Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection
Electronic Ordering of Chemotherapy
Fargo VA Medical Center
Fargo, North Dakota

Report No. 10-02882-11 **October 20, 2010**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations:
Telephone: 1-800-488-8244
E-Mail: vaoighotline@va.gov
(Hotline Information: http://www.va.gov/oig/contacts/hotline.asp)

Executive Summary

The purpose of this review was to determine the validity of allegations a complainant made to the OIG Hotline Section regarding unresolved software problems with the electronic ordering of chemotherapy at the Fargo VA Medical Center (the facility), Fargo, North Dakota. The complainant specifically alleged that a patient received an increased dose of chemotherapy because of software problems with the recently installed electronic ordering program (IntelliDose®), and the dosage side effects required the patient to be admitted to the intensive care unit. The complainant further reported that clinical staff was concerned about patient safety and that facility managers were aware of the concerns and refused to stop the use of the electronic software used throughout Veterans Integrated Service Network 23. The complainant alleged that mangers had not provided general education or training on the software.

The IntelliDose® software program automates the ordering of chemotherapy by extracting data from the patient's electronic medical record and providing evidence-based protocols for the many high risk medications needed for cancer treatment. The software alerts clinicians of possible drug interactions, laboratory values that fall out of the approved parameters, and other clinically significant findings from the medical record.

We did not substantiate there were unresolved patient safety concerns related to IntelliDose® software problems. We did not find chemotherapy dosing was inaccurate as a result of the software. A new formula used to calculate dosing created a difference in dosage but was within approved guidelines. All orders for chemotherapy are checked by the oncologist, the chemotherapy registered nurse, and the pharmacists. We found no evidence that patients had been harmed due to an inaccurate dose of chemotherapy.

We substantiated that staff pharmacists were uncomfortable verifying IntelliDose® chemotherapy orders. When staff pharmacists were required to check patients' clinical data, validate chemotherapy dosage, and sign-off orders prior to dosing, pharmacists began voicing concerns to managers. No single pharmacist was assigned responsibility for chemotherapy and the duties were rotated, leaving pharmacists with gaps in actual hands on experience. The Chief of Staff responded to concerns and instructed staff that oncologists would assume all responsibility for verifying dosages of chemotherapy.

We did not find a lack of education on the software. Staff reported they had received initial training and were provided ongoing support and training from the facility super-user. We determined managers responded to concerns; therefore, we made no recommendations.

The Veterans Integrated Service Network and Medical Directors concurred with our findings.

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

TO: Director, VA Midwest Health Care Network (10N23)

SUBJECT: Healthcare Inspection – Electronic Ordering of Chemotherapy, Fargo VA Medical Center, Fargo, North Dakota

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted a review to determine the validity of allegations a complainant made to the OIG Hotline Section regarding unresolved software problems with the electronic ordering of chemotherapy at the Fargo VA Medical Center (the facility), North Dakota.

Background

The facility provides a broad range of inpatient and outpatient health care services for approximately 28,000 veterans residing in North Dakota, western Minnesota, and northern South Dakota. The facility has 42 acute care beds and provides oncology services through a full time physician (oncologist) and oncology registered nurses (RNs). It is part of Veterans Integrated Service Network (VISN) 23.

The OIG Hotline Division received a complaint that a patient received an increased dose of chemotherapy because of software problems with a recently installed electronic chemotherapy ordering program, and the dosage side effects required the patient to be admitted to the intensive care unit (ICU). The complainant further reported that clinical staff was concerned about patient safety and that facility managers were aware of the concerns and refused to stop the use of the electronic software used throughout VISN 23.

In October 2003, VISN 23 implemented a patient safety initiative with the goal of reducing risk in ordering chemotherapy medications. The VISN Chemotherapy Safety Initiative Team included a physician, pharmacist, and technical support person. Their purpose was to review the IntelliDose®[1] software system for potential use within the VISN. The goal was to implement a scientifically based practice for the ordering of chemotherapy. The software program automates the ordering of chemotherapy by

[1] IntelliDose website, http://www.intrinsiq.com/Intellidose.aspx/Overview

extracting data from the patient's electronic medical record and providing evidence-based protocols for the many high risk medications needed for cancer treatment.

The templates produce legible, complete orders, and reduce risk in a complex prescribing process. The oncologist can select a diagnosis based protocol or a chemotherapy drug based protocol. The software takes the provider through a series of questions such as dosage and pre and post-chemotherapy agents. Before the oncologist signs the order, he/she has been alerted to possible drug interactions, laboratory values that fall out of the approved parameters, and other clinically significant findings from the medical record. The oncologist can make changes to the order or override the software parameters based on judgment of individual patient needs. Facility medical staff reviewed and approved the templates and protocols before the program was implemented.

After the oncologist electronically signs an order, the order goes to the chemotherapy RNs who will be administering the medications. The patient is informed of the plan of care and the RN makes arrangements to administer the chemotherapy to the patient. The RN also checks laboratory values and body mass index (BMI)[2] prior to administration. When the RN signs off the orders, the pharmacists are ready to begin dose preparation. The software directs the pharmacists to a series of questions, as it did with the oncologist and RN. The pharmacists are alerted to laboratory values, BMI, and possible drug interactions. The pharmacists are required to sign the orders saying validation has occurred, and begin compounding the drugs for administration.

Prior to use of this software, the oncologist would complete a written order and send it to the pharmacists who would then prepare the medications for administration. The RN would get the medication and review the order and laboratory values for accuracy, then administer the chemotherapy. Pharmacists were not involved in validating orders based on patient clinical information.

An accurate evaluation of renal function is important for the appropriate prescribing and safe delivery of chemotherapy that will be excreted by the kidneys. This is especially true in elderly patients. The formula to calculate drug doses changed with the new software. In addition to approving the protocols, the facility oncologist wanted to use a different method to calculate chemotherapy doses. The facility oncologist reported that most oncologists within the VA system were using a different dosing method from the one used at the facility. Both methods were supported by research, but in order to standardize practices, the oncologist agreed to change to the method others were using. The formula used to determine kidney function and calculate dosage prior to the new software was based on the glomerular filtration rate (GFR)[3] while the formula used with the new software is the method using actual body weight for creatinine clearance.

[2] A measure of body fat based on height and weight that applies to adult men and women.
[3] A test used to measure level of kidney function.

The Minneapolis VA Medical Center (VAMC) pilot tested the software and now all but one of VISN 23 facilities are using the software. The software is in Phase 1 and extracts data from the electronic medical record, but cannot export data back into the records. Phase 2 involves an interface to make exporting data possible and has a target implementation date of approximately 1 year. The facility implemented IntelliDose® in May 2010.

The complainant specifically alleged that:

- The IntelliDose® system has unresolved software problems that create patient safety concerns due to inaccurate dosing of chemotherapy. One patient allegedly received an increased chemotherapy dose that resulted in hospitalization in the ICU.

- Nurses, physicians, and pharmacists have found the system to be unsafe and have voiced their concerns to senior managers, but managers refuse to discontinue the program.

- Managers have not provided general education or training on the software.

Scope and Methodology

We conducted a site visit on June 28, 2010, during our Combined Assessment Program review. During this time, we interviewed the pharmacist in charge of the program, reviewed local policy, and were given a demonstration of the software. We conducted telephone interviews with staff from nursing, pharmacy, quality management, oncology, VISN 23, and the complainant after we left the facility. We also interviewed pharmacy staff from the Minneapolis VAMC with expertise in chemotherapy ordering and the use of the software. We reviewed medical records, quality management documents, chemotherapy protocols, and standards of practice from professional organizations.

This review was performed in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Inspection Results

Clinical Case Review

The patient was a male in his sixties followed in the private sector until diagnosed with metastatic lung cancer. According to the medical record, the private physician did not offer therapy and the patient was advised to consider finding comfort care. The patient and his wife wanted chemotherapy and sought care at the facility where biopsies of multiple lung nodules confirmed cancer with a high probability of gastrointestinal (GI)

tract as the primary site. Although subsequent GI evaluations were negative for cancer, the patient's prognosis was documented as poor. A multidisciplinary group of clinical specialists in cancer diagnosis and treatment (Tumor Board) met and documented that staging, (a method of determining the extent of cancer, prognosis and possible treatments) was not needed at this time due to the documented widespread nature of his cancer. The Tumor Board noted there was nothing to offer the patient surgically, and would only offer limited chemotherapy and radiation that would be provided as comfort measures. The patient was noted to have fluid around both lungs and was admitted to the facility in late March 2010, for increasing shortness of breath. He was seen by a general surgeon for possible treatment to remove the fluid around his lungs. The surgeons determined that treatment was not indicated because the risk outweighed the benefits. He was placed on medications and oxygen to improve his breathing and was discharged 2 days later to his home with follow up for hospice/comfort care.

Five days after discharge, he was seen in the outpatient oncology clinic and reported to the oncologist he wanted chemotherapy. It was noted that the patient had low blood counts and the plan was to delay chemotherapy for 1 week due to his low laboratory values. In early April, because of his low blood counts, he received the first cycle of chemotherapy at a 25 percent reduction in dose. He received 130mg of docetaxel and 560mg of carboplatin. Cycle 2, administered 21 days later, was a dose of 175mg of docetaxel and 745mg of carboplatin. Neither of these was ordered using the new software. The patient tolerated the first 2 cycles without problems.

In May, cycle 3 was ordered with the new software. The dose was docetaxel 180mg and carboplatin 870mg based on height, weight, body surface area, sex, and creatinine clearance levels— the new formula for dose calculations. This was a 14 percent increase from the prior dose, but the patient's laboratory values had improved from cycle 1 and 2. The RN noted in the medical record that she re-calculated the dose prior to administration using GFR, the formula used prior to implementing IntelliDose®, and the dose calculation was 600mg rather than the 870mg. She gave only a portion of the dispensed dose for this reason. The patient went home without any problems noted.

Two days later, the patient complained of chest pain, shortness of breath, and became increasingly confused. His wife took him to the facility emergency department. Physicians' diagnosed pneumonia with impending respiratory failure. He was in significant distress and his providers noted they had conversations with the family about the patient's terminal status. The patient was electively placed on a ventilator and admitted to the ICU. The patient failed multiple attempts to discontinue ventilator support. His prognosis was very poor, and he remained on a ventilator for 21 days. The patient's wife elected to discontinue the ventilator and he died in mid-June . Physicians requested an autopsy but it was denied by family. The cause of death was noted as respiratory failure.

Issue 1: Patient Safety Concerns with Chemotherapy Dosing Due to Unresolved Software Problems

We did not substantiate there were unresolved patient safety concerns related to IntelliDose® software problems. We did not find chemotherapy dosing was inaccurate as a result of the use of the software.

According to the facility policy on chemotherapy ordering oncologists are only allowed to select evidence-based disease specific or drug specific protocols that have been approved by the facility medical staff. These protocols are referenced to the literature that supports their use and the evidence of effectiveness for each type of corresponding cancer. The provider is alerted to potential drug interactions and patient specifics that could be a problem such as laboratory values that are out of range. The software extracts the patient's most current weight and height and laboratory values in order to calculate the dose.

This is different from the past practice where the oncologist had to obtain the information, calculate the dose, and then the RN double checked it. The dose is now calculated using the creatinine clearance laboratory value rather than the GFR used in the past. This creates a difference in the dose. The oncologist supported use of creatinine clearance as the dosing method, but this created concerns among staff accustomed to the old method of dose calculation. All orders for chemotherapy are checked by the ordering oncologist, the chemotherapy RN, and the pharmacists.

The facility patient safety officer tracked medication errors for the time prior to and since the electronic software implementation. The facility IntelliDose® committee is evaluating problems during implementation and has not identified any chemotherapy ordering errors. Since the software was implemented there have been three situations reported for incorrect dosing, but upon further review, all doses were found to be correct. We found no evidence that patients had been harmed due to an inaccurate dose of chemotherapy.

We spoke to a pharmacist at the Minneapolis VAMC who is knowledgeable of the IntelliDose® system. She shared with us that the software has actually improved the safety of chemotherapy orders throughout VISN 23. In the past, chemotherapy orders were hand written, calculations were confusing, and it was difficult to tell what protocol was being used. Clinical staff often had questions. From her point of view, staff has learned a new system and they are satisfied that the process has improved. She was not aware of any dosing errors or patient safety concerns.

Issue 2: ICU Admission Due to an Inaccurate Chemotherapy Dose

We did not substantiate that a patient required ICU admission due to an inaccurate dose of chemotherapy because of IntelliDose® software.

The patient received 3 cycles of chemotherapy appropriate for lung cancer treatment. Cycles 1 and 2 were ordered under the old system. Cycle 3 was ordered using the new software IntelliDose®. The dose was calculated using a different formula and the dose was correct based on this methodology. It was a higher dose than the previous cycles, but within published guidelines. The RN administered a partial dose since she was concerned about the higher dosage and the patient's overall condition. The patient tolerated the chemotherapy well and went home after the treatment. The patient returned to the hospital 2 days later with increased difficulty breathing that was related to the progression of his cancer. He was diagnosed with pneumonia and pleural effusions and was placed on a ventilator and died 21 days later.

Issue 3: Lack of Clinical Staff Training and Managers Concern

We substantiated the allegation that staff pharmacists were uncomfortable verifying chemotherapy orders and that managers returned responsibility for chemotherapy order verification to the oncologist.

Clinical pharmacists are Pharm D prepared and have been trained to assess and intervene with patients on a clinical level. Staff pharmacists are technically trained in mixing and dispensing medications based on the clinical assessment of other healthcare providers. We validated with another VISN 23 VAMC that facility staff pharmacists' IntelliDose® duties were well within the scope of a staff pharmacist.

When staff pharmacists were required to check patients' clinical data, validate chemotherapy dosage, and sign-off orders prior to dosing, pharmacists began voicing concerns to managers. We were told that other VA facilities that had implemented IntelliDose® had clinical pharmacists who were trained to perform these duties and that the facility staff pharmacists were not trained, and did not feel competent in this requirement. We validated that all staff had training in IntelliDose® prior to implementation and had ongoing support from the designated clinical pharmacist super-user.

No single facility pharmacist was assigned responsibility for chemotherapy and the duties were rotated leaving pharmacists with gaps in actual hands on experience. The leadership of the facility was informed of these concerns and assured the pharmacy staff they could call the oncologists at any time if they had questions. These calls were so frequent that they began to be a burden to the one oncologist on duty. Because of this, the Chief of Staff instructed the pharmacists that they were no longer accountable to verify dosage on chemotherapy orders and that the oncologist would assume all responsibility.

Conclusions

We did not find inaccurate chemotherapy orders for the patient involved in this complaint. Patients with end stage metastatic lung cancer may progress to respiratory failure, as was the case for this patient. The patient had limited options for therapy. Although the patient was informed of his poor prognosis, he still wanted chemotherapy. His request was met, but proved to be futile. The patient was offered palliative care, which he declined.

We did not find any patients that received inaccurate doses of chemotherapy as a result of utilizing the IntelliDose® software.

We found that concerns regarding the implementation and use of the software were presented to facility leadership and that their responses were appropriate. Multiple actions have been taken to address these concerns. We believe that the fact that this system used a different method for calculation of doses of chemotherapy caused many of the concerns and when fully reviewed, concerns were determined to be unfounded. Multiple staff shared with us that they had a learning curve and now that they have used the system for a period of time, they better understand the process.

We did not find a lack of education on the software. We were told by everyone we interviewed that they had received initial training on how to use the software and were provided ongoing support and training from the facility super-user. Everyone shared that the super-user and the Chief of Staff had been involved and several meetings had occurred to discuss issues and come up with solutions.

Although we have no formal recommendations, we discussed with the VISN 23 Patient Safety staff the possibility of integrating and comparing the data collected by the various IntelliDose® committees and patient safety programs at VISN 23 facilities. We believe this would assist in analysis of the performance of this new process.

Comments

The VISN and Medical Center Directors concurred with the inspection results (see Appendixes A and B, pages 9–10, for the full text of their comments).

(original signed by:)
JOHN D. DAIGH, JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 22, 2010

From: Director, VA Midwest Health Care Network (10N23)

Subject: Healthcare Inspection – Electronic Ordering of Chemotherapy, Fargo VA, Fargo, North Dakota

To: Director, Kansas City Office of Healthcare Inspections

Thru: Director, Management Review Service (10B5)

After review of the report and Fargo's response, I concur with findings and also thank the team for their professionalism.

Janet P. Murphy, MBA

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: **September 17, 2010**

From: Director, Fargo VA Medical Center, Fargo, ND (437/00)

Subject: **Healthcare Inspection –** Electronic Ordering of Chemotherapy, Fargo VA, Fargo, ND

To: Director, VA Midwest Health Care Network 23 (10N23)

I have reviewed and concur with the findings in this report. I would like to express my appreciation to the team who conducted the review for their professional and comprehensive review and approach.

Michael J. Murphy, FACHE

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	Dorothy Duncan Director, Kansas City Office of Healthcare Inspections (816) 997-6966
Acknowledgments	Jennifer Kubiak, Team Leader Laura Tovar Jennifer Whitehead Michael Shepherd, Physician Consultant

Appendix D

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, VA Midwest Health Care Network (10N23)
Director, VA Medical Center, Fargo, North Dakota (437/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Kent Conrad, Byron Dorgan
U.S. House of Representatives: Earl Pomeroy

This report is available at http://www.va.gov/oig/publications/reports-list.asp.