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Healthcare Inspection

Alleged Access Delays and Surgery Service Concerns
VA Roseburg Healthcare System
Roseburg, Oregon

July 11, 2017

Washington, DC 20420

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Executive Summary

At the request of Representative Peter A. DeFazio, the VA Office of Inspector General (OIG) conducted a healthcare inspection of the VA Roseburg Healthcare System (system), Roseburg, OR, in response to allegations regarding access delays and surgery service quality of care concerns in 2014. Specifically, Representative DeFazio communicated in a letter sent to the OIG the following allegations from a constituent:

- Surgeries are performed inappropriately without intensive care unit back-up.
- Surgeons are unable to keep up surgical skills.
- Access to care (clinic appointments and procedures) in some surgical areas is delayed.
- Patient safety concerns are not reported due to fear of retaliation.[1]

We received additional allegations during complainant interviews, specifically:

- A surgeon performed colonoscopies in an unsafe manner.
- Access is delayed due to a backlog for colonoscopies.

We did not substantiate that surgeries were performed inappropriately without intensive care unit back-up. From 2010 to 2013, the system was designated as a Standard Inpatient Surgical Complexity Program, but received a waiver to perform standard complexity surgeries with the telemetry unit designated as an equivalent to a level 4 Intensive Care Unit. Surgical cases were continuously monitored to ensure the system was operating within the designated complexity level.

We did not substantiate that surgeons were unable to maintain surgical skills. We discovered surgeons could be detailed to other facilities to perform procedures not normally done at the system.

We substantiated access delays in some surgery and gastroenterology service areas; however, system leadership and clinical program managers were aware of the delays and implemented action plans to reduce wait times.

We did not substantiate that a surgeon performed colonoscopies unsafely, but found that he practiced in an outdated manner. In the summer of 2014, system leaders hired a Chief of Surgery (COS) who had experience performing colonoscopies at another Veterans Health Administration (VHA) facility and asked him to help reduce a long colonoscopy wait list. A couple of months after he started, gastroenterology staff voiced concerns about the COS's competency. System leaders arranged for him to go to the Mann-Grandstaff VA Medical Center in Spokane, WA, for proctoring. Three surgeons and a gastroenterologist signed a letter concluding that the COS met or exceeded their

[1] This allegation is addressed in a previously published report: VAOIG, *Healthcare Inspection—Nurse Staffing and Patient Safety Reporting Concerns*, VA Roseburg Healthcare System, Roseburg, Oregon, (Report No. 15-00506-420, October 12, 2016). http://www.va.gov/oig/pubs/VAOIG-15-00506-420.pdf. Accessed November 2, 2016.

expectations after proctoring 16 cases. The Mann-Grandstaff VA Medical Center COS reviewed the EHRs for 75 out of 79 patients who received colonoscopies by the system COS and found that they all met his (the Mann-Grandstaff COS) review criteria.

We performed an independent review of the 79 cases in conjunction with an independent surgeon and gastroenterologist. We found no complications such as oversedation, bleeding, perforation, or missed cancers to indicate unsafe practice. We determined the COS had no difficulties finding polyps because his polyp detection rate[2] exceeded established rates.

The COS's documentation often did not include data such as polyp size, how much of the polyp was removed, and the quality of bowel preparation. Professional society guidelines recommend documenting photographic proof that the provider reached the end of the colon (cecal intubation) and the length of time spent examining the colon for abnormalities (cecal withdrawal time) because they are indicators that a complete and thorough colonoscopy has been performed. The COS did not obtain photodocumentation, but rather wrote that he saw the typical landmarks. He also did not document cecal withdrawal time.

The COS fulgurated (burnt) polyps, which is a practice that has fallen out of favor due to the risk of colon perforation. He also made recommendations for surveillance colonoscopies without waiting for pathology results and in some cases recommended longer wait times than published guidelines. Although we did not find complications during our independent review of the system's 79 cases, some of these practices had the potential to result in poor patient outcomes.

We identified one patient who received an institutional disclosure for a delayed diagnosis of colon cancer because he had waited almost a year after a consult request for the procedure was submitted before undergoing a colonoscopy.[3] The COS took timely follow-up action on the biopsy results, but did not inform the patient of the cancer diagnosis for 15 days.

Over all, we determined that the COS practiced in an outdated manner. He stopped performing colonoscopies in August 2014. While we did not identify system patients who experienced poor outcomes after colonoscopies performed by the COS, we were concerned that the COS's colonoscopy documentation practices at the system may have implications for the quality of the 2000 colonoscopies he performed at a prior VA facility.

This inspection also raised larger questions regarding VHA's requirements for verifying the quality of colonoscopy care. The VHA *Colorectal Cancer Screening* Directive[4] does not require documentation of many of the established quality indicators but suggested

[2] Polyp detection rate is defined, "as the number of colonoscopies in which one or more polyps was removed and sent for histology, divided by the total number of colonoscopies performed by the gastroenterologist." Boroff et al., Polyp and Adenoma Detection Rates in the Proximal and Distal Colon, *AM J Gastroenterol* 2013:108. http://www.medscape.com/viewarticle/806338. Accessed October 14, 2016.
[3] The time frame of the patient's delay in scheduling a procedure was prior to the COS's arrival at the system.
[4] VHA Directive *1015, Colorectal Cancer Screening,* December 30, 2014.

using adenoma detection rates[5] and cecal intubation rates[6] for monitoring of Ongoing Professional Practice Evaluation.[7] VHA should require more accurate and stringent data collection aligned with professional society guidelines and published studies to monitor the quality of providers' colonoscopies.

We also reviewed how VHA ensured that providers of different specialty training or experience performed quality colonoscopies. VHA requires facilities to guarantee "one standard of care" by using the same credentialing criteria for granting privileges regardless of the provider's medical specialty, training, or experience.[8] In one of our 2015 Healthcare Inspection reports, we found that the Gastroenterology Program Office staff had not issued guidance or expectations for credentialing and privileging, and lacked tools to track the quality of colonoscopies.[9] VHA concurred with our recommendations and submitted action plans. In September 2016, VHA developed credentialing and privileging criteria for gastroenterologists requiring monitoring of cecal intubation rates and documentation of bowel preparation but did not specifically require photodocumentation of cecal intubation and cecal withdrawal time.

In our 2012 and 2014 Combined Assessment Program Review reports for the system,[10] we recommended "…that facility managers ensure patient notification of diagnostic test results within the required timeframe and that clinicians document notification." The case patient described in this report was not informed of his cancer diagnosis by the COS for 15 days—a similar noncompliance in notification as that identified through our system Combined Assessment Program reviews.[11]

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[5] The adenoma detection rate is defined, "as the percentage of patients age 50 and older undergoing screening colonoscopy, who have one or more precancerous (adenoma) polyps detected." http://patients.gi.org/gi-health-and-disease/questions-and-answers-about-quality-in-colonoscopy. Accessed October 14, 2016.

[6] The cecal intubation rate is the frequency that a provider is able to reach the end of the colon and is a measure of technical abilities.

[7] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012. Ongoing Professional Practice Evaluation is part of a system's quality assurance program that includes a review of provider specific activities and data that are used to grant renewal of provider privileges. This process is similar to the Focused Professional Practice Evaluation that typically occurs at the time of initial appointment to the medical staff, the granting of new, additional privileges or when a question arises regarding a currently privileged practitioner's ability to provide safe, high-quality patient care.

[8] VHA Handbook 1100.19. "The requirements or standards for granting privileges to perform any given procedure, if performed by more than one service, must be the same. One standard of care must be guaranteed regardless of practitioner, service, or location within the facility."

[9] VAOIG *Healthcare Inspection - Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities,* (Report No. 15-00911-362), June 3, 2015. http://www.va.gov/oig/pubs/VAOIG-15-00911-362.pdf Accessed November 4, 2016.

[10] *Combined Assessment Program Review of the VA Roseburg Healthcare System, Roseburg, Oregon,* (Report No. 11-03667-108, March 13, 2012), http://www.va.gov/oig/pubs/VAOIG-11-03667-108.pdf Accessed November 2, 2016; *Combined Assessment Program Review of the VA Roseburg Healthcare System*, *Roseburg, Oregon*, (Report No. 14-04222-141, March 4, 2015), http://www.va.gov/oig/pubs/VAOIG-14-04222-141.pdf Accessed November 2, 2016.

[11] VHA Directive 2009-019, *Ordering and Reporting Test Results,* March 24, 2009, required clinicians to notify patients within 14 days after routine test results became available but cautioned that earlier notification was required "for abnormalities that require[d] immediate attention," in order to minimize the risk to the patient. This Directive was rescinded and replaced by VHA Directive 1088, *Communicating Test results to Providers and Patients*, October 7, 2015 that established as a general rule that test results would be communicated to patients within 7 calendar days for results requiring action and 14 days for those that do not require any action.

We recommended that:

- The Acting Under Secretary for Health perform a quality review of the Chief of Surgery's colonoscopies performed in the prior Veterans Health Administration facility.

- The Acting Under Secretary for Health revise the Veterans Health Administration *Colorectal Cancer Screening* directive to include standardized documentation of quality indicators based on professional society guidelines and published literature (including but not limited to photodocumentation of anatomical landmarks establishing cecal intubation and documentation of cecal withdrawal times).

- The Acting Under Secretary for Health consider adding photodocumentation of cecal intubation and cecal withdrawal time to the standardized criteria for quality colonoscopy for Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation.

- The System Director ensure patient notification of diagnostic test results within the required timeframe, particularly for critical results, and that clinicians document notification.

Comments

The Acting Under Secretary for Health, the Veterans Integrated Service Network and Facility Directors reviewed the report. The Acting Under Secretary for Health and the System Director concurred with our recommendations and provided acceptable action plans. (See Appendixes A, B, and C, pages 34–39 for the Acting Under Secretary and Directors' comments.) We will follow up on the planned actions until they are completed.

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Purpose

At the request of Representative Peter A. DeFazio, the VA Office of Inspector General (OIG) conducted a healthcare inspection of the VA Roseburg Healthcare System (system), Roseburg, OR, in response to allegations regarding access delays and surgery service quality of care concerns in 2014. The purpose of the inspection was to determine if the allegations had merit.

Background

System Profile

The system is part of Veterans Integrated Service Network (VISN) 20 and provides care for veterans residing in central and southern Oregon and northern California. The main campus includes an Emergency Department and provides primary care and inpatient services in medicine, surgery, and mental health. The system includes an Ambulatory Surgery Center in Roseburg[12] and three community based outpatient clinics located in Eugene, Brookings, and North Bend, OR.

Surgery Services

The system's Surgery Service includes general surgery, urology, orthopedics, optometry, ophthalmology, and podiatry.

The Veterans Health Administration (VHA) defines surgical complexity levels separately for inpatient[13] and outpatient[14] (ambulatory) programs. VHA policy requires that each medical facility with an Ambulatory Surgery Center possess a surgical complexity designation based on the facility's infrastructure, and only perform surgical procedures within the capabilities of the facility.[15] The system's surgery program was initially designated as a Standard Inpatient Surgical Complexity program with three surgery beds.[16]

In 2009, the system's surgical leadership determined that it lacked adequate infrastructure to support a Standard Inpatient Surgical Complexity rating due to the inability to recruit and retain qualified professionals and a consistently low intensive care unit (ICU) census. System leadership closed the ICU and created a continuous monitoring (telemetry) unit.[17] Between 2010 and 2013, it operated at the Standard

[12] An Ambulatory Surgery Center is a free standing VHA facility separate from an Inpatient VHA Surgery Program.
[13] VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This directive expired May 21, 2015 and has not been updated.
[14] VHA Directive 2011-037, *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*, October 14, 2011. This directive expired October 31, 2016 and has not been updated.
[15] Ibid.
[16] VHA Directive 2010-018.
[17] Telemetry is a continuous electrocardiogram reading that shows the heart's electrical rhythm through external electrodes placed on a patient's body.

Inpatient Surgical Complexity level under a waiver where the telemetry unit was designated as "equivalent" to a level 4 ICU.[18] Through continued internal and external reviews, system leadership recognized the system was not in compliance with VHA policy and formally requested revised designation of the surgical program. The system has been designated as an Ambulatory Basic Surgical Program since 2013.

Gastroenterology Services

National Colonoscopy Providers

Colonoscopies are performed by a physician, usually a gastroenterologist or a surgeon.[19] However these procedures can be performed by a family practitioner, particularly in rural areas. Training requirements for endoscopy[20] vary by specialty.[21] The American Board of Surgeons (ABS) requires general surgery residents to perform a minimum of 50 colonoscopies.[22] The American Academy of Family Practitioners requires the same number.[23] The American Society for Gastrointestinal Endoscopy (ASGE) recommends performing a minimum of 140 colonoscopies before technical competency can be assessed.[24] While these numbers represent minimum requirements for graduation from training programs, experts agree that the numbers do not equate to proficiency and clinical privileges should be granted based on objective evaluation of skill.[25]

VHA Credentialing and Privileging

In order for clinical providers to deliver care to patients, each provider must undergo a credentialing[26] process by supplying his or her qualifications and credentials to the

[18] VHA has four levels of ICUs: 1, 2, 3, and 4, in descending order of complexity.
[19] http://www.cancer.org/healthy/findcancerearly/examandtestdescriptions/faq-colonoscopy-and-sigmoidoscopy. Accessed October 14, 2016.
[20] Endoscopy refers to medical procedures that insert fiberoptic cameras into the body's orifices, such as the mouth and anus, to diagnose and treat diseases. Colonoscopy is one type of endoscopy.
[21] American Gastroenterological Association, ASGE, American Association for the Study of Liver Diseases and ACG Statement Regarding the ABS Mandate for Surgery Resident Training in Endoscopy. February 11, 2011. http://www.gastro.org/joint_abs_training_statement.pdf. Accessed July 27, 2016.
[22] American Board of Surgery Statement on GI Endoscopy. February 24, 2011. https://www.absurgery.org/default.jsp?newsgiresponse. Accessed July 27, 2016.
[23] AAFP Position Paper on Colonoscopy. http://www.aafp.org/about/policies/all/colonoscopy.html. Accessed July 27, 2016.
[24] American Gastroenterological Association, ASGE, American Association for the Study of Liver Diseases and ACG Statement Regarding the ABS Mandate for Surgery Resident Training in Endoscopy. February 11, 2011. http://www.gastro.org/joint_abs_training_statement.pdf. Accessed July 27, 2016.
[25] American Gastroenterological Association, ASGE, American Association for the Study of Liver Diseases and ACG Statement Regarding the ABS Mandate for Surgery Resident Training in Endoscopy. February 11, 2011. http://www.gastro.org/joint_abs_training_statement.pdf. Accessed July 27, 2016. American Board of Surgery Statement on GI Endoscopy. February 24, 2011. https://www.absurgery.org/default.jsp?newsgiresponse. Accessed July 27, 2016.
[26] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012, defines credentialing as "the systematic process of screening and evaluating qualifications and other credentials, including, but not limited to: licensure, required education, relevant training and experience, and current competence and health status."

hiring facility. The facility then screens and evaluates these qualifications before privileging[27] the provider to care for patients. "Clinical privileges must be facility-specific, practitioner-specific, and within available resources." For example, a provider who wishes to perform two different types of endoscopic procedures must request each one separately and may only be granted privileges to perform one procedure if the facility determines that the provider does not meet the qualifications to perform both. VHA requires that facilities "guarantee" the same criteria for granting privileges regardless of whether the procedure is performed by more than one service, practitioner, or location to maintain "one standard of care." For example, providers who request privileges to perform colonoscopies should meet the same qualifications and credentials regardless of whether they were trained by a surgical, family practice, or gastroenterology (GI) program.[28]

VHA requires completion of a Focused Professional Practice Evaluation (FPPE) for new providers and those requesting new privileges. The FPPE process may include direct supervision, proctoring or chart reviews for a limited period of time.[29] In contrast, providers who have already received privileges participate in periodic Ongoing Professional Practice Evaluation (OPPE) using pre-set criteria to monitor the quality of care.[30]

System Colonoscopy Providers

At the system, the GI section falls under Specialty and Surgical Services and had one VHA-employed full-time gastroenterologist at the time of the events discussed in this report (summer 2014).[31] Additional colonoscopy support was provided by general surgeons or locum tenens[32] gastroenterologists on a part-time or as needed basis. According to the system's 2013 Medical Staff Bylaws, Rules, and Regulations, each service was authorized to establish its own procedures for performance monitoring including: criteria, methods, and circumstances for external evaluation (proctoring). Beginning in November 2014, the general surgery service allowed surgeons to obtain colonoscopy privileges[33] by documenting "acceptable supervised training in residency, or successful completion of an approved course, and competence in performing that

[27] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012 defines privileging as "the process by which a practitioner, licensed for independent practice is permitted by law and the facility to practice independently, to provide specified medical or other patient care services within the scope of the individual's license, based on the individual's clinical competence as determined by peer references, professional experience, health status, education, training, and licensure."
[28] Ibid.
[29] Ibid.
[30] Ibid.
[31] As of October 2016, GI physician staffing remained the same.
[32] In this context, the Latin term, locum tenens, means a medical practitioner who temporarily takes the place of another.
[33] At the system, colonoscopy is a supplemental privilege that surgeons may request, but is not part of core privileges that are considered within the general scope of practice after completing residency.

procedure."[34] Prior to November 2014, the system did not have performance monitoring criteria for colonoscopies.

Colorectal Cancer and Colorectal Cancer Screening

Colorectal cancer (CRC) occurs in the colon or rectum[35] and is the second leading cause of cancer deaths for men and women in the United States.[36] The risk for developing CRC increases with age; greater than 90 percent of cases occur in individuals who are 50 years of age or older.[37] Other risk factors[38] could require earlier screening.[39] In most cases, CRC develops from pre-cancerous polyps in the large intestine.[40]

Regular screening is critical to preventing CRC. The U.S. Preventive Services Task Force (USPSTF) recommends that adults age 50 to 75 be screened for CRC.[41] Several screening tests are used to find polyps or CRC. The USPSTF outlines the following CRC screening strategies:[42] stool tests, flexible sigmoidoscopy,[43] colonoscopy,[44] and Computed Tomography (CT) colonography.[45]

Colonoscopy

In addition to CRC screening and surveillance, colonoscopy is often used in evaluation of symptoms and other positive CRC screening tests.[46] High quality colonoscopy is essential in finding and removing polyps.

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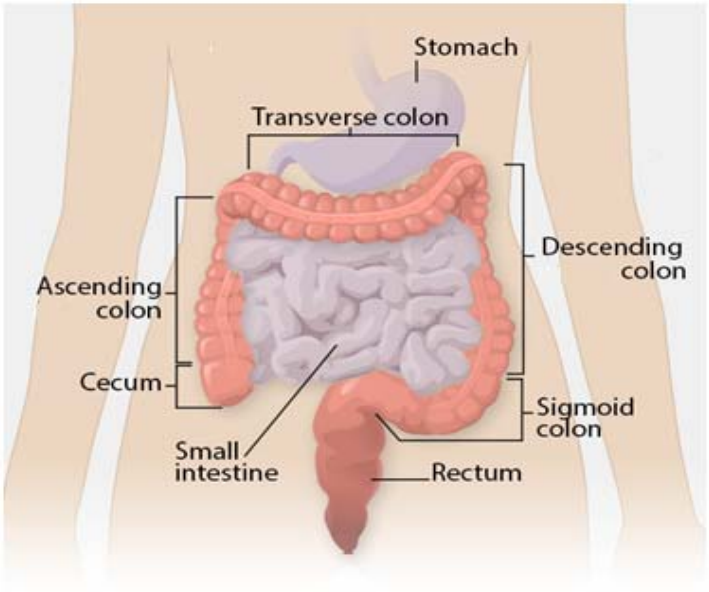
[34] Northwest Network VISN 20 Centralized Delineation of Clinical Privileges. General Surgery Request for Clinical Privileges.
[35] The colon is also called the large intestine or large bowel. The passageway that connects the colon to the anus is called the rectum.
[36] http://www.cdc.gov/vitalsigns/cancerscreening/colorectalcancer/. Accessed October 13, 2016.
[37] Ibid.
[38] Risk factors include inflammatory bowel disease, Crohn's disease, ulcerative colitis, a personal or family history of CRC or colorectal polyps (abnormal growths), and genetic syndromes such as familial adenomatous polyposis or hereditary non-polyposis CRC (Lynch syndrome).
[39] http://www.cdc.gov/vitalsigns/cancerscreening/colorectalcancer/. Accessed October 13, 2016.
[40] http://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm. Accessed October 13, 2016.
[41] Zauber Aann G, et al. Evaluating Test Strategies for Colorectal Cancer Screening: A Decision Analysis for the U.S. Preventative Services Task Force. Ann Intern Med 2008; 149: 659-669.
[42] Ibid
[43] To perform a flexible sigmoidoscopy, the doctor puts a short, thin, flexible, lighted tube into the rectum, checking for polyps or cancer inside the rectum and lower third of the colon.
[44] A colonoscopy is similar to flexible sigmoidoscopy, except the doctor uses a longer, thin, flexible, lighted tube to check for polyps or cancer inside the rectum and the entire colon. During the test, the doctor can find and remove most polyps and some cancers. Colonoscopy also is used as a follow-up test if anything unusual is found during one of the other screening tests.
[45] CT colonography, also called a virtual colonoscopy, uses x-rays and computers to produce images of the entire colon, which are displayed on a computer screen for the doctor to analyze.
[46] Johnson, David A. et al. Optimizing adequacy of bowel cleansing for colonoscopy: recommendations from the U.S. multi-society task force on colorectal cancer, American Gastroenterological Association Section, *Gastroenterology* 2014; 147: 903-942, 903.

In VHA facilities, the process of obtaining a colonoscopy typically starts with the patient's primary care physician generating a consult to the GI service stating why the patient needs the procedure. A gastroenterologist reviews the consult and assigns a priority based on the urgency of the patient's needs. The patient must take medication the day prior to the procedure to empty the contents of the bowel. (See bowel preparation section.) On the day of the procedure, the physician performing the colonoscopy discusses the risks, benefits, and alternatives to the procedure and obtains a written informed consent from the patient. The procedure begins with the GI nurse or nurse anesthetist placing the patient on cardiopulmonary monitoring equipment and administering sedating medications under the direction of the physician. (See sedation section.)

Once the patient achieves adequate sedation, the physician inserts the colonoscope and maneuvers it to the cecum,[47] the transition point between the small and large intestine that marks the end of the colon. (See Figure 1.) Some providers may have an assistant advance the colonoscope into the colon while they navigate the turns. The physician then slowly withdraws the colonoscope looking for abnormalities such as polyps and removes them for biopsy. (See polyps and withdrawal time sections.) He or she sends the specimens to the pathology lab for evaluation and makes recommendations on how soon the patient would need to return for his or her next colonoscopy. (See surveillance colonoscopy section.) The colonoscopy equipment has photographic capabilities so that physicians can take images of landmarks, polyps, and other abnormalities. The images are scanned into the patient's electronic health record (EHR).

Figure 1. Large Intestine Anatomy



Source: NYC Health, http://www1.nyc.gov/site/doh/health/health-topics/colon-cancer.page with OIG edits. Accessed November 2, 2016.

[47] The cecum is the cul-de-sac at the beginning of the large intestine and the end of the small intestine.

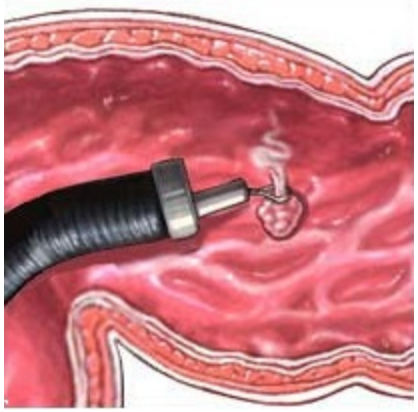
Polyps

Polyp is a general term used to describe a growth on the lining, or inside, of a mucous membrane.[48] This includes mucous membranes that are found in the digestive tract, like the colon.[49] Some colon polyps, such as small hyperplastic polyps are noncancerous while others, like adenomas, are precursors of colon cancer. About two-thirds of all colon polyps are adenomas. Studies show that adenomas can typically progress to cancer in about 7 to 10 years.[50]

The majority of polyps encountered in a colonoscopy are less than 10 millimeters in diameter and physicians must decide which technique should be used for polyp removal (polypectomy).[51] Providers can use either forceps or a snare (wire) to remove polyps, depending on the size of the polyp.[52] They can then choose to apply an electrical current to the forceps or snare ("hot" technique) or not use electricity ("cold" technique). For example, the physician may choose to use cold forceps to remove small polyps.[53] To do this, he or she grabs the polyp with forceps, engulfs it completely, and removes it in a single bite, without applying an electrical current.[54] In contrast, hot forceps have an electrical current that burns polyp tissue. The physician can also choose to use a cold snare to loop a wire around the polyp and tighten the wire until the polyp falls off. (See Figure 2.) In contrast, the physician applies electrical current through the snare to cut the polyp in hot snare polypectomy.[55] Cold snaring has become the preferred technique for most small lesions due to speed, comprehensive resection, and safety.[56]

[48] https://www.verywell.com/what-are-the-different-types-of-colon-polyps-796830. Accessed October 20, 2016.
[49] Ibid.
[50] Up-to-date. Approach to the patient with colonic polyps, August 2016. http://www.uptodate.com/contents/approach-to-the-patient-with-colonic-polyps?source=machineLearning&search=colonoscopy+guidelines&selectedTitle=2%7E150&sectionRank=1&anchor=H27. Accessed September 13, 2016.
[51] "Resection Techniques for Small Colonic Polyps: Cold Forceps Polypectomy, Hot Biopsy, Cold Snare and Hot Snare," JE East, http://www.sciencedirect.com/science/article/pii/S221209711370178X.
[52] Fyock CJ, Draganov PV. Colonoscopic Polypectomy and Associated Techniques. World J Gastronenterol 2010; 16 (29): 3630-3637.
[53] "Resection Techniques for Small Colonic Polyps: Cold Forceps Polypectomy, Hot Biopsy, Cold Snare and Hot Snare," JE East, http://www.sciencedirect.com/science/article/pii/S221209711370178X .
[54] Ibid.
[55] Ibid.
[56] Ibid.

Figure 2. Snare Polypectomy



Source: National Library of Medicine, Medline Plus. Accessed 11/3/2016.

Surveillance Colonoscopy

After the colonoscopy, the physician makes recommendations on how soon the patient needs to return for his or her surveillance colonoscopy based on the polypectomy pathology findings. As the system's pathology laboratory did not have the capability to examine polyps, polyps were sent to the VA Portland Health Care System. The pathologist determines the histology (cell type) of the polyps under the microscope and generates a report to the physician who ordered the biopsy. In 2012, the USPSTF in collaboration with multiple gastroenterology societies published guidelines on recommended intervals for surveillance colonoscopy.[57] At the system, the GI nurses called the patient with the results and the physician's follow-up recommendation about a week after the colonoscopy.

Quality Indicators of Colonoscopies

Professional Society Guidelines

In 2006, the ASGE and American College of Gastroenterology (ACG) published a set of quality indicators which was revised in 2015.[58] Some of the recommended markers to determine the quality of colonoscopies are listed below:

- Quality of bowel preparation.
- Cecal intubation rate with photodocumentation of the cecum.
- Withdrawal time.
- Adenoma detection rate.
- Complications.

[57] Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: A consensus update by the U.S. Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2012; 143: 844-857.
[58] Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. *Am J Gastroenterol* 2006; 101:873-885.

The surgical societies have not published guidelines for colonoscopy quality indicators.

VHA Directives

While the 2007 VHA Colorectal Cancer Screening directive did not require documentation of quality indicators, the revised December 2014 VHA Colorectal Cancer Screening Directive, (published after our July 23 through August 21, 2014 review period) required documentation of bowel preparation quality, cecal intubation rate, and adenomatous detection rate. VHA suggests using the last two elements as part of OPPE.[59] The VHA Moderate Sedation Directive[60] that was in effect at the time of our review period required monitoring of patients undergoing procedures and receiving moderate sedation; the revised December 2014 VHA Moderate Sedation Directive[61] required documentation of the amount of medication given as well as monitoring.

Bowel Preparation

Adequate bowel preparation prior to the procedure is necessary to perform a successful colonoscopy.[62] The 2006 ASGE/ACG guideline recognized that qualitative evaluation of bowel preparation (using terms such as "poor" "moderate" and "medium") had no standardized meaning and adopted a more objective evaluation where adequate meant a bowel preparation that allowed visualization of polyps ≥5 millimeters. The 2015 ASGE/ACG guideline gives the option of bowel preparation documentation using a validated scale.[63] The VHA CRC Directive published in December 2014 states that providers should document, at a minimum, if the preparation quality is adequate for detecting ≥5 millimeter polyps, ideally using a validated scale.[64] If the bowel preparation is inadequate,[65] the procedure should be terminated and rescheduled.[66]

[59] VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014.
[60] VHA Directive 2006-023, *Moderate Sedation by Non-Anesthesia Providers*, May 1, 2006. This directive expired May 31, 2011 but was considered active until rescinded and replaced by VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers*, December 30, 2014.
[61] VHA Directive 1073, *Moderate Sedation by Non-Anesthesia Providers,* December 30, 2014.
[62] Johnson, David A. et al, "Optimizing Adequacy of bowel cleansing for colonoscopy: Recommendations from the U.S. Multi-Society Task Force on Colorectal Cancer," American Gastroenterological Association Section, *Gastroenterology* 2014; 147:903-942, 904.
[63] Rex DK, Schoenfeld PS, Cohen J, et al., "Quality Indicators for Colonoscopy," *Gastrointest Endosc* 2015; 81 (1) 31-53.
[64] VHA Directive 1015, *Colorectal Cancer Screening,* December 30, 2014. The 2007 VHA Colorectal Cancer Screening directive had no recommendation on bowel preparation.
[65] Adequate bowel prep allows for the detection of lesions larger than 5 millimeters.
[66] Johnson, David A. et al, "Optimizing adequacy of bowel cleansing for colonoscopy: Recommendations from the U.S. Multi-Society Task Force on Colorectal Cancer," American Gastroenterological Association Section, *Gastroenterology* 2014; 147:903-942, 904.

Sedation

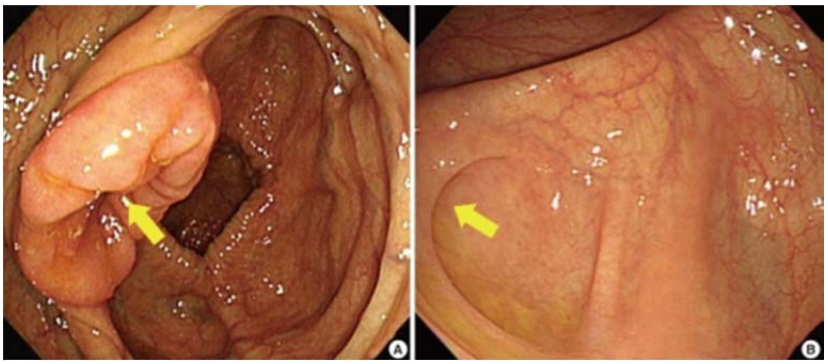
To allow for patient comfort and ease of the procedure, moderate or deep sedation is used during a colonoscopy.[67] During moderate sedation (formerly called conscious sedation) the patient can respond purposefully to verbal commands.[68] During deep sedation the patient is not easily aroused but can respond following repeated or painful stimulation.[69] Monitoring of vital signs must be done throughout the procedure when moderate or deep sedation is being administered and documented at 5-minute intervals. The provider must take care to administer enough medication to ensure that the patient is comfortable during the colonoscopy but not give too much medication that the patient stops breathing. Typically GI nurses are responsible for documentation of medications, vital signs, and other intraprocedural data for moderate sedation. Nurse anesthetists with specialized training on stronger sedation medications are responsible for administering and documenting deep sedation medications.

Cecal Intubation

Cecal intubation is defined, "as the passage of the tip of the colonoscope to a point proximal (just before) to the ileocecal valve[70] so that the entire cecum is visualized."[71] (See Figure 3.) The appendiceal orifice which is the entrance to the appendix is another landmark at the cecum. Providers must visualize the landmarks to ensure that they reached the end of the colon for a complete examination because a high percentage of CRC is located not only in the beginning of the colon but also at the cecum.[72] Cecal intubation rates vary by provider and are an indicator of technical abilities. The 2006 and 2015 ASGE/ACG guidelines recommend documenting cecal intubation by photographing the identified cecal landmarks while the 2014 VHA directive required cecal intubation documentation but did not specify how it should be documented.[73][74]

[67] Lewis, J., Cohen, L., "Update on Colonoscopy Preparation, Premedication and Sedation," http://www.medscape.com/viewarticle/778967_8. Accessed Oct 13, 2015.
[68] Orlewicz, M. et al., "Procedural Sedation" Medscape, http://emedicine.medscape.com/article/109695-overview, Accessed October 14, 2016.
[69] Ibid.
[70] The ileocecal valve separates the small intestine from the large intestine.
[71] Fayad, N., Kahi, C., "Quality Measures for Colonoscopy: A Critical Evaluation," Clin Gastroenterol Hepatol 2014:12(12), http://www.medscape.com/viewarticle/840981_3, Accessed October 13, 2016.
[72] http://www.news-medical.net/news/2006/09/13/20137.aspx. Accessed October 13, 2016.
[73] End of colon landmarks include the appendiceal orifice and the ileocecal valve.
[74] The 2007 VHA Colorectal Cancer Screening directive had no recommendation regarding cecal intubation.

Figure 3: Anatomy of Cecal Landmarks



Source: *National Library of Medicine. https://openi.nlm.nih.gov/detailedresult.php?img=PMC3890483_jkms-29-98-g003&req=4. Accessed November 3, 2016.*

A: Yellow arrow points to ileocecal valve
B: Yellow arrow points to appendiceal orifice

Withdrawal Time

The amount of time spent examining the colon during withdrawal of the scope can be an indicator of quality.[75] Longer times are associated with greater detection of polyps.[76] Withdrawal time is defined as, "an appropriate secondary measure of quality in instances of low Adenoma Detection Rates (ADR). Physicians who spent longer than 6 minutes of withdrawal time had a significantly increased detection rate of adenomas compared with those who averaged less than 6 minutes."[77]

Adenoma Detection Rate

The ADR is defined, "as the percentage of patients age 50 and older undergoing screening colonoscopy, who have one or more precancerous (adenoma) polyps detected. This rate should be at least 25% in men and 15% in women."[78] This aggregate measurement best reflects how carefully the physician performs his or her colonoscopies.[79] One study involving more than 300,000 colonoscopies found that providers who had higher ADRs had patients with lower risk of interval colorectal cancer development, advanced cancers, and cancer deaths.[80] The Polyp Detection Rate is easier to calculate and can be used as a surrogate to the ADR.[81] The Polyp Detection

[75] http://www.news-medical.net/news/2006/09/13/20137.aspx Accessed October 13, 2016.
[76] Ibid.
[77] Rex et al, Quality indicators for colonoscopy, *Am J of Gastroenterol* 878; http://www.news-medical.net/news/2006/09/13/20137.aspx. Accessed October 13, 2016.
[78] http://patients.gi.org/gi-health-and-disease/questions-and-answers-about-quality-in-colonoscopy. Accessed October 14, 2016.
[79] Ibid.
[80] Corley DA, Jensen CD, Marks AR, et al. Adenoma detection rate and risk of colorectal cancer and death, *N Engl J Med*. 2014; 370:1298-306.
[81] Boroff et al., Polyp and adenoma detection rates in the proximal and distal colon, *AM J Gastroenterol* 2013:108, http://www.medscape.com/viewarticle/806338, Accessed October 14, 2016.

Rate is readily available from colonoscopy reports.[82] Polyp Detection Rate is defined, "as the number of colonoscopies in which one or more polyps was removed and sent for histology, divided by the total number of colonoscopies performed by the gastroenterologist."[83]

Complications

Colonoscopy complications can be immediate or delayed.[84] Measurable complications include perforation and bleeding.[85] Perforation is the most serious complication during or after colonoscopy. Perforations greater than 1 in 500 overall or greater than 1 in 1,000 in screening patients should raise concerns.[86] Bleeding is the most common complication of polypectomy and is typically less than 1 percent.[87] At the system, the GI nurses called the patients the day after the procedure to determine if the patient experienced any adverse outcomes. The most important long-term complication for a poorly performed colonoscopy is missed colorectal cancer, which may take years to discover. The risk of a delayed cancer diagnosis may be increased when providers recommend longer than indicated surveillance times for repeat colonoscopies.

Allegations. Representative DeFazio communicated, in a letter sent to the OIG, the following allegations from a constituent about events that occurred in 2014:

- Surgeries are performed inappropriately without ICU back-up.
- Surgeons are unable to keep up surgical skills.
- Access to care (clinic appointments and procedures) in some surgical areas is delayed.
- Patient safety concerns are not reported due to fear of retaliation.[88]

We received additional allegations during complainant interviews, specifically:

- A surgeon performed colonoscopies in an unsafe manner.
- Access is delayed due to a backlog for colonoscopies.

During on-site interviews in December 2014 and October 2015, staff informed us about staff conflicts with collaboration and communication within the GI unit.

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[82] Boroff et al. Polyp and adenoma detection rates in the proximal and distal colon. *AM J Gastroenterol* 2013:108, http://www.medscape.com/viewarticle/806338. Accessed October 14, 2016.
[83] Boroff et al. Polyp and adenoma detection rates in the proximal and distal colon. *AM J Gastroenterol* 2013:108, 2013:108, http://www.medscape.com/viewarticle/806338. Accessed October 14, 2016.
[84] http://www.news-medical.net/news/2006/09/13/20137.aspx. Accessed October 13, 2016.
[85] Ibid.
[86] Ibid.
[87] Ibid.
[88] This allegation is addressed in a previously published report: VAOIG, *Healthcare Inspection—Nurse Staffing and Patient Safety Reporting Concerns*, VA Roseburg Healthcare System, Roseburg, Oregon, (Report No. 15-00506-420, October 12, 2016). http://www.va.gov/oig/pubs/VAOIG-15-00506-420.pdf. Accessed November 2, 2016.

Scope and Methodology

We initiated our review in October 2014 and completed our work in November 2016.

We reviewed system documentation, including VHA handbooks and directives, Joint Commission Standards, system policies and procedures, EHRs, quality management documents, committee minutes, and other relevant documents. We conducted site visits December 1–3, 2014, and October 28–29, 2015. We interviewed the system Director, Associate Director, Chief of Staff, and the Associate Director for Patient Care Services. We conducted interviews with program directors (National, VISN, and system level), mid-level managers, providers, and other clinical and administrative staff knowledgeable about the system's surgical and GI programs. We interviewed three of the four physicians who proctored the system's Chief of Surgery (COS) at the Mann-Grandstaff VA Medical Center in Spokane, WA.

We conferred with two non-VA specialists who reviewed the 79 colonoscopy and sigmoidoscopy cases[89] performed by the COS from July 23 through August 21, 2014. We reviewed medical journal articles and professional society guidelines.

We did not assess the COS's competence. The American Board of Medical Specialties (ABMS), which collaborates with 24 specialty medical boards to set standards for physician certification, defines competence in terms of six general domains:[90] medical knowledge,[91] practice-based learning and improvement,[92] patient care and procedural skills,[93] system-based practice,[94] interpersonal and communication skills,[95] and professionalism.[96] The system's FPPE/OPPE adopted the six domains for performance evaluation. Physicians must meet all six domains and have the physical capacity to

[89] Within this report, we use the global term colonoscopy to include colonoscopy and sigmoidoscopy. We realize that some colonoscopy quality indicators such as cecal intubation will not apply to sigmoidoscopy.
[90] American Board of Medical Specialties. A Trusted Credential Based on Core Competencies. http://www.abms.org/board-certification/a-trusted-credential/based-on-core-competencies/ Accessed September 12, 2016.
[91] For the medical knowledge domain, physicians should demonstrate knowledge of scientific principles in patient care. Examples include using colonoscopies for the appropriate indications and ordering the proper amount of sedation.
[92] For the practice-based learning and improvement domain, physicians should evaluate their patient care practices by using and applying scientific literature to improve on the practice of medicine. Examples include applying professional society guidelines to change practice or learning via audit and feedback.
[93] For the patient care and procedural skills domain, physicians should provide compassionate, appropriate and effective patient care and treatment. Examples include the ability to maneuver effectively the colonoscope to the cecum and using appropriate polypectomy techniques.
[94] For the systems-based practice domain, physicians should use resources available in the healthcare system to provide optimal patient care. Examples include using pathology results to guide follow-up recommendations and working effectively in interprofessional teams.
[95] For the interpersonal and communication skills domain, physicians should effectively exchange information with patients, family, and colleagues. Examples include effectively communicating critical findings to patients and appropriate completion of medical records.
[96] For the professionalism domain, physicians should show commitment to carrying out duties of the profession and follow ethical principles. Examples include accepting responsibility and following through on tasks.

perform their duties to be deemed competent. We were limited in our ability to review these domains because our data were confined to interviews and EHR review. Some of these domains, such as professionalism and communication skills, must be observed first hand. Although we evaluated aspects of some domains, we focused our assessment on whether the COS practiced unsafely in terms of whether patients experienced harm within the context of short-term and long-term complications. (See discussion of complications on p. 11.)

Delayed access is defined for this report as a wait of 30 days or greater for an appointment. Allegations relating to patient safety are addressed in a previous report.[97]

The following policies cited in this report were expired:

1. VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. (Expired May 21, 2015.)

2. VHA Directive 2011-037, *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*, October 14, 2011. (Expired October 31, 2016.)

3. VHA Directive 2006-041, *Veterans Health Care Service Standards*, June 27, 2006. (Expired September 30, 2013.)

We considered these policies to be in effect as they had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),[98] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[99] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[100]

We **substantiate** allegations when the facts and findings supported that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

[97] VAOIG. *Healthcare Inspection-Nurse Staffing and Patient Safety Reporting Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*, (Report No. 15-00506-420, October 12, 2016). http://www.va.gov/oig/pubs/VAOIG-15-00506-420.pdf . Accessed November 2, 2016.
[98] VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016.
[99] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.
[100] Ibid.

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

Inspection Results

Issue 1: Surgical Program

ICU Backup

We did not substantiate the allegation that surgeries were performed inappropriately without ICU back-up. From 2010 to 2013, the system was designated as a Standard Inpatient Surgical Complexity Program, but received a waiver to perform standard complexity surgeries with the telemetry unit designated as an equivalent to a level 4 ICU. The system has been a designated Ambulatory Basic Surgical Program since 2013. According to VHA Directive 2011-037, an ICU is not required for Ambulatory Basic Surgical Programs.[101]

We determined that surgical cases were continuously monitored to ensure the system was operating within their designated complexity level. We found that cases beyond the surgical complexity level of the system are reported to and discussed in the VISN 20 Surgical Committee, which conveys them to the National Surgery Office. The system's then-COS reviewed cases in 2014 that appeared to be beyond the system's designated surgical complexity level and determined the cases were not beyond the scope of the system's designated complexity level.

Provider Surgical Skills

We did not substantiate the allegation that surgeons were unable to maintain surgical skills.

The system is a designated Ambulatory Basic Surgical Program and mainly performs skin biopsies and hernia repairs. Some surgeons reported concerns that they were losing their skills for procedures they no longer performed. However, we interviewed other surgeons at the system and VISN level and learned that surgeons could be detailed to other facilities to perform procedures not normally done at the system. For example, one surgeon reported traveling to VA facilities in Portland, OR, and Seattle, WA, in order to maintain skills.

Issue 2: Access to Care

We substantiated the allegation of delayed access to care in some surgical areas (clinic appointments and procedures). We also substantiated delayed access to GI care due to a backlog for colonoscopies. However, we found that access had improved drastically over time, especially in the GI Endoscopy service.

[101] VHA Directive 2011-037, *Facility Infrastructure Requirements to Perform Invasive Procedures in an Ambulatory Surgery Center*, October 14, 2011. This directive expired on October 31, 2016 and has not been updated.

Surgery Services Access

VHA provides policy for implementing processes and procedures for scheduling outpatient clinic appointments including use of the electronic wait list (EWL), which is the official VHA wait list.[102] The system tracks wait times for all clinics, and the data are reviewed weekly.

Surgery service wait times are tracked at the system level and through the VISN 20 Surgery Committee. Additionally, the committee tracks the number of surgical patients waiting for a procedure at all medical centers within the VISN and monitors implementation of action plans.

In December 2014, three surgery clinics (podiatry, orthopedics, and optometry) had patients on EWLs. In March 2015, EWLs for general surgery and urology included 29 patients waiting over 30 days for surgical procedures. In addition, EWLs included 28 patients waiting over 30 days for clinic appointments in ophthalmology, optometry, orthopedics, and urology. As of September 30, 2016 three patients were waiting over 30 days for clinic appointments in the surgery clinics.

GI Endoscopy Service Access

In 2012, one of two gastroenterologists left the system. System leadership encountered difficulties finding a replacement provider due to the system's rural location. The system had limited ability to refer for non-VA Care[103] since they employed the only gastroenterologist in a 60-mile radius. While approved to do so, leadership had been unsuccessful in hiring a temporary provider via a locum contract citing a number of economic and demographic changes in the community. The resulting lack of staff and limited ability to refer for non-VA Care led to the GI Endoscopy service having the largest EWL in the local system.

In October 2014, the GI Endoscopy Service EWL had over 600 patients waiting for appointments. System leadership developed action plans to reduce demand while expanding sites for endoscopies. Staff reviewed the EHR for each patient listed on the GI Endoscopy EWL and physicians contacted those patients. The system offered stool testing for appropriate patients and pursued contracts with alternative (VA and distant community) facilities for additional colonoscopy capacity.

The system met weekly with VISN 20 leaders and bi-weekly with VHA Central Office to monitor progress in implementing the action plans. In December 2014, the

[102] VHA Directive 2010-027. VHA *Outpatient Scheduling Processes and Procedures*, June 9, 2010. This directive was in effect at the time of our review but was rescinded and replaced by VHA Directive 1230. *Outpatient Scheduling Process and Procedures*, July 15, 2016.

[103] Non-VA Care Coordination is medical care provided to eligible Veterans outside of the VA. It was formerly known as 'Fee Basis', 'Purchased Care', or 'Non-VA Care'. The use of Non-VA Care Coordination as a means to provide non-VA care to Veterans is strictly governed by federal laws containing eligibility criteria and other policies specifying when and why it can be used.

GI Endoscopy EWL had been reduced to 370, and as of March 2015, the system reported only 1 patient waiting greater than 30 days for GI Endoscopy. By the end of September 2016, the system reported no patients waiting greater than 30 days.

We substantiated access delays in the Surgery and GI Services in an earlier period that had largely improved over time. System leadership and clinical program managers were aware of the access delays, placed patients on the EWL per VHA policy,[104] and implemented action plans to reduce the wait times prior to December 2014.

Issue 3: Alleged Unsafe Colonoscopy Practice

We did not substantiate that a surgeon, the COS, performed colonoscopies unsafely, but found that he practiced in an outdated manner. We did not identify any patients who suffered immediate complications (bleeding, perforations, or over sedation issues) as a result of colonoscopies performed by the COS. At the time of our review (about 2 years after the last procedure performed by the COS), we did not identify any patients who had been diagnosed with interval colon cancer. Three surgeons and a gastroenterologist at another VHA facility observed the COS's technique in 16 cases and determined that he met or exceeded expectations. However, we found that the COS practiced in an outdated fashion and had concerns with his documentation (polyp size, withdrawal times, or photodocumentation of cecal intubation), polypectomy techniques, and surveillance recommendations.

Summary of Staff Concerns and Actions Taken

COS Hired

In the summer of 2014, system leaders hired a COS who had experience performing colonoscopies at another VHA facility. Coinciding with this period, the system had a long colonoscopy EWL. (See Issue 2: GI Endoscopy Service Access above.) The endoscopy clinic had one full-time gastroenterologist and a surgeon who performed colonoscopies part time. When the COS arrived at the system, he was asked by the Chief of Staff to help reduce the colonoscopy EWL. From July 23 through August 21, 2014, the COS performed 69 colonoscopies and 10 sigmoidoscopies[105] at the system.

Staff Concerns

During our on-site visits, December 1–3, 2014 and October 28–29, 2015, we found contentious interactions in the GI unit between and among providers of different specialties, nursing staff, and system leadership. Few opportunities for permanent

[104] VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures*, June 9, 2010. This directive was in effect at the time of our review but has since been replaced by VHA Directive 1230, *Outpatient Scheduling Process and Procedures*, July 15, 2016.

[105] A sigmoidoscopy is similar to a colonoscopy but only examines the first section of the colon, closest to the anus, and does not require manipulation of the scope around curves of the large intestine. Patients often do not need to be sedated for this procedure.

resolution of intra- and inter-departmental issues existed partly because several of system's leadership positions had been in flux during this time.[106] Tensions became even more strained when the new COS was hired. Staff told us that they had looked forward to having a new colonoscopy provider to help with the backlog. However, the staff grew concerned about the COS's practice within a few weeks of his arrival.

Nurses

We interviewed 11 nurses who worked directly with the COS during colonoscopies and one nurse manager. Nine of them had brought forward concerns to their supervisors, Quality Management staff, and risk management stating that:

- He was "forceful" with the colonoscope causing patients to need more sedation than usual.
- He was unable to reach the cecum in some cases.
- He asked the nurses to push the colonoscope, which was not in their scope of practice.
- He failed to remove some polyps, stating they were not cancerous by appearance.
- He did not acknowledge the nurses' concerns leading to a lack of teamwork.

Colonoscopy Providers

Several weeks after the COS started performing colonoscopies, other colonoscopy providers also voiced concerns. The COS asked twice for assistance from one of the surgeons with pushing the scope during a procedure. The surgeon stated that the COS:

- Did not undergo proctoring with the one person technique when he started practicing at the system.
- Burnt a polyp before taking a biopsy which did not lead to a clean biopsy and could potentially burn the colon.
- Said he was at the cecum when the assisting surgeon did not see the typical landmarks.
- Took a biopsy of the cecum which was not diagnostic when the assisting surgeon asked the COS to take a photo of the cecum.

[106] Six different individuals have held the Chief of Staff position since July 2014, and a new Facility Director was named in September 2014.

The gastroenterologist stated that she observed four and assisted in one case. She stated the COS:

- Looped the scope multiple times in the colon causing the patient pain.
- Wrote in the medical record that he had reached the cecum when he was not there.
- Had no photos of the cecum to prove he was at the end of the colon.
- Removed a large polyp in pieces with forceps instead of using a snare to remove it all at once.
- Recommended longer surveillance colonoscopy intervals than expected.

COS's Response to Concerns

When interviewed, the COS stated that he performed colonoscopies to help with the backlog, but the GI unit staff did not behave as if there was a wait-time "crisis." He said 800 patients were waiting for colonoscopies, with some later diagnosed with cancer (including the case summary patient) while the GI staff were doing fewer colonoscopies than the number of consults received monthly. He had set up a task force with the Chief of Medicine to offer alternative colorectal cancer screening methods to qualified patients on the colonoscopy EWL. He clashed with the gastroenterologist on whether patients should use alternative screening methods (such as stool tests) instead of colonoscopies. The COS stated that he used different colonoscopy techniques than the gastroenterologist. He thought that their differences in training and specialty contributed to the friction. The COS told us that his competency came into question because he had pushed to improve access to GI services. The Chief of Medicine said he also tried to decrease the GI backlog which caused discontent among the staff.

VHA Review of the COS's Colonoscopy Practice

In response to concerns voiced by staff, system leaders contacted VISN 20 leadership and VHA Central Office. Upon their advice, system leadership recommended that the COS go to another VHA facility for proctoring as part of his FPPE. He went to the Mann-Grandstaff VA Medical Center in Spokane, WA, where three board certified surgeons and one board certified gastroenterologist proctored him separately for 16 colonoscopies. He reached the cecum in all cases and had an average withdrawal time of 6 minutes. They concluded that his ability met or exceeded the proctors' expectations. The COS at the Mann-Grandstaff VA Medical Center reviewed the EHRs for 75 (out of 79) patients who had undergone procedures at the system by the system COS and found that they all met his (the Mann-Grandstaff COS) criteria.[107]

[107] The criteria identified by the proctor were appropriate procedural technique, bowel preparation documentation, photodocumentation verification that cecum was reached, appropriate recommendations based on initial findings, appropriate use of intra-procedural consultation, and quality of care concerns. We were unable to determine why he did not review the remaining 4 patients' EHRs. We were also unable to correlate the 75 patients' findings with our review because all of the 75 patients were de-identified.

He told us that the system COS had no difficulties using the one-person technique and did not identify any concerns related to documentation practices.

After returning from proctoring, the COS tried to resume performing colonoscopies. However, he decided not to perform any more colonoscopies due to tensions within the GI unit.

Congressional Briefing

In October 2015, we briefed Representative DeFazio's staff regarding our initial findings. The congressional staff informed us that during a hearing in front of the Committee on Homeland Security and Governmental Affairs on September 22, 2015, Carolyn Lerner from the Office of Special Counsel (OSC) testified about "Improving VA Accountability: Examining First-Hand Accounts of Department of Veterans Affairs Whistleblowers." The testimony included a resolution summary for an OSC whistleblower claim at the system.

According to the written testimony submitted by OSC to the Committee prior to the hearing, the gastroenterologist said 90 percent of the COS's colonoscopies were performed incorrectly. The surgeon who had reported those concerns to system leadership subsequently experienced retaliation. He was relieved of his surgical duties and sent to perform outpatient clinical duties. He received a lower performance evaluation, and was denied permission to go to another facility to practice procedures in order to maintain his surgical skills. OSC settled the case, which included VA reassigning the surgeon to another VA facility and reissuing his performance evaluation.

Congressional staff raised concerns to us regarding the COS's ability to perform colonoscopies and requested that we perform an independent review of the GI care that the 79 patients experienced.

Colonoscopy Practices

Our Assessment

We reviewed the EHRs of all 79 patients who received a colonoscopy performed by the COS from July 23 through August 21, 2014. We did not substantiate that the COS performed colonoscopies unsafely at the system, but found that he practiced in an outdated manner. We did not identify any patients who suffered immediate complications (bleeding, perforations, or over sedation) as a result of colonoscopies performed by the COS. At the time of our review (about 2 years after the last procedure performed by the COS), none of the patients had been diagnosed with interval colon cancer. However, we could not confidently assess the quality of the 79 colonoscopies given the inconsistent documentation in the EHRs.

We determined that the COS appeared to practice in an outdated fashion. His notes did not include the quality indicators recommended by professional society guidelines. We did not find that the COS used more sedation than necessary. Some patients were under-sedated. The COS's written documentation of cecal intubation was within the

range recommended by published literature. However, his photodocumentation of cecal intubation did not meet professional society guidelines. His polyp detection rate exceeded established rates. He told us that he used clinical judgement to determine which polyps needed to be biopsied; experts recommended generally biopsying all polyps because their appearance is not a good indicator of their pathological (diseased) nature. The failure to biopsy polyps may potentially lead to undiagnosed precancerous or cancerous abnormalities. He used hot forceps to fulgurate (burn) polyps, which was a practice that had fallen out of favor because it increased the risk of colon perforation and changed the specimen's pathological nature. He gave follow-up recommendations without waiting for pathology results, which may have required subsequent patient notification of changes in interval follow-up times, leading to confusion amongst patients and providers. For some patients, he recommended longer intervals for follow-up colonoscopy than guidelines suggested.

Complications

Indications of safe practice for colonoscopies include the lack of immediate post-procedural complications (bowel perforation, bleeding, or over-sedation) and the absence of a delayed diagnosis of colorectal cancer. None of the 79 patients experienced immediate complications. As of September 2016, none of the patients had developed colorectal cancer subsequent to their colonoscopies, including the four patients we identified as receiving longer than indicated surveillance times for follow-up colonoscopies. (See Recommendations for Surveillance Interval section below.)

Proctoring

The system did not have specific colonoscopy proctoring requirements for FPPE during the review period. Thus, the COS did not need to be proctored on the one person technique prior to performing the procedures at the system. Once system leadership became aware of staff concerns, they sent him to the Mann-Grandstaff VA Medical Center in Spokane, WA. This proctoring became part of his FPPE as a new provider.

Quality Indicators for Colonoscopy

We compared the ASGE/ACG and VHA quality indicators with the COS's EHR documentation in the table below.

Table. Quality Indicators Recommended by ASGE/ACG Guideline and VHA Compared to the COS's Documentation

2006 ASGE/ACG Guideline	2007 VHA Colorectal Cancer Screening Directive	July-August 2014 COS's Documentation	December 2014 VHA Colorectal Cancer Directive
Provider Indicators			
Document appropriate indication[108]	None Specified	Yes, consistently	None Specified
Obtained informed consent	None Specified	Yes, consistently	None Specified
Document if quality of bowel preparation adequate for visualizing ≥5mm polyps	None Specified	Qualitative documentation ("good," "moderate," "medium," "poor")	Document if quality of bowel preparation adequate for visualizing >5mm polyps, ideally using a validated score
Documented cecal intubation ("Visualization of the cecum by notation of landmarks and photodocumentation in every procedure")	None Specified	92% had written documentation of landmarks, 57% had photodocumentation, no documentation of the depth of scope	Required for OPPE, document the depth of colonoscope insertion, no photodocumentation required
Document withdrawal time	None Specified	No documentation	None Specified
Document that polyps <2cm are resected** or unresectability[109]	None Specified	Qualitatively documented polyp size ("small" or "large"), did not document whether they were removed (completely, partially, or unresectability)	None Specified
Document post polypectomy bleeding	None Specified	No documentation but no reported incidence of bleeding[110]	None Specified
Document incidence of perforation	None Specified	No documentation but no reported incidence of perforation	None Specified
Recommended surveillance intervals based on guidelines	None Specified	Yes, documented surveillance intervals. In some cases recommended longer time frame than guidelines	None Specified
System Indicator			
Monitor provider's Adenoma Polyp Detection Rate (ADR)	None Specified	Not required	"Suggested" for OPPE

Source: OIG evaluation of journal article, VHA directives, and EHR data

[108] Providers should document reasons for the colonoscopy, such as colorectal cancer screening or evaluations of GI symptoms. Indications were documented in the colonoscopy consult requests and in the COS's preoperative notes.
[109] The guideline stated that providers should be able to endoscopically remove polyps up to 2 centimeters. However, polyps >2 centimeters may need to be marked and referred for surgery at a later time if the provider was not able to remove it endoscopically.
[110] The system has a GI nurse who would call the patient a day or two after the procedure to check and see if the patient experienced any complications. In lieu of documenting complications, the COS would write "patient tolerated procedure well" at the end of his procedure note.

Documentation

Although ASGE and ACG published guidelines in 2006 for colonoscopy quality indicators, VHA had no directive requiring documentation of those elements during our review period. While the COS did not belong to these professional organizations, he held privileges to perform colonoscopies. Therefore, he should have been held to the same quality of practice as any provider who performed colonoscopies. VHA requires "one standard of care" to be provided to VA patients regardless of their treating physicians' medical specialty, training, and experience.[111] Ideally, the COS's documentation should have included all the elements listed in the table above. Given the staff's allegations and the COS's inconsistent documentation in the patients' EHRs, we could not confidently assess the quality of the 79 colonoscopies.

Bowel Preparation

The COS described the quality of bowel preparation as "medium," "moderate," or "poor" but did not convey whether the bowel preparation was adequate for visualizing ≥5 millimeters polyps. In December 2014, VHA adopted similar language as the 2006 ASGE/ACG guideline, and added that ideally providers should use a validated scale to evaluate bowel preparation to minimize subjective interpretations.

Sedation

We evaluated the COS's sedation practice given the staff's concerns about patients receiving large amounts of medications. We found that the sedation medication amounts used were generally appropriate for patients. We did not find EHR documentation that indicated the COS over-sedated patients. However, we found a variation in management for some patients who may have been under sedated. Sometimes the nurse anesthetist came into the room to assist with sedation while in other instances, the COS withdrew the colonoscope and aborted the procedure after ordering large doses of medication (8mg midazolam[112] and 200-250mcg fentanyl).

Cecal Intubation

We found that the COS had written that he saw landmarks at the end of the colon in 92 percent of the patients but only took photos in 57 percent of the cases. Published literature shows that a provider should be able to intubate the cecum in 90 to 95 percent of cases depending on the patient's health and the indication for the colonoscopy. The ASGE/ACG guideline recommended obtaining photos of the cecum in "every procedure" but VHA does not require photodocumentation. Although the COS had a 57 percent photodocumentation rate, we found that most of the photos taken actually showed an area proximal to (before) the cecum. Without quality photos to support

[111] VHA Handbook 1100.19 Credentialing and Privileging (page 38).
[112] Midazolam is a benzodiazepine and used as a sedative to impair consciousness. Fentanyl is an opioid used for pain. Physicians commonly use this combination of medications for moderate sedation.

written assertions that he saw cecal landmarks, we could not confidently determine that he intubated the cecum.

Polyp Detection Rate

The ASGE/ACG guideline and VHA 2014 directive recommended tracking providers' ADRs for quality assurance. ASGE considered the ADR as the "single most important quality measure in colonoscopy."[113] During the review period, the system did not monitor providers' ADRs and was not required to do so. We used polyp detection rates[114] as a surrogate marker for ADR and found that the COS had an overall polyp detection rate of 44.4 percent, indicating that he had no difficulties finding polyps.

Polypectomy and Fulguration

ASGE/ACG guideline suggested providers document that polyps <2 centimeters (cm) were resected or why they were unable to resect the polyps. We found that the COS qualitatively documented polyp size (small or large), and their location in the section of the colon; occasionally he would note the depth of the scope where the polyp was located. He did not document whether the polyps were removed completely, partially, or if they were unable to be resected. This documentation is important for determining the interval for surveillance colonoscopy and risk of colon cancer. One study suggested that 25 percent of cancers that develop post colonoscopy may be due to incomplete polypectomy.[115]

Experts generally advocate for removing all polyps and sending them for biopsy.[116] Published literature has shown that the appearance of a polyp is not a good indicator of its pathological nature, since as many as 70 percent of diminutive polyps (<5 millimeters) may be adenomas.

The COS told us that he did not remove every polyp that he encountered. According to him, a screening colonoscopy was "not a polyp clearing procedure" because it had a fail rate of 20-25 percent.[117] He would use his clinical judgement, mainly based on polyp size, to determine which ones needed to be removed and sent for biopsy.

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[113] Rex DK, Schoenfeld PS, Cohen J, et al. Quality indicators for colonoscopy, *Gastrointest Endosc*. 2015; 81 (1): 31-53.

[114] The polyp detection rate is calculated by the number of screening colonoscopies where polyps were found divided by the total number of screening colonoscopies. The benefit of using a polyp detection rate is that it can be calculated without pathology data.

[115] Rex DK. Have we defined best colonoscopic polypectomy practice in the United Sates? *Clin Gastroenterol Hepatol* 2007; 5:674-677.

[116] Fyock CJ, Draganov PV. Colonoscopic polypectomy and associated techniques. *World J Gastronenterol* 2010; 16 (29): 3630-3637. Up-to-date. Approach to the patient with colonic polyps. August 2016. http://www.uptodate.com/contents/approach-to-the-patient-with-colonic-polyps?source=machineLearning&search=colonoscopy+guidelines&selectedTitle=2%7E150&sectionRank=1&anchor=H27. Accessed September 13, 2016.

[117] Published literature showed that upon repeat colonoscopy in 1 year, even qualified providers may typically have 20–25 percent of patients with new polyps not found in the original colonoscopy.

In our EHR review, we found that the COS wrote that he fulgurated (burnt) polyps in 12 patients but did not document what technique he used. He told us in an interview, that he would use hot forceps for small polyps; that is, he used forceps to pull a polyp off the colon wall and then applied electricity to fulgurate the base of the polyp. The polyp would fall off and be caught in the forceps. He would send the specimen to pathology for a biopsy. He would use a snare for large polyps and could apply electricity to the tip of the snare to burn those polyps. The advantage of fulguration was to use electricity to prevent or stop bleeding. It could also provide extra power to cut polyps off the colon wall. The ASGE/ACG guideline noted that electrocautery burn caused "virtually every case" of colon perforation from polypectomies.[118] The COS was aware of this potential complication and told us that he tried to pull the polyp away from the wall before applying electricity. Fulguration with hot forceps was a practice that had mostly fallen out of favor.

We found that in one colonoscopy performed by the COS where he applied fulguration, the biopsy sample sent was too small to be analyzed by the pathologist. In a flexible sigmoidoscopy case, the COS sent one of three fulgurated polyps for biopsy and it was positive for a precancerous polyp (tubular adenoma).

Recommendations for Surveillance Interval

Colonoscopy findings and pathology results determine the surveillance interval the patient needs to have a repeat screening colonoscopy. Polyps >10 millimeters, a higher number of polyps, and certain types of polyps increase the likelihood of developing colorectal cancer in the interval between colonoscopies. Patients with those findings would need shorter intervals between colonoscopies.[119] The COS often did not quantify polyp size but rather, stated subjectively if it was small or large, making it difficult to determine if he made the appropriate follow-up recommendations. With 1-2 small (<10 millimeters) adenomas, the recommended surveillance interval was 5 to 10 years but with 3 to 10 small adenomas or adenomas ≥10 millimeters, the interval decreased to 3 years.[120] In the fulguration case above, he sent one of three polyps for biopsy, so we could not determine if the proper follow up recommendation was selected. However, the patient received a repeat colonoscopy and polypectomy of two tubular adenomas one year later.

The COS also made recommendations for surveillance intervals without waiting for the pathology results to become available. When the pathology results became available, he or the gastroenterologist would sometimes change the initial recommendations. (See examples below.) The multiple changes in recommendations caused confusion among the patients.

[118] Rex DK, Petrini JL, Baron TH, et al. Quality indicators for colonoscopy. *Am J Gastroenterol* 2006; 101:873-885.
[119] Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: A consensus update by the U.S. Multi-Society Task Force on Colorectal Cancer, *Gastroenterology*. 2012; 143: 844-857.
[120] Ibid.

In several cases, he recommended a longer time frame for follow-up than the published guidelines, particularly for polyps which could not be retrieved. (See examples below.) In these instances, the colonoscopy surveillance interval should be treated as if the provider could not visualize polyps ≤5 millimeters (such as a patient who had an inadequate bowel preparation). The society guidelines recommend repeating the procedure in one year. The COS's recommendation for a longer surveillance interval had important implications because patients could develop colorectal cancer in the interim. Below are some examples where he should have recommended a one year follow up colonoscopy.

Examples of Inappropriate Surveillance Interval Recommendation

In one patient, the COS had removed a polyp but it was lost in the stool, which is not an uncommon occurrence. He recommended that the patient have a repeat colonoscopy in 3 years.

In two patients, the COS stated, a "small"[121] polyp was seen but could not be found again, thus the polyps were not removed and sent to the pathologist. The COS recommended repeat colonoscopy in 5 years.

The COS removed a polyp from a patient during a sigmoidoscopy and recommended follow-up in 5 years without waiting for the pathology results. The pathology result showed a 1 centimeter precancerous polyp (tubular adenoma). The USPSTF guideline on surveillance colonoscopy recommends a repeat colonoscopy in 3 years with high quality of supporting evidence based on that finding.[122] The COS changed his recommendation after the pathology result to repeat colonoscopy in 1 year.

Despite the COS recommendations, all four of these patients received a follow-up colonoscopy in 1 year and no evidence of colorectal cancer was found.

We identified one of the 79 patients who was diagnosed with colon cancer. System leadership provided the patient with an institutional disclosure. (See case summary below.)

Case Summary of a Patient who Received Institutional Disclosure

The patient, who was in his 50s with a family history of colon cancer, was referred by his primary care physician (PCP) for a screening colonoscopy in 2013. One month later, the gastroenterologist reviewed the consult request and assigned a routine urgency.[123] System staff informed the patient that due to the backlog of cases, he

[121] The COS did not give the actual measurement of the polyp so we were unable to determine if the polyp was ≤5 millimeters.
[122] Lieberman DA, Rex DK, Winawer SJ, Giardiello FM, Johnson DA, Levin TR. Guidelines for colonoscopy surveillance after screening and polypectomy: A consensus update by the US Multi-Society Task Force on Colorectal Cancer. *Gastroenterology*. 2012; 143: 844-857.
[123] Routine consults should be completed in 30 days according to the VHA Consult Management Directive.

would be placed on the EWL and the estimated wait was 4 to 6 months. Almost a year after the consult request, the COS performed a colonoscopy on the patient. The COS wrote that he saw the typical landmarks at the end of the colon before withdrawing the scope. He removed and fulgurated [burned] a "smaller" polyp. He removed a second "smaller" polyp with snare and cautery. He encountered difficulty with the removal of a third "large hard polyp" and took "multiple attempts" with a snare before the gastroenterologist came into the room to help complete the polyp removal. The COS marked the polyp removal site in the colon with ink and recommended that the patient return in 3 months for a flexible sigmoidoscopy for a recheck and to remove a different polyp. He sent all three polyps to pathology for biopsy at the VA Portland Health Care System because the system laboratory did not perform the test.

The pathology results showed invasive cancer.[124] The next day, the COS documented the pathology results and wrote a progress note stating that the patient needed CT scans and a referral to another surgeon[125] for a colectomy (colon removal). A provider co-signed the progress note on the behalf of the patient's PCP and ordered CT scans and a surgery consult at the VA Portland Health Care System.

Fifteen days after the pathology results, the gastroenterologist who assisted with the colonoscopy documented that the nurse flagged her about this case and that no one had yet contacted the patient about the cancer diagnosis. The gastroenterologist called the patient with the plan of care and the VA Portland Health Care System regarding the surgery consult for the colectomy.

The next day, the COS called the patient to inform him of the diagnosis and treatment plan. Approximately 4 weeks later, the Chief of Staff performed an institutional disclosure[126] to the patient regarding the diagnostic delay that might have resulted in the need for a colectomy.

Analysis of Case Summary Patient's Care

The case summary patient illustrated some of the system's issues with GI access and the COS's colonoscopy practice. The patient had a family history of colon cancer and waited more than a year for a screening colonoscopy. During this time, the system had a long EWL for GI care. Routine VHA consults were generally expected to be completed in 30 days but the patient did not receive a colonoscopy until almost a year after the consult request.[127][128] The COS encountered difficulties removing a large polyp

[124] Adenocarcinoma is a type of colon cancer.
[125] The system was not able to perform this type of surgery due to their surgical complexity designation.
[126] An institutional disclosure is a process where system leaders and providers inform the patient about adverse events in his/her care that may have resulted in harm.
[127] VHA Directive 2006-041, *Veterans Health Care Service Standards*, June 27, 2006, stated that patients must be able to schedule an appointment with a specialist and receive a routine diagnostic test within 30 days of referral. The directive expired September 30, 2013 but has not been renewed.

and required assistance from the gastroenterologist. The COS did not quantify the size of the polyps nor provide photodocumentation of cecal intubation. He made follow-up recommendations at the conclusion of the colonoscopy without the pathology results. When the biopsy results became available, he made his recommendations to the patient's covering PCP via a progress note without informing the patient of the diagnosis for 15 days.

Although the system provided an institutional disclosure to the patient because of the 13 month delay in receiving a colonoscopy, we identified other concerns in the patient's care beyond the delay in receiving the colonoscopy. First, VHA Directive 2008-056 required consult action (such as clinician review) within 7 days.[129] The gastroenterologist took more than 1 month to review the consult and assign a priority level.

Second, the 2007 VHA Directive *Colorectal Cancer Screening* stated the ordering provider must inform patients of their test results within 14 calendar days of the receipt of the biopsy results.[130] The current 2014 *Colorectal Cancer Screening* directive does not require a timeframe for result notification.[131] Neither directive specifies a time frame for informing patients of critical results, such as a cancer diagnosis. However, the 2009 VHA Directive *Ordering and Reporting Test Results* stated that "for abnormalities that require immediate attention, the 14-day limit is irrelevant, as the communication should occur in the timeframe that minimizes risk to the patient."[132] We determined that waiting more than 2 weeks after receipt of the critical pathology result to inform the patient of his cancer diagnosis was an unnecessary delay.

Third, the COS was the biopsy-ordering provider, thus was responsible for contacting the patient with the results. However, the patient received his cancer diagnosis from the gastroenterologist, a provider whom he had not met. Overall, the staff involved did not communicate well with each other regarding who would inform the patient of his cancer diagnosis.

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[128] Veterans Access, Choice, and Accountability Act of 2014. The 30-day requirement for routine care was articulated in the VHA Choice Act enacted August 7, 2014, that defined VHA wait time goals as "…not more than 30 days from the date on which a veteran requests an appointment for hospital care or medical services from the Department."

[129] VHA Directive 2008-056 *VHA Consult Policy,* September 16, 2008, expired on September 30, 2013. The current VHA Directive 1232 *Consult Processes and Procedures* requires action within 7 days of consult receipt.

[130] VHA Directive 2007-004 *Colorectal Cancer Screening*, January 12, 2007. This directive expired on January 31, 2012 and was considered active until replaced by VHA Directive *1015 Colorectal Cancer Screening,* December 30, 2014.

[131] VHA Directive *1015, Colorectal Cancer Screening,* December 30, 2014.

[132] VHA Directive 2009-019 *Ordering and Reporting Test Results*. March 24, 2009. This directive was in effect at the time of the events discussed in this report; it was rescinded and replaced by VHA Directive 1088 *Communicating Test Results to Provider and Patients,* October 7, 2015 which required that test results to be communicated to patients within 7 calendar days for results requiring action and 14 days for those that do not require any action.

The Gastroenterologist's Review

During an interview, the gastroenterologist stated system leadership told her to review the COS's colonoscopies. Despite multiple attempts, we were unable to contact the former interim Chief of Staff and former Quality Management Chief because they had both retired. We were also unable to obtain written documentation of this review request. The gastroenterologist also stated she was the "de facto Chief of GI" (as the sole gastroenterologist in the system) and the person responsible for triaging all the colonoscopy consults, so she felt obligated "to go back in and look at the charts."

She stated that for her review, she would recommend a repeat colonoscopy, typically within 1–5 years if she determined that the case had inadequate photodocumentation or poor bowel preparation. After she reviewed the patient's EHR, she would document her recommendation; the PCP would see the recommendation and take follow-up actions. Sometimes the patient would be scheduled a little earlier than 1 year for a repeat colonoscopy depending on when he/she sees the PCP.

Upon reviewing the EHRs, the gastroenterologist informed us that she had concerns about the COS's colonoscopies. The gastroenterologist contacted the VA National GI Director about these concerns rather than system leadership.

System Leadership Response

On September 4, 2015, the VA National GI Director forwarded an email to the system Chief of Staff from the gastroenterologist stating, "I elected to rescope all the patient's [sic] in whom there was no photodocumentation of cecal intubation. It looks like [it] was a good call." The Chief of Staff and Chief of Medicine conducted a review and found that the gastroenterologist performed or "caused [other providers] to perform" repeat colonoscopies on 12 of the 79 patients. They concluded that "there was no clinical indication of the need for a follow-up endoscopy within 1 year" and patients unnecessarily assumed the risk of the procedure. The Chief of Staff opened an Administrative Investigation[133] and placed the gastroenterologist on administrative leave. The Chief of Medicine subsequently cancelled several scheduled repeat colonoscopies.

The gastroenterologist told us that she was being retaliated against when she went to her office one day and found that her property had been removed. She filed for Whistleblower Protection with the OSC and hired legal representation. The COS also hired legal representation.

[133] An Administrative Investigation is formal process used to gather and analyze evidence to determine what happened and why it happened so that corrective actions can be taken at the individual or system level.

System and VHA Implications

Test Results Notification at the System

In our 2014 system Combined Assessment Program Review report we made a repeat recommendation "that facility managers ensure patient notification of diagnostic test results within the required timeframe and that clinicians document notification." [134] This recommendation was first reported in the system's 2012 Combined Assessment Program Review report.[135] As of August 2016, this recommendation remains open. The system continues to implement planned actions including changes to the system's critical values test notification policy.

Colonoscopies at a Prior VHA Facility

We had concerns that the COS's documentation practices at the system might have implications for the approximately 2000 colonoscopies he performed at a prior VHA facility. Missed precancerous polyps and colon cancers may result from poorly performed screening colonoscopies and may take several years to be diagnosed. VHA should perform a review of those cases to ensure that patients did not experience adverse outcomes.

Accurate Data Collection to Determine Quality of Colonoscopies

This inspection raised larger questions regarding the quality of colonoscopy care within VHA. In the summer of 2014 while the COS was performing colonoscopies, VHA did not have requirements for data collection of quality indicators. The current VHA *Colorectal Cancer Screening* directive, published in December 2014, suggested that facilities monitor providers' ADR and cecal intubation rates for OPPE. However, it did not require other quality indicators recommended by ASGE/ACG such as photodocumentation to prove cecal intubation or withdrawal time to denote how long the provider spent looking for abnormalities in the colon. We determined that VHA should require more accurate data collection aligned with professional society guidelines and published studies to ensure that high quality colonoscopies are performed. In this particular case, the COS's documentation of his procedures made it difficult to determine whether he performed quality colonoscopies.

"One Standard of Care" Regardless of Training[136]

VHA should ensure that all colonoscopy providers deliver quality care to patients regardless of their specialty or differences in training. Nationally, colonoscopies may be

[134] *Combined Assessment Program Review of the VA Roseburg Healthcare System, Roseburg, Oregon,* (Report No. 14-04222-141, March 4, 2015), http://www.va.gov/oig/pubs/VAOIG-14-04222-141.pdf Accessed November 2, 2016.
[135] *Combined Assessment Program Review of the VA Roseburg Healthcare System, Roseburg, Oregon,* (Report No. 11-03667-108, March 13, 2012), http://www.va.gov/oig/pubs/VAOIG-11-03667-108.pdf Accessed November 2, 2016.
[136] VHA Handbook 1100.19 Credentialing and Privileging October 15, 2012.

performed by surgeons, gastroenterologists, and family practitioners. Providers may graduate from training programs with anywhere between 50 (for surgeons and family practitioners) to 140 proctored colonoscopies (for gastroenterologists). These numbers may indicate minimal criteria for competence but do not ensure that providers are performing quality, safe colonoscopies. Some community hospitals require newly hired providers be proctored for a number of cases before allowing them to practice independently. VHA does not have this requirement but rather offers proctoring on an as needed basis.

VHA requires staff at facilities to "guarantee" the same credentialing criteria for granting privileges regardless of the provider's training or experience so that patients are provided "one standard of care."[137] In the 2015 OIG Healthcare Inspection report "*Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*,"[138] we found that Gastroenterology Program Office staff had not issued guidance or expectations for FPPE or OPPE and lacked tools to track the quality of colonoscopies. In September 2016, VHA had developed FPPE/OPPE criteria for gastroenterologists requiring monitoring of cecal intubation rates and documentation of bowel preparation (as required in the 2014 *Colorectal Cancer Screening* directive)[139] but did not specifically require photodocumentation of cecal intubation and cecal withdrawal time.

Conclusions

We did not substantiate the allegation that surgeries were performed inappropriately without ICU back-up. Surgical cases were continuously monitored to ensure the system was operating within their designated complexity level.

We did not substantiate the allegation that surgeons were unable to maintain surgical skills. Surgeons can be detailed to other facilities to perform procedures not normally done at the system.

We substantiated access delays in some surgery and GI service areas; however, system leadership and clinical program managers were aware of the delays and implemented action plans to reduce the wait times. In December 2014, the system had three surgery clinics (podiatry, orthopedics, and optometry) with patients on the EWL. Between October 2014 and December 2014, the system reduced the number of patients waiting over 30 days for GI Endoscopy to 370, and as of the end of September 2016, the system reported no patients waiting greater than 30 days. System and VISN leadership were aware of the delayed access, implemented action plans, and

[137] VHA Handbook 1100.19 Credentialing and Privileging October 15, 2012.
[138] VAOIG *Healthcare Inspection - Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities,* (Report No. 15-00911-362) , June 3, 2015. http://www.va.gov/oig/pubs/VAOIG-15-00911-362.pdf Accessed November 4, 2016. The two recommendations also applied to the pathology, nuclear medicine, and radiation oncology programs.
[139] VHA Directive *1015, Colorectal Cancer Screening,* December 30, 2014.

monitored implementation of the action plans to reduce the GI Endoscopy wait times prior to our December 2014 visit.

We did not substantiate that a surgeon, the COS, performed colonoscopies unsafely because he had no complications and four VHA physicians proctored him separately and determined that he met or exceeded expectations. We found that he practiced in an outdated manner. We had concerns related to his documentation practices, polypectomy techniques, and surveillance recommendations. However, he had stopped performing the procedure in August 2014.

The case summary patient received an institutional disclosure for delayed cancer diagnosis because he waited more than a year to receive a colonoscopy. Contributing factors included the extended delay for staff to review the consult and assign a priority, and poor GI colonoscopy access during this time frame. The COS also waited more than two weeks to inform the patient of his critical finding, which was an unnecessary delay. Since 2012, OIG Combined Assessment Program Review reports have made repeated recommendations that system managers ensure patients are notified of diagnostic test results within the required timeframe and that clinicians document the notification. The recommendation is still open.

We were concerned that the COS's colonoscopy documentation practices at the system may have implications for assessing the quality of the 2000 colonoscopies he performed at a prior VA facility. The patients who underwent those colonoscopies need to undergo a quality review to make sure they did not have undiagnosed colon cancer.

This inspection also raised larger questions regarding VHA's requirements for verifying the quality of colonoscopy care. The VHA *Colorectal Cancer Screening* directive[140] does not require documentation of many of the established quality indicators but suggested using adenoma detection rates and cecal intubation rates for monitoring of Ongoing Professional Practice Evaluation.[141] VHA should require more accurate and stringent data collection aligned with professional society guidelines and published studies to monitor the quality of providers' colonoscopies.

We also reviewed how VHA ensured that providers of different specialty training or experience performed quality colonoscopies. VHA requires facilities to guarantee "one standard of care" by using the same credentialing criteria for granting privileges regardless of the provider's medical specialty, training or experience.[142] One of our 2015 Healthcare Inspection reports found that the Gastroenterology Program Office staff had not issued guidance or expectations for credentialing and privileging, and lacked tools to track the quality of colonoscopies.[143] VHA concurred with our

[140] VHA Directive *1015, Colorectal Cancer Screening,* December 30, 2014.
[141] VHA Handbook 1100.19, *Credentialing and Privileging,* October 15, 2012.
[142] Ibid.
[143] VAOIG *Healthcare Inspection - Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities,* (Report No. 15-00911-362), June 3, 2015. http://www.va.gov/oig/pubs/VAOIG-15-00911-362.pdf Accessed November 4, 2016.

recommendations and submitted action plans. In September 2016, VHA had developed credentialing and privileging criteria for gastroenterologists requiring monitoring of cecal intubation rates and documentation of bowel preparation but did not specifically require photodocumentation of cecal intubation and cecal withdrawal time.

Recommendations

1. We recommended that the Acting Under Secretary for Health perform a quality review of the Chief of Surgery's colonoscopies performed in the prior Veterans Health Administration facility.

2. We recommended that the Acting Under Secretary for Health revise the Veterans Health Administration *Colorectal Cancer Screening* directive to include standardized documentation of quality indicators based on professional society guidelines and published literature (including but not limited to photodocumentation of anatomical landmarks establishing cecal intubation and documentation of cecal withdrawal times).

3. We recommended that the Acting Under Secretary for Health consider adding photodocumentation of cecal intubation and cecal withdrawal time to the standardized criteria for quality colonoscopy for Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation.

4. We recommended that the System Director ensure patient notification of diagnostic test results within the required timeframe, particularly for critical results, and that clinicians document notification.

Acting Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: May 04, 2017

From: Acting Under Secretary for Health (10N)

Subj: Healthcare Inspection— Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the draft report, Alleged Access Delays and Surgery Service Concerns VA Roseburg HCS Roseburg Oregon. The Veterans Health Administration (VHA) is strongly committed to developing long-term solutions that mitigate risks to the timeliness, cost-effectiveness, quality and safety of the Department of Veterans Affairs (VA) health care system. VHA is using the input from VA's Office of Inspector General, and other advisory groups to identify root causes and to develop critical actions. As VHA implements corrective measures, we will ensure our actions are meeting the intent of the recommendations. VHA is dedicated to sustained improvement in the high risk areas.
2. The recommendations in this report apply to GAO high risk areas 1 and 4. VHA's actions will serve to address ambiguous policies and inconsistent processes and inadequate training for VA staff.
3. I have reviewed the draft report, and provide the attached action plan to address the report's three USH recommendations.
4. If you have any questions, please email Karen M. Rasmussen, M.D., Director, Management Review Service at VHA10E1DMRSAction@va.gov.

Poonam Alaigh, M.D.

Comments to OIG's Report

The following comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Acting Under Secretary for Health perform a quality review of the Chief of Surgery's colonoscopies performed in the prior Veterans Health Administration facility.

Concur

Target date for completion: June 2017

Acting Under Secretary for Health Response:

The Office of the Assistant Deputy Under Secretary for Health for Clinical Operations, through the Clinical Executive Response Team (CERT), will conduct a meaningful review of the provider's colonoscopies that were performed at the Oscar G. Johnson VA Medical Center in Iron Mountain, Michigan (Iron Mountain VAMC). A random sample of colonoscopy studies across the provider's tenure at the Iron Mountain VAMC will be selected for review. This review will be designed, monitored, and reviewed by appropriate subject matter experts on the CERT. The CERT will receive monthly updates and the review will be completed within 30 days.

At completion of this action, the Office of the Assistant Deputy Under Secretary for Health for Clinical Operations will provide results of a comprehensive quality review of a random sample of patients that received a colonoscopy by the Chief of Surgery at the prior VHA facility (Iron Mountain VAMC).

Recommendation 2. We recommended that the Acting Under Secretary for Health revise the Veterans Health Administration Colorectal Cancer Screening directive to include standardized documentation of quality indicators based on professional society guidelines and published literature (including but not limited to photodocumentation of anatomical landmarks establishing cecal intubation and documentation of cecal withdrawal times).

Concur

Target date for completion: June 2017

Acting Under Secretary for Health Response:

The Office of Specialty Care agrees that documentation of colonoscopy quality indicators is a key element in the performance of colonoscopy. The National Gastroenterology Program has disseminated the professional society guidelines on colonoscopy quality to the field of colonoscopy providers and has provided a series of

webinars dedicated to improving colonoscopy quality. These webinars are hosted as enduring materials on the VA Talent Management System (TMS) website. Furthermore, the National Gastroenterology Program's SharePoint site includes links to key colonoscopy quality documents.

As part of the National Gastroenterology Program's efforts to assure high quality colonoscopy, the Colorectal Cancer Screening Directive, published in 2014, included a requirement that the chief of staff monitor the quality of colonoscopy at each facility. The National Gastroenterology Program and the Gastroenterology Field Advisory Committee will review this Directive in light of the colonoscopy quality guidelines published in 2015 by the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology and will make recommendations to VHA for how best to assure high quality colonoscopy and what quality indicators (as defined by ASGE) will be developed to ensure a consistent and standardized process is utilized nationally.

At completion of this action, the Office of Specialty Care will provide recommendations from the National Gastroenterology Program and the Gastroenterology Field Advisory Committee, that will include expectations for documentation and quality indicators based on professional society guidelines, as well as other published literature.

Recommendation 3. We recommended that the Acting Under Secretary for Health consider adding photodocumentation of cecal intubation and cecal withdrawal time to the standardized criteria for quality colonoscopy for Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation.

Concur

Target date for completion: September 2017

Acting Under Secretary for Health Response:

The Office of Specialty Care agrees that all providers who perform colonoscopy should be held to the same standard of care, irrespective of specialty. We will explore the possibility of standardizing the Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation criteria for all such providers and will consider including photo documentation of cecal intubation and cecal withdrawal time to these standardized criteria, as well as other quality indicators based upon the evaluation. Once the expected standards have been established, as noted in recommendation 2, the Office of the National Gastroenterology Program will work with the Office of Credentialing and Privileging, to ensure standardized criteria for quality colonoscopy for Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation is in place.

At completion of this action, the Office of Specialty Care will provide recommendations from the National Gastroenterology Program and the Gastroenterology Field Advisory Committee for the expected criteria that will be used and included in the Focused Professional Practice Evaluation/Ongoing Professional Practice Evaluation process.

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 27, 2017

From: Director, VA Northwest Health Network Director (10N20)

Subj: Healthcare Inspection— Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon

To: Director, Seattle Office of Healthcare Inspections (54SE)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review and comment on the draft report of Healthcare Inspection – Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon.

2. Attached please find the facility concurrence and response to the finding from the review.

3. If you have additional questions or need further information, please contact Terisa Sjue-Loring, Deputy Quality Management Officer, VISN 20 at (360) 619-5930.

(original signed by:)

Michael J. Murphy
VISN Director

System Director Comments

Department of Veterans Affairs

Memorandum

Date: Date: April 19, 2017

From: Director, VA Roseburg Healthcare System (653/00)

Subj: Healthcare Inspection— Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon

To: Director, VA Northwest Health Network Director (10N20)

1. On behalf of the VA Roseburg Healthcare System, Roseburg, Oregon, I would like to provide a status update of the finding from the Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System.

2. Attached is our response to the open OIG Recommendation 4.

3. Please feel free to contact Elizabeth Ruegg, Acting Quality Manager at (541) 440-1000, x40201 if you have any concerns or questions regarding the information included in our response.

(original signed by:)
Douglas V. Paxton, Sr., MSW, SES
Medical Center Director

Comments to OIG's Report

The following comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 4. We recommended that the System Director ensure patient notification of diagnostic test results within the required timeframe, particularly for critical results, and that clinicians document notification.

Concur

Target date for completion: June 15, 2017

Facility response:

Medical staff were notified by email from the Chief of Staff outlining the time requirements for pathology result notifications to patients and documentation of those notifications. Providers have seven days to notify the patient once the provider is notified of the results. Quality Management is auditing gastroenterological procedure charts to confirm seven day compliance and reporting their findings to the Chief Of Staff. The targeted resolution date is June 15, 2017 after verification of compliance is greater than 90 percent for three months.

For gastroenterology providers on leave, a surrogate will be assigned to receive and address all pathology results with patients in a timely manner.

Focused Professional Practice Evaluation for gastroenterology providers regarding notification and documentation of pathology results to the patients within seven days was implemented on April 3, 2017.

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Appendix E

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