



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Poor Quality of
Cancer Care at the VA
Caribbean Healthcare
System

San Juan, Puerto Rico



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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection to review an allegation of poor patient care at the VA Caribbean Healthcare System (facility) in San Juan, Puerto Rico. Specifically, a complainant alleged that medical oncology, radiation oncology, and community living center (CLC) staff inadequately monitored a CLC patient receiving combined chemotherapy and radiation therapy for anal cancer, leading to the patient's death from complications of treatment toxicity. The complainant also provided the OIG with a list of 55 cancer patients alleging failure to diagnose, delay in diagnosis and treatment, avoidable death, and other quality of care concerns. The OIG sent these cases to the Veterans Integrated Service Network (VISN) 8 Director for review and comment. In its response, the VISN included an action plan developed to address identified deficiencies in the care of the 55 patients.¹ In this report, the OIG assessed the care of the CLC patient, and the adequacy and implementation status of the action items.

The OIG substantiated that CLC and medical oncology staff inadequately monitored the CLC patient and found CLC and medical oncology staff documentation insufficiencies. The OIG did not substantiate that the radiation oncology staff inadequately monitored the patient. While the patient had an attending physician in the CLC as well as an attending physician from medical oncology, there were no care coordination agreements between the CLC and other services to clearly delineate clinical responsibilities and clarify information transfer. The OIG determined that patient monitoring by CLC licensed practical nurses (LPN)s was evident in their documentation; however, the LPNs did not follow the facility's requirement of adding the registered nurses as co-signers to notes to alert them of changes in a patient's status. As such, the registered nurses were not alerted to early warning signs of the CLC patient's treatment toxicity.

Another CLC documentation failure involved the patient's care plan, which had not been modified to include the initiation of chemotherapy, potentially creating a situation in which the LPNs did not realize the patient was taking oral chemotherapy and were not aware of the importance of reporting stool output changes. While the patient's course of care may have been managed differently with additional monitoring and communication, the OIG was unable to determine that the inadequate monitoring, lack of communication, and an incomplete care plan contributed to the patient's death.

Although an action plan had been created and implemented to address identified deficiencies in the care of the 55 identified oncology patients, the action items did not comprehensively address all findings identified by the non-facility VISN reviewers. The action plan did not include primary care providers in the multidisciplinary training conference on the topic of management

¹ Non-facility VISN providers conducted a non-confidential, management review of the patients.

of patients with prostate cancer and did not address the concern of a VISN 8 reviewer who identified two documentation failures related to an oncologic patient's physical examination.

While not an allegation, the OIG found that VISN 8 had contracted with a non-Veterans Health Administration reviewer to independently review eight patient cases for interrater reliability; however, the information provided to the interrater reviewer was not identical to the information provided to the non-facility VISN reviewers. Management reviews conducted concurrently do not meet standards for interrater reliability if the concurrent reviewers are not reviewing the same care issues.

The OIG made one recommendation to the VISN Director related to clear and consistent instructions for concurrent management reviews and six recommendations to the Facility Director related to the monitoring of chemotherapy patients, care coordination agreements between the CLC and specialty services, utilization of procedures regarding the communication of patient status changes, completion and accuracy of patient care plans, primary care provider training on the management of patients with prostate cancer, and addressing the findings of the non-facility VISN reviewers.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided an acceptable action plan. (See appendixes A and B, pages 17–23.) The OIG considers all recommendations open and will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.



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Abbreviations

CLC	community living center
EHR	electronic health record
LPN	licensed practical nurse
MDS	Minimum Data Set
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted an inspection to review an allegation of poor patient care at the VA Caribbean Healthcare System (facility) in San Juan, Puerto Rico. Specifically, a complainant alleged that medical oncology, radiation oncology, and community living center (CLC) staff inadequately monitored a CLC patient receiving combined chemotherapy (capecitabine) and radiation therapy for anal cancer, leading to the patient's death from complications of treatment toxicity.²

Background

The facility, part of the Veterans Integrated Service Network (VISN) 8, is the largest federal medical facility in Puerto Rico. The facility provides primary and tertiary care. It also provides short- and long-term care within the CLC. The facility is classified as a Level 1a, high-complexity facility with 280 inpatient and 122 CLC beds.³ Treating specialties within the CLC include long-stay spinal cord injury and diseases, short-stay skilled nursing care, long-stay continuing care, short-stay rehabilitation, short-stay continuing care, short-stay restorative care, and hospice. In fiscal year 2017, the facility served 62,974 patients. The facility is affiliated with four accredited medical schools in Puerto Rico; University of Puerto Rico, Universidad Central del Caribe, Ponce School of Medicine, and San Juan Bautista Medical School.

Anal Cancer Treatment

Anal cancer is a rare type of cancer. Anal cancers are often squamous cell carcinomas that have grown beyond the surface and into the deeper layers of the lining of the anus. Treatments for anal cancer include radiation therapy and intravenous or oral chemotherapy (chemoradiation). While radiation therapy alone may improve the 5-year survival rate, the high doses may cause necrosis

² VHA Handbook 1142.01, *Criteria and Standards for VA Community Living Centers (CLC)*, August 13, 2008. VHA community living centers, formerly known as nursing home care units, provide skilled nursing care to eligible veterans. Capecitabine is an anti-metabolite that interferes with cell replication. While not a radiation treatment, capecitabine is a radio-sensitizing agent in anorectal cancer, meaning that it can make radiation more effective. Capecitabine is generally administered and monitored by a medical oncologist. <https://www.cancer.gov/about-cancer/treatment/drugs/capecitabine>. (The website was accessed on September 25, 2018.)

³ VHA Office of Productivity, Efficiency and Staffing. The VHA Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex. (The website was accessed on August 29, 2018; it is an internal VA website that is not publicly accessible.)

or fibrosis of the anus and surrounding tissue.⁴ The addition of chemotherapy to radiation may improve side effects and survival rates.

Capecitabine

Capecitabine (Xeloda®) is an oral chemotherapy drug used to slow or stop the growth of cancer cells primarily in patients with advanced breast and colorectal cancer. In 2014, a study published in the *British Journal of Cancer* established that it was acceptable to treat patients with locally advanced anal cancer with capecitabine on each day that radiation therapy is administered, rather than continuous intravenous chemotherapy in combination with mitomycin C and intensity-modulated radiotherapy.⁵

According to published drug information, capecitabine can cause serious side effects such as diarrhea, nausea, and vomiting, especially in older adults who may be more sensitive. Patients who experience serious side effects of the medication are directed to “call your physician immediately.”⁶ Patients taking capecitabine should be carefully monitored for toxicity symptoms and doses should be modified based on the patient’s tolerance. The prescribing information emphasizes that patients receiving capecitabine should be monitored by a physician experienced in the use of cancer chemotherapeutic agents, with attention to monitoring adverse effects when prescribed to a geriatric patient.⁷

The dose management guidelines for capecitabine describes diarrhea as one of the adverse effects of the medication. Grade two diarrhea is an increase of four to six stools per day or night. A patient that experiences a grade two diarrhea should stop taking capecitabine immediately. For patients with a colostomy pouch, quantifying stools per day and overall clinical output assessment is challenging.⁸

⁴ National Center for Biotechnology Information. Anal Cancer Treatment (PDQ®). <https://www.ncbi.nlm.nih.gov/books/NBK65778/>. (The website was accessed on February 12, 2019.)

⁵ Meulendijks, D., Dewit, L., Tomaso, N. B., van Tinteren, H., Beijnen, J. H., Schellens, J. H., & Cats, A. (2014). Chemoradiotherapy with capecitabine for locally advanced anal carcinoma: an alternative treatment option. *British Journal of Cancer*, 111(9), 1726-33.

⁶ Genentech. Xeloda-Highlights of Prescribing Information. https://www.gene.com/download/pdf/xeloda_prescribing.pdf%20a/. (The website was accessed on March 11, 2019.)

⁷ Geriatric patients are defined as ≥80 years old. https://www.gene.com/download/pdf/xeloda_prescribing.pdf. (The website was accessed on March 11, 2019.)

⁸ A colostomy is a surgical opening made in the colon or large intestine through the abdominal wall (stoma). Stool drains from the stoma into a bag or pouch adhesively attached to the skin. https://www.hopkinsmedicine.org/healthlibrary/test_procedures/gastroenterology/colostomy_92_p07727. (The website was accessed on January 19, 2019.)

Allegation and Related Concerns

On November 30, 2017, the OIG received an allegation that a CLC patient receiving radiation therapy and capecitabine was poorly monitored for capecitabine toxicities by CLC, medical oncology, and radiation oncology staff leading to the patient's death. In addition, the OIG was provided with a list of 55 additional patients, alleging failure to diagnose, delay in diagnosis and treatment, avoidable death, and other quality of care concerns.

In mid-January 2018, the OIG sent the CLC patient case and the 55 patient cases to the VISN for review. In a response dated April 13, 2018, the VISN did not substantiate inappropriate care of the CLC patient. For the 55 patients, the VISN partially substantiated the allegations of failure to diagnose, delay in diagnosis and treatment, and other quality of care concerns. The VISN did not substantiate the allegation of avoidable death.

A non-confidential, management review was conducted by non-facility VISN providers who determined that, of the 55 cases, 35 cases did not meet the standard of care or had other concerns:⁹

- 15 cases did not meet the standard of care.
- 4 cases evaluated by both Veterans Health Administration (VHA) and external reviewers were discordant regarding standard of care.
- 16 cases met standard of care, but other potential concerns identified.

An action plan accompanied the VISN report that was provided to the OIG and included the following items:

- Host multidisciplinary training conference on current standard treatment for neuroendocrine carcinoma and prostatic adenocarcinoma, to include urology, oncology, and radiation therapy.
- Monitor 30 oncologic patients' electronic health records (EHRs) to determine whether
 - Physical exam findings were documented with 90 percent compliance,¹⁰
 - Delays in treatment coordination and initiation occurred in those patients recently diagnosed with prostate carcinoma, and
 - Informed consent was consistently obtained.

⁹ VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. A management review, conducted by a peer (s), is used to examine an episode of patient care to determine if a specific healthcare provider complied with standards of care. Leaders and managers may use non-confidential management review results to respond to external inquiry or to provide a basis or action that may affect clinical privileges or personnel status. This directive was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. The two directives contain the same or similar language related to the definition of management reviews. The OIG did not use the numbers provided by the VISN, but instead counted the actual cases provided by the complainant.

¹⁰ A sample of patient EHRs was reviewed for quality of documentation.

- Review all cases in which standard of care was not met to determine if institutional disclosures are warranted.

The OIG Hotline Triage team had concerns about the adequacy of the action plan and tasked the OIG inspection team to

1. Evaluate the allegation that medical oncology, radiation oncology, and CLC staff inadequately monitored the CLC patient, leading to the patient's death from complications of treatment toxicity; and
2. Determine the adequacy and implementation status of the action items related to the identified deficiencies in the care of 55 additional patients.

The OIG team also evaluated the interrater reliability of the VISN reviews.

Scope and Methodology

The OIG initiated the inspection on August 28, 2018, and conducted a site visit October 16–18, 2018.

The OIG interviewed the facility Acting Director, Deputy Chief of Staff, Chief of Pathology and Laboratory, Chief of Medical Oncology, Chief of Quality Management and other key staff, including providers directly responsible for the care of the CLC patient. Additionally, the OIG team interviewed VISN and facility staff regarding the care provided to the 55 patients and the response of leaders to noted deficiencies.

The OIG team reviewed VHA directives, handbooks, guidelines and requirements; medical literature; relevant facility policies and procedures; and the CLC patient's EHR.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

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

Patient Case Summary

The patient, who was in their 80s, had received both primary and specialty care at the facility since 2007.¹¹ The patient's medical history included high blood pressure, coronary artery disease, peripheral vascular disease, high cholesterol, obesity, prostate cancer, and hypothyroidism.¹²

At a prostate cancer follow-up visit in 2016, the patient complained of fecal incontinence; the oncologist placed a referral to the gastroenterology service for evaluation.¹³ A month later, the patient was seen by a gastroenterologist who discovered a hard, palpable anal mass, which was confirmed by a colonoscopy procedure.¹⁴ The patient then underwent a biopsy to determine the histology of the mass and establish next steps.¹⁵

The tumor was described as anal squamous cell cancer extending into the prostate gland. Chemotherapy and radiation therapy were recommended. Due to the patient's decreased kidney function and suspected poor social support, it was recommended the patient stay in the CLC during treatments.

In fall 2016, the patient underwent a loop colostomy procedure due to concern for anal stricture.¹⁶ About a week later, a colostomy revision and debridement procedure was performed

¹¹ The OIG uses the singular form of they in this instance to protect the patient's privacy.

¹² Peripheral vascular disease is a blood circulation disorder that causes blood vessels outside of the heart to narrow, block, or spasm. <https://www.hopkinsmedicine.org/health/conditions-and-diseases/peripheral-vascular-disease>. (The website was accessed on October 26, 2018.) Hypothyroidism is a condition that occurs when the thyroid gland does not produce enough hormones which disrupts the normal balance of chemical reactions in the body. <https://www.mayoclinic.org/diseases-conditions/hypothyroidism/symptoms-causes/syc-20350284>. (The website was accessed on October 26, 2018.)

¹³ Fecal incontinence is the inability to hold feces, or stool, within the rectum. <https://www.hopkinsmedicine.org/health/conditions-and-diseases/understanding-fecal-incontinence>. (The website was accessed on May 1, 2019.)

¹⁴ A colonoscopy is the examination of the colon using thin, tube-like instrument, inserted into the rectum. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/colonoscopy>. (The website was accessed on May 1, 2019.)

¹⁵ A biopsy is the removal and microscopic evaluation of tissue or cells from a living body. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/biopsy>. (The website was accessed on May 2, 2019.)

¹⁶ A loop colostomy is a procedure in which a loop of colon (bowel) is brought out onto the abdominal wall. The loop is supported by a plastic channel or rubber tube, two openings are made in the loop. <http://www.nsgmed.com/nursing-procedures/colostomy-care-colostomy-indications-types-of-colostomy-procedure>. (The website accessed on July 1, 2019.) A stricture is an abnormal constriction of a body track or opening, such as from cancer. <https://www.merriam-webster.com/dictionary/stricture>. (The website was accessed on July 1, 2019.)

due to necrotizing infection.¹⁷ The patient was transferred to the CLC for skilled nursing and wound care.

In late 2016, an oncologist wrote recommendations for combined chemotherapy with radiation therapy and reaffirmed this recommendation to include oral chemotherapy with capecitabine three weeks later. At that time, the patient's care plan note stated the patient was full code status and required extensive assistance in activities of daily living.¹⁸

In early 2017, the patient began radiation and chemotherapy treatments (day 1). On day 31, a CLC licensed practical nurse (LPN) documented the patient had three liquid stools; it was the first day more than two liquid stools were documented in a single day. LPNs charted varying stool consistency (normal, soft, liquid) over the ensuing days. On day 32, the radiation oncology weekly treatment plan notes reflected good tolerance to radiation treatment with no concerns and a plan to continue current therapy.

Other providers did not document liquid stools or diarrhea until day 36, when a radiation oncology registered nurse documented the patient's complaint of odorous "diarrheas" and notified the CLC physician for evaluation. A clinical evaluation of the diarrhea revealed a low serum potassium level; stool studies were negative for infection.¹⁹ The evaluation was consistent with dehydration and the patient was treated with intravenous fluids and potassium supplementation. The patient continued to receive radiation treatment until day 38 and capecitabine through day 39.²⁰

On day 39, the patient experienced episodes of dizziness, nausea, low blood pressure, and rapid heart rate. Laboratory studies were ordered, and the results were consistent with continued

¹⁷ Necrotizing skin infections are serious forms of cellulitis exemplified by death of infected skin and tissues and include necrotizing cellulitis and necrotizing fasciitis. <https://www.merckmanuals.com/home/skin-disorders/bacterial-skin-infections/necrotizing-skin-infections>. (The website was accessed on October 26, 2018.)

¹⁸ A code is the gathering of professionals trained in cardiopulmonary resuscitation (CPR) to revive a person whose heart stops (cardiac arrest), whose breathing stops (respiratory arrest), or whose heart and breathing stop (cardiopulmonary arrest). *Merck Manuals*. <https://www.merckmanuals.com/home/fundamentals/legal-and-ethical-issues/do-not-resuscitate-dnr-orders>. (The website was accessed on April 16, 2019.)

¹⁹ Normal serum potassium levels are critical for the proper functioning of nerve and muscles cells, particularly heart muscle cells. Very low levels of potassium can be life-threatening. <https://www.mayoclinic.org/symptoms/low-potassium/basics/definition/sym-20050632?p=1>. (The website was accessed on July 22, 2019.) Serum is a component of blood. <https://www.merriam-webster.com/dictionary/serum>. (The website was accessed on July 22, 2019.)

²⁰ Of a total of six opportunities to receive capecitabine from day 37 to day 39, the patient refused three doses and took two doses. One dose was held before the medication was discontinued.

dehydration and acute kidney injury. According to the CLC physician, the patient may have developed systemic inflammatory response syndrome.²¹

The CLC physician transferred the patient to the emergency department, and the patient was admitted to the internal medicine service on the acute care medical unit. The patient was treated with antibiotics for presumed infection and intravenous fluids for volume replacement. Although the patient's diarrhea decreased, overall health status and laboratory studies continued to worsen despite multiple medical interventions. The patient became critically ill with a poor overall prognosis. On day 44, the patient's code status was changed to Do Not Resuscitate subsequent to a discussion with the patient's son.²² The patient expired the following day (day 45).

²¹ Systemic inflammatory response syndrome is a serious illness where inflammation is found throughout the body. Potential causes are a severe bacterial infection (sepsis), trauma, or pancreatitis. <https://www.cancer.gov/publications/dictionaries/cancer-reemeterms/def/sirs>. (The website was accessed on October 29, 2018.)

²² A Do Not Resuscitate Order (DNR) is an order that establishes cardiopulmonary resuscitation (CPR) shall not be attempted for a person whose heart stops (cardiac arrest), whose breathing stops (respiratory arrest), or whose heart and breathing stop (cardiopulmonary arrest). <https://www.merckmanuals.com/home/fundamentals/legal-and-ethical-issues/do-not-resuscitate-dnr-orders>. (The website was accessed on April 16, 2019.)

Inspection Results

1. Monitoring of a Cancer Patient

The OIG substantiated that CLC and medical oncology staff inadequately monitored the CLC patient receiving combined radiation and chemotherapy. In addition, neither the CLC nor medical oncology staff provided adequate documentation. While the patient had an attending physician in the CLC as well as an attending physician from medical oncology, there were no care coordination agreements between the CLC and other services.²³ Deficits in communication between the CLC attending physician, CLC nursing staff, and medical oncology staff may have delayed recognition of deterioration of patient's condition. The OIG found radiation oncology adequately monitored the patient's symptoms and documented the clinical decision to continue radiation therapy.

CLC Staff

Although patient monitoring by LPNs was evident in their documentation, the LPNs did not add the registered nurse as a co-signer to their documentation alerting them to early warning signs of treatment toxicity. The CLC registered nurse and CLC provider were unaware of the change of stool pattern from soft to liquid. In addition, chemotherapy was missing from the patient's care plan, potentially creating a situation in which the LPNs did not realize the patient was taking oral chemotherapy and therefore were not aware of the importance of reporting the stool output changes.

Facility policy requires registered nurses and LPNs assigned as the direct caregiver for a patient to utilize a specific observation and communication tool to identify early warning signs in a patient's condition. When the tool is completed by an LPN, the policy requires the LPN to document clinically significant changes in the EHR and to add the registered nurse as an additional signor to the note to ensure communication to the registered nurse of the change in status.²⁴ As the direct (daily) caregivers, LPN communication to the registered nurse of changes in patient condition is imperative. Given the conflicting statements made by LPNs and registered nurses during interviews, the OIG was unable to determine if registered nurses were verbally made aware of the patient's increasingly abnormal stool patterns over the course of the CLC stay. Specifically, beginning on day 23, the patient began to experience persistent daily diarrhea,

²³ "An attending [physician] is a medical doctor who is responsible for the overall care of a patient in a hospital or clinic setting." <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/attending-physician>. (The website was accessed on March 12, 2019.) A care coordination agreement is a written agreement or understanding between two or more services within or between facilities, to ensure quality care and establish protocols for supporting effective care transitions. VHA Directive 1232(1), *Consult Processes and Procedures*, amended September 23, 2016.

²⁴ Facility LTC Memorandum 11G-16-66, *Nursing Staff Assignments and Huddles/Hand Off Communication in the Community Living Center (CLC)*, February 2016.

varying in severity, from partial to full liquid stool, upon emptying the colostomy pouch. (See Figure 1, depicting an increase in the number and a change in the nature of the patient’s stools.)

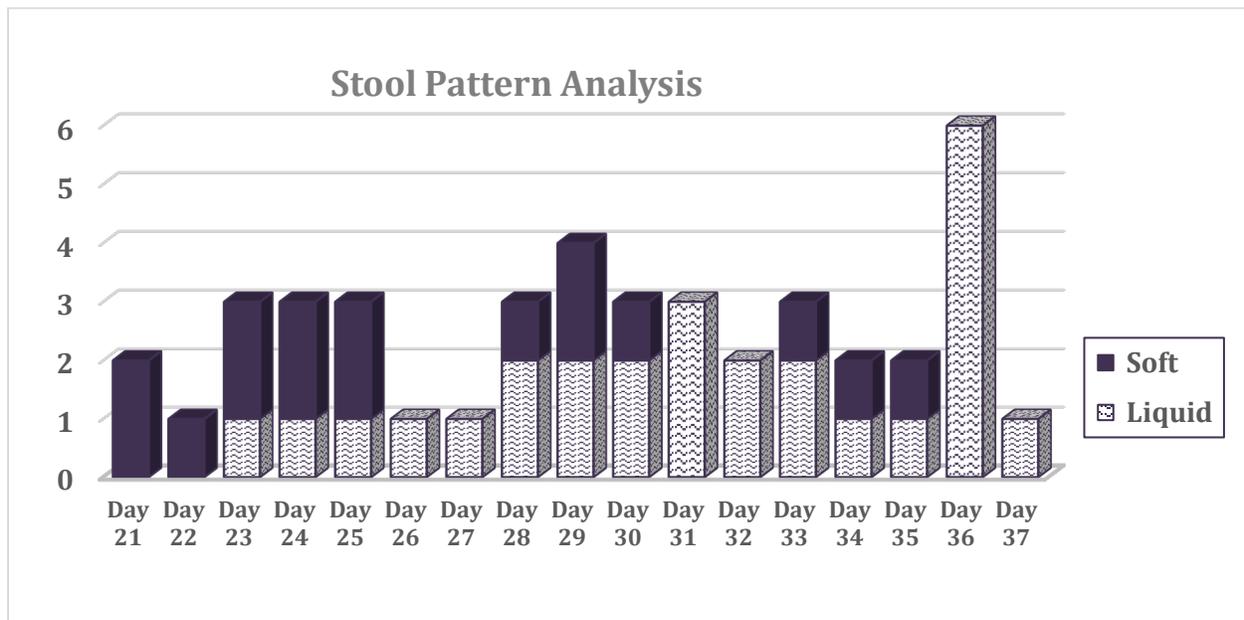


Figure 1. Patient’s stool pattern, day 21 – day 37
 Source: VA OIG analysis

If the registered nurses were made aware of the change in this patient’s status, they may have recognized the change in the patient’s stool as a reaction to the chemotherapy and alerted the medical oncologist and interdisciplinary treatment team potentially prompting an alteration in the patient’s care plan.

A lapse in documentation was also evident in completion of the patient’s care plan. The OIG found that the care plan did not reflect that the patient was receiving oral chemotherapy.

The facility’s CLC staff used the Minimum Data Set (MDS), an assessment and treatment planning process designed to identify the needs of a patient, to create a personalized care plan for each CLC patient.²⁵ An interdisciplinary team was responsible for ensuring that the care plan was an accurate guide for the patient’s individualized care. A registered nurse care coordinator was responsible for updating the interdisciplinary care plan throughout the CLC admission.²⁶

The facility MDS Coordinator reported that a registered nurse care coordinator inaccurately completed the MDS, resulting in the omission of capecitabine and its associated side effects on the patient’s care plan. Because an accurate MDS is the foundation to a comprehensive patient

²⁵ VHA Handbook 1142.03, *Requirements for Use of the Resident Assessment Instrument (RAI) Minimum Data Set (MDS)*, January 4, 2013. The Minimum Data Set is part of a federally mandated process for providing a comprehensive assessment of each nursing home patient’s functional capabilities. This VHA handbook was scheduled for recertification on or before the last working day of January 2018 but has not been recertified.

²⁶ Facility LTC Memorandum 11G-16-66.

care and treatment plan, CLC nursing staff following the patient's care plan may not have been aware that the patient was taking capecitabine or monitored the patient closely for symptoms of toxicity.

Care Coordination Agreements in the CLC

The CLC did not have care coordination agreements with medical oncology or radiation oncology services which may have contributed to a breakdown of communication regarding the patient's condition. VHA facilities must establish and utilize care coordination agreements to aid in the effective management of patients by optimizing referral relationships and establishing clear processes between various services.²⁷ Care coordination agreements are important when a patient is seen by multiple services because they define the workflow rules, outline the responsibilities between care providers including the delineation of clinical responsibility, and standardize information transfer.²⁸ Without workflows defined in a care coordination agreement, there is an absence of clearly defined responsibilities between the CLC and specialty services.

Medical Oncology Staff

Medical oncology staff did not see the patient from the time they ordered oral chemotherapy (capecitabine) and it was initiated (day 1) until the day after the patient was transferred to inpatient care (day 40).²⁹ Prescribers of capecitabine should monitor geriatric patients for toxicity symptoms and doses should be modified based on the patient's tolerance.³⁰ According to the medical oncologist, typical practice is to see patients every two weeks after the initiation of capecitabine to ensure the patient is monitored for side effects.

The OIG found that the patient, while residing in the CLC, was not seen for a scheduled follow-up appointment with the medical oncologist on day 30. Facility policy requires that when a patient is a no show for a scheduled appointment, the responsible provider (in this case, the medical oncologist) is required to review the patient's EHR to determine and initiate appropriate follow-up. A no show progress note was written on day 32 that included the active medication list and a plan to reschedule appointment. The medical oncologist noted availability to see the patient on day 33; however, the patient was neither scheduled for that date nor was the patient seen by a medical oncology provider. During an interview with the OIG team, the medical oncologist confirmed that the patient had not been seen by medical oncology since the day the capecitabine was ordered.³¹

²⁷VHA Directive 1232(1), *Consult Processes and Procedures*, August 24, 2016, amended September 23, 2016.

²⁸ VHA Directive 1232(1).

²⁹ The oral chemotherapy was ordered five days before it was initiated.

³⁰ Genentech. Highlights of Prescribing Information. XELODA® (capecitabine) tablets, for oral use. Dose management guidelines. https://www.gene.com/download/pdf/xeloda_prescribing.pdf. (The website was accessed on March 11, 2019.)

³¹ A two-week post-start appointment would have been Day 15.

On day 39, the patient was transferred from the CLC to the emergency department and admitted as an inpatient with diagnostic impressions including, but not limited to, volume depletion and rule out infectious diarrhea. The medical oncologist further stated that diarrhea can result in dehydration. If the chemotherapy had been dose-reduced prior to the acute care admission, the patient may not have suffered from ongoing diarrhea as a side effect of chemotherapy and subsequent dehydration. The OIG was unable to determine if the dehydration, likely a result of toxicity, led to the patient's death.

When prompted by the OIG to review the patient's stool pattern for days 22-37 post-initiation of the oral chemotherapy (see Figure 1), the medical oncologist stated that if there had been awareness of the change in stool pattern, an order would have been initiated for CLC staff to hold the capecitabine starting on day 26; and once stool returned to baseline or at least two-thirds of stools were formed, an order would have been entered for a dose reduction and the monitoring of patient tolerance.

The medical oncologist's failure to adequately and timely monitor the patient for chemotherapy medication side effects may have hindered the alteration of the patient's care plan (including holding the capecitabine) and contributed to the patient's declining health.

Radiation Oncology Staff

Interdisciplinary team notes that were started when radiation treatment and capecitabine were initiated documented the patient's response to the radiation treatment. The notes were acknowledged as being reviewed by at least one or all of the following: a registered nurse, radiation oncologist and clinical social worker. Although changes in stool consistency and frequency did occur, radiation oncology staff documented monitoring of the patient's symptoms and the clinical decision to continue radiation therapy.

Based on statements made by the radiation oncologist, the OIG determined that despite changes in stool pattern, the course of radiation treatment for the patient would not have changed. According to the radiation oncologist, stopping radiation was not a viable option, even in the setting of diarrhea symptoms, because it would have unnecessarily compromised the patient's chance for cure.

While the patient's course of care may have been managed differently with additional monitoring and communication, given the totality of information, the OIG was unable to determine that the medical oncology staff's inadequate monitoring of the patient, the CLC staff's lack of communication regarding the patient's change in status, or the CLC staff's incomplete care plan, contributed to the patient's death.

2. Adequacy and Implementation Status of the Action Plan

An action plan was created to address identified deficiencies in the care of the 55 cancer patients. The action items were implemented but did not comprehensively address all findings identified

by the non-facility VISN reviewers. Table 1 shows completion dates for the facility’s implementation of the action plan.

Table 1. Status of Action Plan Implementation

Action Items	Target Completion Date	Completion Date
Host multidisciplinary training conference on current standard treatment for neuroendocrine carcinoma and prostatic adenocarcinoma.	May 31, 2018	September 28, 2018
Monitor 30 oncologic patient EHRs to determine whether <ol style="list-style-type: none"> 1. Physical exam findings were documented with 90 percent compliance,³² 2. Delays in treatment coordination and initiation occurred in those patients recently diagnosed with prostate carcinoma, and 3. Informed consent was consistently obtained. 	May 31, 2018	May 25, 2018
Review all cases in which standard of care was not met to determine if institutional disclosures are warranted.	May 31, 2018	August 10, 2018

Source: OIG analysis of Acting Chief of Staff October 17, 2018, data

The OIG team identified two areas of concern with the adequacy of the action plans. First, primary care providers were not included in the multidisciplinary training conference on the topic of management of patients with prostate cancer. Primary care providers are important in the care of prostate cancer patients through screening, ongoing monitoring, and coordination of care.³³ In 4 of 35 non-facility VISN reviews where quality of care issues were identified, the reviewer indicated that primary care providers did not perform a proper exam of the patient or failed to communicate with urologists regarding the patients’ ongoing treatment for prostate cancer despite their shared responsibility for the patients.

A second concern was the lack of a plan to address the failure to document a complete physical exam that a non-facility VISN reviewer had noted. The reviewer found that, on two occasions, an oncology fellow conducted a physical exam of a patient with breast cancer but did not document

³² A sample of patient EHRs was reviewed for quality of documentation.

³³ National Cancer Institute. Prostate Cancer Treatment. The prostate is a part of the male reproductive system. It is a small organ lying below the bladder and partially surrounding the urethra (the tube emptying urine from the bladder). <https://www.cancer.gov/types/prostate/patient/prostate-treatment-pdq>. (The website was accessed on December 3, 2018.)

physical exam findings of the patient’s chest wall or breast.³⁴ These findings are critical to ongoing monitoring and understanding of the disease progression. Two physicians who were supervising the fellow separately co-signed the notes written by the oncology fellow without adding an addendum or comment.³⁵ Neither supervising physician addressed the fellow’s incomplete physical exam or failure “to focus exam on the area of pathology.”

Other Finding: Interrater Reliability Methodology

As part of the VISN’s evaluation of the patients identified in the allegation, an independent review for interrater reliability of eight cases was conducted by a non-VA contractor. Although the contractor did not agree with the non-facility VISN reviewers as to whether the standard of care was met, the OIG determined that the validity of the interrater reliability results was questionable because reviewers did not have the same information.

The OIG determined that VISN 8 provided the reviewers with forms containing incongruent clinical information, timeframes of care, and review instructions. Quality management researchers have noted, and the OIG inspection team’s medical consultants agreed, that if management reviews are conducted concurrently, it is essential that instructions provided be consistent.³⁶

Conclusion

The OIG substantiated that CLC and medical oncology staff did not adequately monitor the CLC patient receiving combined radiation and chemotherapy. Documentation for both services was insufficient. While the patient had an attending physician in the CLC, as well as an attending physician from medical oncology, there were no care coordination agreements between the CLC and other services. The OIG did not substantiate that the radiation oncology service failed to adequately monitor the patient.

Patient monitoring by CLC LPNs was evident in their documentation, however, the LPNs did not add the registered nurse as a co-signer to notes that would alert them to early warning signs of

³⁴ A fellow is a post-residency physician who is pursuing studies in a specialized field of medicine. Merriam-Webster Dictionary, <https://www.merriam-webster.com/dictionary/fellow>. (The website was accessed on July 30, 2019.)

³⁵ VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012. “The supervising practitioner’s co-signature signifies that the supervising practitioner has reviewed the resident note, and absent an addendum to the contrary, concurs with the content of the resident note or entry.” While fellows have completed their residencies, VHA’s resident supervision policy applies to them:

The term resident” refers to an individual who is engaged in an accredited graduate training program...[f]or the purpose of this Handbook, the term “resident” includes individuals in their first year of training, who are sometimes referred to as “interns,” and individuals in approved subspecialty graduate medical education programs, who are also referred to as “fellows.”

³⁶ Goldman, Ronald. *Reliability of Peer Assessments of Quality of Care*. JAMA 1992;267(7):958-960. <https://jamanetwork.com/journals/jama/article-abstract/395193>. (The website was accessed on December 6, 2018.)

treatment toxicity. Therefore, the registered nurse was seemingly unaware of possible early warning signs and did not notify the physician of the changes. In addition, chemotherapy was missing from the patient's care plan, potentially creating a situation in which the LPNs did not realize the patient was taking oral chemotherapy and were not aware of the importance of reporting the stool output changes.

While the patient's course of care may have been managed differently with additional monitoring and communication, the OIG was unable to determine whether the inadequate monitoring of the patient, lack of communication regarding the patient's change in status, and incomplete care plan contributed to the patient's death.

Although an action plan was created and implemented to address deficiencies in the care of the 55 identified cancer patients, the OIG determined that the action items did not comprehensively address all findings noted by the management reviewers:

- Primary care providers were not included in the multidisciplinary training conference on the topic of management of patients with prostate cancer, and
- There was a failure to address the lack of documentation of a complete physical exam by an oncology fellow on two occasions.

While not an allegation, the OIG found that VISN 8 had contracted with a non-VHA reviewer to independently evaluate eight patient cases for interrater reliability; however, the information provided to the interrater reviewer was not identical to the information provided to the non-facility VISN reviewers. Management reviews conducted concurrently do not meet standards for interrater reliability if the concurrent reviewers are not reviewing the same care issues.

Recommendations 1–7

1. The VA Caribbean Healthcare System Director strengthens procedures to ensure that medical oncology staff monitor patients receiving chemotherapy to assess for toxicity symptoms and patient tolerance, and the monitoring is documented in the electronic health record.
2. The VA Caribbean Healthcare System Director ensures that program managers assess the need for care coordination agreements between the community living center and specialty services and, if warranted, implement the agreement(s).
3. The VA Caribbean Healthcare System Director partners with community living center managers to provide education to nursing staff on the communication of patient status changes using the observation and communication tool, and procedures as outlined in VA Caribbean Healthcare System policy.
4. The VA Caribbean Healthcare System Director makes certain that community living center managers conduct a review of patient care plans to confirm their accuracy, update them as necessary, and strengthen processes to prevent future omissions as warranted.

5. The VA Caribbean Healthcare System Director verifies that primary care physicians receive the education on the management of patients with prostate cancer being provided to urology and radiation oncology physicians.
6. The VA Caribbean Healthcare System Director ensures that the findings identified by Veterans Integrated Service Network reviewers as noted in this report are addressed and resolved.
7. The Veterans Integrated Service Network 8 Director makes certain that consistent and clear instructions are provided for all management reviews conducted concurrently by independent reviewers.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 16, 2019

From: Director, VA Sunshine Healthcare Network (VISN 8)

Subj: Healthcare Inspection— Alleged Poor Quality of Cancer Care at the VA Caribbean Healthcare System, San Juan, Puerto Rico

To: Director, Office of Healthcare Inspections (54HL05)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed the OIG's report regarding Alleged Poor Quality of Cancer Care at the VA Caribbean Healthcare System, San Juan, Puerto Rico. I concur with the OIG's recommendations.
2. Additionally, I have reviewed the Healthcare System Director's response and proposed action plans with associated timeline for completion. I concur with the Healthcare System Director's proposed actions.
3. VISN 8 will assist the Healthcare System in completing each action and to implement the improvements as recommended.

(Original signed by:)

Miguel H. LaPuz, M.D., MBA
Network Director, VISN 8

VISN Director Response

Recommendation 7

The Veterans Integrated Service Network 8 Director makes certain that consistent and clear instructions are provided for all management reviews conducted concurrently by independent reviewers.

Concur.

Target date for completion: August 19, 2019

Director Comments

The Network Director will develop and implement a standardized document for soliciting quality of care management reviews when being conducted concurrently by independent reviewers. This task was completed on August 19, 2019, and a copy of the tool sent to the OIG.

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 9, 2019

From: Director, VA Caribbean Healthcare System (672)

Subj: Healthcare Inspection—Alleged Poor Quality of Cancer Care at the VA Caribbean Healthcare System, San Juan, Puerto Rico

To: Director, VA Sunshine Healthcare Network (VISN 8)

1. I have reviewed the OIG's report with its findings and recommendations regarding the allegation of poor quality of cancer care at the VA Caribbean Healthcare System. I concur with the findings and recommendations.
2. Enclosed, please find our plan to comply with each finding and recommendation along with estimated timelines for completion.
3. For questions or additional information requests, please call 787-641-7582 extension 33941.

(Original signed by:)

Carlos R. Escobar, BED-ARCH, MSHP, FACHE
Director, VA Caribbean Healthcare System

Facility Director Response

Recommendation 1

The VA Caribbean Healthcare System Director strengthens procedures to ensure that medical oncology staff monitor patients receiving chemotherapy to assess for toxicity symptoms and patient tolerance and the monitoring is documented in the electronic health record.

Concur.

Target date for completion: December 31, 2019

Director Comments

The VACHS, as accredited by the Commission on Cancer of the American College of Surgeons, ensures that there are in place policies and procedures for the safe administration and handling of systemic therapy, as chemotherapy and other anti-cancer drugs. Also, the Oncology section follows the National Comprehensive Cancer Network guidelines (NCCN) on the diagnosis, treatment and follow-up for cancer patients as well as follows all VHA Directives addressing cancer care. All patients in oral or intravenous chemotherapy and other anti-cancer drugs sign an informed consent in accordance to VHA Handbook 1004.01 that orient them on expected toxicities, risks and benefits of therapy and after every treatment the oncology nurse provides in writing a discharge instruction with orientation of warning signs and symptoms with contact information.

Patients in active therapy have follow up appointments between every treatment cycle, with proper laboratories to document toxicity and tolerance and for interventions with supportive treatments such as growth factors, transfusions and antibiotics that are in the Hospital Pharmacy formulary. In case of patients not showing to scheduled visits, there is potential of serious harm and toxicity; the section has the policy that the cancer navigator and/or primary provider contact the patient, evaluate his (her) condition and provides another appointment and proper follow up as required by his (her) medical status. Audits of oncology patients in active treatment are conducted to ensure that the above described policies are followed. Patients on active radiation therapy treatment are also subject to adverse events from treatment and require similar monitoring and follow up.

To strengthen our current procedures, the Hematology-Oncology inpatient consultation under the responsibility of its assigned rotating staff attending, will evaluate physically at the CLC at least once a week all patients there residing who are undergoing active drug or radiation treatment for cancer and document the encounter in a CPRS outpatient follow up note. The Cancer Navigator will be responsible to manage patients on active cancer treatment for reference of the Hematology-Oncology consultation team and will audit weekly all their CPRS records to ensure that the required evaluations and notes were completed. The CLC will update this list on a weekly basis and have communication with Cancer Navigator to update the data. The Cancer

Navigator will also be responsible to notify the Hematology-Oncology Section Chief of any CLC cancer patients under active treatment who were not evaluated before the end of the week in progress, so that immediate action may be taken. The Cancer Navigator will generate a monthly report on the metric of % of CLC cancer patients on active treatment evaluated weekly to submit to the Hematology-Oncology Section Chief for review. Success will be defined as >90% of CLC patients on any active cancer treatment being evaluated once weekly as evidenced by CPRS documentation. The Hematology-Oncology Section Chief or designee will present the report findings at the Quality, Safety, and Value Committee monthly until the >90% success metric has been met for three consecutive months. Thereafter, the section will continue the same monitoring process to ensure adherence to the >90% goal.

Recommendation 2

The VA Caribbean Healthcare System Director ensures that program managers assess the need for care coordination agreements between the community living center and specialty services and, if warranted, implement the agreement(s).

Concur.

Target date for completion: November 30, 2019

Director Comments

The CLC had an established memo for consultation request to specialty care and level of care provided in the CLC, however, this policy lacked clear guidelines for the coordination of services among specialty care. A Long-Term Care (LTC) Memo 11G-18-24 “Level of Care Provided in the Community Living Center” is being converted to a Center Memo to establish procedures for care coordination for those CLC residents receiving/ needing specialty care (ex. oral, intravenous chemotherapy, dialysis, radiotherapy, spinal cord injury) while in CLC. This center memo will define

- The characteristics of CLC patients who should receive consideration for referral to Specialty Care,
- The mechanism through which such referrals will be made,
- A tracking mechanism for consultation requests,
- The time frame by which a response will be received by the referring service,
- The circumstances and procedures under which the patient continues to be followed by the Community Living Center or referred to other levels of care.

Recommendation 3

The VA Caribbean Healthcare System Director partners with community living center managers to provide education to nursing staff on the communication of patient status changes using the

observation and communication tool, and procedures as outlined in VA Caribbean Healthcare System policy.

Concur.

Target date for completion: January 31, 2020

Director Comments

The CLC Nurse Educator developed a 3-hour training titled, detecting early changes in a Resident Condition and Communicating Changes in Resident's Condition: STOP AND WATCH and SBAR which is currently in process. At present time the percent of staff educated is 29% for CLC-1, 39% CLC-2 and 38% CLC-3. We expect 100% compliance by January 2020.

In addition, the 12-8 shift performs a record audit of medication orders which was now revised to include the progress notes so that we can capture if changes in condition were reported utilizing the notification policy to RN and MD. A 90% record audit is expected and will be monitored by the unit's nurse manager at least weekly.

Recommendation 4

The VA Caribbean Healthcare System Director makes certain that community living center managers conduct a review of patient care plans to confirm their accuracy, update them as necessary, and strengthen processes to prevent future omissions as warranted.

Concur.

Target date for completion: February 2020

Director Comments

Our tracer audit for care plans was enhanced to comply with the new Federal Regulatory Groups for Long Term Care. This tracer audit will be conducted twice monthly by PI Nurse, Nurse Manager, RAC, Chief Nurse and Medical Director.³⁷ Reviewer will participate in the Interdisciplinary Care Planning Meeting to perform live tracer audit; results will be discussed with the team after the audit. Tracer audit will start on November 2019 for three consecutive months until it shows that 90% compliance is achieved.

Starting on November 4, 2019, CLC Clinical Pharmacist will complete the Minimum Data Set (MDS) Section N "Medications" and develop the care plan as determined in the MDS Care Area Assessments (CAA). Starting November 11, 2019, random record audit of resident's care plan will be done by Pharmacy service to ensure high alert medications with required interventions

³⁷ The OIG determined that the Nurse Manager, RAC is the Resident Assessment Coordinator, otherwise known as the Minimum Data Set Coordinator.

are included. Results will be discussed during the Performance Improvement Meeting. Tracer audit will start on November 2019 for three consecutive months until it shows 90% compliance.

Recommendation 5

The VA Caribbean Healthcare System Director verifies that primary care physicians receive the education on the management of patients with prostate cancer being provided to urology and radiation oncology physicians.

Concur.

Target date for completion: October 31, 2019

Director Comments

The Chief of Medical Oncology Section, Chief of Urology Section and a Psychology Attending Practitioner provided a medical grand round education event in the Amphitheater to residents, medical staff, surgeons and primary care providers on March 21, 2019, regarding the management of prostate cancer patients. Additionally, on March 1, 2019, the training/education was provided to staff Urologists and residents at the main campus as well as the Ponce community-based outpatient clinic (CBOC) regarding the management of prostate cancer patients. Additional courses are scheduled to be provided to the main campus and all CBOC teams via live meetings. Hard copies of the presentation will be made available. There is a weekly cancer conference (tumor board) where urology attendings discuss prostate cancer patients and their management and therapy. The activity is open to all providers of the healthcare system, including primary care providers, and a tumor board care option note is documented in the electronic health record for the review by all treatment team members. As prostate cancer is the most common malignancy among veterans in Puerto Rico (over 250 new cases per year), the above educational activities are planned to be repeated on a yearly basis to impact the highest number of providers.

Recommendation 6

The VA Caribbean Healthcare System Director ensures that the findings identified by Veterans Integrated Service Network reviewers as noted in this report are addressed and resolved.

Concur.

Target date for completion: February 3, 2020

Director Comments

The VACHS will track all actions established in this report and the VISN report to completion. A status update will be reported at the Quality, Safety, and Value Committee at least quarterly as well as the VISN 8 Quality Council.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
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