologist advised him to reduce the dose to 30 mg, 4 times daily, or taper off completely if the symptoms did not improve. He was instructed to come to the ED if necessary.

The next day, the patient was seen in the ED with speech problems, inability to chew and swallow solids, double vision, ptosis, and numbness and weakness in his right little finger. The ED physician contacted the neurologist by phone, and the neurologist ordered discontinuation of the Mestinon<sup>®</sup> and requested transfer of the patient to a local hospital, because the system was unable to provide the required intensive care services. The patient was transferred to the local, non-VA hospital and treated for MG with myasthenic crisis and COPD without respiratory failure. He was discharged from the local hospital 6 days later.

After his discharge, the patient chose to have his MG managed by a neurologist in the private sector but continued to see his VA PCP for other care. In late January 2010, the patient had a follow-up visit with his PCP for management of low back pain. According to the EMR, the patient was to return to primary care in 4 months, or earlier if needed.

In early February, the patient called the telephone triage in primary care with complaints of coughing and wheezing. The PCP advised the patient to come to the ED if symptoms did not improve. The patient was seen in the ED 6 days later and was given azithromycin (an antibiotic) for bronchitis. He was seen again in the ED 13 days later for pain and cellulitis of the left arm and received sulfamethoxazole and trimethoprim (an antibiotic) for the cellulitis. The patient returned to the ED for a follow-up visit 4 days later and improvement was noted in the EMR.

The patient returned to the ED 6 days later with continued complaints of left hand swelling and possible infection, and a provider prescribed clindamycin (an antibiotic). The patient returned to the ED 5 days later. The ED physician discontinued the clindamycin, which made the MG worse, and prescribed cefuroxime (an antibiotic), which does not worsen MG symptoms, for the patient's left hand infection. Four days later, the patient presented to the ED provider with left arm paresthesia (numbness and weakness) and resolving cellulitis. The patient was given baclofen (a muscle relaxant) for the left arm paresthesia and was instructed to discontinue the medication if it made his MG symptoms worse.

Four days later, the ED provider contacted the patient regarding an abnormal chest x-ray. The x-ray showed an infiltrate (a sign of possible infection), and the provider ordered azithromycin (an antibiotic) for a lung infection. The patient requested that the pharmacy

review this medication to ensure that it would not exacerbate his MG. Two days later, the pharmacy reported that there was a small chance the medication could cause a reaction, so the provider changed the antibiotic to doxycycline.

During a scheduled appointment with the PCP in early April, the patient's history of MG with intermittent exacerbations, bronchitis, and left hand cellulitis was noted. The treatment plan consisted of occupational therapy, continuation of fee-based neurology services, and a return visit was scheduled for 1 month. Two weeks later, the patient was admitted from the ED to the hospital for aggressive treatment of pneumonia and left hand cellulitis. He was discharged 13 days later with plans to see the PCP in 9 days.

## **Inspection Results**

### **Issue 1: Delay in Communicating Diagnosis**

We substantiated the allegation that a neurologist evaluated the patient in July 2009, but did not inform the patient of an abnormal laboratory test or his correct diagnosis until early December.

The neurologist told us that he was aware of the AChR antibody results 48 hours after the test was done in July, but he did not inform the patient of the results at that time because, according to his exam, the patient was not symptomatic and he wished to explain the diagnosis of MG to the patient in person. The neurologist also stated that he wanted to see the patient acutely symptomatic to confirm the diagnosis, but he did not communicate this to other providers. VHA policy<sup>5</sup> requires patient notification of abnormal test results within 14 days so that a treatment plan can be initiated or changed as soon as possible.

When the neurologist evaluated the patient in July 2009, the differential diagnoses listed in the EMR included possible Giant Cell Arteritis (a condition that can cause headaches), Lyme disease (a condition that can cause rash, fatigue, headache and weakness), and MG. However, the neurologist told us he had not reviewed prior PCP notes or the speech pathologist's note in the EMR, which indicated a history of difficulty with chewing and swallowing. Muscle weakness and fatigue is a cardinal sign of MG, and this important information was not reviewed during the consultation. Incomplete review of the patient's history and physical and lack of timely follow-up of test results contributed to a delay in communicating the diagnosis to other providers and the patient.

### **Issue 2: Delay in Treatment**

We substantiated the allegation that a lack of prompt diagnosis and treatment may have led to multiple ED visits and a hospital admission in mid-December 2009.

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<sup>5</sup> VHA Directive 2009-019, *Ordering and Reporting Test Results*, March 24, 2009.

The patient was originally diagnosed and treated for Bell's palsy in April 2009. The patient was seen by the neurologist in July 2009, but was not diagnosed with MG until December 2009. The neurologist did not inform the patient or other providers of test results in a timely manner, and the patient, believing he had Bell's palsy, cancelled an ENT consult in August and a neurology appointment in October. The delay in diagnosis and cancelled appointments by the patient resulted in missed opportunities to treat his MG.

In September 2009, the patient experienced recurrent neurological symptoms and sought care in the ED at the VA Medical Center in Prescott, AZ. In October 2009, he was seen in the ED at the James Haley VA Hospital, in Tampa, FL, with an exacerbation of his neurologic symptoms.

The patient returned to primary care in Fort Wayne, Indiana with ongoing, acute neurological symptoms in mid-November and early December 2009. Bell's palsy is usually a self-limited process, and most patients achieve complete spontaneous recovery within 2 weeks.<sup>6</sup> Bell's palsy rarely recurs, so the patient's recurrent symptoms, including facial palsy, should have alerted providers to a more serious neurological condition. The patient saw the neurologist in early December 2009, and he was started on a trial dose of Mestinon<sup>®</sup>.

The patient was seen in the ED 9 days later, in acute myasthenic crisis. He was immediately transferred to a local hospital, because the system was unable to provide the required intensive care services. We found that that patient was not aggressively treated for MG until his emergency admission to the local hospital, and that early diagnosis and more aggressive initial treatment of MG by the neurologist may have prevented multiple ED visits and an emergency admission for myasthenic crisis.

### **Issue 3: Complaints of Infection Ignored**

We did not substantiate the allegation that the staff ignored complaints of an infection leading to a hospital admission in mid-April 2010.

The EMR noted that the PCP and ED providers had evaluated and treated the patient for infection and cellulitis on multiple occasions prior to the admission. The patient had two ED visits in February and March, and a follow-up appointment with the PCP in early April 2010, for evaluation and treatment of his cellulitis.

### **Issue 4: Medication Exacerbated Condition**

We substantiated the allegation that a provider in the ED prescribed medication that exacerbated MG.

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<sup>6</sup> Gilden DH, *Bell's Palsy*, New England Journal of Medicine, 351:1323-1331, September 23, 2004.

Clindamycin (an antibiotic used to treat infection) must be used with caution in patients with the diagnosis of MG,<sup>7</sup> as it can cause a significant increase in weakness. Clindamycin was prescribed in early March 2010, in spite of the fact that the patient had given the ED providers a list of medications, including clindamycin, that exacerbated MG. The provider told us that she had a copy of the list when she prescribed the medication but felt that the patient could have had an antibiotic resistant infection and made a clinical judgment to use the medication.

We found no documentation in the EMR that risks, benefits, or alternatives for this medication were considered by the provider or discussed with the patient. An ED physician discontinued the medication 5 days later, when the patient presented with symptoms consistent with an exacerbation of MG.

#### **Issue 5: Breach in Aseptic Technique**

We could neither confirm nor refute the allegation that nurses did not use aseptic technique when connecting his IV tubing because of the lack of specificity of the complaint.

The complainant stated that he observed IV tubing being re-used for intermittent IV medications. It is not known if sterility of the tubing was maintained between uses. We reviewed infection control data, and the facility did not have any documentation of infections related to IV therapy. The system guidelines on IV therapy included steps in a checklist to maintain aseptic technique when changing IV tubing. Nurses must complete an IV class and demonstrate competency before they are permitted to administer any type of IV therapy.

#### **Issue 6: Delay in Primary Care Access**

We could neither confirm nor refute the allegation that it took up to 4 weeks to see a PCP due to the lack of specificity of the complaint.

We reviewed performance measures for the system's primary care clinic and found that in FY 2009 to March 2010 the average wait time for appointments for established patients was less than 5 days. The allegation lacked specificity regarding when this occurred, and the EMR did not reflect that the patient requested to be seen by primary care and was not accommodated. When the patient called the primary care clinic or telephone triage with concerns that required immediate attention, he was referred to ambulatory care or the ED and was seen the same day.

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<sup>7</sup> Bird, SJ, *Treatment of Myasthenia Gravis*, UpToDate®, February 3, 2010.

## Conclusions

We substantiated that there were delays in the notification of test results and the diagnosis of MG and missed opportunities in treatment and follow-up of the patient. We found that a neurologist was aware of abnormal test results suggestive of MG in July 2009, but he did not inform the patient until December 2009.

We substantiated that a lack of prompt treatment and diagnosis may have led to multiple ED visits and a subsequent hospital admission. The patient was seen by multiple ED and primary care providers between April 2009 and December 2009; however, aggressive treatment for his MG was delayed until December 2009 when he was hospitalized in myasthenic crisis.

We substantiated that medication was prescribed that exacerbated the patient's MG. While there were clinical reasons for prescribing an antibiotic, given the known risk of this specific medication, the potential severity of the side effects, and the patient's recent hospitalization for a myasthenic crisis, a more extensive search for a safer medication or a more detailed discussion with the patient was warranted.

We did not substantiate the allegation that complaints of infection were ignored. We were unable to confirm or refute that there were breaches in aseptic technique during intravenous therapy or that there were delays in access to primary care.

## Recommendation

**Recommendation.** We recommend that that an external peer review be completed for appropriateness of care.

## Comments

The VISN and System Directors agreed with the findings and recommendation and provided an acceptable action plan (see Appendixes A and B, pages 10–12, for the Directors' 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 Inspections

## VISN Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** February 8, 2011

**From:** Director, Veterans in Partnership (10N11)

**Subject:** **Healthcare Inspection – Quality of Care Issues, VA Northern Indiana Health Care System, Fort Wayne, Indiana**

**To:** Associate Director, St. Petersburg Office of Healthcare Inspections (54SP)

**Thru:** Director, Management Review Service (10B5)

Attached, please find the response from NIHCS. If you have any questions, please contact Jim Rice, Quality Management Officer, at (734)-222-4314.



Michael S. Finegan  
Network Director, VISN 11

## System Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** February 1, 2011

**From:** Director, VA Northern Indiana Health Care System (610/A4)

**Subject:** **Healthcare Inspection – Quality of Care Issues, VA Northern Indiana Health Care System, Fort Wayne, Indiana**

**To:** Director, Veterans in Partnership (10N11)

1. The Leadership has reviewed the draft inspection report of the Review of Quality of Care conducted by the Office of Healthcare Inspections. Our response to the recommendation is attached.

2. We appreciate the completeness of the review that was conducted for this very complex case involving a veteran with unique medical issues. We concur with the recommendations and our action plan will increase provider education in an effort to mitigate future high-risk situations of this nature.

*(original signed by:)*

Daniel Hendee, FACHE

Director, VA Northern Indiana Healthcare System (610/A4)



## OIG Contact and Staff Acknowledgments

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OIG Contact	Carol Torczon, Associate Director St. Petersburg Office of Healthcare Inspections
Acknowledgments	David Griffith, Team Leader Christa Sisterhen George Wesley, MD Robert Yang, MD

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