



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Alleged Substandard Quality of Care in the Cardiothoracic Surgery Program Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin

To Report Suspected Wrongdoing in VA Programs and Operations

**Telephone: 1-800-488-8244 between 8:30AM and 4PM Eastern Time,
Monday through Friday, excluding Federal holidays**

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Executive Summary

VA's Office of Inspector General, Office of Healthcare Inspections conducted an inspection and oversight review to determine the validity of allegations that subsequent to the transfer of a nurse practitioner (NP) from the Cardiothoracic (CT) Surgery Service at the Clement J. Zablocki VA Medical Center in Milwaukee, Wisconsin, its cardiothoracic surgical mortality rate increased from 150 surgeries and 1 death in a 6-month period (0.67 percent) to 75 surgeries and 7 deaths (9.3 percent) in the succeeding 6 months.

Additionally, it was alleged that after the removal of the NP from the CT Surgery Service, patient wait times increased substantially, and "critically needy" veterans were being underserved.

OHI found that the surgical mortality rate did indeed increase as alleged. However, the Veterans Health Administration's (VHA's) National Surgical Quality Improvement Program was well aware of this spike in mortality, and extensive reviews of the mortality cases were performed.

VHA reviews of the mortality cases revealed several cases where patients might have been managed differently; although overall it is doubtful in these cases that different surgical or postoperative management would have changed the ultimate outcome. Additionally, several cases were identified where, in retrospect, operative risk was so high that perhaps the patients should not have been taken to surgery in the first place. However, it is also doubtful that withholding surgery would have changed patient outcome, inasmuch as in these cases the patients were at extreme risk both with and without surgery. The prime example of this dilemma was that of a patient who presented with an acute and extensive dissecting aortic aneurysm. His prognosis for survival was next to nil both with and without surgery.

Neither VHA in its reviews nor OHI in its oversight and reviews concluded that the mortality cases were attributable to shifting an NP out of the CT Surgery Service.

We also did not substantiate that there was an increase in patient wait times for CT Surgery Clinic appointments after the removal of the NP. In contrast, we found that the CT Surgery Service had added an additional NP, totaling two NPs for the program to share coordination of care responsibilities. We found that patients requiring CT Surgery clinic appointments received them within 1-30 days over 99 percent of the time in fiscal year 2008.

We made no recommendations.



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

TO: Veterans Integrated Service Network 12 Director, VA Great Lakes Health Care System (10N12)

SUBJECT: Healthcare Inspection – Alleged Substandard Quality of Care in the Cardiothoracic Surgical Program, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

Purpose

VA's Office of Inspector General, Office of Healthcare Inspections received allegations that after and due to removal of a nurse practitioner (NP) from the Cardiothoracic (CT) Surgery Service at the Clement J. Zablocki VA Medical Center, cardiac surgical mortality increased and patient waiting times for a CT Surgery Service appointment increased. The purpose of the inspection was to determine the validity of these allegations.

Background

Located in Milwaukee, Wisconsin, the Clement J. Zablocki VA Medical Center (medical center) delivers primary, secondary, and tertiary medical care through 170 acute care operating beds and provides 593,000 outpatient visits annually through an extensive outpatient program. The medical center's programs serve a veteran population of 321,421 in the southeastern and central parts of Wisconsin. The medical center is a part of Veterans Integrated Service Network (VISN) 12.

A complainant made allegations regarding services provided by CT Surgery as follows:

- After the removal of the NP, the mortality rate increased from 150 surgeries and 1 death in a 6-month period to 75 surgeries and 7 deaths in the succeeding 6 months.
- Subsequent to the removal of the NP, patient wait times have increased to receive services related to the CT Surgery Service. Therefore, "critically needy" veterans are being underserved.

Scope and Methodology

We conducted an on-site inspection December 16–18, 2008, and interviewed the complainant, senior and mid-level managers, medical center, and VISN 12 employees. We reviewed Veteran Health Administration (VHA) policies and external reviews, medical center policies, Continuous Improvement in Cardiac Surgery Program (CICSP) data, peer reviews, mortality and morbidity reports, tort claims, incident reports, credentialing and clinical privileging files with related scopes of practice, patient complaint files, and a variety of personnel information.

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

Case Reviews

We confirmed that there were seven cardiac surgical deaths in the October 1, 2007–March 31, 2008 time period that occurred operatively, or within 30 days postoperatively and that were reportable to VHA’s National Surgical Quality Improvement Program.

OHI reviews of these cases are summarized below.

Patient 1. The patient was a man in his 80s, who was admitted to the medical center in November 2007. He had severe pulmonary hypertension, past history of coronary bypass graft surgery (1984), and dual-chamber pacemaker placement (2006). Prior to a left inguinal hernia repair, the patient was evaluated by the medical center Cardiology Service and was found to have symptomatic coronary artery disease.

The patient underwent a coronary bypass graft “redo operation.” At surgery, the patient’s coronary arteries were largely non-graftable. Only one bypass graft was performed along with a repair of the mitral valve, this procedure being less extensive than what had been anticipated pre-operatively.

Postoperatively, the patient did poorly with hemodynamic instability. On postoperative day (POD) 1, while still in the Intensive Care Unit (ICU), he suffered a fatal acute postero-lateral myocardial infarction.

OHI comments: We concluded that this was an extremely high-risk patient for a coronary artery bypass “redo operation.”

The wisdom of performing the operation notwithstanding, we found no evidence that NP staffing issues at the medical center caused or exacerbated the patient’s complicated postoperative course or was responsible for his acute myocardial infarction.

Patient 2. The patient was another man in his 80s, with multiple medical problems including a history of hypertension, anemia, chronic obstructive pulmonary disease, obliterated left pleural cavity after an episode of pneumonia, and colon cancer who was initially admitted to the Iron Mountain, MI, VA medical center with an acute myocardial infarction.

The patient's Iron Mountain course was complicated by pulmonary edema, cardiac arrhythmias, and EKG indications of myocardial ischemia. Accordingly, the patient was transferred from Iron Mountain, a rurally located VA medical center, to the Milwaukee medical center, a tertiary level VA medical center.

At the Milwaukee medical center the patient underwent an extensive cardiac evaluation which included echocardiography and cardiac catheterization. The latter revealed a 3-vessel coronary artery disease. In late November 2007, the patient had a 4-vessel coronary artery bypass graft procedure.

The patient's postoperative course was complicated by cardiac arrhythmia, notably "persistent and recurrent atrial fibrillation." Initially, the patient appeared to stabilize with pharmacologic management of his atrial fibrillation. However, a new complication ensued which was overanticoagulation, which was hypothesized to have occurred due to a drug interaction between amiodarone used to treat the patient's atrial fibrillation and warfarin which had also been prescribed. An attempt was made to reverse the patient's overanticoagulation with vitamin K and fresh frozen plasma.

On POD 10, the patient was noted to be in respiratory distress which was followed by a respiratory arrest from which the patient could not be successfully resuscitated.

An autopsy was performed which revealed, "a small rupture of the postero-lateral LV [left ventricular] wall with blood in the right pleural cavity."

OHI comments: We concluded that in light of the patient's age, comorbidities, and presentation to the Iron Mountain VA medical center with acute myocardial infarction, this was an extremely high-risk patient.

Postoperatively, the patient at first appeared to do well. However, based upon the autopsy, it appears that the patient ultimately suffered a ruptured left ventricular wall accompanied by blood leakage through this rupture that was facilitated by an adverse drug interaction (anticoagulant therapy combined with antiarrhythmic therapy causing overanticoagulation).

Similar to Patient 1 above, this case raises the issue of patient selection. We found no evidence that staffing issues at the medical center caused or exacerbated the patient's complicated postoperative complications.

Patient 3. The patient was a third man in his 80s, with numerous medical problems including diabetes mellitus, hypertension, hyperlipidemia, severe coronary artery disease, congestive heart failure, peripheral vascular disease, carotid stenosis, asbestosis, chronic renal insufficiency, gastroesophageal reflux disease, colonic polyposis, iron deficiency anemia, gastric arterial venous malformation, osteoarthritis, and right eye cataract surgery. His coronary artery disease was characterized by 5-vessel coronary artery bypass graft surgery in 1996 and several percutaneous coronary intervention procedures.

He was admitted to the Milwaukee VAMC in mid December 2007 with an acute myocardial infarction. He was initially treated with an intravenous nitroglycerin drip and heparin. Nevertheless, he continued to have cardiac pain. Despite the high risk, the patient underwent a coronary bypass graft “redo operation” on hospital day 11. The patient did poorly with this procedure.

Postoperatively, the patient went into acute renal failure and was hemodynamically unstable. Despite aggressive care such as renal dialysis and placement of an intra-aortic balloon pump, the patient deteriorated and died 4 days after surgery.

OHI comments: We concluded that, similar to Patient 1 above, this was an extremely high-risk patient for a coronary artery bypass “redo operation.” However, the wisdom of performing the operation notwithstanding, we found no evidence that staffing issues at the medical center caused or exacerbated the patient’s complicated postoperative course or was responsible for his death on POD 4.

Patient 4. The patient was a male in his 60s, with multiple medical problems including a history of diabetes mellitus, myocardial infarction, and cerebral astrocytoma. In mid February 2008, he underwent a 2-vessel coronary bypass graft surgery at the medical center for disease in his left anterior descending and circumflex coronary arteries.

Postoperatively, the patient was returned to the operating room the same day as his bypass graft surgery due to bleeding that was found to originate at the surgery’s aortic cannulation site. On POD 2, the patient was noted to have a right pneumothorax and a chest tube was inserted. The pneumothorax resolved after 3 days, and, on POD 5 his chest tube and pacing wires were removed. Subsequent chest x-rays did not show evidence of either recurrent or new pneumothorax.

The patient was discharged in stable condition on POD 7.

Two days after discharge the patient’s spouse called medical center providers and informed them that the patient had died suddenly at home. No autopsy was performed.

OHI comments: This patient who underwent coronary bypass grafting had a complicated postoperative course that included re-exploration for bleeding and a pneumothorax.

Nevertheless, these complications were successfully treated, and the patient was ultimately discharged from the medical center in apparently stable condition. Chart review records indicate that there was no evidence of further bleeding, pneumothorax, coronary artery ischemia, or cardiac arrhythmia. The patient suffered a sudden death 2 days after discharge. Without an autopsy, it is impossible to state the cause of death. However, we concluded that there is no evidence that staffing issues at the medical center were related to the patient's sudden death.

Patient 5. The patient was a male in his 40s who presented to the medical center Emergency Department (ED) with nausea, vomiting, dizziness, severe shortness of breath, and chest pain.

Medical center ED staff were initially concerned about organophosphate toxicity due to recent exposure to insecticide. The patient was treated with anticholinergic agents. A hemodynamic collapse and cardiopulmonary arrest ensued. Cardio pulmonary resuscitation was initiated, and the patient was admitted to the medical center ICU in cardiogenic shock. The medical center CT Surgery Service was consulted due to concern about aortic dissection and a transesophageal echocardiogram was obtained. It showed "extensive aortic dissection running from the base of the aortic root to beyond the level of the diaphragm, DeBakey type I dissection. The dissection interferes with aortic valve closure with resultant severe aortic regurgitation."

The patient was taken to surgery. While surgeons were able to repair the dissection and transfer the patient to the intensive care unit, the patient was never able to successfully maintain a systolic blood pressure. Also, while the patient did leave the operating room for the intensive care unit, the medical record indicates that the patient arrived in the intensive care unit in asystole (a state of no cardiac electrical activity). He was pronounced dead soon thereafter.

OHI comments: This patient suffered a catastrophic event which for which no satisfactory medical therapy was available and for which surgery is accompanied by an extremely high mortality rate. We do not see any evidence that would relate this patient's death to nurse staffing.

We do note that a misdiagnosis of organophosphate toxicity was made in the emergency room. However, we do not believe that this misdiagnosis altered in any significant way the patient's overall clinical course or ultimate outcome. The medical center is aware of this concern.

Patient 6. The patient was a man in his 70s with multiple medical problems, including diabetes mellitus, obesity, coronary artery disease, chronic obstructive pulmonary disease, obstructive sleep apnea, left nephrectomy, cervical fracture, and a tracheostomy with residual tracheal stenosis. He suffered a syncopal episode sustaining a fall with a

left ankle fracture and chest burns, and was initially admitted to the Iron Mountain VA medical center but then was transferred to the Milwaukee medical center for further treatment.

The Orthopedic Service at the Milwaukee medical center treated the patient's ankle. The Cardiology Service evaluated the patient's syncope and severe, multi-vessel coronary artery disease was identified.

Due to the severe multi-vessel coronary artery disease, a 3-vessel coronary bypass graft surgery was performed. However, the patient did poorly postoperatively with multisystem complications of cardiac arrhythmia, gastrointestinal bleeding, respiratory arrest, pneumonia, renal failure, and hemodynamic instability. Ultimately, he suffered multi-organ failure.

Aggressive treatment was finally halted at the request of the patient's family, and the patient died soon thereafter on POD 27.

OHI comments: This patient was a high-risk patient who suffered a complicated postoperative course characterized by multisystem complications. Approximately one month after coronary bypass graft surgery the prognosis for recovery appeared futile, and the patient died soon after aggressive treatment was halted.

We found no evidence that staffing issues at the medical center were related to the patient's poor postoperative course and death.

Patient 7. The patient was a male in his 80s who had undergone a mitral valve repair in 1997. He was initially admitted to the North Chicago VA medical center due to cardiac failure symptoms but then was transferred to the Milwaukee VA medical center because he was having mitral and tricuspid regurgitation, atrial fibrillation, and a depressed ventricular function.

After admission to the medical center, the patient had a mitral valve replacement, tricuspid ring placement, and a complete CryoMaze closure of a left atrial appendage.

Postoperatively, the patient suffered cardiac arrest with ventricular fibrillation and an acute myocardial infarction. Although he was successfully resuscitated, he became hemodynamically unstable requiring an intra-aortic balloon pump. His condition continued to deteriorate, and multi-organ failure ensued. Aggressive treatment was finally halted at the request of the patient's family, and the patient died soon thereafter.

OHI comments: This patient was the third "redo" case in this series of seven cases, although unlike Patients 1 and 3 above, this case was a redo of a cardiac valvular procedure as opposed to redo of coronary bypass graft surgery.

However, the patient's postoperative myocardial infarction appeared to be the critical event that was determinative in leading to hemodynamic instability and progressive multi-organ failure.

We found no evidence that NP staffing issues at the medical center were related to the patient's myocardial infarction and death.

Inspection Results

Issue 1: Increase in Cardiothoracic Surgery Mortality Rate

We did not substantiate that the removal of the NP contributed to the mortality rate increasing from 150 surgeries and 1 death in a 6-month period to 75 surgeries and 7 deaths in the succeeding 6 months.

Role of the Nurse Practitioner Position. A management decision was made to change the duties and role for the NP for the CT Surgery Service. An additional NP was added to share the coordination of care duties and required responsibilities for the service. We were informed that the NP identified during this inspection was unwilling to accept the change in duties. Therefore, the NP was temporarily detailed from the CT Surgery Service in September 2007 and subsequently permanently assigned to another area of the medical center in January 2008. Managers informed us that the decisions for treatment and care are primarily the responsibility of the surgeon who manages the care for the patients during their hospital stay. Additionally, the NP was not a part of the operative team. According to managers, the NP's responsibilities and duties encompassed care of patients in clinics, responding to non-urgent consults, and some postoperative care under the direction of CT surgeons. Additionally, three of the cases were the direct result of surgery complications and one case was a salvage attempt to give a young patient every opportunity for survival.

Management's Response to the Increase in the Mortality Rate. In response to these patients' deaths, management responded and provided the VHA Office of Patient Care Services with in-depth case summaries regarding the deaths. Additionally, peer reviews were conducted evaluating the care provided and the events surrounding each patient's death with the exception of one patient who died at home. Managers evaluated the deaths and could not identify any trends or patterns that were detrimental to quality of care delivered. We found that these reviews were appropriately monitored by VISN officials. Furthermore, managers informed us that the removal of the NP identified during this inspection would not have changed the outcome for these patients. Nevertheless, managers do acknowledge that some of the patients who were taken to surgery were high-risk for complications. At the completion of our inspection, managers had not received feedback from VHA regarding their report.

The subsequent CICSP biannual report for April 1, 2008, through September 30, 2008, shows that the medical center's Overall Unadjusted Mortality Relative to the VA mean is 3 percent, which is less than 2 times the VA mean. Therefore, no additional audit was required. Medical center managers and personnel shared that they could not recall an occurrence similar to the increase in mortality reported for October 1, 2007, through March 31, 2008.

Overall, in summarizing the seven cases above, VHA wrote:

The in-depth review of these seven case mortalities has made us aware of the fact that there are patients who, regardless of their symptoms, are beyond salvage, and therefore, surgery should not be offered to them. Of course, this is a very difficult decision to make at the time that the patients are presented to the hospital with major problems. All these operations were done by two experienced cardiac surgeons who have been operating at the VA for many years. The outcomes in these seven patients, however, indicate that we should be more selective in very elderly patients with high mortality risks and multiple comorbidities because despite our every effort the adverse outcome may be inevitable. The review, however, has provided us with an opportunity to look at ourselves critically and find ways to improve our outcome and to provide better care to our patients.

Issue 2: Wait Times and Clinic Delays

We did not substantiate an increase in patient wait times for CT Surgery clinic appointments after the removal of the NP. We reviewed fiscal year (FY) 2008 data related to the wait times for appointments for CT Surgery clinic. The following graph illustrates cumulative results for the FY 2008.

FY 2008 CT Surgery Clinic Wait Times					
(results displayed in percentages)					
Patients receiving appointments within	1 st quarter	2 nd quarter	3 rd quarter	4 th quarter	FY total
0-30 days	97.87	99.22	99.33	100	99.13
31-60 days	2.13	0.78	0.67	0	0.87
Total	100	100	100	100	100

CT Surgery clinic is scheduled on Tuesday and Thursday weekly. The Tuesday clinic is focused on patients who have needs related to thoracic surgery. It is held in the mornings and is staffed with one thoracic surgeon and one NP. Patients with cardiac surgery needs can also be scheduled during this allotted clinic time. The Thursday clinic time is focused on patients who have needs related to cardiac surgery. This clinic is held in the afternoons. The clinic is staffed with two cardiac surgeons and two NPs.

After review of the data represented, we found that wait time for patients to be seen by a provider in CT surgery clinic had improved after the reassignment and reorganization of NPs in the CT surgery service. Data shows that patients were seen by providers within 30 days averaging over 99 percent of the time. Additionally, there were no complaints recorded by the Patient Advocate regarding CT Surgery clinic wait times or accessibility to providers.

Conclusions

We did not substantiate that the increase in patient deaths was related to the removal of a NP from the Cardiothoracic Surgery service. Providers admitted to taking high-risk patients to surgery during this timeframe; however, the choice of providing no treatment in some cases would not have improved the overall outcomes. We did find that the medical center conducted a thorough review and presented its data to VA Central Office for review as required, and VISN managers maintained oversight of that process. We did not substantiate that wait times for patients to be seen by providers in CT surgery service had increased due to the removal of an NP. In contrast, wait times improved based upon FY 2008 data provided.

We made no recommendations.

(original signed by:)

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

VISN Director Comments

**Department of
Veterans Affairs**

Memorandum

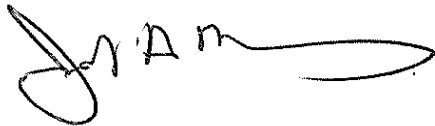
Date: August 24, 2009

From: VISN 12 Director, VA Great Lakes Health Care System
(10N12)

Subject: Healthcare Inspection – Alleged Substandard Quality of Care in
the Cardiothoracic Program, Clement J. Zablocki VA Medical
Center, Milwaukee, Wisconsin

To: Verena Briley-Hudson, MN, RN, Director, Chicago and Kansas City
Office of Healthcare Inspections (54CH), VA Office of Inspector
General

I have reviewed the attached report and concur with the findings.
There are no recommendations to address.

A handwritten signature in black ink, appearing to read 'J. A. Murawsky', with a long horizontal flourish extending to the right.

Jeffrey A. Murawsky, M.D.

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 24, 2009

From: Medical Center Director, Clement J. Zablocki VA Medical Center (695/00)

Subject: Healthcare Inspection – Alleged Substandard Quality of Care in the Cardiothoracic Program, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

To: Verena Briley-Hudson, MN, RN, Director, Chicago and Kansas City Office of Healthcare Inspections (54CH), VA Office of Inspector General

I have reviewed the draft report and concur. There were no recommendations.

If you have any questions, please contact Marylouise K. Felhofer, Deputy, Office of Quality Management and Safety at (414) 384-2000, extension 42517.



Larry L. Berkeley

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, MN, RN, Director Chicago Regional Office of Healthcare Inspections (708) 202-2672
Acknowledgments	Judy Brown, Program Assistant Jennifer Reed, RN George Wesley, MD

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