

# DEPARTMENT OF VETERANS AFFAIRS OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Alleged Care Delays and Inadequate Instrument Precleaning at the New Mexico VA Health Care System Albuquerque

**REPORT #18-03526-230** 

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# **Executive Summary**

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations from two different complainants regarding concerns in the departments of ophthalmology and gastroenterology (GI) at the New Mexico VA Health Care System (facility), Albuquerque.

The first complainant alleged that the facility

• Improperly denied a Veterans Choice Program (CHOICE) referral for cataract surgery, which resulted in delayed cataract surgery.

Additionally, a second complaint from an anonymous source alleged

- Five hundred or more consults for outpatient GI procedures were awaiting scheduling;
- A one to four month delay in access to outpatient GI care;
- GI providers, particularly Fellows, do not provide test results to patients;
- GI Fellows do not receive training on endoscope precleaning processes; and
- GI patients are receiving procedures with endoscopes not properly precleaned by GI Fellows.

The OIG substantiated that the facility denied an eye patient's CHOICE referral for cataract surgery. However, the team found that Veterans Health Administration (VHA) policy supported the denial. The rationale documented in the electronic health record for the CHOICE denial was the facility's ability to provide the service requested within 30 days of the patient indicated date. While the OIG determined that the denial was within VHA policy parameters, the facility failed to inform the patient of the right to appeal the CHOICE referral denial and of the appeals process. Facility staff interviewed, including the Chief of Community Care who was the facility's identified point of contact for a CHOICE appeal, were unfamiliar with the appeals process.

The OIG did not substantiate a delay in the scheduling of an eye patient's cataract surgery. However, during the review of the patient's care, the OIG concluded that the facility's Ophthalmology Department failed to meet VHA consult management scheduling expectations related to physician involvement in the process, failed to include the patient preference when scheduling the appointment, and followed a standard operating procedure for cataract surgery intake evaluations that had not gone through an approval process.

Although not part of the allegations, the OIG found while on-site that the facility's Optometry Department experienced a three to six-month delay in authorizing non-VA Care consults for

routine and diabetic comprehensive eye appointments. The facility's Chief of Optometry told the OIG that the demand for routine eye examinations, which includes diabetic eye examinations, exceeded the facility's capacity. The facility implemented measures to reduce the number of delayed non-VA Care consult authorizations for routine eye appointments including adding provider appointment slots to allow patients to be seen by facility providers.

The OIG did not substantiate that 500 or more consults for outpatient GI procedures were awaiting scheduling. The OIG substantiated significant delays in access to outpatient GI care as a total of 4,356 outpatient appointments between August 1, 2017, and July 31, 2018, were scheduled more than 30 days beyond the patient indicated date.<sup>1</sup> This represented more than 64 percent of GI appointments during this time period. The Chief of Medicine, Deputy Chief of Medicine, Acting Chief of GI, and a GI provider attributed the delays to loss of staff, and according to GI leaders, a decrease in clinic capacity every July due to an eight-week new GI Fellow training during which time the new Fellows do not provide direct patient care. Additionally, the OIG team found that the facility did not monitor and conduct performance improvement efforts on known GI consult performance deficiencies in accordance with VHA guidelines as no staff were assigned for performance improvement efforts in the GI Department .

The OIG substantiated that GI providers did not consistently communicate test results to patients per facility policy.<sup>2</sup> The OIG team identified three factors that may have contributed to the failure to timely communicate test results: a lack of knowledge regarding test result communication requirements, an absence of a standardized process for delegating responsibility, and a failure of GI leaders to address known issues. Facility policy requires providers to communicate test results to patients no later than seven calendar days from the date of the available result, regardless of whether the result requires action. The OIG team reviewed 611 test results ordered by GI providers from August 1, 2017, to July 31, 2018, and found the facility frequently did not meet test result communication timeliness requirements.<sup>3</sup> Of the 611 test results ordered by GI providers, staff did not meet facility timeliness requirements for communication of

- Radiology test results 75 percent of the time,
- Pathology test results 32 percent of the time, and
- Laboratory results 85 percent of the time.

<sup>&</sup>lt;sup>1</sup> VHA defines timely care as an appointment offered within 30 days of the "patient indicated date."

<sup>&</sup>lt;sup>2</sup> Within the context of this report, the OIG uses the term "GI providers" to refer to GI attending physicians, GI nurse practitioners, and GI Fellows.

<sup>&</sup>lt;sup>3</sup> Results reviewed included radiology, pathology, and laboratory tests ordered by GI providers during patient encounters in the GI clinic.

The team conducted an additional review on test results requiring follow-up action to determine whether adverse clinical outcomes occurred because of the communication lapse. The OIG did not identify any adverse clinical outcomes for the patients reviewed.

The facility did not have methods to monitor the timeliness of the communication of test results to GI patients. The facility's GI Department did not have a standardized test result delegation and follow-up process for instances when multiple providers were involved in a patient's care. GI Fellows used a variety of methods for managing pending results when they were leaving the facility to begin a new rotation. The OIG team found that GI leaders were aware but did not resolve the issue of GI providers not consistently communicating test results per VHA and facility policy. While the GI Fellowship Director sought to address this problem by unsuccessfully requesting virtual private network access, another GI leader trusted the GI Fellows to be conscientious in follow-up communications. Overall, however, there was a leadership failure in resolving this known issue.<sup>4</sup>

During an interview, the OIG learned of an almost three-month delay in the communication of a GI patient's abdominal ultrasound result that was positive for a malignant mass. The delay occurred because the ordering provider, a GI Fellow, left the service without delegating a surrogate to assume the responsibility of patient notification including taking action on test results as required by VHA. After receiving the delayed test result, the patient underwent a surgery attempt, radiation treatment, and palliative care prior to dying 12 months later. The OIG reviewed the electronic health record and determined that the patient did not experience an adverse clinical outcome because of the delay in communication of test results and diagnosis.

The OIG did not substantiate a failure to train GI Fellows on endoscope precleaning. GI Fellows received endoscope precleaning training during their first year of training, prior to working after hours, and annually during didactic and demonstrative endoscope precleaning in-services. GI Fellows described endoscope precleaning steps generally in accordance with the manufacturer's instructions for use. However, some variances were reported in the wrapping and tagging of the instrument. The procedural variances reported by the GI Fellows did not affect patient care because the endoscopes were completely processed by sterile processing services (SPS) staff.

While not part of the allegations, the OIG concluded the facility did not document GI Fellow competencies for endoscope precleaning training as required by VHA. The facility began a process prior to the OIG's site visit whereby the GI Department documents and maintains GI Fellows training for endoscopes, including precleaning.

The OIG team did not substantiate that patients received procedures with endoscopes that GI Fellows did not properly preclean, as the facility reprocessed the endoscopes to ensure proper

<sup>&</sup>lt;sup>4</sup> Remote access to VHA applications (examples: VistA, the EHR), network drives and email is available through virtual private network accounts utilizing the Citrix Access Gateway.

sterility for future use with patients. No adverse patient events were identified that were related to the use of an improperly precleaned endoscope. However, the OIG did identify instances that endoscopes were left in the GI clinic SPS area without SPS staff present to begin instrument reprocessing. Because SPS staff were not sure how long the endoscopes had been left in the SPS area, SPS staff treated the endoscopes as if they were not precleaned and started an extended soak. Subsequently, the facility implemented a policy that included an endoscope precleaning step that required staff completing the precleaning to place and start a timer on the endoscope after precleaning. The step informed the SPS staff of the amount of time elapsed between precleaning and reprocessing and would reduce the need for prolonged endoscope soaking.

The OIG made 13 recommendations to the Facility Director related to: (1) non-VA Care appeals process; (2) consult management and scheduling practices of the Ophthalmology and Optometry Departments; (3) Ophthalmology and Optometry Department training of VHA consult management and scheduling practice requirements; (4) overall timeliness of cataract surgery scheduling; (5) timeliness of non-VA Care authorizations for routine eye appointments, including diabetic eye examinations; (6) consult management and scheduling practices of the Gastroenterology Department; (7) consult performance actions of the Gastroenterology Department; (8) a retrospective review of Gastroenterology Department-ordered test results; (9) review of facility policy for ordering and reporting of test results; (10) test result communication of the Gastroenterology Department; (11) facility test results communication policy; (12) consistent endoscope precleaning training; and (13) documentation of endoscope precleaning competencies.

## Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendations and provided acceptable action plans. (See appendixes A and B, pages 30–38.) The OIG considers all recommendations open to allow for the submission of documentation to support closures and will follow up on the planned actions until they are completed.

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# **Abbreviations**

CHOICE	Veterans Choice Program
EHR	electronic health record
GI	gastroenterology
MRI	magnetic resonance imaging
OIG	Office of Inspector General
PID	patient indicated date
RME	reusable medical equipment
SOP	standard operating procedure
SPS	sterile processing services
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network
VPN	virtual private network



# Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess allegations regarding concerns in the departments of <u>ophthalmology</u> and <u>gastroenterology</u> (GI) at the New Mexico VA Health Care System (facility), Albuquerque.

## Background

The facility, part of the Veterans Integrated Service Network (VISN) 22, is affiliated with the University of New Mexico School of Medicine and includes the Albuquerque Veterans Affairs Medical Center and 13 community clinics. The facility's community clinics are located in Alamogordo, Artesia, Espanola, Farmington, Gallup, Las Vegas, NW Metro, Raton, Santa Fe, Silver City, Taos, and Truth or Consequences, New Mexico, and Durango, Colorado. In fiscal year 2017, the facility served over 64,000 patients with a wide range of emergency, inpatient, and outpatient needs. Veterans Health Administration (VHA) classifies the facility as a Level 1b tertiary referral center with a 24-hour Emergency Department.<sup>5</sup>

## **Prior OIG Reports**

A 2016 OIG report, Administrative Summary of Investigation by the VA Office of Inspector General in Response to Allegations Regarding Patient Wait Times—VA Medical Center in Albuquerque, New Mexico, substantiated the allegation that the facility misreported desired appointment dates of patients in primary care. The OIG did not substantiate any negative patient outcomes pertaining to delays in care. The OIG made no recommendations as the report was an administrative summary. However, the OIG referred the investigation's findings to the VA Office of Accountability Review.<sup>6</sup>

A 2016 OIG report, *Lack of Follow-Up Care for Positive Colorectal Cancer Screening New Mexico VA Health Care System Albuquerque, New Mexico*, determined the facility did not inform patients of test results requiring follow-up care and did not have a process to track notification of test results. The OIG made four recommendations, all of which are now closed.

<sup>&</sup>lt;sup>5</sup> 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. VHA Office of Productivity, Efficiency and Staffing. (The website was accessed on October 25, 2018, and is an internal VA website not publicly accessible.)

<sup>&</sup>lt;sup>6</sup> VA Office of Inspector General, Administrative Summary of Investigation by the VA Office of Inspector General in Response to Allegations Regarding *Patient Wait Times —VA Medical Center in Albuquerque, New Mexico*, Report No. 14-02890-344, June 22, 2016.

One of the four closed recommendations addressed an issue that is relevant to the current OIG report:

• The OIG recommended that the Facility Director ensure that providers communicate positive colorectal cancer screening results to patients and document notifications in electronic health records according to VHA test notification policy.<sup>7</sup>

## Allegations

On February 8, 2018, the OIG received a complaint alleging the facility denied a patient a Veterans Choice Program (CHOICE) referral for <u>cataract surgery</u>, even though the patient resided more than 160 miles from the Albuquerque VA Medical Center and the facility scheduled an appointment in May for cataract surgery, which was greater than (>) 30 days from the patient indicated date (PID).<sup>8</sup> On April 10, 2018, the OIG requested the facility review the ophthalmology allegations and submit a response.

On April 17, 2018, the OIG received a second complaint from an anonymous source alleging issues in the facility's GI Department . The issues included the following: 500 or more outpatient GI procedures awaiting scheduling; a one to four month delay in GI care access; GI providers, particularly <u>GI Fellows</u>, not providing test results to patients; GI Fellows not receiving training for <u>endoscope precleaning</u> processes; and patients receiving treatment with endoscopes not properly precleaned by GI Fellows working after hours.

In June 2018, the OIG reviewed the GI allegations and the facility's response to the ophthalmology allegations. The OIG determined that the receipt of the GI allegations coupled with an inadequate facility response to the ophthalmology allegations warranted the initiation of a healthcare inspection.

# **Scope and Methodology**

The OIG initiated the inspection in August 2018 and performed an unannounced site visit on August 27–28, 2018. The OIG team conducted an additional site visit September 11–14, 2018. The inspection included selected data and documents from August 2017 through July 2018.

<sup>&</sup>lt;sup>7</sup> VA Office of Inspector General, Healthcare Inspection, *Lack of Follow-Up Care for Positive Colorectal Cancer Screening New Mexico VA Health Care System*, Albuquerque, New Mexico, Report No. 15-00018-349, September 27, 2016.

<sup>&</sup>lt;sup>8</sup> While the allegation stated the distance was 160 miles, a mileage calculator showed 149. The PID is 30 calendar days from the date a provider believes an appointment is clinically appropriate for a patient to be next seen or, in the absence of a clinically appropriate date, 30 calendar days from the date a veteran request an appointment (previously known as the preferred date).

The OIG team interviewed facility leaders including the Chiefs of Medicine, Optometry, and Community Care, Acting Chiefs of Surgery and GI, and the Deputy Chief of Medicine.<sup>9</sup> Staff interviewed included multiple ophthalmologists and a gastroenterologist, GI Fellows, the Patient Safety Manager, Group Practice Manager, the Business Manager of Surgery, former and acting GI nurse managers, and GI staff, an Ophthalmology nurse manager and Ophthalmology staff, Sterile Processing Services (SPS) staff, and medical staff administration supervisors, a non-VA Care coordinator, and the cataract surgery complainant.

The OIG team reviewed VHA and facility policies, electronic patient event reports, joint patient safety reports, Patient Advocate Tracking System information, training documents, a fact finding, meeting minutes, patient electronic health record (EHRs), and other relevant documents. During both site visits, the team conducted observational walk throughs of the SPS area in the GI procedure clinic.

The OIG team performed a data review involving 11,370 GI encounters and 611 GI provider ordered tests for the period August 1, 2017, through July 31, 2018, to determine compliance with VHA and facility requirements.

For purposes of this report, and to review scheduling and timeliness issues, the OIG team defined a scheduling delay as a consult request that occurred or was scheduled beyond 30 days of the original consult PID. The OIG team defined risk as a delay in care that could result in an adverse clinical outcome. The risk associated with a scheduling delay is a function of both the potential acuity and severity of the patient's condition, in combination with the length of the delay. Risk may or may not result in an actual adverse clinical outcome.

This report focuses on patient harm in terms of adverse clinical outcomes. Within the context of this report, the OIG team considered an adverse clinical outcome to be death, a progression of disease, worsening prognosis, suboptimal treatment, or a need for higher level care. The OIG recognizes that in addition to the potential for adverse clinical outcomes, avoidable delays and cancelations associated with the deficiencies discussed in this report may impact the convenience and quality of care received.

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

<sup>&</sup>lt;sup>9</sup> The Chief of Optometry acted in a collateral duty role as the Chief of Ophthalmology from August 2017 to August 2018.

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 Summaries**

## **Eye Patient**

A patient in their 60s had a history of diabetes, obstructive sleep apnea, and joint replacements due to arthritis.<sup>10</sup>

In 2016, the patient's primary care provider placed a CHOICE consult for an eye exam. Within eight days of the patient accepting the CHOICE referral, the community ophthalmologist examined the patient and noted <u>cataracts</u> in both eyes. Surgery was not advised, and a one-year follow-up appointment was recommended.

Another primary care provider placed a non-VA Care optometry consult for a routine annual diabetic retinal exam in spring 2017. Geographic inaccessibility was documented as the justification for not scheduling the appointment at the facility. A facility program support assistant discontinued the consult, commenting, "If pt [patient] needs a routine exam please place a CHOICE-first Diabetic Comprehensive Eye consult."<sup>11</sup>

In fall 2017, the patient's primary care provider placed a non-VA Care Comprehensive Diabetic Eye consult with a 30-day PID. The facility verified administrative eligibility and scheduled the patient for early 2018. The community ophthalmologist performed the examination as scheduled. The patient reported worsening of vision and inability to drive at night due to glare. The community ophthalmologist noted bilateral cataracts, suspected glaucoma, scheduled right eye cataract surgery, and submitted a secondary authorization request for a surgery that was scheduled approximately six weeks later.<sup>12</sup>

Ten days after the visit to the community ophthalmologist, a non-VA Care coordinator processed the secondary authorization request for cataract surgery submitted by the community ophthalmologist, placed an ophthalmology outpatient e-consult, and alerted an ophthalmology technician about the consult.<sup>13</sup> The next day, the ophthalmology technician commented on the consult, "per protocol for cataract surgery created by Dr. [name omitted] and Dr. [name omitted], Veteran meets criteria for surgery. Veteran will be scheduled at Albuquerque VAMC with a

<sup>&</sup>lt;sup>10</sup> The OIG uses the singular form of they in this instance to protect patient privacy.

<sup>&</sup>lt;sup>11</sup> Although there was a delay between the spring 2017 diabetic retinal eye exam consult, its subsequent denial, and the fall 2017 consult, the OIG team did not identify an adverse clinical outcome.

<sup>&</sup>lt;sup>12</sup> A secondary authorization request was required as the surgery exceeded the services provided under the diabetic eye consult authorization.

<sup>&</sup>lt;sup>13</sup> E-consult, an electronic alternative to face-to-face provider visits, has the same requirements as an outpatient clinical consultation. VA Deputy Under Secretary for Health Operations and Management. Memorandum—*Update to Workload Specifications for the Electronic Consult (E-Consult) Program.* January 10, 2014. The PID entered for this consult was the same day as the submission date.

clinically indicated date of 3 months."<sup>14</sup> The non-VA Care coordinator disapproved the secondary authorization request because the service would be provided at the facility. The ophthalmology technician made an appointment for the patient at the VA for a cataract consult visit that would take place in four months.

About one week after the community provider's request for the cataract surgery was disapproved, the primary care provider saw the patient for complaints of palpitations. The provider commented in the appointment notes that the patient stated it would be a hardship to travel to the facility for cataract surgery and requested care in the community. The provider documented that the ophthalmology technician would be contacted regarding the request for non-VA Care cataract surgery.

Over the next four weeks, the patient completed the paperwork for eye surgery and was cleared medically by the VA primary care provider. Soon after being cleared, the patient decided to use private insurance and underwent cataract surgery within the community several weeks before the appointment scheduled at the VA for the cataract consult.

#### **GI** Patient

The GI patient was in their 60s with a history of hypertension, osteoarthritis, and hepatitis C when evaluated for hepatitis C antiviral medication treatment.

In early 2017, the GI Department 's Hepatology Coordinator documented a review of the patient's EHR to determine eligibility for hepatitis C antiviral medication treatment. The Hepatology Coordinator noted that the patient would be reassessed for treatment in six months as the patient had a foot surgery scheduled in the coming weeks.

After the foot surgery, a primary care provider saw the patient for a routine appointment and noted the patient was willing to begin hepatitis C treatment. A hepatitis C clinic appointment was scheduled.

A GI Fellow evaluated the patient for hepatitis C treatment in early summer 2017. The Fellow reviewed earlier blood work and documented there was no liver imaging, "though [the] labs don't seem to suggest cirrhosis." The Fellow ordered additional blood work and a same day abdominal ultrasound to "minimize travel" for the patient. The Fellow documented a return to clinic date of four weeks to review labs and imaging studies. A GI supervising physician documented review of the case and agreed with the assessment and plan.

Following the appointment with the Fellow, the patient received an abdominal ultrasound. The radiologist's findings included a 6.0 centimeter mass in the right lobe of the liver worrisome for

<sup>&</sup>lt;sup>14</sup> Clinically indicated date is the date a provider believes an appointment is clinically appropriate; VHA Directive 1230.

hepatocellular carcinoma.<sup>15</sup> The radiologist recommended a magnetic resonance imaging (MRI) for a complete evaluation. The patient canceled a mid-summer, hepatitis C clinic appointment.

Approximately one week after the canceled appointment, a hepatitis C treatment team pharmacist documented a call from the patient reporting constipation and stomach pain. Three days later, the pharmacist discussed the patient's complaints with the GI attending and provided the patient with recommendations for medication changes. The pharmacist documented a plan to follow up with the patient at an early fall hepatitis C evaluation appointment.

At the early fall appointment a second GI Fellow saw the patient in the hepatitis C clinic. The Fellow documented that the patient had not been informed of the results of the abdominal ultrasound that had been performed 83 days earlier. The Fellow discussed the results and arranged for a same day MRI to "further evaluate the mass." The abdominal MRI showed a greater than 6.0 centimeter hepatocellular carcinoma mass and cirrhosis. The following day, a GI nurse practitioner returned the patient's call to discuss the MRI results. The GI nurse practitioner documented that the MRI results were discussed and that the patient's treatment plan would be determined at the next, hepatocellular carcinoma conference that occurred almost three weeks later.<sup>16</sup>

A GI physician documented the discussion of the patient's case at the hepatocellular carcinoma conference and the plan to present options of either a surgical removal of the liver mass or Y-90 treatment to the patient at the next follow-up appointment.<sup>17</sup> Four days later, the patient returned to the facility to discuss imaging results, the diagnosis of hepatocellular carcinoma, and the treatment plan. The GI nurse practitioner documented the discussion and education provided to the patient regarding both treatment options. The patient elected to pursue surgical removal and if not considered a candidate, would undergo Y-90 treatment. The process for a surgical removal referral at a second VA facility was initiated by requesting imaging disks be sent to that facility's surgical provider for review. hepatitis C treatment was not started pending treatment of hepatocellular carcinoma.

Approximately three weeks later, a surgeon at the second VA facility reviewed the patient's imaging disk and asked that the referring GI physician place an inter-facility consult for surgery.<sup>18</sup> A GI physician placed the inter-facility consult and scheduled an appointment at the

<sup>&</sup>lt;sup>15</sup> Hepatocellular carcinoma is a cancer that forms in the liver.

<sup>&</sup>lt;sup>16</sup> The facility's hepatocellular carcinoma conference is a meeting where providers evaluate the cancer diagnosis and determine a treatment plan.

<sup>&</sup>lt;sup>17</sup> Y-90 (Yttrium-90) is therapy that combines embolization and radiation (radioembolization) to treat liver cancer. <u>https://www.cancer.gov/publications/dictionaries/cancer-terms/def/radioembolization</u>. (The website was accessed on December 26, 2018.)

<sup>&</sup>lt;sup>18</sup> An inter-facility consult is a consult sent from one VA provider to another VA provider located at a different VA medical center.

second facility. The surgeon at the second facility evaluated the patient, and scheduled surgery for late fall.

As scheduled, the patient underwent surgery however, the surgeon could not remove the liver mass due to its invasion of the tissue and muscle surrounding the abdomen. Prior to discharge, the surgeon attempted to have the patient receive further imaging studies post-procedure, however the patient had not tolerated an MRI the day prior and did not want to stay longer for further imaging studies. The patient was discharged eight days post-surgery; the surgeon planned to contact and update the facility's referring GI physician to obtain further imaging.

In early 2018, the patient had an MRI and met with the GI physician to discuss treatment options. The GI physician placed a non-VA Care radiation consult for the patient to receive Y-90 treatment at a non-VA hospital, as the facility did not offer this treatment. The request was approved and the patient proceeded with radiation treatment a few weeks later. The patient received another abdominal MRI in spring 2018, showing an increase in size of the original mass and new lesions.

In early summer 2018, the GI physician placed a non-VA Care Medical Hematology Oncology consult to review chemotherapy options. The patient explored chemotherapy options with a community oncologist 29 days later and decided upon palliative care. The patient died in fall 2018.

# **Inspection Results**

#### Allegation 1: Denial of a CHOICE Referral

The OIG substantiated that the facility denied the eye patient's CHOICE referral for cataract surgery; however, the OIG team found that VHA policy supported the denial.<sup>19</sup>

Congress established CHOICE under the Veterans Access, Choice, and Accountability Act of 2014 to allow eligible veterans to receive care from providers in their communities, rather than a VHA facility. CHOICE was created to improve veterans' access to medical services. Eligibility for VA's CHOICE program is based on a set of criteria. Veterans are eligible to receive care through CHOICE if, for example, they live more than 40 miles from the nearest VHA facility with a full-time primary care provider or would wait >30 days past the date the veteran's

<sup>&</sup>lt;sup>19</sup> While the patient resided 149 miles from the Albuquerque VA Medical Center, the patient lived within 40 miles of a VA facility with a full-time primary care provider. U.S. Department of Veterans Affairs, Veterans Health Administration. *Veterans Choice Program Eligibility Details*.

https://www.va.gov/opa/choiceact/documents/FactSheets/Veterans-Choice-Program-Eligibility-Details.pdf. (The website was accessed on November 8, 2018.) VHA Directive 1230.

physician determines the veteran needs to be seen or the date the veteran would like to receive services through VHA.<sup>20</sup>

In the eye patient's case, the rationale for denial documented in the patient's EHR was not based on proximity but instead was based on the facility's ophthalmologist's availability within the PID.<sup>21</sup> Ultimately, the eye patient was scheduled for a cataract surgery evaluation at the Albuquerque VA Medical Center.

## **CHOICE Referral Appeals Process**

In reviewing the denial of the patient's CHOICE referral, the OIG team determined that, although the denial was within VHA policy parameters, the facility failed to inform the patient of the right to appeal the denial and of the appeals process as required by VHA.<sup>22</sup>

VHA policy states that

...when a Veteran expresses a disagreement with a VA determination regarding benefits, the Veteran must be advised of the Veterans' right to appeal that decision, and the correct process for initiating such an appeal.<sup>23</sup>

The Community Care Department manages non-VA Care consults for the facility. Per facility policy, after a VA provider places a non-VA Care consult, a program support assistant verifies patient eligibility and documents the consult status in the patient's EHR.<sup>24</sup> The medical/clinical director or a registered nurse case manager provides a clinical review of the consult for necessity and renders a documented disposition decision. If approved, the facility or the third-party contractor contacts the patient to schedule an appointment. If denied, the director or case manager documents the reason for denial in the EHR. Facility policy states, "[p]atient appellate rights will be included with a denial letter, if one is requested by the provider or patient."<sup>25</sup>

In an interview with the OIG, the patient reported being frustrated that the CHOICE referral was denied, called the facility, and spoke with three employees and received three different answers

<sup>&</sup>lt;sup>20</sup> Pub. L. No. 113-146. U.S. Department of Veterans Affairs, Veterans Health Administration. *Veterans Choice Program Eligibility Details*. <u>https://www.va.gov/opa/choiceact/documents/FactSheets/Veterans-Choice-Program-Eligibility-Details.pdf</u>. (The website was accessed on November 8, 2018.)

<sup>&</sup>lt;sup>21</sup> VHA Directive 1230; VA Deputy Under Secretary for Health Operations and Management Memorandum, *Scheduling and Consult Policy Updates*, June 5, 2017.

<sup>&</sup>lt;sup>22</sup> New Mexico VA Health Care System Memorandum 007-1, *Community Care Medical Program*, December 27, 2017. VHA Directive 1700, *Veterans Choice Program*, October 25, 2016. VHA Directive 1032, *Health Benefit Appeals Processing*, August 16, 2013. This VHA directive was scheduled for recertification on or before the last working day of August 2018, but has not been recertified.

<sup>&</sup>lt;sup>23</sup> VHA Directive 1032.

<sup>&</sup>lt;sup>24</sup> New Mexico VA Health Care System Memorandum 007-1.

<sup>&</sup>lt;sup>25</sup> New Mexico VA Health Care System Memorandum 007-1.

about why the patient was not eligible for CHOICE. The patient told the OIG team of speaking with someone in the VA Director's office and being informed of the requirement to live 40 miles away and wait more than 30 days. The EHR showed no documentation that the patient was informed of the reason for the CHOICE denial or of an appeals process, leaving the patient unaware of options once the referral was denied.<sup>26</sup> Facility staff, including the Chief of Community Care who was the facility's identified point of contact for a CHOICE appeal, were unfamiliar with the facility appeals process.<sup>27</sup>

#### Allegation 2: Timeliness of Cataract Surgery

The OIG did not substantiate a delay in scheduling the patient for cataract surgery at the facility. However, the OIG team found that the Ophthalmology Department developed and used a standard operating procedure (SOP) that did not meet VHA consult management guidelines by failing to have providers review patient consults and include patient preference when scheduling appointments.<sup>28</sup>

## **Scheduling Consults**

VHA's goal is for patients to be scheduled less than 30 calendar days from the PID, and for providers sending the consult to include the PID on the consult request.<sup>29</sup> The receiving provider or scheduler cannot change the PID unless it was entered incorrectly.<sup>30</sup> During the consult process, the receiving service updates the consult status. VHA memorandum, *Scheduling and Consult Policy Updates*, required consults to be reviewed and scheduled (or an initial attempt at contacting the patient must be made) within two business days of the consult creation.<sup>31</sup> When a VHA facility is unable to provide care within 30 calendar days, the patient may be eligible for

<sup>&</sup>lt;sup>26</sup> New Mexico VA Health Care System Memorandum 007-1; VHA Directive 1032.

<sup>&</sup>lt;sup>27</sup> New Mexico VA Health Care System Memorandum 007-1.

<sup>&</sup>lt;sup>28</sup> VHA Directive 1232(1), *Consult Processes and Procedures*, September 23, 2016, amended June 28, 2019. A consult is a request for healthcare services that a provider makes on behalf of a patient. The sending provider seeks an opinion, advice, expertise, or treatment regarding the management of a specific problem, the receiving provider responds to the request. VHA uses software embedded in the electronic health record (EHR) to enter, approve, schedule, and document consult information. The software generates an automatic notification in the EHR to alert the sending provider of updates made to the consult. New Mexico VA Health Care System Standard Operating Procedure: SOP for Routine Cataract Evaluations, August 23, 2017.

<sup>&</sup>lt;sup>29</sup> VHA Directive 1230, *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended May 14, 2019; VA Deputy Under Secretary for Health Operations and Management Memorandum, *Scheduling and Consult Policy Updates*, June 5, 2017.

<sup>&</sup>lt;sup>30</sup> VHA Directive 1230.

<sup>&</sup>lt;sup>31</sup> VA Deputy Under Secretary for Health Operations and Management Memorandum, June 5, 2017.

non-VA Care; however, the scheduler must ask whether the patient would prefer to make a non-VA appointment in the community or wait more than 30 calendar days for a VA appointment.<sup>32</sup>

Facility policy assigns facility leaders the responsibility of ensuring consult management practices follow VHA guidelines. Clinical service chiefs are tasked with: ensuring timely access into their service line; developing procedures to monitor consult management processes; and creating and effectively utilizing service agreements, communication methods and electronic templates.<sup>33</sup>

The facility's medical bylaws outline the requirements for responses to consult requests:

- The clinical service chief and/or subspecialty section chief determines the department's policy for answering consults.
- The individual "examining and writing the consultation advice" should sign the consult note.
- If the individual documenting is not medical staff, a medical staff member is required to co-sign the note and add a comment to the consult.<sup>34</sup>

#### **Scheduling Cataract Evaluations**

In 2011, VHA recognized the need to provide practical, attainable, and all-inclusive eye care and established a mission, "...to optimize the visual functioning of the Veterans health care system patients" with emphasis on providing "...needed, high-quality eye care in a timely manner to all eligible Veterans."<sup>35</sup>

When scheduling cataract surgery at the facility, patients must first be evaluated to determine whether they are a candidate for the procedure. The facility's SOP regarding the scheduling of cataract evaluations included an algorithm that calculated a PID of the consult day plus 90 days.<sup>36</sup> Providers reported they use the 90 day PID as the upper limit for what would be considered acceptable.

VHA requires a PID in the original sent consult indicating the earliest appropriate date to schedule an appointment based upon patient preference and the patient's clinical needs. The receiving provider or scheduler cannot change the PID, and appointments are to be scheduled within 30 days of the PID. If providers cannot see the patient within 30 days of the PID, patients

<sup>&</sup>lt;sup>32</sup> VHA Directive 1230.

<sup>&</sup>lt;sup>33</sup> New Mexico VA Health Care System Memorandum 11-29, *Consult Management*, February 24, 2017.

<sup>&</sup>lt;sup>34</sup> New Mexico VA Health Care System, Bylaws Rules and Regulations of the Medical Staff, March 25, 2015.

<sup>&</sup>lt;sup>35</sup> VHA Handbook 1121.01, *VHA Eye Care*, March 10, 2011. This VHA handbook was scheduled for recertification on or before the last working day of March 2016, but has not been recertified.

<sup>&</sup>lt;sup>36</sup> New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

are referred to the community.<sup>37</sup> As such, the facility's 90 day PID plus the 30 day scheduling allowance may result in a patient waiting 120 days before being seen for a cataract surgery evaluation.

In interviews, the OIG team learned that the facility ophthalmologists considered their next available surgery appointment when determining if a patient should be referred to the community for cataract surgery. Providers reported that surgical wait times following a cataract evaluation varied from six weeks to 120 days.

For some patients, the Ophthalmology Department's multi-step scheduling process could result in a patient waiting up to 240 days or eight months for cataract surgery. (See figure 1.)



*Figure 1. A potential facility timeframe for cataract evaluations and surgery Source: VA OIG* 

## Requests for Additional Services

After a patient is seen in the community and the community provider determines that additional tests or procedures are required beyond those originally authorized, a request for additional services, known as a secondary authorization request, is placed.<sup>38</sup> However, the facility may require a facility primary care provider to re-evaluate the patient before the community provider's request is approved. Additionally, the Chief of Staff, the Community Care Director or a designee must approve the continuation of care.<sup>39</sup>

The eye patient saw a non-VA Care provider in early 2018, for a comprehensive diabetic eye examination. The provider requested a secondary authorization request for cataract surgery and, prior to receiving approval, scheduled the surgery for approximately six weeks later. Ten days

<sup>&</sup>lt;sup>37</sup> VA Deputy Under Secretary for Health Operations and Management Memorandum, June 5, 2017;VHA Directive 1230.

<sup>&</sup>lt;sup>38</sup> VA Community Care. Secondary Authorization Requests (SAR) Process Guide, October 23, 2017.

<sup>&</sup>lt;sup>39</sup> New Mexico VA Health Care System Memorandum 007-1.

after the visit to the community ophthalmologist, the non-VA Care coordinator placed an ophthalmology outpatient e-consult. A facility ophthalmology technician responding to the e-consult denied the request, documenting that the service was available at the facility and applied the PID algorithm identified in the SOP.<sup>40</sup>

The eye patient was scheduled to be seen at the facility for a cataract surgery evaluation 119 days from the date of the consult. While the appointment date for the cataract surgery intake evaluation at the facility exceeded the date set by the non-VA Care provider for the unapproved surgery, the appointment met VA policy as it was scheduled in less than the 120 days. Ultimately, the eye patient chose to use private insurance and pursue cataract surgery in the community rather than wait to be seen at the VA.

## **Other Finding—SOP Process**

Although a scheduling delay was not identified in this case, the OIG team identified concerns with the facility's application of a standard 90-day PID delineated in the facility's SOP rather than the PID being determined following an individualized review of the patient by a provider and in concert with the patient as required by VHA. VHA requires that the PID "…determination is made based upon the needs of the patient and should be at the soonest appropriate date care is needed…[and] should not be used to indicate the latest appropriate date."<sup>41</sup>

In August 2017, two ophthalmologists, directed by the Chief of Community Care, developed and implemented an SOP to manage the large volume of ophthalmology cataract consults.<sup>42</sup> The SOP outlined a clinically based algorithm to identify patients who would be appropriate for a cataract surgery intake evaluation and provided a standardized PID of "3 months" for the initial appointment.<sup>43</sup>

While the SOP provided criteria for appointment scheduling, it did not allow for consultation with providers unless the secondary authorization request reviewer, a non-clinician, identified "anything about the consult requiring additional review beyond this protocol....be forwarded to/reviewed by an ophthalmologist with an explanation of abnormal findings." <sup>44</sup> Further, the SOP algorithm did not identify criterion for abnormal findings. The SOP eliminated a provider's

<sup>&</sup>lt;sup>40</sup> New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

<sup>&</sup>lt;sup>41</sup> VHA Directive 1232(1).

<sup>&</sup>lt;sup>42</sup> New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

<sup>&</sup>lt;sup>43</sup> New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

<sup>&</sup>lt;sup>44</sup> New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

direct review and input on the PID for patient consults identified as "normal," as required by VHA policy, the local medical bylaws, and the local consult management directive.<sup>45</sup>

The patient stated the facility scheduled the cataract surgery intake evaluation appointment date without consulting the patient. A review of the EHR showed staff did not document a discussion with the patient about appointment date preferences. VHA mandates that during the consult scheduling process the medical facility staff ask the patient for a preferred visit date.<sup>46</sup> The OIG team found the facility did not account for patient preference as required and scheduled the patient's cataract surgery intake evaluation appointment based upon the PID outlined in the cataract evaluation SOP.<sup>47</sup>

The OIG team also found through interviews that the above referenced SOP did not go through a review and approval process prior to implementation. The SOP lacked the signature and date of one of the two identified authors, and was not reviewed by a committee, facility leaders, or the service chief. A formal review process, while not required, would have provided an opportunity for the facility to align the SOP with VHA consult management policies and the facility's medical bylaws.<sup>48</sup>

In September 2017, an internal administrative review of the Ophthalmology SOP was completed. The OIG was told that the Chief of Staff initiated the review due to ophthalmology staff disagreements regarding a standard PID determination. While the review identified a lack of physician leadership in the Department, clinic access issues, and a "clear lack of understanding of consult management and responsibility across the service," the review did not offer any recommendations to guide staff. The review also determined staff developed a PID algorithm in an attempt to manage consult backlog, and noted a "gradual change in the clinically indicated dates (CID) that correlates with clinic availability." At the completion of the review, leaders failed to prompt a change in the process. It was not until the SOP was discontinued in August 2018, that the facility began a new process whereby consults are forwarded to providers for disposition.

## Other Finding—Delay in Authorizing Certain Non-VA Care Consults

The facility's Chief of Optometry told the OIG that the demand for routine eye examinations, which includes diabetic eye examinations, exceeded the facility's capacity. Therefore, patients were referred to community providers through non-VA Care. During the September site visit, the

<sup>&</sup>lt;sup>45</sup> New Mexico VA Health Care System, *Bylaws Rules & Regulations of the Medical Staff*, March 25, 2015; New Mexico VA Health Care System Memorandum 11-29; VHA Directive 1232(1).

<sup>&</sup>lt;sup>46</sup> VHA Directive 1230.

<sup>&</sup>lt;sup>47</sup> VHA Directive 1232(1); New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

<sup>&</sup>lt;sup>48</sup> New Mexico VA Health Care System, March 25, 2015; VHA Directive 1232(1); New Mexico VA Health Care System Standard Operating Procedure, August 23, 2017.

OIG was told of a three to six-month delay in authorizing non-VA Care consults for routine and diabetic comprehensive eye appointments, and a plan for Saturday "Stand Downs" to reduce the backlog.<sup>49</sup> As of November 2018, the facility had not performed the Saturday "Stand Downs." However, the facility took actions to improve local Optometry access with the goal of reducing the need for non-VA Care consults and the number of delayed authorizations.

The facility informed the OIG they had added 200 additional appointments with providers as of October 2018, thereby increasing optometry patient access at the facility. In January 2019, the facility reported that a portion of non-VA Care consults were scheduled into the added appointment slots. The facility's capacity to provide timely care subsequently improved such that the optometry service could see patients in-house rather than send them to non-VA Care. A facility employee stated that newly hired Community Care administrative personnel would help improve the timeliness of processing non-VA Care optometry consults.

#### Allegation 3: GI Consult Scheduling

The OIG did not substantiate that 500 or more consults for outpatient GI procedures were awaiting scheduling. The anonymous complainant did not identify the specific time period accounting for the 500 GI consults or define "awaiting scheduling." The team interpreted "awaiting scheduling" to mean that a received consult was in pending or active status and an appointment had not been scheduled. During its review of August 1, 2017–July 31, 2018, outpatient GI procedures, the OIG found 116 active GI procedure consults were without an appointment and none were pending.

#### **Allegation 4: Delays in GI Access**

The OIG substantiated delays in access to outpatient GI care. Per VHA guidelines, appointments must occur within 30 days of the PID.<sup>50</sup> Since the complainant was anonymous and therefore unavailable to provide an explanation of delayed patient care access, the OIG team defined delayed access to care as scheduling of GI procedures and GI clinic appointments in excess of 30 days of the PID.

The OIG team reviewed outpatient GI procedure and GI clinic appointment data between August 1, 2017, and July 31, 2018, to determine the difference, if any, between the date of the scheduled appointments and the PID. GI outpatient procedures included: routine screening and diagnostic colonoscopies; esophagogastroduodenoscopies; and endoscopic retrograde

<sup>&</sup>lt;sup>49</sup> "Stand Downs" are a method used by the facility to quickly process backlogged consults.

<sup>&</sup>lt;sup>50</sup> VHA Directive 1230. VHA defines timely care as an appointment offered within 30 days of the "patient indicated date;" VA Deputy Under Secretary for Health Operations and Management Memorandum, *Scheduling and Consult Policy Updates*, June 5, 2017.

cholangiopancreatographies.<sup>51</sup> GI outpatient clinic consults included evaluation and management of GI disorders, such as hepatitis and other liver disease.

The OIG team reviewed 4,719 outpatient GI procedure appointments and 2,054 outpatient GI clinic appointments with a completed or scheduled status and determined a delay existed in access to GI care. A total of 4,356 outpatient appointments, or greater than 64 percent, were scheduled more than 30 days beyond the PID as found in table 1.<sup>52</sup>

Appointment Type	>30 Days	>60 Days	>90 Days	>120 Days	Total Number Scheduled>30 Days or More Past PID
Outpatient GI Procedure Appointments	479	594	846	1400	3,319
Outpatient GI Clinic Appointments	608	292	83	54	1,037

Table 1. Number of Outpatient GI Appointments Scheduled Past PID

Source: VA OIG analysis of August 1, 2017, through July 31, 2018, facility consult data

The OIG found that facility leaders were aware of the delays. The Chief of Medicine, Deputy Chief of Medicine, Acting Chief of GI, and a GI provider attributed the delays to loss of staff.<sup>53</sup> Employee losses in the GI Department since approximately September 2017 included attending providers, clinic nurses, technicians, and a nurse manager. GI leaders stated another factor that contributed to the delays was the decrease in clinic capacity every July due to an eight-week new GI Fellow training during which time the new Fellows do not independently provide direct patient care.

<sup>&</sup>lt;sup>51</sup> Colonoscopy is a procedure that uses an endoscope to view the inside of the colon and rectum. Veterans Health Library, *Colonoscopy*, <u>http://www.veteranshealthlibrary.org/Encyclopedia/142,82148\_VA</u>. (The website was accessed on January 3, 2019.) Esophagogastroduodenoscopy, also known as upper endoscopy, is a procedure that uses an endoscope to view the inside of the esophagus, stomach and top of the small intestine. American Society of Clinical Oncology, *Upper Endoscopy*, <u>https://www.cancer.net/navigating-cancer-care/diagnosing-cancer/tests-and-procedures/upper-endoscopy</u>. (The website was accessed on January 3, 2019.) Endoscopic retrograde cholangiopancreatography (ERCP) is a procedure that uses an endoscope to view the pancreatic and bile ducts. Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), *ERCP*, <u>https://www.sages.org/publications/patient-information/patient-information-for-ercp-endoscopic-retrograde-cholangio-pancreatography-from-sages/</u>. (The website was accessed on January 3, 2019.)

<sup>&</sup>lt;sup>52</sup> VHA Directive 1230.

<sup>&</sup>lt;sup>53</sup> Two GI physicians left the facility in June and August 2018. Both physicians worked with GI Fellows seeing patients in clinic and performing endoscopies. The GI Nurse Manager left the position in January 2018.

## Consult Monitoring

In addition to the scheduling delays, the OIG found that the facility did not monitor, and conduct consult performance efforts or perform improvement processes on known consult performance deficiencies in the GI Department . VHA guidelines require facilities to monitor and measure consult performance monthly and to implement improvements if outcomes are not met.<sup>54</sup>

The Chief of Medicine stated that the facility's Consult Access and Management Committee met regularly to review consults. The OIG team reviewed committee meeting minutes and determined that while the committee met and evaluated the overall trending of facility consults, meeting minutes did not identify specific GI Department performance or improvement processes. The Chief of Medicine reported the Administrative Officer for Medicine Service was responsible for tracking GI consults; however, the Administrative Officer for Medicine Service stated the tracking and trending of GI consults was performed by the GI Nurse Manager. The Acting GI Nurse Manager was not a part of reviewing clinic "wait times" but did participate in closing backlogged consults.<sup>55</sup>

## Allegation 5: Failure to Timely Communicate Test Results

The OIG substantiated that GI providers did not consistently communicate test results to patients according to the time frame outlined in facility policy.<sup>56</sup> The OIG team reviewed 611 test results ordered by GI providers from August 1, 2017, to July 31, 2018.<sup>57</sup> Results of the OIG team's review are listed in table 2.

Clinical providers interpret and classify test results as abnormal or normal.<sup>58</sup> VHA requires that the ordering provider or designee communicate test results requiring follow-up action to the patient within seven calendar days from the date when the results are available. A designee must be assigned to receive and communicate test results when the ordering provider is unavailable, or when multiple providers are involved in the patient's care. For test results ordered by physician

<sup>&</sup>lt;sup>54</sup> VHA Directive 1232(2).

<sup>&</sup>lt;sup>55</sup> The Acting GI Nurse Manager stated the GI service's goal was closure of consults quickly and considered this process a reduction of "wait time."

<sup>&</sup>lt;sup>56</sup> Test results encompass radiology, pathology, and laboratory procedures. Within the context of this report, the OIG uses the term GI providers to refer to GI attending physicians, GI nurse practitioners, and GI Fellows. New Mexico VA Health Care System test results reporting policy is more limiting than VHA's policy for reporting test results. New Mexico VA Health Care System Memorandum 11-81. VHA policy requires communication no later than 7 calendar days for actionable test results and 14 calendar days for non-actionable results, from the date on which the results are available. VHA Directive 1088, *Communicating Test Results to Providers and Patients*, October 7, 2015. For this report, the OIG used the facility's policy requirements to evaluate the merit of the allegation.

<sup>&</sup>lt;sup>57</sup> Results reviewed included radiology, laboratory and pathology tests ordered by GI providers during patient encounters in the GI clinic.

<sup>&</sup>lt;sup>58</sup> VHA Directive 1088.

trainees, the supervising provider remains responsible for ensuring that required communication and documentation occurs.<sup>59</sup>

For results not requiring action, the ordering provider or designee has 14 calendar days to inform the patient from the date when the results are available.<sup>60</sup> VHA facilities are obligated to implement a process to ensure timeliness of test result communication and follow up.<sup>61</sup> Failure to follow up and communicate test results contributes to missed diagnoses and poor patient outcomes.<sup>62</sup> VHA also requires the ordering provider or designee to document efforts to communicate actionable test results, including interventions that follow, in the patient's EHR.<sup>63</sup> VHA does not provide specific requirements for documenting communication of non-actionable results by the ordering provider.<sup>64</sup>

Per facility policy, providers are required to communicate test results to patients no later than seven calendar days from the date of the available result, regardless of whether the result requires action. Providers must document their communication of results to the patient, including attempts to contact, in the EHR. Facility policy identifies clinical service chiefs as responsible for implementing the communication process and ensuring the service incorporates monitoring of compliance through ongoing peer review.<sup>65</sup>

The facility's GI Department SOP outlined provider responsibilities for pathology test result communication. The SOP designated the GI provider who obtained the specimen as responsible for communication of test results and follow up. The GI provider must check pathology results within one week of procedure completion, contact the patient by telephone or mail with results within one week of the results being available, and document the communication of results to the patient, including attempts to contact and any needed follow up in the EHR.<sup>66</sup>

<sup>&</sup>lt;sup>59</sup> VHA Directive 1088.

<sup>&</sup>lt;sup>60</sup> VHA Directive 1088.

<sup>&</sup>lt;sup>61</sup> VHA Directive 1088

<sup>&</sup>lt;sup>62</sup> Joanne Callen, Andrew Georgiou, Julie Li and Johanna Westbrook, "The Impact for Patient Outcomes of Failure to Follow-Up on Test Results," *The Journal of the International Federation of Clinical Chemistry and Laboratory Medicine*, Vol. 26, no. 1 (January 2015): 38-46.

<sup>&</sup>lt;sup>63</sup> VHA Directive 1088.

<sup>&</sup>lt;sup>64</sup> VHA Directive 1088.

<sup>&</sup>lt;sup>65</sup> New Mexico VA Health Care System Memorandum 11-81, *Ordering and Reporting Test Results*, November 25, 2013. This memorandum was scheduled for recertification on or before January 6, 2017, and has not yet been recertified.

<sup>&</sup>lt;sup>66</sup> New Mexico VA Health Care System Standard Operating Procedure: *Standard Operating Procedure for Followup of Pathology*, October 1, 2012. This standard operating procedure was scheduled for recertification on or before October 31, 2014, and has not yet been recertified.

# Table 2. Timeliness of GI Providers' Communication of Test Results to Patientsby CategoryAugust 1, 2017—July 31, 2018

Test Result Category	Tests Ordered by a GI Provider*	Not Within Facility Seven-day Time Frame	Percentage Not Meeting Facility Time Frame (%)
Radiology	244	182	75
Pathology	111	36	32
Laboratory	256	217	85

Source: VA OIG analysis of Corporate Data Warehouse data for the facility's GI test results from August 1, 2017, through July 31, 2018 \*N = 611

Because of the number of GI test results not communicated to patients within the seven-day timeframe, the OIG team conducted an additional review on test results requiring follow-up action to determine whether adverse clinical outcomes occurred due to the communication lapse. The OIG did not identify adverse clinical outcomes for the patients reviewed.

The OIG team identified three factors, detailed in the subsequent sections, that may have contributed to the failure to timely communicate test results: a lack of knowledge regarding test results communication requirements, an absence of a standardized process for delegating responsibility, and a failure of GI leaders to address known issues.

#### **Knowledge of Test Results Communication Policy**

The OIG team determined through interviews that GI providers lacked knowledge of VHA and facility requirements for test results communication. The Acting Chief of GI as well as all three of the GI Fellows interviewed were unclear or unaware of the VHA and facility requirement to notify patients of normal test results within 14 and 7 calendar days respectively.<sup>67</sup>

The OIG team identified that the facility's GI Department did not implement methods to monitor patient test result communication as required by VHA and facility policy.<sup>68</sup> During an interview, the Acting Chief of GI stated that the former nurse manager had monitored test result communication, however, was unsure of methods used or when it occurred. As of October 2018, the facility's Chief of Medicine, the Acting Chief of GI, and the GI Fellowship Director were

<sup>&</sup>lt;sup>67</sup> VHA Directive 1088; New Mexico VA Health Care System Memorandum 11-81.

<sup>&</sup>lt;sup>68</sup> VHA Directive 1088; New Mexico VA Health Care System Memorandum 11-81.

aware of the VHA or facility requirements to monitor test result communication and confirmed there was no current process to monitor provider compliance.

#### **Delegation of Responsibility**

The OIG team found that the facility's GI Department did not have a standardized process for delegating responsibility and accountability for test results and follow up when multiple providers were involved in a patient's care as required by VHA policy.<sup>69</sup> GI Fellows used a variety of methods for managing pending test results when leaving the facility. These methods included

- Adding supervising providers as cosigners on test orders,
- Using virtual private network (VPN) access to look up test results in an EHR while off rotation, and<sup>70</sup>
- Coordinating follow-up with other GI Fellows.

The lack of a standardized process for communicating test results when multiple providers are involved in a patient's care increases the risk that failures in patient notification will occur. During an interview, the OIG team learned of a GI patient who experienced an almost three-month delay in the communication of an abnormal abdominal ultrasound. (See GI patient case summary.) In an interview, the OIG was told that the Acting Chief of GI had determined that the delay was related to a failure to plan for follow-up; an ordering provider had left the service without delegating a surrogate to assume the responsibility of patient notification. Although the Acting Chief discussed the need to implement a process with GI staff regarding delegation of this responsibility, one had not been developed as of October 2018. After review of the patient's EHR, the OIG determined that despite the patient being diagnosed with cancer, the patient did not experience an adverse clinical outcome due to the delay in diagnosis.

#### Physician Leaders Did Not Address Known Issues

The OIG team found that the Acting Chief of GI and the GI Fellowship Director were aware that GI providers did not consistently communicate test results and failed to resolve the issue. The Acting Chief of GI stated that providers in the clinic met the seven-day reporting requirement for abnormal pathology results, but not the VHA 14-day requirement for communication of normal results.<sup>71</sup> The GI Fellowship Director told the OIG team of doubts that GI Fellows communicated normal test results to patients. The facility tried to resolve the problem by

<sup>&</sup>lt;sup>69</sup> VHA Directive 1088.

<sup>&</sup>lt;sup>70</sup> Remote access to VHA applications (examples: VistA, the EHR), network drives and email is available through VPN accounts utilizing the Citrix Access Gateway.

<sup>&</sup>lt;sup>71</sup> VHA Directive 1088; New Mexico VA Health Care System Memorandum 11-81.

obtaining VPN access for GI providers as a method to facilitate access to test results so that reporting could occur. However, staff stated that VPN access was not guaranteed due to delays in approval or log-in difficulties. The GI Fellowship Director told the OIG that challenges with obtaining access to the VPN had been communicated to the department's Automated Data Processing Application Coordinator, but as of September 2018, the issues had not been resolved.

#### Allegation 6: GI Fellow Training on Endoscope Precleaning Processes

The OIG did not substantiate that the facility failed to train GI Fellows on endoscope precleaning processes. The facility's SOP, *Set-up and Pre-cleaning of the Olympus GIF, CF, PCF, and SIF 180 and 190 Series Endoscopes,* addresses endoscope precleaning steps and post procedural handling processes.<sup>72</sup> As reported by the GI Fellowship Director, during normal hospital business hours GI technicians perform post procedure endoscope precleaning, however, after hours there was no GI technician support and GI Fellows were responsible for precleaning. The OIG found that the facility provided training to GI Fellows on the precleaning process. Multiple GI physicians interviewed stated training that included precleaning endoscopes was provided to new staff each year before they could take call after hours, and that they had participated in such training. Although training was provided, the facility did not document GI Fellow competencies for endoscope precleaning as required by VHA.

#### Facility's GI Fellowship Training - Endoscopes

The Centers for Disease Control identifies precleaning as an essential step to reprocessing.<sup>73</sup> Reprocessing is a multi-step method to ensure a contaminated instrument is reusable. Reprocessing must occur to enable the subsequent use of the device to be safe. Reprocessing includes: cleaning; functional testing; repackaging; relabeling; and disinfection or sterilization.<sup>74</sup> VHA requires that facilities meet the reprocessing guidelines specified in the manufacturer's instructions for use.<sup>75</sup> Facility policy states the director must ensure a process for performing and documenting <u>reusable medical equipment</u> (RME) training and initial competency for staff prior to its use.<sup>76</sup>

<sup>&</sup>lt;sup>72</sup> New Mexico VA Health Care System Standard Operating Procedure, POU-SOP-GI-3601, *Set- up and Precleaning of the Olympus GIF, CF, PCF, and SIF 180 and 190 Series Endoscopes*, August 18, 2016.

<sup>&</sup>lt;sup>73</sup> Centers for Disease Control, Essential Elements of a Reprocessing Program for Flexible Endoscopes, Recommendations of the HICPAC, <u>https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html</u>. (The website was accessed on November 14, 2018.)

<sup>&</sup>lt;sup>74</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>75</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>76</sup> New Mexico VA Health Care System, Memorandum 129-2, *Use and Reprocessing of Reusable Medical Equipment that Require High Level Disinfection or Sterilization*, March 3, 2017.

VHA outlines specific precleaning steps and assigns the responsibility to the provider performing the procedure.<sup>77</sup> If precleaning does not immediately occur following a procedure, residual organic material, known as bioburden, solidifies. This hardened material becomes a barrier to sterilization in two ways; it prevents infiltration of disinfecting agents and it may make disinfectants ineffective. These barriers are problematic as infectious material can remain on the instrument, resulting in a potentially unsterile device that is not safe for reuse.<sup>78</sup>

The Acting Chief of GI stated GI Fellows were trained in the process for endoscope precleaning when they started at the facility as first year Fellows and acknowledged that prior to this year, documentation of that training did not occur. Previously, GI nurses trained the Fellows on the process for endoscope precleaning; however, that process changed and GI technicians certified in endoscope precleaning were tasked to provide the training. The GI Fellow training consisted of

- Reviewing a two-page endoscope precleaning competency checklist based on the endoscope manufacturer's instructions,
- Observing GI technicians demonstrating the endoscope precleaning steps,
- Participating in a one-hour endoscope manufacturer vendor training held during their second month on service that includes a demonstration of the key components of endoscope precleaning,
- Viewing a training DVD from the endoscope manufacturer, and
- As of 2017, viewing a YouTube video of the vendor endoscope training.

The GI Fellowship Director stated the focus of the GI Department in July and August of each year was to provide endoscope training to first year GI Fellows. The GI Fellowship Director stated that GI Fellows began to take after-hours calls in September and were instructed not to work after hours until they are trained by the GI technicians in specific after-hours endoscope precleaning processes and procedures. GI Fellows confirmed that they received endoscope precleaning training during the first weeks of their fellowship. An interviewee described the training: (1) Fellows observed a GI technician complete an endoscope precleaning, and (2) the GI technician observed the GI Fellows complete a precleaning. GI Fellows also reported receiving annual didactic and demonstrative endoscope precleaning in-services.

<sup>78</sup> Bradley Catalone and George Koos, "Reprocessing Flexible Endoscopes," *Managing Infection Control*, (June 2005): 74-80.; Olympus Reprocessing Manual, Instructions.

<sup>&</sup>lt;sup>77</sup> VA Deputy Under Secretary for Health Operations and Management. Memorandum - Clarification on Current Processes for Pre-Treatment and Transportation of Soiled Reusable Medical Equipment (RME), April 20, 2018.

<sup>&</sup>lt;u>https://medical.olympusamerica.com/sites/default/files/pdf/TJF-Q180V\_ReprocessingManual.pdf</u>. (The website was accessed on August 13, 2018.)

## Travel Cart and Post Procedure Instructions

SPS is assigned with the responsibility to: decontaminate; disinfect; sterilize RME; and oversee high-level disinfection and sterilization practices for each VA facility. The facility mandates that SPS begin reprocessing RME within an hour of use, including after hours.<sup>79</sup>

The OIG identified through interviews that there was no training provided to the GI Fellows specific to the endoscope management process following precleaning, however, there was an instructional sheet located on the travel cart (used to transport equipment to the unit) that identified SPS as the service to contact for endoscope reprocessing.<sup>80</sup>

During the OIG team's unannounced site visit on August 27, 2018, the GI travel cart for after-hours procedures was observed to have a sign on it that identified the after-hours SPS phone number and SPS staff pager numbers; instructions to contact SPS for endoscope reprocessing; and instructions to write the time of precleaning on the material used to wrap the scope. During the OIG team's announced site visit on September 12, 2018, the GI travel cart for after-hours procedures no longer had a sign on it with SPS contact information; instead, the travel cart had a more detailed instructional sheet stating that after completion of a procedure and the associated precleaning, SPS is to be called, a yellow timer tag is to be activated and the endoscope placed in a biohazard bin.<sup>81</sup>

The OIG learned through interviews that SPS staff worked after-hours shifts during the week and were on call on weekends and holidays. On weekends and holidays, SPS staff are contacted prior to emergency <u>endoscopy</u> procedures. The Acting Chief of GI stated that by the time the emergency endoscopy procedure is completed, SPS staff are usually in the hospital although sometimes GI Fellows may have to wait for SPS staff to arrive and take possession of the endoscope in need of reprocessing. The Acting Chief of GI stated that after a GI Fellow completes endoscope precleaning, the Fellow transports the endoscope on a travel cart to the GI clinic where there is a dedicated space for SPS reprocessing. The Fellow then calls SPS and sets the endoscope through a pass-through window into a space known as the decontamination area.

GI Fellows described some variances in the management of the endoscope following precleaning. One GI Fellow reported SPS staff were not present after 10:30 p.m., so they left the precleaned endoscope in the GI clinic with the understanding that SPS would reprocess it in the morning. Another GI Fellow reported at least twice having left the endoscope in the GI clinic space with no SPS staff present after calling them and waiting over 30-40 minutes. Since the

<sup>&</sup>lt;sup>79</sup> New Mexico VA Health Care System, Memorandum 129-2.

<sup>&</sup>lt;sup>80</sup> Travel cart is specific to a medical unit, assembled and stocked pursuant to provider/user choice, and used for easy access.

<sup>&</sup>lt;sup>81</sup> A timer tag allows facility staff to see the duration of time between instrument precleaning and the next step during the instrument's reprocessing.

OIG's site visit, the facility implemented an after-hours policy for the precleaning and transportation of soiled RME.<sup>82</sup>

#### **Other Finding—Incidences of Unattended Endoscopes**

The OIG team interviewed staff and learned

- The Acting Chief of GI had not received complaints of GI Fellows failing to notify SPS when endoscopes had been precleaned and were ready for SPS to reprocess,
- An SPS after-hours supervisor was unaware of any occurrences that involved GI Fellows leaving endoscopes unattended for reprocessing, and
- An SPS technician reported that the weekday overnight staff checks the GI clinic for endoscopes in need of reprocessing.

The SPS technician stated there were incidents on Monday mornings when staff found endoscopes in the GI clinic sitting or soaking and some endoscopes had not been precleaned. The SPS technician reported SPS managers were informed of these incidents, and in the past year the number of incidents has decreased to that of a bimonthly occurrence.

The OIG team reviewed patient safety incident reports, RME Committee and Infection Control Committee meeting minutes, and did not identify documented incidents of used, precleaned endoscopes left unattended and awaiting reprocessing in SPS.

#### Endoscope Extended Soaking

According to an SPS supervisor, if SPS staff found an unattended endoscope with no indication of when or if precleaning was performed, SPS staff must assume that the manufacturer's instructions for use reprocessing timeframe was not followed. In those cases, an extended precleaning soak is initiated and, if warranted, additional brushing or aspiration of the endoscope. The dangers of soaking an endoscope for an extended period of time is the risk of instrument deterioration.

At the time of the OIG's site visit in September 2018, the facility had recently added a new endoscope precleaning step that used a yellow timer tag to identify how much time had passed since an endoscope had been precleaned. The facility was optimistic that knowledge of this timeframe would, in some cases, reduce the need for an extended soak. To begin the timer the yellow timer tag is turned on and attached to the wrapped endoscope immediately after precleaning. The new process helps SPS evaluate the endoscope's precleaning status and ensures manufacturer instructions for use reprocessing timeframes are followed. During the announced

<sup>&</sup>lt;sup>82</sup> New Mexico VA Health Care System, Standard Operating Procedure, VHA-V22-501-POU-GI-4, *Process for Pre-cleaning and Transportation of Soiled RME during off hours*, October 31, 2018.

site visit on September 12, 2018, the OIG team observed the yellow timer tag on the travel cart used by GI for after-hours procedures. A GI Fellow reported completing the step during endoscope precleaning.

#### Other Finding—VHA Competency Requirements for Endoscopes

VHA policy outlines endoscope cleaning and reprocessing steps and requires documented competency for staff trained on all endoscope models used by the facility.<sup>83</sup> The policy states "[t]he required competency assessment must be documented by the individual assessing competence to ensure compliance with current standards and manufacturer's [instructions for use]."<sup>84</sup>

The OIG team determined that prior to the OIG team's unannounced site visit on August 27, 2018, the facility did not document GI Fellow competency training for the precleaning of endoscopes.<sup>85</sup> The Chief of Medicine reported there was not a documented competency for every set of skills for GI Fellows. The GI Fellowship Director stated the GI Department generally exceeded what was needed for competencies in terms of the number of procedures the Fellows perform. However, the GI Fellowship Director reported they put a process in place to document competencies for endoscope precleaning processes and to maintain training records. The facility provided an employee training and competency assessment document that contained signatures of the GI Fellows that attended vendor endoscope training, which occurred in August and September of 2018.

#### Allegation 7: Use of Properly Cleaned Endoscopes in Patient Care

The OIG did not substantiate that patients received procedures with endoscopes that GI Fellows did not properly preclean. The OIG team determined that GI Fellows precleaned endoscopes after GI procedures as required by facility policy after which the facility SPS staff reprocessed the endoscopes to ensure proper sterility for use with subsequent patients.

The GI Fellows described endoscope precleaning steps generally consistent with the manufacturer's instructions for use although variances in endoscope wrapping and tagging of the instrument were reported. The procedural variances reported by the GI Fellows did not affect patient care because the endoscopes were completely reprocessed by SPS staff.

The Acting Chief of GI reported no knowledge of there having been any adverse events for patients related to endoscope precleaning. The GI Fellowship Director stated the precleaning kit was on the travel cart and precleaning was what Fellows do. The GI Fellowship Director could

<sup>&</sup>lt;sup>83</sup> Competency as defined by VHA Directive 1116(2) focuses on the knowledge, skills, and abilities required until an employee is deemed proficient to work independently.

<sup>&</sup>lt;sup>84</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>85</sup> New Mexico VA Health Care System, Bylaws Rules and Regulations of the Medical Staff, March 25, 2015.

not recall instances when the endoscope precleaning process was not completed. The Patient Safety Manager reported no awareness of incidents involving procedures with endoscopes not precleaned by GI Fellows. The OIG team reviewed facility incident reporting data for adverse events related to endoscopes not being properly precleaned, RME Committee meeting minutes and Infection Control Committee meeting minutes and found no documented incidents of patients receiving procedures with endoscopes not properly precleaned.<sup>86</sup>

# Conclusion

The eye patient's CHOICE referral for cataract surgery was denied by the facility because the service was available at the facility and could be timely scheduled, a rationale supported by VHA policy. However, the OIG determined that the patient was not informed of the CHOICE referral appeals process as required by VHA policy.

A delay in the scheduling of an eye patient's cataract surgery evaluation was not substantiated. The facility's Ophthalmology Department followed an SOP for cataract surgery evaluations. Although a delay in scheduling was not found, the OIG determined that, despite an internal administrative review identifying that the local SOP failed to meet VHA consult management scheduling expectations related to physician involvement in the process, changes were not made to the process for many months. Further, the OIG identified a leadership failure at the time of the internal review. While the review identified clinic access issues and a lack of physician leadership in the department, facility leaders did not offer recommendations to guide the staff tasked with addressing the consult backlog.

The OIG found that the facility's Optometry Department experienced a three to six-month delay in authorizing non-VA Care routine eye appointments, which includes diabetic eye examinations. The facility has since implemented measures to reduce the number of delayed authorizations for non-VA Care routine eye appointments including adding provider appointment slots to allow patients to be seen by facility providers.

The OIG did not substantiate that 500 or more consults for outpatient GI procedures were awaiting scheduling. The OIG substantiated significant delays in access to outpatient GI care as a total of 4,356 outpatient appointments between August 1, 2017, and July 31, 2018, were scheduled more than 30 days beyond the PID. The facility did not monitor and conduct performance improvement efforts on known GI consult performance deficiencies in accordance with VHA guidelines.

The OIG team substantiated that GI providers did not provide test results to patients per facility policy. Facility policy requires providers to communicate test results to patients no later than seven calendar days from the date of the available result, regardless of whether the result requires

<sup>&</sup>lt;sup>86</sup> Incidents reviewed included reports for events with instrument contamination.

action. The OIG team reviewed 611 test results ordered by GI providers from August 1, 2017, to July 31, 2018, and found the facility did not meet test results communication timeliness requirements.

The facility did not have methods to monitor the timeliness of communication of test results to GI patients. The facility's GI Department did not have a standardized test result delegation and follow-up process for instances when multiple providers were involved in a patient's care. GI Fellows used a variety of methods to notify other GI providers of pending patient test results when they were leaving the facility to begin a new rotation.

The OIG did not substantiate that GI Fellows lacked training related to endoscope precleaning or that improperly cleaned endoscopes were used during patient procedures. GI Fellows received endoscope precleaning training during their first year of training and prior to their after-hours work in addition to annual in-service trainings. GI Fellows described endoscope precleaning steps generally in accordance with the manufacturer's instructions for use. However, some variances were reported in the wrapping and tagging of the instrument. The procedural variances reported by the GI Fellows did not affect patient care because the endoscopes were completely processed by SPS staff.

While not part of the allegations, the OIG concluded the facility did not document GI Fellow competencies for endoscope precleaning training as required by VHA. The facility began a process prior to the OIG's site visit whereby the GI Department documents and maintains GI Fellows training for endoscopes, including precleaning.

The OIG team did not substantiate that patients received procedures with endoscopes that GI Fellows did not properly preclean as the facility reprocessed the endoscopes to ensure proper sterility for future use with patients. No adverse patient events were identified that were related to the use of an improperly precleaned endoscope. However, the OIG did identify instances that endoscopes were left in the GI clinic SPS area without SPS staff present to begin instrument reprocessing. Because SPS staff were uncertain how long the endoscopes had been left in the SPS area, SPS staff treated the endoscopes as if they were not precleaned and started an extended soak. The facility implemented a policy that included an endoscope precleaning step that required staff completing the precleaning to place and start a timer on the endoscope after precleaning. The step informed the SPS staff of the amount of time elapsed between precleaning and reprocessing and would reduce the need for prolonged endoscope soaking.

# **Recommendations 1–13**

1. The New Mexico VA Health Care System Director ensures that patients denied a Veterans Choice Program referral are informed of their rights to appeal, that facility policy is consistent with Veterans Health Administration requirements, and monitors compliance. 2. The New Mexico VA Health Care System Director verifies that the Ophthalmology and Optometry Departments' consult management and scheduling practices are consistent with Veterans Health Administration patient indicated date timeframe requirements, incorporates patient preference, and includes receiving provider review of consults, and monitors compliance.

3. The New Mexico VA Health Care System Director makes certain the Ophthalmology and Optometry Departments' clinical and administrative staff receive training regarding Veterans Health Administration requirements of consult management and scheduling practices.

4. The New Mexico VA Health Care System Director reviews the Ophthalmology Department's eye cataract intake surgery scheduling practice and ensures that overall timeliness is consistent with Veterans Health Administration directives, and monitors compliance.

5. The New Mexico VA Health Care System Director conducts a timeliness review of the authorization process for non-VA Care routine eye appointments, including diabetic eye examinations, and implement action plans if the process fails to adhere to Veterans Health Administration directives.

6. The New Mexico VA Health Care System Director ensures the Gastroenterology Department's consult management practices are consistent with Veterans Health Administration scheduling requirements for patient indicated dates, and monitors compliance.

7. The New Mexico VA Health Care System Director establishes a routine review of Gastroenterology Department consult performance measures and a method to monitor identified deficiencies consistent with Veterans Health Administration requirements.

8. The New Mexico VA Health Care System Director evaluates whether test results within the past 12 months, ordered by the Gastroenterology Department were communicated to patients according to Veterans Healthcare Administration and facility policy, and takes action as necessary based on the results of the evaluation.

9. The New Mexico VA Health Care System Director reviews facility policy for the ordering and reporting of test results to be in alignment with Veterans Health Administration directives and completes revisions, if needed.

10. The New Mexico VA Health Care System Director ensures that Gastroenterology Department-ordered test results are communicated timely in accordance with Veterans Health Administration and facility policy and the timeliness is monitored through the ongoing peer review process as required by facility policy.

11. The New Mexico VA Health Care System Director ensures that the Gastroenterology Department Service Chief develop a process for delegating responsibility and accountability for test results and follow-up when multiple providers are involved, and monitors compliance.

12. The New Mexico VA Health Care System Director ensures documented endoscope precleaning training for Gastroenterology Fellows, and monitors compliance.
13. The New Mexico VA Health Care System Director verifies that documentation of endoscope precleaning competencies for Gastroenterology Fellows is consistent with Veterans Health Administration requirements.

## **Appendix A: VISN Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

- Date: August 15, 2019
- From: Director, VA Desert Pacific Healthcare Network (10N22)
- Subj: Healthcare Inspection—Alleged Care Delays and Inadequate Instrument Precleaning at the New Mexico VA Health Care System, Albuquerque
- To: Director, Office of Healthcare Inspections, (54HL05) Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)
  - I have reviewed and concur with the findings, recommendations, and action plans as submitted for the Office of Inspector General (OIG) report entitled Healthcare Inspection – Alleged Care Delays and Inadequate Instrument Precleaning at the New Mexico VA Health Care System, Albuquerque, New Mexico.
  - If you have any questions, please contact Teresa A. Elsholz, Acting Quality Management Officer/Deputy Quality Management Officer, VA Desert Pacific Health Care Network at (480) 397-2782.

(Original signed by:)

Michael W. Fisher VISN 22 Network Director

## **Appendix B: Facility Director Memorandum**

#### **Department of Veterans Affairs Memorandum**

- Date: August 15, 2019
- From: Director, New Mexico VA Health Care System (501/00)
- Subj: Healthcare Inspection—Alleged Care Delays and Inadequate Instrument Precleaning at the New Mexico VA Health Care System, Albuquerque
- To: Director, VA Desert Pacific Healthcare Network (10N22)
  - 1. We appreciate the Office of Inspector General's review of the allegations of care delays and inadequate instrument precleaning. The facility has already worked on many of the recommendations based on the understanding of the issues at the time of the site visit.
  - 2. I have reviewed and concur with the findings, recommendations and action plan as submitted. The action plans will be followed through to completion and sustainment.
  - 3. If you have any questions or require additional information, please contact Carol H. Moore, Chief, Quality, Safety & Value (QSV), at 505-265-1711, extension 3696.

(Original signed by:)

Andrew M. Welch, MHA, FACHE Medical Center Director

# **Facility Director Response**

#### **Recommendation 1**

The New Mexico VA Health Care System Director ensures that patients denied a Veterans Choice Program referral are informed of their rights to appeal, that facility policy is consistent with Veterans Health Administration requirements, and monitors compliance.

Concur.

Target date for completion: March 2020

#### **Director Comments**

Veterans Choice Program is now replaced by the Mission Act. Under the Mission Act, Veterans who wish to appeal a community care related decision are referred to the Facility Patient Advocates for assistance. Prior to the implementation of the Mission Act, the Chief of Staff provided 8 training sessions for NMVAHCS providers and the Patient Advocates about the appeals process and their role.

The advocates assist the Veteran to prepare an appeal, as necessary, and promptly refer the appeal to the Chief of Staff (COS). The COS is to review the appeal and finalize the decision within 72 hours. Quality, Safety and Value (QSV) and COS will monitor clinical appeals to ensure time frame requirements are met  $\geq$ 90% and this is sustained for 6 months.

The facility policy on community care consults will be updated to be consistent with the Mission Act.

#### **Recommendation 2**

The New Mexico VA Health Care System Director verifies that the Ophthalmology and Optometry Departments' consult management and scheduling practices are consistent with Veterans Health Administration patient indicated date timeframe requirements, incorporates patient preference, and includes receiving provider review of consults, and monitors compliance.

Concur.

Target date for completion: March 2020

## **Director Comments**

After the OIG site visit in July 2018, ophthalmology and optometry discontinued use of the standard operating procedure (SOP) that was found to not be consistent with VHA guidance. The facility has implemented the Mission Act and no longer has ophthalmology/optometry specific SOPs. The Mission Act requires all specialty care to be scheduled in 28 days from the date the

referring provider enters the consult and if unable to be scheduled, the patient is eligible to be seen in the community.

Surgical Service will track and report on all ophthalmology and optometry consults, including the receiving providers review to ensure time frame requirements are met  $\geq$ 90% and this is sustained for 6 months.

#### **Recommendation 3**

The New Mexico VA Health Care System Director makes certain the Ophthalmology and Optometry Departments' clinical and administrative staff receive training regarding Veterans Health Administration requirements of consult management and scheduling practices.

Concur.

Target date for completion: June 2019, Completed and Request Closure

## **Director Comments**

All NMVAHCS Surgical Service clinical and administrative staff completed the TMS training modules for Mission Act concerning consult management and scheduling practices.

## **OIG Comments**

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

#### **Recommendation 4**

The New Mexico VA Health Care System Director reviews the Ophthalmology Department's eye cataract intake surgery scheduling practice and ensures that overall timeliness is consistent with Veterans Health Administration directives, and monitors compliance.

Concur.

Target date for completion: March 2020

## **Director Comments**

The facility has implemented the Mission Act which requires all specialty care, including cataract surgery consults to be scheduled in 28 days from the date the referring provider enters the consult and if unable the patient is eligible to be seen in the community. The date of the surgery is coordinated based on patient preference and necessary medical clearance. Surgical Service will track and report on ophthalmology surgery scheduling to ensure time frame requirements are met  $\geq$ 90% and this is sustained for 6 months.

## **Recommendation 5**

The New Mexico VA Health Care System Director conducts a timeliness review of the authorization process for non-VA Care routine eye appointments, including diabetic eye examinations, and implement action plans if the process fails to adhere to Veterans Health Administration directives.

Concur.

Target date for completion: March 2020

## **Director Comments**

At this time all comprehensive and diabetic eye exams are being sent to the community due to a lack of optometry services. Due to the increased demand, Community Care staff have been unable to review and process these consults within 48 hours. Additional Community Care staff have been hired and are being trained and will be assigned to focus on ophthalmology & optometry consults. The facility will continue to monitor until 90% of referrals to Community Care for ophthalmology and optometry care are reviewed by Community Care staff within 48 hours and this is sustained for 6 months.

#### **Recommendation 6**

The New Mexico VA Health Care System Director ensures the Gastroenterology Department's consult management practices are consistent with Veterans Health Administration scheduling requirements for patient indicated dates, and monitors compliance.

Concur.

Target date for completion: March 2020

## **Director Comments**

The facility has implemented the Mission Act; specialty care, including Gastroenterology care is to be scheduled based on rules and guidelines set forth in Mission Act, including referring eligible patients to community care. Currently, GI staff review and triage consults to determine urgency and patients needing a procedure within 2 weeks are overbooked at the facility. Screening colonoscopies have been referred to community care due to a shortage of endoscopists (recruitments in process). Medicine Service is reviewing VSSC data for capability to monitor compliance and/or will develop local reports as necessary.

Medicine Service will track and report on Gastroenterology scheduling to ensure time frame requirements are met  $\geq$ 90% and this is sustained for 6 months

## **Recommendation 7**

The New Mexico VA Health Care System Director establishes a routine review of Gastroenterology Department consult performance measures and a method to monitor identified deficiencies consistent with Veterans Health Administration requirements.

Concur.

Target date for completion: March 2020

## **Director Comments**

The Medicine Service is reviewing VSSC data for capability to monitor consult performance measures and is reviewing local automation capabilities to assist in identifying deficiencies more easily. Once the review process is in place, the facility will review at least monthly and will report compliance to the Quality Board.

## **Recommendation 8**

The New Mexico VA Health Care System Director evaluates whether test results within the past 12 months, ordered by the Gastroenterology Department were communicated to patients according to Veterans Healthcare Administration and facility policy, and takes action as necessary based on the results of the evaluation.

Concur.

Target date for completion: December 2019

## **Director Comments**

Medicine Service and the Gastroenterology Department is completing a review of all pathology results related to a Gastroenterology procedure July 2018 through July 2019. So far it is known that all patients with a cancer result were notified, however complete review results are pending so it is not yet known if patients with results requiring action were notified within 7 days and if patients with results that did not require action were notified within 14 days.

Medicine Service is developing a Registry based solution to identify all imaging results and will complete a review of all tests July 2018 through July 2019.

A pull of all general labs ordered by Gastroenterology July 2018 through July 2019 identified over 500,000 results. A manual review of each patient's medical record would be required to determine if the result required action or not, if a patient was notified and what the time frame for the notification was. The facility will explore the ability to identify the general lab results considered "critical" results during that time period to determine the feasibility of a manual review of critical results to ensure patients were notified.

## **OIG Comments**

The intent of this recommendation is to ensure that all appropriate communication and actions occur to manage critical laboratory abnormalities processed during the time frame at issue. OIG appreciates the magnitude of testing results that would require review and will monitor the progress of this review to ensure the approach and ultimately the critical findings are addressed in a timely and reasonable manner.

## **Recommendation 9**

The New Mexico VA Health Care System Director reviews facility policy for the ordering and reporting of test results to be in alignment with Veterans Health Administration directives and completes revisions, if needed.

Concur.

Target date for completion: August 9, 2019, Completed and Request Closure

## **Director Comments**

The facility chartered a multidisciplinary team to review and update the facility policy for ordering and communication of test results. The updated policy is consistent with the VHA directive and requires all test results requiring action to be communicated by the ordering provider, or designee, to patients no later than seven calendar days from the date on which the results are available and for test results that require no action, results must be communicated within 14 days. For abnormalities that require immediate attention (i.e. critical values), the 7-day limit is irrelevant, as the communication should occur within a timeframe that minimizes risk to the patient.

## **OIG Comments**

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

## **Recommendation 10**

The New Mexico VA Health Care System Director ensures that Gastroenterology Department-ordered test results are communicated timely in accordance with Veterans Health Administration and facility policy and the timeliness is monitored through the ongoing peer review process as required by facility policy.

Concur.

Target date for completion: March 2020

## **Director Comments**

Gastroenterology clarified for staff the time frame requirements for notifying patients of test results shortly after the OIG site visit (e.g. all test results requiring action to be communicated by the ordering provider, or designee, to patients no later than seven calendar days from the date on which the results are available and for test results that require no action, results must be communicated within 14 days).

Medicine service is now working to develop methods to monitor compliance and verify that pathology, general lab and imaging results are reviewed by providers and are communicated to patients within the required time frames. The service will continue to monitor to ensure time frame requirements are met  $\geq$ 90% and this is sustained for 6 months.

## **Recommendation 11**

The New Mexico VA Health Care System Director ensures that the Gastroenterology Department Service Chief develops a process for delegating responsibility and accountability for test results and follow-up when multiple providers are involved, and monitors compliance.

Concur.

Target date for completion: March 2020

## **Director Comments**

Immediately after the OIG site visit, the Gastroenterology Department implemented inclusion of the attending provider on all tests ordered by the fellows. Medicine service will develop a method to monitor compliance with including the attending as a surrogate in the Gastroenterology Department and will monitor at least until compliance is  $\geq$ 90% for six months.

#### **Recommendation 12**

The New Mexico VA Health Care System Director ensures documented endoscope precleaning training for Gastroenterology Fellows, and monitors compliance.

Concur.

Target date for completion: August 2018, Completed and Request Closure

## **Director Comments**

Training by the scope (Olympus) representative was attended by Gastroenterology Fellows on 08/30/2018. Fellows who did not attend were trained by local subject matter experts. Any additional training will be on an as needed basis when identified as needed (e.g. process changes, new staff, as found during competency check).

## **OIG Comments**

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

#### **Recommendation 13**

The New Mexico VA Health Care System Director verifies that documentation of endoscope precleaning competencies for Gastroenterology Fellows is consistent with Veterans Health Administration requirements.

Concur.

Target date for completion: September 2019

## **Director Comments**

The Gastroenterology Fellows were competency assessed using a standardized method and form that is consistent with VHA requirements shortly after the training in 2018. Competency is assessed annually and requires two verification methods (e.g. direct observation, return demonstration, verbalization). All fellows with on-call duties will have annual competency assessment completed before on call starts. Medicine service will track and report completion to the Quality Board in September 2019.

# **Glossary of Terms**

**cataract**. A clouding of the lens of the eye that has the potential to reduce clarity of vision. Left untreated, cataracts may impact quality of life as the progression of cataracts effects the ability to see clearly and complete activities of daily living.<sup>87</sup>

**cataract Surgery**. An eye surgery that is not an emergency. A delay in surgery will not result in long-term damage to the eye. However, cataract surgery is necessary when it impedes care of a coexisting eye condition such as diabetic retinopathy, even if not impacting quality of life.<sup>88</sup>

**critical items.** Reusable medical equipment such as instruments or objects that are introduced directly into the bloodstream or other normally sterile body areas.

**endoscope**. A reusable medical instrument that gastroenterology providers use to perform endoscopic procedures. Endoscopes are rigid or flexible tubes that allow for visual inspection and photography; they also enable biopsy of tissue and removal of foreign objects.<sup>89</sup>

endoscopy. A minimally invasive diagnostic procedure used to assess the interior surfaces of an organ.<sup>90</sup>

**gastroenterology**. A subspecialty that includes the study of the normal function, conditions, and diseases of the gastrointestinal tract, including the esophagus, stomach, intestines, colon, rectum, pancreas, gallbladder, bile ducts, and liver.<sup>91</sup>

**gastroenterology fellow**. A physician enrolled in a graduate medical training program through the university affiliate, typically rotating monthly throughout the facility and the affiliate. A gastroenterology fellow provides patient care under the supervision of an attending gastroenterology physician. The program encompasses three years of advanced training and includes a minimum of 18 months of clinical training experience.

**non-VA care.** Community-based patient care that is purchased by VHA and coordinated through VHA or a third party when VHA does not provide the service; when medical conditions preclude safe travel to a VA facility; when timely care cannot be provided; or when care is inaccessible due to geographic location.

<sup>88</sup> National Eye Institute, The National Institutes of Health, *Facts About Cataract*.

<sup>&</sup>lt;sup>87</sup> National Eye Institute, The National Institutes of Health, *Facts About Cataract*. <u>https://nei.nih.gov/health/cataract/cataract\_facts</u>. (The website was accessed on November 2, 2018.)

<sup>&</sup>lt;sup>89</sup> VHA Directive 1116(2).

<sup>&</sup>lt;sup>90</sup> American College of Gastroenterology, *What is a Gastroenterologist?* <u>http://patients.gi.org/what-is-a-gastroenterologist/</u>. (The website was accessed on August 28, 2018.)

<sup>&</sup>lt;sup>91</sup>American College of Gastroenterology, What is a Gastroenterologist?

**non-VA care coordination.** One of two non-VA programs for community-based patient purchased care.

**ophthalmology**. A branch of medicine specializing in comprehensive medical and surgical care of eyes. Ophthalmologists train in the treatment of eyes and diagnosis of respective problems such as cataracts, glaucoma and disease of the retina and cornea. Ophthalmologists receive a higher level of medical training than optometrists and perform surgical eye procedures.<sup>92</sup>

**optometry**. A medical profession that focuses on the treatment and management of diseases, disorders, and injuries of the eye, and identifies related medical conditions affecting the visual system. Optometrists train in the medical treatment of eyes and refer care to ophthalmologists for surgical intervention.<sup>93</sup>

precleaning. The act of immediate cleaning of reusable medical equipment after its use.<sup>94</sup>

**reusable medical equipment**. Devices, such as endoscopes, intended for use on numerous patients that can withstand repeated reprocessing.<sup>95</sup>

**semi-critical items**. Reusable medical equipment that comes in contact with non-intact skin or mucous membranes.

**Veterans Choice Program (CHOICE)**. One of two non-VA programs for community-based patient purchased care.

<sup>&</sup>lt;sup>92</sup> VHA Handbook 1121.01; American Academy of Ophthalmology, What is an Ophthalmologist?

https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist. (The website was accessed on November 1, 2018.)

<sup>&</sup>lt;sup>93</sup> VHA Handbook 1121.01; American Academy of Ophthalmology, What is an Ophthalmologist?

<sup>&</sup>lt;sup>94</sup> Bradley Catalone and George Koos, "Reprocessing Flexible Endoscopes," *Managing Infection Control*, (June 2005): 74-80.

<sup>&</sup>lt;sup>95</sup> VHA Directive 1116(2).

## **OIG Contact and Staff Acknowledgments**

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