



DEPARTMENT OF VETERANS AFFAIRS
OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Quality of Colonoscopies in
Multispecialty Community-
Based Outpatient Clinics



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Executive Summary

The VA Office of Inspector General (OIG) conducted a national review to evaluate colonoscopy care delivered in the Veterans Health Administration (VHA) multispecialty community-based outpatient clinic (CBOC) setting.¹ This review focused on the quality of care provided to CBOC colonoscopy patients as represented by selections of quality indicators for CBOC colonoscopy providers' practice evaluations, the extent to which quality assurance monitoring occurred in colonoscopy procedures, emergency care preparation, and monitoring quality assurance at facility and national levels.

Underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the “alt” and “left arrow” keys together.

[Colorectal cancer](#) (CRC) is the third leading cause of cancer-related deaths in men and in women in the United States.² CRC risk can be identified through various types of screening methods including a colonoscopy.³

Colonoscopies performed in multispecialty CBOCs have the potential for patient safety risks because these clinics operate without after-hours emergency medical support services and cannot provide on-site surgical interventions for serious complications. Colonoscopies are high-volume procedures with significant risk.⁴

Quality indicators represent the skill of the provider and lead to appropriate surveillance intervals (or time between colonoscopies) that result in reduced CRC risk to patients.⁵ In 2015, the joint American College of Gastroenterology and American Society for Gastrointestinal Endoscopy task force (task force) recommended monitoring several quality indicators including

¹ VHA Handbook 1006.02, *VHA Site Classifications and Definitions*, December 30, 2013. Multispecialty CBOCs deliver primary and mental health care as well as two or more specialty care services. Clinic providers may be credentialed and privileged to perform colonoscopies in multispecialty CBOCs that have the necessary infrastructure to support the level of care that involves minimal sedation of patients

² “Key Statistics for Colorectal Cancer,” American Cancer Society, <https://www.cancer.org/cancer/colon-rectal-cancer/about/key-statistics.html>. (The website was accessed on December 16, 2020.)

³ “Colonoscopy: Quality Indicators” *Clinical and Translational Gastroenterology*, February 26, 2015, Vol 6, Issue 2, page e77, <http://dx.doi.org/10.1038/ctg.2015.5> (The website was accessed on April 14, 2020.) VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014. This directive was rescinded and replaced by VHA Directive 1015, *Colorectal Cancer Screening*, April 3, 2020. The two policies contain the same or similar requirements related to colonoscopy screening.

⁴ Audrey H. Calderwood, MD and Brian C. Jacobson, MD, “Colonoscopy Quality: Metrics and Implementation,” *Gastroenterol Clin North Am*, 42, no 3: (September 2013): 599–618.

⁵ American Society for Gastrointestinal Endoscopy and American College of Gastroenterology, “Quality Indicators for Colonoscopy,” *Gastrointestinal Endoscopy* 81, no.1 (2015): 31-53. Nabil F. Fayad and Charles J. Kahi, “Quality Measures for Colonoscopy: A Critical Evaluation,” *Clinical Gastroenterology and Hepatology* no. 12, (2014):1973–1980.

documentation of bowel preparation quality, cecal intubation rate, [adenoma detection rate](#), documentation of withdrawal time, and surveillance interval recommendations.⁶

Two prior OIG healthcare inspections identified issues regarding VHA's ability to evaluate colonoscopy quality. These reports included recommendations for VHA to (1) define, apply, and monitor the use of specialty-specific criteria in professional practice evaluations consistently across VHA facilities; (2) revise the CRC screening directive to include standardized documentation of quality indicators; and (3) consider adding photodocumentation of cecal intubation and cecal withdrawal time to the standardized criteria for quality colonoscopy for professional practice evaluations.⁷

In response to the OIG recommendations, in 2016, VHA required the following quality indicators consistent with recommendations of the task force:

- Frequency with which visualization of the cecum by notation of landmarks and photodocumentation of landmark is documented in every colonoscopy
- Documentation of bowel preparation quality
- Frequency with which colonoscopies follow recommended post-polypectomy and post-cancer resection surveillance intervals

gastroenterology section chiefs at 6 of the 10 CBOCs that performed colonoscopies during the review period (October 1, 2019, through December 31, 2019) monitored the three required quality indicators outlined by VHA in 2016 (bowel preparation quality, visualization of the cecum, and surveillance intervals) in professional practice evaluations. However, the OIG determined that colonoscopy quality was not monitored in a standardized way, in accordance with VHA requirements, that would allow for verification of the quality of colonoscopies performed by providers in multispecialty CBOCs. Without consistent compliance with requirements, VHA leaders were hindered from monitoring the quality of colonoscopies performed by CBOC providers.

The OIG further determined that colonoscopy quality indicator data were not analyzed for multispecialty CBOC providers in a way that facilitated comprehensive quality assurance. CBOC, facility, and VHA leaders could not consistently identify gaps in colonoscopy quality at the CBOCs due to lack of standardized monitoring processes and may have missed opportunities to take actions for quality improvement. Through systematic monitoring of documented

⁶ *Quality Indicators for Colonoscopy*. Douglas Rex, MD, et.al., "Quality in the Technical Performance of Colonoscopy and the Continuous Quality Improvement Process for Colonoscopy: Recommendations of the U.S. Multi-Society Task Force on Colorectal Cancer," *The American Journal of Gastroenterology* 97, no. 6 (2002): 1296–1308.

⁷ VA OIG, *Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*, Report No. 15-00911-362, June 3, 2015. VA OIG, *Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*, Report No. 15-00506-535, July 11, 2017.

colonoscopy quality indicators, VHA can determine whether colonoscopy providers are providing quality care.

Staff at the CBOCs managed potential risks associated with colonoscopy procedures and complied with VHA requirements for monitoring patients during colonoscopies, having emergency medical equipment available, and developing CBOC-specific policies or procedures for managing after-hours medical emergencies.

VHA updated the CRC screening directive in April 2020. The OIG noted that the updated 2020 directive lacks requirements for monitoring compliance with VHA's colonoscopy quality indicators. The OIG identified the potential for recurring gaps in colonoscopy quality monitoring.

Finally, the OIG identified limitations in the VHA National Gastroenterology Program Office's ability to monitor colonoscopies for quality assurance because of variations in quality indicator data collection and a lack of consistency in implementation of endoscopy software as a data collection tool. In turn, the National Gastroenterology Program Office may miss opportunities to provide needed guidance across VHA.

The OIG made three recommendations to the Under Secretary for Health related to requirements for colonoscopy quality indicators used for professional practice evaluation, colonoscopy quality assurance monitoring, and evaluating and recommending endoscopy software for standardized implementation for quality assurance monitoring.⁸

Comments

The Acting Under Secretary for Health concurred with the recommendations and provided technical comments and an acceptable action plan (see appendix B). The OIG will follow up on the planned actions until they are completed.



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⁸ Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

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Abbreviations

CBOC	community-based outpatient clinic
EHR	electronic health record
GI	gastroenterology
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



Introduction

The VA Office of Inspector General (OIG) conducted a review to evaluate colonoscopy care delivered in the Veterans Health Administration (VHA) multispecialty community-based outpatient clinic (CBOC) setting. This review focused on quality of care provided to CBOC colonoscopy patients as represented by selections of quality indicators for CBOC colonoscopy providers' practice evaluations, the extent to which quality assurance monitoring occurred in colonoscopy procedures, emergency care preparation, and monitoring quality assurance at facility and national levels.

Underlined terms are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

Background

Colorectal cancer (CRC) is the third leading cause of cancer-related deaths in men and women in the United States, and the American Cancer Society estimates that there are 104,610 new cases of colon cancer and 43,340 new cases of colorectal cancer in the country for 2020. The majority of CRC starts as growths or polyps on the lining of the colon or rectum. Some polyps are caused by inherited genetic mutations, but most colon cancers are caused by acquired genetic mutations.¹

Colorectal Cancer Screening

CRC screening "is the process of looking for cancer in people who have no symptoms" and provides the opportunity to take early action.² CRC screening is a high priority in VHA because of the burden of disease, the cost of treatment, and the increasing demand for colonoscopy as the primary method for screening and prevention. VHA offers CRC screening to veterans who may benefit from it. Several screening tests are available, for example, fecal occult blood test, fecal immunochemical test, or sigmoidoscopy; however, any positive screening should be followed up with a colonoscopy.³

¹ American Cancer Society, "About Colorectal Cancer," <https://www.cancer.org/cancer/colon-rectal-cancer/causes-risks-prevention/what-causes.html>. (The website was accessed on December 16, 2020.)

² American Cancer Society, "Colorectal Cancer Screening Tests," <https://www.cancer.org/cancer/colon-rectal-cancer/detection-diagnosis-staging/screening-tests-used.html>. (The website was accessed on September 28, 2020.)

³ VHA Directive 1015, *Colorectal Cancer Screening*, December 30, 2014. This directive was rescinded and replaced by VHA Directive 1015, *Colorectal Cancer Screening*, April 3, 2020. The two policies contain the same or similar requirements related to colonoscopy screening.

VHA providers performed approximately 163,000 colonoscopies from October 1, 2019, through September 30, 2020.⁴

Gastrointestinal Colonoscopy Quality Indicators

A colonoscopy is a highly technical procedure requiring a skilled provider who can recognize what is normal and abnormal and expertly remove suspicious polyps during the procedure. Colonoscopies are also high-volume procedures with significant clinical risk and financial costs, and the quality of colonoscopies performed by providers may be variable.⁵ However, when “properly performed, colonoscopy is generally safe, accurate, and well-tolerated.”⁶

Healthcare quality “can be measured by comparing the performance of an individual with an ideal or benchmark. The particular parameter that is being used for comparison is termed a quality indicator.”⁷ Quality indicators are “reported as a ratio between the incidence of correct performance and the opportunity for correct performance or as the proportion of interventions that achieve a predefined goal” and thus represent the skill of the provider and the quality of a colonoscopy.⁸ There are several quality indicators relevant to detecting and removing precancerous polyps and decreasing the risk for CRC.⁹

Bowel Preparation

Optimization of bowel preparation (emptying the bowel of fecal debris) is important in providing good visualization of the colon during a colonoscopy. Inadequate bowel preparation is associated with risk of missed polyps, prolonged procedure times, and shorter intervals between colonoscopies. Additionally, inadequate bowel preparation can lead to cancellation of procedures, resulting in increased costs and poor resource utilization.¹⁰ Therefore, “the endoscopist should document the quality of the bowel preparation for each colonoscopy, reporting, at a minimum, whether or not the preparation was adequate for the detection of lesions larger than 5mm [millimeters].”¹¹

⁴ The OIG team pulled data covering all facility encounters for colonoscopies from the VHA Support Service Center.

⁵ Audrey H. Calderwood, MD and Brian C. Jacobson, MD, “Colonoscopy Quality: Metrics and Implementation,” *Gastroenterol Clin North Am*, 42, no 3: (September 2013): 599–618.

⁶ American Society for Gastrointestinal Endoscopy and American College of Gastroenterology, “*Quality Indicators for Colonoscopy*,” *Gastrointestinal Endoscopy* 81, no.1 (2015): 31–53.

⁷ Quality Indicators for Colonoscopy.

⁸ *Quality Indicators for Colonoscopy*. Nabil F. Fayad and Charles J. Kahi, “Quality Measures for Colonoscopy: A Critical Evaluation,” *Clinical Gastroenterology and Hepatology* no. 12, (2014):1973–1980.

⁹ Quality Measures for Colonoscopy: A Critical Evaluation.

¹⁰ Quality Indicators for Colonoscopy.

¹¹ VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contain the same or similar requirements related to bowel preparation.

Cecal Intubation

The colon, also called the large intestine, consists of the cecum, and ascending, transverse, and descending sections of the colon, ending with the sigmoid colon, which is connected to the rectum (see figure 1).¹² The cecum is the beginning point for the large intestine.¹³ [Cecal intubation](#) (reaching the [ileocecal valve](#)), marks the start of the examination of the colon as the colonoscope is withdrawn and is indicative of a “complete” colonoscopy. Providers document this by a description of anatomic landmarks or with photodocumentation in the patient’s electronic health record (EHR).¹⁴ The importance of cecal intubation is based on the persistent finding that a substantial fraction of colorectal cancers are located in the area of the colon that includes the cecum.¹⁵ CRC rates increase when the entire colon is not examined for polyps.¹⁶ The provider’s ability to visualize the walls and reach the end of the colon can be reduced by poor bowel preparation.¹⁷

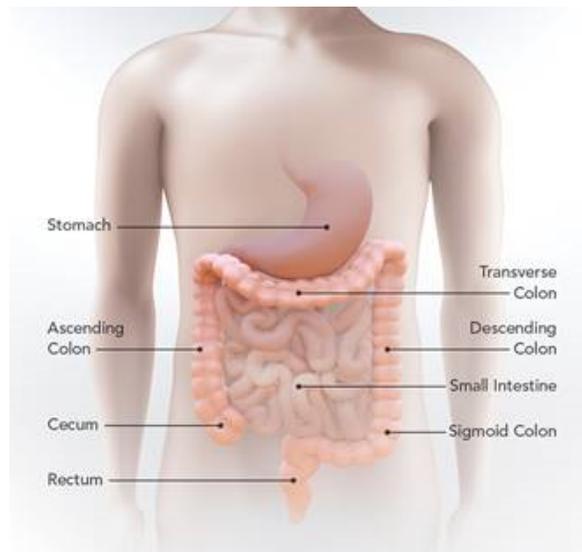


Figure 1: The anatomical structure of the large intestine
Source: Centers for Disease Control and Prevention

¹² Merck Manual, Consumer Version, “Large Intestine,” topic resource, October 2019. <https://www.merckmanuals.com/home/digestive-disorders/biology-of-the-digestive-system/large-intestine>. (The website was accessed on September 15, 2020.)

¹³ Merck Manual, Consumer Version, “Large Intestine,” topic resource, October 2019. <https://www.merckmanuals.com/home/digestive-disorders/biology-of-the-digestive-system/large-intestine>. (The website was accessed on September 15, 2020.)

¹⁴ Quality Indicators for Colonoscopy.

¹⁵ Quality Indicators for Colonoscopy.

¹⁶ Quality Indicators for Colonoscopy.

¹⁷ Quality Indicators for Colonoscopy.

Withdrawal Time

A brief colonoscope [withdrawal time](#) may indicate that the provider did not thoroughly examine the colon for polyps.¹⁸ Longer withdrawal times generally correlate with a more thorough exam. The value of measuring withdrawal times may increase when combined with other quality indicators, for example, when identifying sustained low [adenoma](#) detection rate levels accompanied by short withdrawal times in a provider's panel of patients who received colonoscopies.¹⁹ "Studies have demonstrated increased detection of significant neoplastic lesions in colonoscopic examinations in which the average withdrawal time is \geq [greater or equal to] 6 minutes."²⁰

Adenoma Detection Rate

The success of a colonoscopy procedure is dependent on provider visualization. The skill and experience of the provider to identify and remove difficult polyps and the care taken to look for polyps that are difficult to detect, translate to a higher rate of detecting and removing [adenomatous](#) polyps. The [adenoma detection rate](#) is calculated as the frequency with which adenomas are detected in screening colonoscopies (screening colonoscopies with adenomas identified divided by the total number of screening colonoscopies in a time period) for an individual provider.²¹

Careful visualization and longer withdrawal times are associated with higher adenoma detection rates. Higher adenoma detection rates are essential in the determination of recommended re-screening and surveillance time frames for patients.²²

Surveillance Interval

Most polyps are not cancerous, but over time, some polyps may develop into cancer if not removed by a provider during a screening colonoscopy.²³ When colonoscopy is used as a screening test, it both identifies the risk for CRC and provides prevention of future CRC when precancerous polyps are removed during the procedure.²⁴ Interval cancer is cancer diagnosed in the time period between colonoscopies, called the [surveillance interval](#).²⁵ Most interval CRC

¹⁸ Quality Measures for Colonoscopy: A Critical Evaluation.

¹⁹ Quality Measures for Colonoscopy: A Critical Evaluation.

²⁰ Quality Indicators for Colonoscopy.

²¹ Quality Indicators for Colonoscopy.

²² Quality Indicators for Colonoscopy.

²³ American Cancer Society, "If You Have Colon or Rectal Cancer," <https://www.cancer.org/cancer/colon-rectal-cancer/if-you-have-colon-rectal-cancer.html>. (The website was accessed on December 9, 2020.)

²⁴ Douglas Rex, MD, et.al., "Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer," *Gastrointestinal Endoscopy* 86, no. 1 (2017): 18-33.

²⁵ Quality Measures for Colonoscopy: A Critical Evaluation.

cases develop from polyps missed during a colonoscopy.²⁶ Surveillance intervals between colonoscopies can be safe and effective in preventing CRC only when the colon is cleared of polyps.²⁷

Optimal surveillance intervals result in CRC prevention, cost-effectiveness, and minimal risk to patients. Detailed and thorough examination of the colon is critical to the safety of surveillance intervals recommended between colonoscopies.²⁸ Safe and effective recommendations for surveillance intervals depend on the provider examining the entire colon, having clear visualization of the colon wall, and the provider's skill in detecting and removing adenomas. Therefore, cecal intubation followed by adequate withdrawal time, adequate bowel preparation, and the provider's adenoma detection rate together express the quality of the colonoscopy and lead to recommended optimal surveillance intervals.²⁹

American Society for Gastrointestinal Endoscopy Quality Indicators

The joint American College of Gastroenterology and American Society for Gastrointestinal Endoscopy task force (task force) on colonoscopy quality issued recommendations in 2015 and prioritized quality indicators that had broad clinical application and were associated with variations in provider practice and patient outcomes.³⁰ According to the task force, "A useful approach for an individual endoscopist is to first measure their performances with regard to these priority indicators."³¹ The task force recommended monitoring several quality indicators including

- Documentation of bowel preparation quality,
- Cecal intubation rate,
- Documentation of withdrawal time,
- Adenoma detection rate, and
- Surveillance interval recommendations.³²

²⁶ Quality Measures for Colonoscopy: A Critical Evaluation.

²⁷ Quality Indicators for Colonoscopy.

²⁸ Quality Indicators for Colonoscopy.

²⁹ Quality Indicators for Colonoscopy.

³⁰ Quality Indicators for Colonoscopy.

³¹ Quality Indicators for Colonoscopy.

³² Quality Indicators for Colonoscopy.

VHA National Gastroenterology Program Office

The National Gastroenterology (GI) Program Director is responsible for providing guidance and technical assistance to VHA medical facilities about CRC screening as well as monitoring guidelines in published literature and recommendations from national guideline groups such as the task force. The National Program Director collaborates with other VHA program offices and evaluates the need for new or revised policies, clinical tools, and processes that may be integrated into CRC screening across VHA.³³

VHA Quality Indicators

In 2014, VHA issued a directive requiring the quality of a provider's colonoscopies be monitored as part of an ongoing quality assurance program.³⁴ VHA service chiefs were responsible for monitoring the performance of providers under their clinical supervision by conducting professional practice evaluations.³⁵

VHA established quality indicators for colonoscopies that included

- Documentation of bowel preparation quality,
- Cecal intubation rate, and
- Adenoma detection rate.³⁶

VHA included adenoma detection rate in quality indicators with the understanding that calculation of the rate may not be possible for every provider, possibly due to a small number of eligible procedures or technical challenges in data collection.³⁷

The OIG report, *Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*, published in 2015, included a recommendation for VHA's GI program office to define, apply, and monitor the use of specialty-specific criteria in professional practice evaluations consistently across VHA facilities. The OIG also reported that VHA lacked good tools to track the quality of colonoscopy procedures.³⁸

³³ VHA Directive 1015, 2020.

³⁴ VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contain the same or similar requirements related to monitoring the quality of colonoscopy.

³⁵ VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012.

³⁶ VHA Directive 1015, 2014.

³⁷ VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contain the same or similar requirements related to monitoring the quality of colonoscopy. A colonoscopy is performed for varying indications such as cancer screening, diagnosis of symptoms, or follow-up after treatment. Adenoma detection rate is based on numbers of screening colonoscopies. Providers who perform few screening colonoscopies would not be able to calculate an adenoma detection rate.

³⁸ VA OIG, *Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*, Report No. 15-00911-362, June 3, 2015. As of March 27, 2017, the recommendation was closed.

In 2016, in response to the OIG recommendation, VHA updated the requirements and included the following quality indicators as criteria in professional practice evaluations for colonoscopy providers:

- Frequency with which visualization of the cecum by notation of landmarks and photodocumentation of landmarks is documented in every colonoscopy
- Documentation of bowel preparation quality
- Frequency with which colonoscopies follow recommended post-polypectomy and post-cancer resection surveillance intervals³⁹

VHA required facilities to report compliance with using the criteria listed above for two consecutive quarters to their respective Veterans Integrated Service Networks (VISN). The OIG closed the recommendation on March 27, 2017.⁴⁰

In 2017, the OIG published the report, *Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*.⁴¹ Two recommendations were made relevant to this review: (1) VHA revise the CRC 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), and (2) VHA consider adding photodocumentation of cecal intubation and cecal withdrawal time to the standardized criteria for quality colonoscopy for professional practice evaluations.

The Acting Under Secretary for Health concurred with the recommendations.⁴² In an internal memorandum from the National GI Program Director to the Chief Officer, Specialty Care Services, the National GI Program Director delineated documentation of required colonoscopy procedure elements in patients' EHRs and requirements for colonoscopy quality indicators for professional practice evaluations.⁴³

³⁹ VA Memorandum 2016-08-29, *Requirements for Peer Review of Solo Practitioners*, August 29, 2016.

⁴⁰ VA OIG, *Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*, Report No. 15-00911-362, June 3, 2015. The OIG recommended that GI, among other program offices, define specialty-specific criteria or monitors for use in focused and ongoing professional practice evaluations and require consistent application across VHA and that program offices monitor compliance.

⁴¹ VA OIG, *Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*, Report No. 15-00506-535, July 11, 2017. As of November 27, 2017, these recommendations were closed.

⁴² VA OIG, *Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*, Report No. 15-00506-535, July 11, 2017.

⁴³ VA Memorandum, *Ensuring High Quality Colonoscopy Procedures and Documentation*, October 24, 2017.

Community-Based Outpatient Clinics

A CBOC is an outpatient site of healthcare services located geographically apart from a VHA medical facility. CBOCs may be VA-owned or VA-leased. CBOCs provide healthcare services in primary care, specialty care, mental health care, or in any combination. Most CBOCs do not provide care 24 hours a day and may operate from one to seven days per week.⁴⁴

VHA classifies these remotely located clinics as primary care or multispecialty CBOCs or healthcare centers. The designations are based on the complexity and amount of services utilized. Primary care CBOCs offer both medical and mental health care. Multispecialty CBOCs deliver primary and mental health care as well as two or more specialty care services. Clinic providers may be credentialed and privileged to perform colonoscopies in multispecialty CBOCs that have the necessary infrastructure to support the level of care that involves minimal sedation of patients.⁴⁵

Indications for the OIG Review

Colonoscopies performed in multispecialty CBOCs have the potential for patient safety risks because these clinics cannot provide on-site surgical interventions for serious complications and operate without after-hours emergency medical support services for patients.⁴⁶ To assess the quality of screening colonoscopies in multispecialty CBOCs, the OIG reviewed

- Quality indicators selected for CBOC providers' professional practice evaluations,
- EHR documentation of quality indicators and quality assurance monitoring for CBOC screening colonoscopies,
- Emergency care preparations, and
- Monitoring quality assurance at facility and national levels.

⁴⁴ VHA Handbook 1006.02, *VHA Site Classifications and Definitions*, December 30, 2013. For the purposes of this report, none of the CBOCs in this review operated 24 hours a day.

⁴⁵ VHA Handbook 1006.02.

⁴⁶ VHA Directive 1220, *Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting*, May 13, 2019. Amended February 11, 2020.

Scope and Methodology

The OIG identified 10 multispecialty CBOCs that performed screening colonoscopies from October 1 through December 31, 2019, and on February 18, 2020, the OIG initiated a review of the quality of colonoscopies performed at these CBOCs. The OIG team completed six unannounced site visits on March 10 and March 12, 2020. Due to the ensuing COVID-19 pandemic, the OIG reviewed the remaining four sites virtually through document reviews and telephone interviews with selected leaders and staff at the respective CBOCs and their parent facilities.⁴⁷

The OIG team selected screening colonoscopy cases for review and defined the following inclusion criteria:

- A first colonoscopy performed for a patient at or around age 50
- A subsequent colonoscopy performed following one with no polyps removed
- A subsequent colonoscopy performed following one in which polyps were removed and diagnosed as noncancerous, or the results were unknown

The OIG reviewed EHR documentation to determine whether a patient case met the definition for screening colonoscopy. The OIG team excluded colonoscopies performed for reasons other than screening, for patients undergoing diagnostic colonoscopies, or if a previous colonoscopy revealed precancerous polyps.

The OIG team considered 1,781 colonoscopies performed in multispecialty CBOCs during the specified time frame. Of the 1,781 colonoscopies, the OIG determined that 718 met the definition for a screening colonoscopy. Eighteen of the 718 screening colonoscopies were discontinued before reaching the cecum and were excluded from analysis of the related quality indicators of withdrawal time and cecal intubation. The OIG included available documentation in the 18 colonoscopies in analysis of bowel preparation quality, cecal intubation rate, and surveillance intervals. The early discontinuation of the 18 colonoscopies did not affect analysis of adenoma detection rate.

The OIG team also reviewed 14 CBOC colonoscopy providers' professional practice evaluations conducted from October 2018 through December 2019 and assessed whether VHA leaders had a colonoscopy quality assurance process in place.

⁴⁷ COVID-19 is "an infectious disease caused by a newly discovered coronavirus." World Health Organization, Health Topics, Coronavirus. https://www.who.int/health-topics/coronavirus#tab=tab_1. (The website was accessed on November 5, 2020.) VHA Handbook 1006.02. Parent Station Name: also called Administrative Parent site is "defined as a collection of all the points of service that a leadership group [...] manages [...] All of the data that originate from these points of service roll up to a single station number representing the administrative parent for management and programmatic activities."

Colonoscopy procedure documentation in EHRs was reviewed by the OIG for evidence of quality indicators and use of endoscopy software.

The OIG team reviewed medical literature on the subject matter; professional practice guidelines from the task force; relevant VHA handbooks, directives, and operational memoranda; and facility and CBOC policies or procedures.

The OIG team interviewed the Director of VHA's National GI Program Office, GI section chiefs, and providers who performed colonoscopies at multispecialty CBOCs. Colonoscopy procedure rooms and adjacent areas were inspected during on-site visits.

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

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence within a specified scope and methodology and makes recommendations to VA leaders, if warranted. Findings and recommendations do not define a standard of care or establish legal liability.

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

Review Results

1. Quality Indicators for CBOC Colonoscopy Providers

The OIG found that GI section chiefs at 6 of the 10 CBOCs monitored the three required quality indicators outlined by VHA in 2016 (bowel preparation quality, visualization of the cecum, and surveillance intervals) in professional practice evaluations.

Of the remaining four CBOCs, two of the GI section chiefs omitted one or two of the VHA required quality indicators. Of these two CBOCs, one GI section chief did not monitor surveillance intervals and the other GI section chief did not monitor bowel preparation quality and surveillance intervals. The GI section chiefs from the remaining two CBOCs did not use any of VHA's required quality indicators. GI section chiefs in these two CBOCs evaluated alternate criteria for professional practice evaluations, including colonoscopy complication rates, follow-up on lab results, or information not specific to colonoscopy such as progress note documentation or clinic utilization.

In exploring the reasons for these variations, the OIG team interviewed nine GI section chiefs for the 10 CBOCs (one chief had responsibility for two sites). Of the nine section chiefs

- Four attributed their quality indicators as VHA requirements,
- Three indicated the quality indicators were GI professional standards,
- One described the quality indicator selection as a local (facility-made) GI service decision,
- One expressed interest in using other criteria but stated that the lack of electronic tracking and trending systems for quality data collection was an obstacle to reviewing additional quality indicators, and
- One allowed the provider to select the metric for the professional practice evaluation and the provider chose cecal intubation rate.

The OIG determined that colonoscopy quality was not monitored in a standardized way in accordance with VHA requirements that would allow verification of quality of colonoscopies performed by providers in multispecialty CBOCs. Without consistent compliance to requirements, VHA leaders were hindered from monitoring the quality of colonoscopies performed by CBOC providers.

2. CBOC Provider Professional Practice Evaluations and Quality Assurance Monitoring

The OIG determined that colonoscopy quality indicator data were not analyzed for multispecialty CBOC providers in a way that facilitated comprehensive quality assurance.

VHA requires that the “[q]uality of colonoscopy is monitored as part of an ongoing quality assurance program.”⁴⁸ VHA also maintains that “accurate and complete documentation of colonoscopy procedural details and quality indicators are key to ensuring high-quality colonoscopy in the VHA.”⁴⁹ Additionally, according to The Joint Commission, “successful organizations measure and analyze their performance. When data are analyzed and turned into information, this process helps organizations see patterns and trends and understand the reasons for their performance.”⁵⁰

The task force described the quality of the colonoscopy as a combination of the review of the quality indicators.⁵¹

Optimal effectiveness of colonoscopy depends on patient acceptance of the procedure, which depends mostly on acceptance of the bowel preparation.

⁴⁸ VHA Directive 1015, 2014.

⁴⁹ VA Memorandum, Ensuring High Quality Colonoscopy Procedures and Documentation, 2017-10-24; VHA Directive 1015, 2020.

⁵⁰ The Joint Commission, *Meet the Standards Interpretation Group*. February 19, 2020. <https://www.jointcommission.org/resources/news-and-multimedia/blogs/ambulatory-buzz/2020/02/19/meet-the-standards-interpretation-group/> (The website was accessed on December 3, 2020.)

⁵¹ Quality Indicators for Colonoscopy.

Preparation quality affects the completeness of examination, procedure duration, and the need to cancel or repeat procedures at earlier dates than would otherwise be needed. Ineffective preparation is a major contributor to costs. Meticulous inspection and longer withdrawal times are associated with higher adenoma detection rates (ADR). A high ADR is essential to rendering recommended intervals between screening and surveillance examinations safe.

The OIG found that for the procedures reviewed, provider EHR documentation was generally complete and contained details needed to assess quality indicators. However, the OIG determined that GI section chiefs did not critically analyze the data collected for professional practice evaluations to evaluate the quality of providers' colonoscopies and confirm that the resulting surveillance interval was appropriate for the patient.

To evaluate the CBOCs' quality assurance programs, the OIG assessed provider EHR documentation and professional practice evaluations in relation to each quality indicator required by VHA in 2016 (bowel preparation quality, visualization of the cecum, and surveillance intervals) as well as two quality indicators recommended by the task force (documentation of withdrawal time and adenoma detection rate) but not required by VHA in 2016.

VHA Required: Bowel Preparation Quality

The OIG determined that GI section chiefs need to monitor bowel preparation in their quality assurance efforts to determine when improvement is indicated.

In 2014, VHA required facilities to monitor bowel preparation quality and made recommendations for improving inadequate bowel preparation, including changes in the bowel cleansing regimen and pre-procedure education classes for patients.⁵² According to VHA, bowel preparation quality is dependent on a number of patient-level factors. Although it is not possible to define generalized minimum thresholds for acceptable bowel preparation, the quality should be monitored at the facility level.⁵³

In review of documentation of bowel preparation quality in patients' EHRs, the OIG identified that only 1 of 718 screening colonoscopies reviewed did not include documentation of bowel preparation quality.

Six of the 10 CBOCs used bowel preparation quality in colonoscopy providers' professional practice evaluations. However, the OIG found that GI section chiefs used only checkmarks to record documentation of bowel preparation quality as done or not done. By not analyzing the adequacy of bowel preparation, VHA leaders could not identify gaps in colonoscopy quality

⁵² VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contained the same or similar requirements related to documentation of bowel preparation quality.

⁵³ VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contain the same or similar requirements related to monitoring bowel preparation quality.

related to inadequate bowel preparation and may have missed opportunities to take actions for improvement.

VHA Required: Visualization of the Cecum

The OIG found providers generally documented visualization of the cecum and included photodocumentation in the EHR. During the review, the OIG identified that CBOCs used a variety of endoscopy software with varying capabilities, leading to inconsistent EHR documentation.

VHA's 2016 quality indicator requirements included documenting visualization of the cecum by notation (in writing) and photodocumentation of landmarks in every colonoscopy.⁵⁴ GI providers during interviews described a process where photographs are taken with the colonoscope and when endoscopy software is interfaced with the EHR system, they become a part of the EHR and allow for post-procedural evaluation of colonoscopy quality. In addition, VHA asserts that "Endoscopic report-generating software generally facilitates the tracking of quality across all colonoscopy procedures."⁵⁵

The OIG found in EHR reviews that 700 of 718 (97 percent) colonoscopies started at the cecum. The OIG found photodocumentation in 597 of 700 (85 percent) procedures; however, in 165 of 597 (28 percent) colonoscopies, photographs did not have identifiers establishing location within the colon. Of the remaining 432 procedures with identified photodocumentation, 370 (86 percent) established visual confirmation that the provider started the procedure at the cecum.

The OIG found that GI section chiefs should review completeness of cecal intubation photodocumentation as part of a comprehensive quality assurance program.

Related Finding

The OIG found that at 8 of 10 CBOCs, providers used endoscopy software that facilitated their procedure documentation, including notation of recommended quality indicators. GI providers stated during interviews that the software recorded the providers' details about the procedure, including photographs of cecal intubation and other clinical observations, and electronically uploaded the information into documentation in patients' EHRs.

Two of the CBOCs did not have endoscopy software that integrated documentation into the patients' EHRs. During interviews, the GI providers at these two CBOCs stated that they wrote their procedure notes in the EHR and printed the photographs for patients to keep. Staff at one of these CBOCs used image scanning software that uploaded photodocumentation into the patients'

⁵⁴ VA Memorandum 2016-08-29.

⁵⁵ VHA Directive 1015, 2014; VHA Directive 1015, 2020. The two directives contain the same or similar requirements related to endoscopic report-generating software.

EHRs. Staff at the remaining CBOC did not have available software to transfer photodocumentation in the EHR.

Of the eight CBOCs with endoscopy software, the OIG found five different systems in use with varying capabilities.

Because VHA identified endoscopy software as a valuable tool for tracking quality across colonoscopy procedures, the OIG determined VHA leaders have an opportunity to improve quality assurance by implementing standardized endoscopy software capability across VHA.

VHA Required: Surveillance Intervals

The OIG found that more than 90 percent of procedure documentation included surveillance interval recommendations. However, GI section chiefs reviewed surveillance intervals in professional practice evaluation at only 4 of 10 (40 percent) CBOCs.

VHA required that professional practice evaluations include the “Frequency with which colonoscopies follow recommended post-polypectomy intervals and 10-year intervals between screening colonoscopies in average-risk patients who have negative examination results and adequate bowel cleansing.”⁵⁶

In EHR reviews, the OIG team found surveillance interval recommendations were documented in 653 of 718 (91 percent) screening colonoscopies and determined that in most EHRs reviewed, surveillance interval recommendations were readily available to GI section chiefs to use in quality assurance processes.

As noted above, the OIG found surveillance interval documentation was recorded as a quality indicator for providers at 4 of 10 (40 percent) CBOCs.

Colonoscopies have intervals that can span a decade, and ensuring that providers complete a quality procedure provides patients with assurance that a 10-year interval is a safe time to wait before the next colonoscopy. Conversely, if a poor-quality colonoscopy is performed, the provider can recommend a follow-up colonoscopy for the patient sooner. If poor quality is not recognized, a longer surveillance interval increases the risk of CRC for the patient.

Appropriate surveillance intervals result in reduced CRC risk to patients.⁵⁷

The OIG found that GI section chiefs should review surveillance intervals for appropriateness to minimize CRC risk for patients as part of a comprehensive quality assurance program.

⁵⁶ VA Memorandum 2016-08-29.

⁵⁷ Quality Indicators for Colonoscopy.

Task Force Recommended: Withdrawal Time

The OIG determined that in most of the patient EHRs reviewed, withdrawal time met or exceeded the task force recommendations and was readily available in the provider's documentation.

The task force recommends a minimum of six minutes for withdrawal time in screening colonoscopies if polyps are not identified during the procedure.⁵⁸ In addition, the task force identified studies that demonstrated an association between longer withdrawal time and higher polyp detection rates.⁵⁹

Through EHR reviews, the OIG found documentation of withdrawal time in 586 of 700 (84 percent) screening colonoscopies. In addition, of the 238 screening colonoscopies where polyps were not identified, the OIG found that two (less than one percent) had withdrawal times of less than six minutes.

Although withdrawal time is an important quality indicator according to the task force, VHA did not include withdrawal time as a required element for colonoscopy quality monitoring. The OIG found that none of the reviewed CBOCs used withdrawal time as a quality indicator on professional practice evaluations.

The OIG concluded that VHA GI section chiefs have an opportunity to include withdrawal time in criteria for professional practice evaluations for more comprehensive quality assurance monitoring.

Task Force Recommended: Adenoma Detection Rate

While not required by VHA, the OIG found that some providers calculated their adenoma detection rates but the information was not easily obtained and not monitored as part of a quality assurance program.

According to the task force, the most important quality indicator is the endoscopist's adenoma detection rate.⁶⁰ A high adenoma detection rate is essential to rendering recommended safe intervals between screening and surveillance examinations, and directly correlates with a decrease in CRC risk. The adenoma detection rate depends on multiple factors including adequate bowel preparation, cecal intubation, and appropriate colonoscope withdrawal times.⁶¹

The OIG found that when asked, 6 of 13 CBOC colonoscopy providers stated their adenoma detection rates; however, providers described an indirect, multistep method for determining the

⁵⁸ Quality Indicators for Colonoscopy.

⁵⁹ Quality Indicators for Colonoscopy.

⁶⁰ Quality Indicators for Colonoscopy.

⁶¹ Quality Indicators for Colonoscopy.

rates.⁶² The process started with the provider using endoscopy software or CBOC procedure records to identify patients screened for CRC by colonoscopy during a period of time, totaling the number of screenings, accessing individual patients' EHRs to review laboratory results for [adenomas](#), and ended with the provider calculating the adenoma detection rate.

The OIG found GI section chiefs at 9 of 10 CBOCs did not collect adenoma detection rate data for professional practice evaluations even when the provider's rate was available. The OIG determined that by not including available adenoma detection rates, VHA leaders had an incomplete assessment of the quality of colonoscopies.⁶³ The OIG concluded that VHA needs to establish a process that would readily incorporate the calculation and monitoring of adenoma detection rates into a comprehensive quality assurance program.

The OIG determined that CBOC, facility, and VHA leaders could not consistently identify gaps in colonoscopy quality at the CBOCs and may have missed opportunities to take actions for quality improvement.⁶⁴ Through systematic monitoring of documented colonoscopy quality indicators, VHA can determine whether colonoscopy providers are providing quality care.

3. Emergency Care Preparations

The OIG determined that staff at the CBOCs managed potential risks associated with colonoscopy procedures and complied with VHA requirements.

VHA requires equipment be available including continuous cardiac monitoring, pulse oximetry, suction, and a nearby code cart with a defibrillator when patients undergo colonoscopies.⁶⁵ In addition, VHA requires facilities performing colonoscopies to be able to obtain an [electrocardiogram \(EKG\)](#) "within 60 minutes during the hours of operation."⁶⁶

Each CBOC colonoscopy area had monitoring and emergency medical equipment available and staff had CBOC-specific policies or procedures in place to manage medical emergencies.⁶⁷

The OIG found during interviews that 8 of 10 CBOCs were staffed with one colonoscopy provider. The providers described methods for discussing cases with colleagues, such as electronic consult or telephone, if questions arose regarding a procedure. Two CBOCs were staffed with multiple providers who described conferring with each other as needed. No

⁶² The OIG excluded one of the original 14 providers because the provider did not perform colonoscopies during the study period.

⁶³ Quality Indicators for Colonoscopy.

⁶⁴ VA Memorandum 2016-08-29.

⁶⁵ VHA Directive 1220, Facility Procedure Complexity Designation Requirements to Perform Invasive Procedures in Any Clinical Setting, May 13, 2019. Amended February 11, 2020.

⁶⁶ VHA Directive 1220, amended February 11, 2020.

⁶⁷ The OIG determined this through observations and interviews.

providers described experiences of needing to confer with another colonoscopy provider as a result of an emergency or unexpected event.

Since most CBOCs do not operate 24 hours a day, it is important to ensure patient safety after clinic hours by providing guidance about resources for questions or concerns that may arise post-procedure.⁶⁸ Each CBOC in the review provided discharge instructions with after-hours telephone numbers and steps to take in the event of an emergency.

4. Monitoring Quality Assurance at Facility and National Levels

The OIG identified two processes that could improve VHA's ability to evaluate colonoscopy care at both the facility and national level: standardization of collection and monitoring of quality indicator data.

Standardized Quality Indicators

The OIG determined that requiring an expanded set of quality indicators consistent with the task force's recommendations could improve VHA's ability to evaluate colonoscopy quality.

As noted previously, two prior OIG inspections addressed VHA's ability to evaluate the quality of colonoscopy care. One inspection noted that VHA lacked good tools to track colonoscopy quality and recommended that the National GI Program Office monitor compliance with using defined colonoscopy quality criteria.⁶⁹ The second inspection noted that VHA should require more accurate and stringent data collection to monitor the quality of providers' colonoscopies and recommended that VHA revise its CRC directive to include standardized documentation of quality indicators based on professional society guidelines and published literature.⁷⁰

In April 2020, VHA rescinded and replaced the 2014 directive and updated requirements that include "accurate and complete documentation of colonoscopy procedural details," such as the "adequacy of bowel preparation quality," "extent of examination (depth of insertion) with photodocumentation of cecal landmarks," and "duration of the examination, including the withdrawal time."⁷¹ The 2020 directive indicates that quality indicators for colonoscopies performed by VA providers should include

- Adenoma detection rate,
- Cecal intubation rate,

⁶⁸ VHA Handbook 1006.02.

⁶⁹ VA OIG, *Review of Solo Physicians' Professional Practice Evaluations in Veterans Health Administration Facilities*, Report No. 15-00911-362, June 3, 2015.

⁷⁰ VA OIG, *Alleged Access Delays and Surgery Service Concerns, VA Roseburg Healthcare System, Roseburg, Oregon*, Report No. 15-00506-535, July 11, 2017.

⁷¹ VHA Directive 1015, 2020.

- Documentation of bowel preparation quality during colonoscopy, and
- Appropriate surveillance interval recommendations.

The OIG noted that the updated 2020 directive lacks requirements for monitoring compliance with using VHA’s colonoscopy quality indicators. The OIG identified the potential for recurring gaps in colonoscopy quality monitoring. The National GI Program Director clarified expectations for evaluating the quality of VHA’s colonoscopy care. The Program Director told the OIG team that the quality of colonoscopies could be evaluated by reviewing the combined documentation of bowel preparation quality, cecal intubation, polyp removal, and the provider’s adenoma detection rate. The Program Director stated that if the quality indicators were not reviewed together, it would be difficult to evaluate the quality of a procedure.

When asked about the 2020 directive, the Program Director stated that additional indicators would be acceptable to expand quality assurance; however, professional practice evaluations should include the four quality indicators listed above. Adenoma detection rate remains recommended as a quality indicator to acknowledge that colonoscopy providers who complete a low number of screening procedures would not be able to calculate a reliable rate.⁷²

Standardized Endoscopy Software

The OIG determined that implementing nationally standardized endoscopy software could improve the National GI Program Office’s ability to monitor colonoscopy quality and compliance with required quality indicators across VHA.

According to the 2014 directive, “Endoscopic report-generating software generally facilitates the tracking of quality across all colonoscopy procedures performed at a VA medical facility.”⁷³ The 2020 directive states, “Accurate and complete documentation of colonoscopy procedural details facilitates both clear communication among providers and quality assurance programs. Efficient documentation of the recommended data elements may best be achieved through implementation of endoscopic report-generating software with required fields for key subject areas.”⁷⁴

The National GI Program Director described endoscopy software as a tool available in VHA for monitoring quality. The program office’s goal of tracking colonoscopy quality across VHA was only partially met because of variations in types of endoscopy software in use across VHA, and some sites did not have endoscopy software available. A vendor’s discontinuation of commonly used software, contract issues with vendors, and decreased performance of colonoscopies by university affiliates because of a lack of proficiency in using VA’s endoscopy software were

⁷² VHA Directive 1015, 2020.

⁷³ VHA Directive 1015, 2014.

⁷⁴ VHA Directive 1015, 2020.

factors adversely affecting the use of endoscopy software as a tracking tool at some VHA facilities.

Conclusion

Intervals between a patient's colonoscopy can span a decade, and a high-quality procedure reduces the risk of a patient developing cancer between colonoscopies. Multiple elements of the colonoscopy influence the appropriate surveillance interval, including bowel preparation quality adequate for good visualization of the colon, exploration of the entire bowel starting with cecal intubation, and sufficient withdrawal time for a thorough examination for the presence of polyps. For a colonoscopy to be of high quality overall, each element must be performed well.⁷⁵ Conversely, if a poor-quality colonoscopy is performed, the provider can recommend a shorter surveillance interval for the follow-up colonoscopy. If poor quality is not recognized, a longer surveillance interval increases the risk of CRC for the patient.

To determine the quality of colonoscopies, VHA leaders must collect, measure, and track data. Further, VHA requires a plan for improvement when leaders identify deficiencies.⁷⁶ VHA provided three quality indicators to be measured that were in effect at the time of this review. The OIG found some CBOC leaders did not measure or track colonoscopy quality data in accordance with VHA requirements. The OIG also found CBOC leaders confirmed through professional practice evaluations that colonoscopy providers documented various quality data. However, an evaluation acknowledging only that documentation was done does little to express quality without further analysis that could identify the need for action plans to enhance care.

The OIG determined that colonoscopy procedure documentation included VHA's specified criteria as well as quality indicators recommended by the task force. Colonoscopy quality data were readily available for facility leaders to use in quality assurance monitoring although data were not analyzed to identify patterns and trends. Professional practice evaluations included only certain quality data for evaluating colonoscopy care, some of which were not as VHA required.

VHA updated the CRC screening directive in April 2020. The OIG noted that the updated directive lacks requirements for monitoring compliance with using VHA's colonoscopy quality indicators and that the responsibilities for quality assurance processes remain unchanged from the previous 2014 directive.

Further, the OIG identified limitations in the VHA National GI Program Office's ability to monitor colonoscopies for quality assurance because VHA lacked consistency in implementation of endoscopy software as a data collection tool and because of variations among the quality

⁷⁵ Quality Indicators for Colonoscopy.

⁷⁶ VHA Handbook 1100.19

indicator data collected at sites. In turn, the National GI Program Office may miss opportunities to provide needed guidance across VHA.

The OIG identified the potential for recurring gaps in colonoscopy quality monitoring and made three recommendations.

Recommendations 1–3

1. The Under Secretary for Health clarifies requirements for colonoscopy quality indicators for professional practice evaluation and ensures a process is in place to monitor compliance.⁷⁷
2. The Under Secretary for Health strengthens requirements for colonoscopy quality assurance monitoring that includes analysis of quality indicators to identify trends and monitors for compliance.
3. The Under Secretary for Health, in conjunction with the National Gastroenterology Program Director, evaluates implementation of standardized endoscopy software across Veterans Health Administration facilities where colonoscopies are performed and takes action as indicated.

⁷⁷ Recommendations directed to the Under Secretary for Health were submitted to the Executive in Charge, who had the authority to perform the Under Secretary's functions and duties. Effective January 20, 2021, he was appointed to Acting Under Secretary for Health with the continued authority to perform the functions and duties of the Under Secretary.

Appendix A: Multispecialty CBOCs with Colonoscopy Services, October 1–December 31, 2019

	Clinic Name	VISN	Location	Parent Facility Name
CBOC 1	Greenville VA Clinic	6	Greenville, NC	Durham VA Medical Center
CBOC 2	Wilmington VA Clinic	6	Wilmington, NC	Fayetteville VA Medical Center
CBOC 3	William "Bill" Kling VA Outpatient Clinic	8	Sunrise, FL	Bruce W. Carter VA Medical Center
CBOC 4	Sergeant Ernest I. "Boots" Thomas VA Clinic	8	Tallahassee, FL	Malcom Randall VA Medical Center
CBOC 5	The Villages VA Clinic	8	The Villages, FL	Malcom Randall VA Medical Center
CBOC 6	Wyoming VA Clinic	10	Wyoming, MI	Battle Creek VA Medical Center
CBOC 7	Pensacola VA Clinic	16	Pensacola, FL	Biloxi VA Medical Center
CBOC 8	Austin VA Clinic	17	Austin, TX	Olin E. Teague Veterans' Center
CBOC 9	Fort Worth VA Clinic	17	Fort Worth, TX	Dallas VA Medical Center
CBOC 10	Redding VA Clinic	21	Redding, CA	Sacramento VA Medical Center

Source: OIG analysis of VHA Support Service Center (VSSC) data accessed on January 24, 2020

Appendix B: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: January 25, 2021

From: Acting Under Secretary for Health (10)

Subj: OIG Draft Report, Veterans Health Administration: Quality of Colonoscopies in Multi-Specialty Community-Based Outpatient Clinics (OIG 2020-01386-HI-1020) (VIEWS # 4189497)

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General draft report titled Veterans Health Administration: Quality of Colonoscopies in Multi-Specialty Community-Based Outpatient Clinics. The Veterans Health Administration (VHA) concurs with the three recommendations and provides an action plan in the attachment. VHA also provides some technical comments to improve accuracy of the draft report.
2. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at [REDACTED]

(Original signed by:)

Richard A. Stone, M.D.

Attachments

VHA Technical Comments

VHA Comment 1

Draft location: Page 1 and page 6, second paragraph:

Current language: Colorectal cancer (CRC) is the third leading cause of cancer-related deaths in the United States.

Comment and justification: As referenced in the source listed as footnote 1, CRC is the third leading cause of cancer death in men and the third leading cause of cancer death in women, but the second leading cause of cancer death in men and women combined because women do not get prostate cancer and men rarely get breast cancer. For purposes of accuracy, VHA asks OIG to consider changing this sentence to, “Colorectal cancer is the second leading cause of cancer-related deaths in the United States.”

OIG Comment

The OIG used American Cancer Society as the source for the information presented in this report.

VHA Comment 2

Draft location: Page 14, second paragraph

Current language: The OIG team selected screening colonoscopy cases for review and defined the following inclusion criteria:

- The first colonoscopy performed for a patient at or around age 50
- A subsequent colonoscopy performed following one with no polyps removed
- A subsequent colonoscopy performed following one in which polyps were removed and diagnosed as non-cancerous, or the results were unknown

Comment and justification: VHA asks OIG to consider removing the word “screening” from the first line for purposes of clarity. The third bullet identifies colonoscopies that may be classified as “surveillance colonoscopy,” not “screening colonoscopy,” and the concern is that this may confuse some readers. The next paragraph notes cases where “a previous colonoscopy revealed pre-cancerous polyps” were excluded, thus it seems screening colonoscopies were ultimately excluded.

OIG Comment

The criteria are OIG identified. The paragraph that follows the bulleted list clearly distinguishes scopes that were included in the review did not include ones with previous precancerous polyps. The OIG does not believe the reader will be confused.

VHA Comment 3

Draft location: Page 14, fourth paragraph and page 21, second paragraph

Current language: Eighteen of the 718 screening colonoscopies were discontinued before reaching the cecum and were excluded from analysis of the related quality indicators withdrawal time and cecal intubation. The OIG included available documentation in the 18 colonoscopies in analysis of bowel preparation quality, and surveillance intervals.

Comment and justification: It is appropriate to exclude these cases from withdrawal time calculation; however, it is not clear why these 18 cases were excluded from the analysis of cecal intubation. The intent of the cecal intubation quality metric is to determine how often the cecum is not reached. Thus, 700/718 yields a cecal intubation rate of 97.5%. In the second paragraph of page 21, it is stated that “698 of 718 (97 percent) colonoscopies started at the cecum.” Thus, it seems that these cases were not excluded.

For purposes of clarity, VHA asks OIG to consider revising the statement to, “Eighteen of the 718 screening colonoscopies were discontinued before reaching the cecum and were excluded from analysis of withdrawal time. The OIG included available documentation in the 18 colonoscopies in analysis of bowel preparation quality, cecal intubation rate, and surveillance intervals.”

OIG Comment

The OIG used 700/718 for analysis of cecal intubation; therefore, 18 were included in that cecal intubation rate analysis.

VHA Comment 4

Draft location: Page 24, third paragraph

Current language: A vendor’s discontinuation of commonly used software, contract issues with vendors, and decreased performance of colonoscopies by non-VA community providers because of a lack of proficiency in using VA’s endoscopy software were factors adversely affecting the use of endoscopy software as a tracking tool at some VHA facilities.

Comment and justification:

For purposes of accuracy, VHA asks OIG to consider revising the latter half of the sentence, that references decreased performance of colonoscopies. VHA has no data on colonoscopy quality from non-VA community providers because non-VA community providers do not submit any quality data to VHA. Furthermore, non-VA community providers would not have access to VA endoscopy software at their non-VA endoscopy facility. The National Gastroenterology Program Director recalls discussing an example situation with OIG regarding how the purchase of an

endoscopy software program that was different from the university affiliate, contributed to the end of a call-sharing agreement between one VA facility and their affiliate.

VHA suggests OIG to consider revising the sentence to read, “Factors adversely affecting the use of endoscopy software as a tracking tool at some VHA facilities included a vendor’s discontinuation of commonly used software, contract issues with vendors, and funding.”

OIG Comment

Consistent with the GI Program Director’s interview with the OIG “non-VA community providers” was changed to “university affiliates.”

VHA Comment 5

Draft location: Page 23, last paragraph

Current language: Adenoma detection rate remains suggested as a quality indicator to acknowledge that colonoscopy providers who complete a low number of screening procedures would not be able to calculate a reliable rate.

Comment and justification: For purposes of clarity, VHA asks OIG to consider revising the statement to, “Adenoma detection rate is now recommended as a quality indicator by both the VHA Directive 1014, Colorectal Cancer Screening, and the memo, Implementation of Enterprise-wide Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) Specialty-specific Clinical Indicators, dated December 18, 2020. These documents acknowledge that quality indicators are more reliable with larger sample sizes, as such, colonoscopy providers who complete a low number of screening procedures would not be able to calculate a reliable rate.”

OIG Comment

The OIG changed “suggested” to “recommended” as stated on VHA’s Colorectal Cancer Screening Directive 1015 Updates web page ([Colorectal Cancer Screening Directive 1015 Updates](#)).

Acting Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health clarifies requirements for colonoscopy quality indicators for professional practice evaluation and ensures a process is in place to monitor compliance.

Concur.

Target date for completion: October 2021

Acting Under Secretary for Health Comments

VHA will improve and clarify current colonoscopy quality indicators for professional practice evaluation. The National Gastroenterology and Hepatology Program Office will establish a workgroup to get recommendations for finalization of these indicators and a standardized process to monitor compliance with these quality indicators. These recommendations will be then implemented by revision of the quality metrics specified in VHA policy (VHA Directive 1014: Colorectal Cancer Screening).

Recommendation 2

The Under Secretary for Health strengthens requirements for colonoscopy quality assurance monitoring that includes analysis of quality indicators to identify trends and monitors for compliance.

Concur.

Target date for completion: January 2022

Acting Under Secretary for Health Comments

VHA will strengthen the process for quality assurance monitoring that will include an analysis of trends in quality indicators and monitoring for compliance. The National Gastroenterology and Hepatology Program will develop a new colonoscopy quality assurance plan that will be communicated to VA medical facilities.

Recommendation 3

The Under Secretary for Health, in conjunction with the National Gastroenterology Program Director, evaluates implementation of standardized endoscopy software across Veterans Health Administration facilities where colonoscopies are performed and takes action as indicated.

Concur.

Target date for completion: January 2022

Acting Under Secretary for Health Comments

VHA has established an integrated procurement team (IPT) to evaluate commercially available endoscopy software. The National Gastroenterology and Hepatology Program Director chairs the IPT. The IPT will identify a preferred product for acquisition by VHA facilities performing colonoscopy. Once a product is identified, VA medical centers will be encouraged to move to this product or otherwise provide a timeline for such transition that meets enterprise needs with regard to electronic health record modernization.

Glossary

To go back, press “alt” and “left arrow” keys.

adenoma. A benign tumor of a glandular structure or of glandular origin.⁷⁸

adenoma detection rate. “The proportion of screening colonoscopies that detect at least one adenoma.”⁷⁹

cecal intubation. “Cecal intubation is defined as passage of the colonoscope tip to a point proximal to the ileocecal valve, so that the entire cecal caput, including the medial wall of the cecum between the ileocecal valve and appendiceal orifice, is visible.”⁸⁰

colonoscopy. “A colonoscopy (koe-lun-OS-kuh-pee) is an exam used to detect changes or abnormalities in the large intestine (colon) and rectum.”⁸¹

colorectal cancer. “Colorectal cancer is a cancer that starts in the colon or the rectum.”⁸²

electrocardiogram A test that records the electrical signals of the heart.⁸³

fecal immunochemical test. A test that uses antibodies to find hidden blood in the stool.⁸⁴

fecal occult blood test. “A test that checks for occult (hidden) blood in the stool.”⁸⁵

ileocecal valve. The valve formed by two folds of mucous membrane at the opening of the ileum into the large intestine.⁸⁶

⁷⁸ Merriam-Webster Dictionary, *Definition of adenoma*, <https://www.merriam-webster.com/dictionary/adenoma>. (The website was accessed on June 1, 2020.)

⁷⁹ The American College of Gastroenterology, *Colonoscopy: Quality Indicators*, e77, Published on February 26, 2015.

⁸⁰ American College of Gastroenterology, American Gastroenterological Association and American Society for Gastrointestinal Endoscopy., *Photodocumentation of Cecal Intubation – National Quality Strategy Domain: Effective Clinical Care*, Measure #425, Published in 2015.

https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2017_Measure_425_Claims.pdf (The website was accessed on May 28, 2020.)

⁸¹ Mayo Clinic, *Colonoscopy*, <https://www.mayoclinic.org/tests-procedures/colonoscopy/about/pac-20393569>. (The website was accessed on April 9, 2020.)

⁸² American Cancer Society, *What Is Colorectal Cancer?* <https://www.cancer.org/cancer/colon-rectal-cancer/about/what-is-colorectal-cancer.html> (The website was accessed on May 29, 2020.)

⁸³ Mayo Clinic, *Electrocardiogram (ECG or EKG)*, <https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983>. (The website was accessed on June 1, 2020.)

⁸⁴ National Cancer Institute Dictionary of Cancer Terms, *Fecal Immunochemical Test*, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/fecal-immunochemical-test>. (The website was accessed on June 1, 2020.)

⁸⁵ National Cancer Institute Dictionary of Cancer Terms, *Guaiac fecal occult blood test*. <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/guaiac-fecal-occult-blood-test>. (The website was accessed on June 1, 2020.)

⁸⁶ Merriam-Webster Dictionary, *Medical Definition of ileocecal valve*. <https://www.merriam-webster.com/medical/ileocecal%20valve>. (The website was accessed on June 1, 2020.)

polyp. A growth projecting from a mucous membrane (as of the colon or vocal cords).⁸⁷

surveillance interval. Interval between colonoscopies.⁸⁸

sigmoidoscopy. “A sigmoidoscopy is a diagnostic test used to check the sigmoid colon, which is the lower part of your colon or large intestine.”⁸⁹

withdrawal time. “Withdrawal time, defined as the time from the colonoscope reaching cecum to removal of the instrument from the patient.”⁹⁰

⁸⁷ Merriam-Webster Dictionary, *Definition of polyp*. https://www.merriam-webster.com/dictionary/polyp?utm_campaign=sd&utm_medium=serp&utm_source=jsonld. (The website was accessed on June 1, 2020.)

⁸⁸ American Society for Gastrointestinal Endoscopy and American College of Gastroenterology, “Quality Indicators for Colonoscopy,” *Gastrointestinal Endoscopy* 81, no.1 (2015): 31–53.

⁸⁹ Johns Hopkins Medicine. *Sigmoidoscopy*. <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/sigmoidoscopy>. (The website was accessed on June 1, 2020.)

⁹⁰ Audrey H. Calderwood, MD and Brian C. Jacobson, MD, “Colonoscopy Quality: Metrics and Implementation,” *Gastroenterol Clin North Am*. 2013 Sep; 42(3): 599–618.

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