THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

November 29, 2018

The Honorable Henry Kerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

Re: OSC File No. DI-18-0857

Dear Mr. Kerner:

I am responding to your March 26, 2018, letter regarding allegations made by a whistleblower at the Dwight D. Eisenhower Department of Veterans Affairs (VA) Medical Center in Leavenworth, Kansas, and the Colmery-O'Neil VA Medical Center in Topeka, Kansas, which comprise the VA Eastern Kansas Health Care System (Eastern Kansas), that employees may have engaged in conduct that constitutes gross mismanagement and a substantial and specific danger to public health. The whistleblower, [redacted] alleged a backlog of approximately 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings at the two medical centers.

The Executive in Charge directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. We substantiated that the medical centers did indeed have patients who had not received follow-up endoscopy screenings, but we did not substantiate that their actual number was close to that alleged. We make nine recommendations to Eastern Kansas and one to the Veterans Health Administration.

Thank you for the opportunity to respond.

Sincerely,

Robert L. Wilkie

Robert L. Wilkie

Enclosure

DEPARTMENT OF VETERANS AFFAIRS
Washington, DC

Report to the

Office of Special Counsel

OSC File Number DI-18-0857

Department of Veterans Affairs (VA)

VA Eastern Kansas Health Care System (Eastern Kansas)

Dwight D. Eisenhower VA Medical Center (VAMC)
Leavenworth, Kansas
and the
Colmery-O'Neil VAMC
Topeka, Kansas

Report Date: October 10, 2018

TRIM 2018-D-1369

Executive Summary

The Executive in Charge, Office of the Under Secretary for Health directed that the Office of the Medical Inspector (OMI) assemble and lead a VA team to investigate allegations lodged with the Office of Special Counsel (OSC) concerning the Dwight D. Eisenhower VAMC in Leavenworth, Kansas (Leavenworth) and the Colmery-O'Neil VAMC in Topeka, Kansas (Topeka), which comprise the VA Eastern Kansas Health Care System (Eastern Kansas). [redacted] (the whistleblower), who consented to the release of [redacted] name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to Eastern Kansas on April 30–May 3, 2018.

Specific Allegation of the Whistleblower

The Eisenhower and Topeka, Kansas, VAMCs have a backlog of approximately 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings.

We **substantiated** allegations when the facts and findings supported that the alleged events or actions took place and **did not substantiate** allegations when the facts and findings showed the allegations were unfounded. We were **not able to substantiate** allegations when the available evidence was not sufficient to support conclusions with reasonable certainty about whether the alleged event or action took place.

After careful review of findings, we make the following conclusions and recommendations.

Conclusions for the Allegation

- We **substantiate** that Leavenworth and Topeka locations have patients who did not receive timely follow-up endoscopy. We found a total number of 1,107 Veterans between both facilities who needed timely follow-up endoscopy which is being addressed.

- We **do not substantiate** a backlog of 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings.

- The Veteran who was identified by the facility as delayed and was diagnosed with Colorectal Cancer had a follow-up colonoscopy performed within the nationally recommended timeframe.

- Gastroenterology (GI) Consult reviews are provided predominately by nursing staff and scheduled directly into the GI endoscopy clinic. However, in Topeka, there is no capacity to see new GI patients and requests for colonoscopy are referred directly to

the community as the site currently has the one 0.25 full-time employee (FTE), part-time provider and no full-time GI provider.

- One scheduling staff member was incorrectly exempted from training and six of eight did not complete both modules of required Schedule Veterans Health Information Systems and Technology Architecture Scheduling Enhancements (VSE) Training Modules.

- There is no consistent documentation of Veterans opting out of the Community Care in the appointment comments by the schedulers.

- The mapping of the full-time Leavenworth GI provider does not match the clinical practice as there is underutilization of the GI clinics (stop codes 307, 321) at Leavenworth; however, there is open access to the GI clinic (stop code 307) at this time.

- GI staff needs to fully adhere to the Eastern Kansas' standard of notifying patients of results within 14 days of receiving them, as noted in the Health System Policy Memorandum 111-02.[1] In addition, the Memorandum is expired and needs renewal.

- Eastern Kansas is not in compliance with monitoring the quality of colonoscopy as required by Veterans Health Administration (VHA) Directive 1015.

- Access to colonoscopy is important, but access to quality colonoscopy is even more important. Efforts to ensure that the care being provided meets quality benchmarks is necessary, including the monitoring of cecal intubation rates, bowel preparation quality, and adenoma detection rates.

Recommendations to Eastern Kansas

1. Request and schedule a consultative site visit from the National GI program office.

2. Send the case of the Veteran identified as delayed for outside review.

3. Ensure Veterans requiring follow-up endoscopy are seen within the appropriate timeframe.

4. Review the training records of schedulers. Ensure schedulers complete all required VSE training modules.

5. Transition to a GI clinical reminder system and eliminate the use of the Future Care Consult to track future GI endoscopy follow-up appointments.

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[1] Health System Policy Memorandum 111-02, *Ordering and Reporting Test Results*, September 12, 2014.

6. Monitor the quality of colonoscopy as required in VHA Directive 1015. Additional quality metrics are also encouraged.[2]

7. Utilize a Nurse Leader or Registered Nurse (RN) Care Coordinator to coordinate screening schedules, procedures, and to ensure that all levels of the program are working together (e.g., review of consults, follow-up on requested information, retrieval of in-house and outside medical records, follow-up of no-shows, follow-up on positive fecal occult blood tests, etc.).

8. Review, update, and reissue Health System Policy Memorandum 111-02. Educate all relevant clinical staff upon renewal.

9. Collaborate with Human Resources (HR) and Workforce Development to recruit and utilize all available incentives to hire a full-time gastroenterologist for the Topeka campus.

Recommendation to VHA

1. Advocate and support Eastern Kansas' use of an electronic tracking system that assists in clear documentation of endoscopy reports and facilitates appropriate follow-up of Veterans and procedure quality monitoring.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Eastern Kansas may have violated law, rule or regulation, engaged in gross mismanagement and created a substantial and specific danger to public health and safety. In particular, VHA HR has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VA and VHA policy, and note that a substantial and specific danger to public health and safety existed at Eastern Kansas.

[2] Rex DK, Schoenfeld PS, Cohen J, Pike IM, Adler DG, Fennerty MB, Lieb JG 2nd, Park WG, Rizk MK, Sawhney MS, Shaheen NJ, Wani S, Weinberg DS. *Quality Indicators for Colonoscopy.* Am J Gastroenterol. 2015 Jan;110(1):72-90. doi: 10.1038/ajg.2014.385.

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I. Introduction

The Executive in Charge, Office of the Under Secretary for Health directed that OMI assemble and lead a VA team to investigate allegations lodged with OSC concerning the Dwight D. Eisenhower VAMC in Leavenworth, Kansas (Leavenworth) and the Colmery-O'Neil VAMC in Topeka, Kansas (Topeka), which comprise the VA Eastern Kansas Health Care System (Eastern Kansas). [redacted] (the whistleblower), who consented to the release of [redacted] name, alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to Eastern Kansas on April 30 – May 3, 2018.

II. Facility Profile

Eastern Kansas, part of Veterans Integrated Service Network (VISN) 15, is a two-division Joint Commission accredited, complexity level 1c health care system serving Veterans in Eastern Kansas and Northwestern Missouri. In addition to the two main campuses in Topeka and Leavenworth, it operates seven Rural Health Clinics in Kansas in Chanute, Emporia, Fort Scott, Garnett, Junction City, Kansas City, and Lawrence, and two in Missouri at Platte City and St. Joseph. Its primary service area consists of 37 counties in Kansas and Missouri. Eastern Kansas offers inpatient and outpatient services with a focus on primary care (PC), psychiatric treatment, and extended care, supported by nursing home care units and a domiciliary.

Eastern Kansas provides primary through secondary treatment in general medicine and surgery, and primary through tertiary levels of care in psychiatry, substance abuse, and posttraumatic stress disorder treatment. Clinical services are offered in PC, internal medicine, cardiology, infectious disease, GI, dermatology, rheumatology, nephrology, pulmonology, oncology, hematology, neurology, gynecology, emergency medicine, geriatric medicine, physical medicine and rehabilitation, chiropractic care, general surgery, vascular surgery, orthopedic surgery, urology, and ophthalmology. It employs nearly 1,900 full-time employees. In Fiscal Year (FY) 2017, Eastern Kansas provided care to approximately 37,000 unique patients, and operated a total of 41 medical/surgical inpatient hospital beds, 89 long-term-care beds, 73 inpatient behavioral health beds, and 150 domiciliary beds.

III. Specific Allegation of the Whistleblower

The Eisenhower and Topeka, Kansas, VAMCs have a backlog of approximately 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of the Chief Medical Investigator, a Senior Medical Investigator, and a Clinical Program Manager, all of OMI; the National Program Director for Gastroenterology, the National Scheduling Program Manager, VHA Office of Veterans Access to Care, a Chief, Employee/Labor Relations Officer, and a Program Analyst, Clinical Integration, VHA Office of Community Care. We reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A. We toured both of Eastern Kansas' GI Departments and held entrance and exit briefings with Medical Center and Veterans Integrated Service Networks (VISN) Leadership, including:

VISN 15

- Chief Medical Officer
- Quality Management Officer

Eastern Kansas

- Medical Center Director (MCD)
- Acting Chief of Staff (CoS)
- Associate Director for Patient Care Services (ADPCS)
- Chief, Quality Management

We initially interviewed the whistleblower via teleconference on April 18, 2018, and conducted a face-to-face interview April 30, 2018. We also interviewed the following employees:

- MCD
- Former Associate Director
- Acting CoS
- ADPCS
- Associate Chief Nurse (Leavenworth)
- Associate Chief Nurse, (Topeka); Chief, Non-VA/Community Care
- Chief, Acute and Specialty
- Chief, Surgery
- Gastroenterologist #1
- Gastroenterologist #2
- Former Surgery Service Line Manager
- Chief, Ambulatory Care Medicine
- PC Physician (Topeka)
- PC Physician
- Associate CoS for Education (Former, CoS)
- Program Manager for Audiology and Speech (Topeka)
- Chief Quality Officer (CQO)

- Nurse Manager, Specialty Clinics
- RN, Leavenworth #1
- RN, Leavenworth #2
- Licensed Practical Nurse (LPN)
- Group Practice Manager (GPM)
- Business Office Manager
- Patient Advocate
- Risk Manager
- Patient Safety Officer
- Supervisory Employee/Labor Relations Officer
- Supervisory Administrative Officer (Topeka)
- Medical Support Assistant (MSA) Supervisor
- MSA Lead
- MSA, GI
- Nurse Manager, Specialty Clinics (Topeka)
- Nurse Manager, PC (Topeka)
- RN, Topeka #1
- RN, Topeka #2
- Health Systems Specialist (HSS) to the CoS
- MSA, GI (Topeka)
- Chief, Health Administrative Services
- GI Action Team

    1. ADPCS
    2. CQO
    3. Nurse Manager, Specialty Clinics (Leavenworth)
    4. Nurse Manager, Specialty Clinics (Topeka)
    5. GPM

We held an exit briefing with Eastern Kansas and VISN 15 Leadership, including:

VISN 15

- Chief Medical Officer
- Quality Management Officer

Eastern Kansas

- MCD
- Acting CoS
- Associate ADPCS
- Acting Assistant Director
- Chief, Quality Management

V. Findings, Conclusions, and Recommendations

Allegation

The Eisenhower and Topeka, Kansas, VAMCs have a backlog of approximately 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings.

Background

Endoscopy procedures include a variety of different interventions including, but not limited to, colonoscopy, upper gastrointestinal endoscopy, and specialty procedures such as endoscopic retrograde cholangiopancreatography. Each intervention has different indications, and the determination on when the specific endoscopy procedure is needed is based on these clinical indications. Some procedures are required immediately, such as for active bleeding, and others, such as average risk screening procedures, may be scheduled later than 30 days in the future as these are not related to a known or suspected dysfunction.

In 2016, the U.S. Preventive Services Task Force concluded with high certainty that screening for colorectal cancer in average-risk, asymptomatic adults aged 50 to 75 years is of substantial net benefit. Multiple screening strategies are available to choose from (e.g., colonoscopy every 10 years, flexible sigmoidoscopy every 5 years, annual fecal immunochemical testing) with different levels of evidence to support their effectiveness, as well as unique advantages and limitations.[3]

Screening should begin at age 50 in average-risk persons. Colorectal Cancer (CRC) incidence is rising in persons under age 50, and a thorough diagnostic evaluation of young persons with suspected colorectal bleeding is recommended. Discontinuation of screening should be considered when persons are up to date with screening, who have prior negative screening (particularly colonoscopy), reach age 75 or have less than 10 years of life expectancy. Persons without prior screening should be considered for screening up to age 85, depending on age and comorbidities. Persons with a family history of CRC or a documented advanced adenoma in a first-degree relative aged less than 60 years or two first-degree relatives with these findings at any age are recommended to undergo screening by colonoscopy every 5 years, beginning 10 years before the age at diagnosis of the youngest affected relative or age 40, whichever is earlier. Persons with a single first-degree relative diagnosed at more than or equal to 60 years with CRC or an advanced adenoma can be offered average-risk screening options beginning at age 40 years.[4]

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[3] *Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement*, Journal of the American Medical Association, *JAMA* 2016;315(23):2564-2575. doi:10.1001/jama.2016.5989 https://www.uspreventiveservicestaskforce.org/Home/GetFile/1/522/rec-statement-colorectal-cancer-final/pdf.

[4] Rex, et al, "Colorectal Cancer Screening: Recommendations for Physicians and Patients from the U.S. Multi-Society Task Force on Colorectal Cancer," American Journal of Gastroenterology, 2017 July; 153 (1):307-323. Copyright © 2017 AGA Institute. https://www.ncbi.nlm.nih.gov/pubmed/28600072.

VHA recommends CRC screening for adults aged 50 through 75, at intervals recommended by the U.S. Preventive Services Task Force. The decision to screen for CRC in adults aged 76 through 85 should be an individual one, taking into account the patient's overall health and prior screening history. VHA recommends against routine screening for CRC in adults older than 85.[5]

Findings

An LPN assigned to the GI clinic discovered on September 23 and 24, 2017, that Veterans did not have recall reminders placed. The LPN noted that only the whistleblower's patients were on the recall reminder list, despite the fact that other physicians performed colonoscopies. The hospital's senior leaders were notified and a plan put in place for a clinical review.

VISN 15 pulled data at both Leavenworth and Topeka and provided them for staff to sort and review. A 10-year review was begun for the GI Clinic reviews from August 2007 to August 2017, and took place from October through December 2017. Approximately 1,204 nursing hours were used for the Leavenworth review and 450 for the Topeka review. Clinic staff used the following guidance provided by the gastroenterologist to review medical records:

Pathological Finding	Recommended Follow-up[6]
Barrett's Esophagus (intestinal metaplasia on pathology)	3 years
Esophageal Varices	3 years
Gastric Ulcer	8 weeks
Tubular Adenoma	5 years
Tubulovillous Adenoma	3 years
Hyperplastic polyp	7 years
Crohn's/Ulcerative Colitis	3 years
No Pathologic Findings	10 years

The initial review by Eastern Kansas revealed that Leavenworth had 24,511 total GI procedures of which 15,349 were colonoscopies. Of 6,886 unique Veterans, 4,317 were potentially impacted as just under half of the total group did not require further testing, were under the care of another VA or non-VA facility, or refused further testing.

Clinical staff reviewed all potentially impacted Veterans. Of the 4,317 records, 2,340 needed consults. There were 1,643 for future care consults, and 697 for now consults, meaning they met the criteria for a return visit either overdue or due within 90 days. In 30 records, the clinical staff indicated that both future care and now consults were needed.

[5] VHA National Center for Health Promotion and Disease Prevention (NCP). http://vaww.prevention.va.gov/CPS/Colorectal_Cancer_Screening.asp.

[6] Note that these recommended follow-up intervals are not entirely consistent with current recommendations from the GI professional societies.

For Topeka using the same methodology, 6,786 unique Veterans were identified with 2,330 potentially impacted. After clinical review, 826 needed consults; 416 were ordered for future care and 410 were now consults.[7]

Of the total 1,107 now consults found at both Eastern Kansas campuses, as of September 19, 2018, all consults have been scheduled and 1,098 of them have been seen. The nine remaining Veterans have appointments scheduled in September or October 2018.

Provider Staffing

Leavenworth currently has one full-time gastroenterologist, [redacted] and one fee-basis gastroenterologist who performs procedures on Tuesday afternoons. Leavenworth had a GI Physician Assistant (PA) working with the gastroenterologist, but the PA (a reservist) was deployed for a military assignment from approximately April 2017 through April 2018, and planned to leave VA effective June 2018. The PA was responsible for reviewing the post-procedure note and notifying the patient either by phone or by letter of the results, in addition to other clinical duties. A full-time gastroenterologist left Topeka in February 2018, leaving only one 0.25 FTE employee gastroenterologist who performs procedures on Mondays.[8] Currently, there is no other gastroenterologist in Topeka although there is a recruitment action listed for a GI physician at Topeka on USA Jobs.[9] Several interviewees commented on the recruiting challenges for gastroenterologists to work in Eastern Kansas. The primary issue mentioned was the salary disparity between VA and the private sector. Private practice salaries are at least $350,000 to $370,000, while VA salaries offered were reported as being well below $300,000.

Procedure Schedules

In April 2015, Eastern Kansas elected to use future care consults for care scheduled more than 90 days in the future. This decision included follow-up GI endoscopy procedures. The process of using future care consults for tracking and scheduling these procedures was not fully adopted, but was supplemented by future care consults, Veterans Health Information Systems and Technology Architecture (VistA) Scheduling Recall Reminder software, and reliance on documentation in the clinical note alone.

Eastern Kansas' equivalent to the Consult Management Steering Committee is the Scheduling Practices Committee which meets biweekly. Chaired by the Assistant Chief,

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[7] The Medical Center's definition of Now Consult is appointments that needed to be scheduled within 90 days. Those greater than 90 days needed a Future Care Consult.

[8] Full-time equivalent employment is defined as the total number of regular straight-time hours (not including overtime or holiday hours) worked by employees divided by the number of compensable hours applicable to each fiscal year. Work years, or FTEs, are not employee "head counts." One work year, or one FTE, is equivalent to 2,080 hours of work. Congressional Research Service, *Federal Workforce Statistics Sources: OPM and OMB*, January 12, 2018. https://fas.org/sgp/crs/misc/R43590.pdf

[9] The recruitment action for the Gastroenterology Physician in Topeka, Kansas, opened March 8, 2018, and closes March 7, 2019. The Announcement Number is CBCH-10142158-18-CJK. https://www.usajobs.gov/GetJob/ViewDetails/493394000

Health Administration, it is comprised of members who are in clinical, administrative, and technical roles. The standard agenda covers the elements required per VHA Directive 1232, and minutes are recorded. We found no evidence of committee review/discussion of the GI program scheduling issues brought forth in September 2017 in any of the minutes from that date to the present.

There are no new appointments being scheduled in the GI Clinic in Topeka, and only four are scheduled or in pending status at Leavenworth, using stop code 307. The consult review process there consists largely of a clinical review by nursing staff, followed by direct placement in the GI Endoscopy Clinic schedule. There is no prior consultative appointment or follow-up visit in stop code 307 associated with GI endoscopy. As of May 16, 2018, Leavenworth had 516 open GI endoscopy clinical consults (476 were scheduled, 7 were pending, and 33 were in active status) and 4,108 open future care consults. In addition, there are two clinician providers; one contracted part-time provider, and one full-time VHA provider. The contracted provider is at capacity and had his first opening at the time of our site visit on August 14, 2018.

The VA provider at Leavenworth has 34 hours per week mapped to clinical time and his expected bookable hours per week are 27.2. The actual allocated hours (per the VHA Support Service Center (VSSC) Provider Dashboard report) are 18.0: 14 hours to GI endoscopy and 4 hours to GI Clinic. Wait times for GI endoscopy are 76 days for established patients, based on provider indicated date, and 127 days for new patients, based on appointment create date. Procedure slots became available August 9, 2018. There is open access or available clinic appointments to the GI Clinic (307) at this time.

In Topeka, there is no capacity to see new patients in the GI Clinic, and requests for GI endoscopy are referred directly to Community Care. There is potential for over utilization of GI endoscopic procedures due to the consults not routinely screened by the provider or the opportunity of the patient to be seen in the Clinic for consultation. Topeka GI endoscopy current consult activity includes 97 open clinical consults (2 active, 95 scheduled) and 3,196 Future Care consults. The provider was fully booked through November 5, 2018. The average wait time for established patients in the clinic is 99 days from the clinically indicated date.

Clinic Schedulers

Eight staff members scheduled GI appointments in one or both of Eastern Kansas' facilities during September 2017 – May 2018. Appointment records were reviewed through the Business Intelligence Service Line Appointment List report.[10] VHA Directive 1230 requires that any patient with a wait time of more than 30 days from the Patient Indicated Date is to be offered the option to receive Community Care. Patients who decline Community Care are able to opt out, and the scheduler indicates such in the appointment comments using the abbreviation #COO#. Five of the eight schedulers

[10] Business Intelligence Service Line Supervisory Appointment Tool Appointment List Report.

consistently documented patients' desires to opt out in the appointment comments when the wait time was more than 30 days.[11]

VHA Directive 1230 also requires that all who schedule appointments complete the National Scheduling Training, VSE Scheduler Training, and participate in the National Scheduling Audit program (with some exceptions). Both Leavenworth and Topeka are active participants in the program. For seven of the eight schedulers, appointment audit requirements were met. One was incorrectly placed in an exempted status by both facilities; this individual had not qualified for this exemption by achieving 100 percent accuracy in the previous audit cycle. All eight staff members completed the required National MSA Onboarding and/or Refresher training and two completed both required Scheduler VSE Training modules (VA 33382, VA 33395).[12] The remaining six completed one of the two modules.

Space and Procedure Throughput

The Leavenworth Endoscopy Unit consists of four pre-/post-procedure rooms (i.e., admission/recovery) and one procedure room with an adjacent reprocessing area containing two Medivators double-bay automated endoscope reprocessors (AER).[13] The Endoscopy Unit is used by the Pain Clinic on Tuesday mornings, but is otherwise available for GI procedures. Endoscopy is performed on Thursday mornings from 8:00 – 11:00 a.m. and Monday through Friday afternoons from approximately 12:00 p.m. – 3:00 p.m. Procedures are scheduled every 30 minutes and performed with anesthesia assistance (i.e., monitored anesthesia care with Propofol) in most cases. Almost all patients are scheduled on a direct access basis (i.e., the patients are first seen by the physician on the day of the procedure). Education regarding the arrival process, informed consent, bowel prep procedure, and post-procedure steps are initially reviewed with the Veteran by the consulting provider and the GI nursing team. Therefore, the 30-minute time slot includes the time required for performing and documenting the patient history, physical exam, informed consent process, documenting pre-procedure orders, sedation of the patient, performance of the endoscopic procedure, documentation of the endoscopic findings, post-procedure orders, completion of the encounter form, and review of the results with the patient and/or family members.

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[11] #COO#: Indicates the Veteran opted out of the Choice program. #Choice Opt Out#. The # identifies the appointment for reporting purposes.

[12] VA 33382: National Scheduler Vista Scheduling Enhancements Training (Initial training course, 4 hours); VA 33395: National VistA Scheduling Enhancements (VSE) Scenario Skill Review (competency review and skill check off on VSE usage in scheduling appointments).

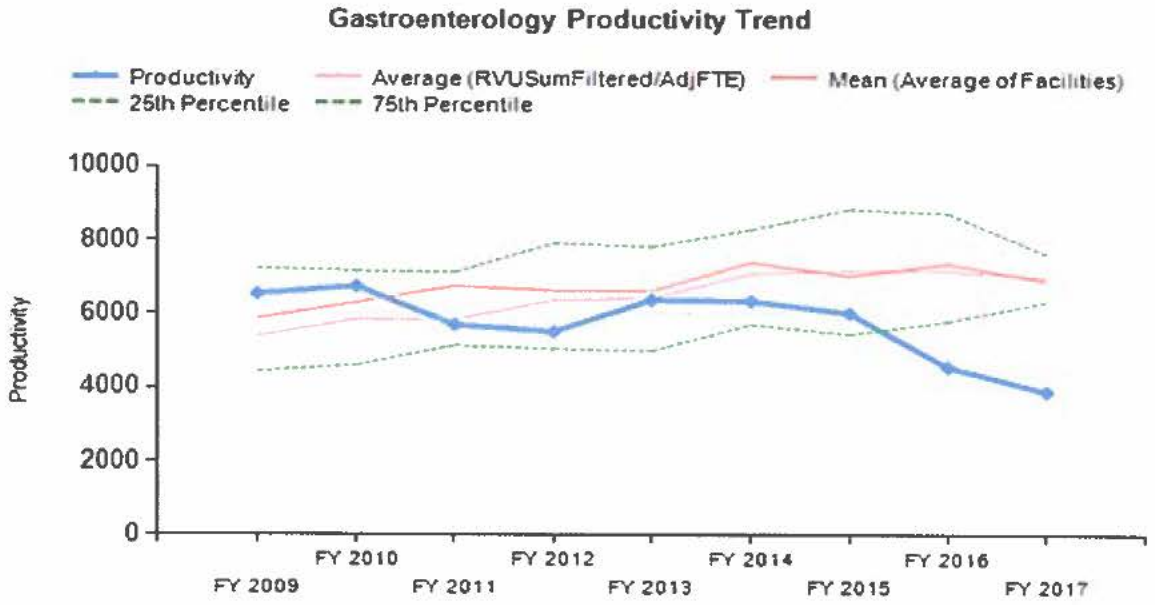
[13] AERs are machines designed for the cleaning and high-level disinfection (HLD) of heat-sensitive endoscopes. AERs replace some of the manual steps involved in endoscope reprocessing. AERs offer several advantages over manual reprocessing. They automate and standardize several important reprocessing steps, thereby eliminating the possibility of missed steps because of human error, and minimize exposure of endoscopy or sterile processing department personnel to HLDs or chemical sterilants. ASGE Technology Committee, *Automated Endoscope Reprocessors*, Volume 84, No. 6 : 2016 Gastrointestinal Endoscopy, 885-892; http://dx.doi.org/10.1016/j.gie.2016.08.025 Copyright © 2016 by the American Society for Gastrointestinal Endoscopy. https://www.giejournal.org/article/S0016-5107(16)30531-4/pdf.

There is no dedicated Outpatient GI Clinic in Leavenworth, as the full-time Leavenworth physician has elected to rely upon e-consults or endoscopy to provide consultative services to Veterans at Eastern Kansas. According to the GI physician, upon receipt of an e-consult, the physician will review and schedule the Veteran for a colonoscopy in a virtual electronic manner rather than utilizing a physical clinic setting. When he is not scheduled to do endoscopic procedures, he is responsible for managing the inpatient and outpatient consults, seeing occasional walk-ins or Emergency Department patients, following up on pathology and other clinical results. Since the departure of the full-time gastroenterologist at Topeka, he has overall responsibility for processing consults from that facility as well.

The Topeka Endoscopy Unit consists of two pre-procedure chairs and three post-procedure recovery rooms that are shared with the Operating Room. There are two procedure rooms with an adjacent reprocessing area containing three Medivators single-bay AERs. Endoscopy is performed all day Monday by the 0.25 FTE gastroenterologist. Since the departure of the full-time gastroenterologist, GI procedures are only performed on Mondays, excluding Federal holidays. It was reported that the previous GI provider performed very few (approximately 4) procedures each week, largely due to the provider's medical limitations. There are plans in place to move the reprocessing area to the basement and then remodel the Endoscopy Unit, though the number of procedure rooms and recovery beds will remain unchanged. There are eight endoscopies scheduled each Monday when procedures are conducted. Procedures are scheduled every 45 minutes beginning at 7:30 a.m. and are performed with anesthesia assistance in most cases. As at Leavenworth, most patients are scheduled on a direct access basis. The 45-minute timeslot includes the same step-by-step procedures followed by Leavenworth. Topeka has a small inpatient ward that permits occasional consults for endoscopic procedures.

Depicted below are data from the Physician Productivity Cube for Eastern Kansas. Prior to 2009, productivity exceeded the average rate of endoscopies performed by comparable medical centers. However, in 2009 and 2010, it fell between the 25th and 50th percentile until 2016 when productivity fell far below the 25th percentile. As productivity is a ratio of Relative Value Units (RVU) production divided by clinical FTE, these results can be influenced by several factors, including actual physician productivity as well as incomplete data capture (e.g., missing encounter form information or inaccurate labor mapping of physician time).[14]

[14] RVUs are used for calculating Medicare payments; budgeting; measuring productivity; and allocating expenses. It is a numerical value that represents the amount of physician effort, risk, and resources, provided or consumed, for one service relative to other services. http://medgroup.ucsf.edu/data-warehouse/rvu-rbrvs-basics.



GI Endoscopy Result Notification

Staff members reported that following completion of an endoscopic procedure, all patients were given copies of their endoscopy reports. This report, generated with Olympus EndoWorks software, would typically include recommendations regarding the timing for a follow-up examination. When recommendations relied upon pathology results, the physician would write a post-op note with recommendations (e.g., "repeat colonoscopy in 3, 5, or 10 years"). In addition to notification of Veterans about surveillance recommendations at the time of the procedure, the whistleblower would place a future care consult to prompt recall at the time that surveillance endoscopy was due. It was reported that some of the other GI providers were not placing these future care consults.

According to Health System Policy Memorandum 111-02, Paragraph 4.B. (2) (a) *Non-Critical Results*, both abnormal and normal results,

> *Will be communicated to Patients or Personal representative no later than 14 calendar days from the date on which the results are available to the Ordering Practitioner. Results are to be communicated in a time frame that minimizes risk to a patient especially with regards to significant abnormalities.*

We noted that eight Veterans were not notified within the recommended time frame referenced in the Eastern Kansas policy. Although the Veterans were not notified per the recommended time frame, each was contacted and provided appropriate follow-up care.

There is no established standard of care requirement to remind individuals to schedule an appointment once that surveillance time has elapsed. While the health care facility

certainly may remind and encourage patients to return for follow-up procedures, the individual patient has the ultimate responsibility to seek his or her care.

VHA is currently deploying an enterprise-wide CRC Screening and Surveillance Reminder that will require the setting of a health factor after colonoscopy is performed, in order to indicate what the follow-up recommendations are for that Veteran. Specialized Gap Reports can then be run by VSSC to identify Veterans who had a colonoscopy without specification of the follow-up plans.[15] When surveillance colonoscopy is recommended, a separate reminder will be activated to prompt the referral for colonoscopy. These specialized VSSC reports have been developed to facilitate this process, even when the Veteran does not have any scheduled clinic appointments.

Eastern Kansas is deploying the new CRC Screening and Surveillance Reminder, which should help to ensure that surveillance recommendations are properly managed going forward, assuming proper use of the reminder and VSSC reports. According to staff, training in the use of the new reminder is ongoing. The facility has also replaced its EndoWorks endoscopy software with ProVation, which has the capability of documenting recall recommendations in a relational database.[16] Eastern Kansas began implementation of the provider portion of ProVation in March 2018. Nurses were trained in May and full nursing implementation began in June.

Colonoscopy Quality Assurance

VHA Directive 1015 sets requirements for monitoring the quality of colonoscopy at all VAMCs.[17] However, it is not clear that the recommended quality metrics are being met at Eastern Kansas. Staff reported that scope withdrawal times are generally over the 6-minute benchmark. It was not specified whether this withdrawal time was restricted only to those colonoscopies where no biopsy or polypectomy was performed, as indicated in the published guidelines. Other staff reported that the adenoma detection rates were measured by one of the nurses; however, we were unable to verify this. Current benchmarks for adenoma detection in the general population during screening colonoscopy are 30 percent for males and 20 percent for females, though these are generally felt to be low benchmarks. Veterans have been found to have higher rates of adenomas.

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[15] The VHA VSSC Database is a web-based project application and tracking database used for capital project application submissions and capital project tracking for the VHA Minor, Clinical Specific Initiative (CSI) and Non-Recurring Maintenance (NRM) Programs. This metadata record is available for the public, but the data are not public for privacy or security reasons. https://catalog.data.gov/dataset/vha-support-service-center-capital-assets-vssc.

[16] ProVation is a software tool that facilitates gastrointestinal clinical procedure documentation, coding, physician order sets and patient care plans. © 2018 ProVation Medical, Inc. and/or its affiliates. All rights reserved. https://www.provationmedical.com/procedure-documentation/.

[17] VHA Directive 1015, *Colorectal Cancer Screening*, December 20, 2014, updates recommended screening tests, which are now based upon the screening guidelines coordinated by the VHA National Center for Health Promotion and Disease Prevention (NCP). Guidance has been clarified to increase flexibility in recommending screening options. Other changes include the addition of colonoscopy quality monitoring and recommendations for optimizing bowel preparation.

It was noted that GI nursing staff assisted with the education of Veterans about bowel prep and scheduling questions as part of the process. In spite of this, staff reported that bowel preparation quality has been a major limitation. In an effort to improve it, the staff changed the protocol from a 1-day to a 2-day preparation. We noted the GI Department is not following established recommendations for split-dose bowel preparation (i.e., administration of at least one liter of laxative on the day of the procedure).[18] Split-dose preparations are shown to not only improve bowel preparation quality, but also to improve patient tolerance. Given that most procedures are scheduled in the afternoon, it is unclear why split-dose preparations are not being used. This may obviate the need for the 2-day preparation, which should improve patient tolerance.

Case Review

Per our review, only one Veteran identified by Eastern Kansas as delayed, was diagnosed as having CRC. The cancer was diagnosed on a follow-up study to a previous colonoscopy performed in 2009 for the finding of blood in the stool when the Veteran was 70 years old. At that time, a hyperplastic polyp less than 10 mm in size was removed from the descending colon and additional diagnoses of hemorrhoids and diverticulosis were noted. Though the Veteran was diagnosed with cancer, the endoscopy occurred within the national GI-recommended time period of follow-up based on the pathology from the prior study. The Veteran subsequently underwent surgery and is reportedly doing well.

Incident Reports

We reviewed incident reports from FY 2016 to the present and found 46 related to the GI clinic, including 8 on patient notification, 7 on the EndoWorks system, 5 for incorrect labelling, and 3 for patient falls.[19,20] There were no negative outcomes.

Patient Complaints

We reviewed patient complaints from the Patient Advocate from April 23, 2015, to April 23, 2018, specifically focusing on GI concerns. There were 17 complaints, but none related to the allegations we investigated. We also reviewed the Electronic Medical Record of each Veteran who filed a complaint to ensure proper GI care had

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[18] Johnson DA, Barkun AN, Cohen LB, Dominitz JA, Kaltenbach T, Martel M, Robertson DJ, Boland CR, Giardello FM, Lieberman DA, Levin TR, Rex DK; US Multi-Society Task Force on Colorectal Cancer. Optimizing adequacy of bowel cleansing for colonoscopy: recommendations from the US multi-society task force on colorectal cancer. Gastroenterology. 2014 Oct;147(4):903-24. doi: 10.1053/j.gastro.2014.07.002.

[19] Health System Policy Memorandum 111-02, Ordering and Reporting Test Results, September 12, 2014 is expired.

[20] EndoWorks is a web-based information management solution for GI and pulmonary patient care and provides tools to capture HD clinical images and videos, generate physician procedure reports and letters, and archive critical patient data to Heath Information Systems/Electronic Medical Record systems. EndoWorks is designed to ensure interoperability with a wide range of systems used to produce, store, display, process, send, retrieve, query, or print medical images and derived structured documents. On April 1, 2015, after 26 years of development and support of the EndoWorks software platform, Olympus announced it will be discontinuing the product, effective March 31, 2018. http://technology.healthcareinspired.com/applications/endoworks/.

been completed, and found that all of the concerns were appropriately referred; either in-house, to the community via either community care or Non-VA consult, to the proper department (billing issue), or for the proper service (general surgery). Our review noted that two Veterans expired this year in January and March. The first Veteran last had a colonoscopy in December 2014, and at that time, a follow-up was recommended in 5 years. In September 2017, he was offered a GI consult but refused, stating he didn't want another colonoscopy. The second Veteran had a colonoscopy in February 2016, which found a cecal mass, and he underwent a surgical resection to remove it. He subsequently was treated with chemotherapy. Both Veterans were followed appropriately.

Office of Inspector General (OIG) Complaint

The whistleblower informed us [redacted] had filed an OIG complaint in mid-October 2017, expressing [redacted] concerns that Eastern Kansas was jeopardizing patient safety and quality of care by pressuring staff to increase the number of endoscopies performed, as [redacted] was not comfortable performing an increased total number per day. OIG sent the hotline complaint to Eastern Kansas for a response:

> *Allegedly, management at VAMC Leavenworth, KS has ordered staff to increase the number of endoscopy procedures performed to 40 per week instead of 30, thus placing patients' safety in jeopardy. This increase in procedures does not allow for time to regroup in between procedures and does not account for fatigue which could lead to mistakes such as perforations, etc. The alleged victims are the 50 plus patients who are overbooked for endoscopy for the following dates November 3 and 17; December 1, 8, 15, 22, and 29, 2017.*[21]

On December 15, 2017, Eastern Kansas responded to OIG, partially substantiating the allegation that at Leavenworth, management had directed staff to increase the number of weekly endoscopy procedures from 30 to 40; however, it did not substantiate that this increase jeopardized patient safety or quality of care. The CoS and then Acting HSS for the CoS researched standards of care for gastroenterologists, including the guidance from the National Director of GI, prior to initiating this increase. Based on this research, they determined that the number of gastroenterologists at Leavenworth (one full-time, two part-time) could safely perform 35-42 endoscopy procedures a week and complete clinic responsibilities. We found that the plan to increase the number of procedures on Fridays was not implemented.

Conclusions for the Allegation

- We **substantiate** that Leavenworth and Topeka locations have patients who did not receive timely follow-up endoscopy. We found a total number of 1,107 Veterans between both facilities who needed timely follow-up endoscopy which is being addressed.

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[21] December 15, 2017, *Response to CA/VHA/OCT VA OIG Hotline Referral Case 2018-00568-HL-0569/Leavenworth, KS VAMC*; RP06.

- We **do not substantiate** a backlog of 4,500 and 2,500 patients, respectively, who did not receive timely follow-up endoscopy screenings.

- The Veteran who was identified by the facility as delayed and was diagnosed with CRC had a follow-up colonoscopy performed within the nationally recommended timeframe.

- GI Consult review is provided predominately by nursing staff and scheduled directly into the GI endoscopy clinic. However, in Topeka, there is no capacity to see new GI patients, and requests for colonoscopy are referred directly to the community as the site currently has only the one 0.25 FTE provider and no full-time GI provider.

- One scheduling staff member was incorrectly exempted from training, and six of eight did not complete both modules of required Schedule VSE Training Modules.

- There is no consistent documentation of Veterans opting out of Community Care in the appointment comments by the schedulers.

- The mapping of the full-time Leavenworth GI provider does not match the clinical practice, as there is underutilization of the GI Clinics (stop codes 307, 321) at Leavenworth; however, there is open access to the GI Clinic (stop code 307) at this time.

- GI staff needs to fully adhere to Eastern Kansas' standard of notifying patients of results within 14 days of receiving them, as noted in the Health System Policy Memorandum 111-02. In addition, the Memorandum is expired and needs renewal.

- Eastern Kansas is not in compliance with monitoring the quality of colonoscopy as required by VHA Directive 1015.

- Access to colonoscopy is important, but access to quality colonoscopy is even more important. Efforts to ensure that the care being provided meets quality benchmarks is necessary, including the monitoring of cecal intubation rates, bowel preparation quality, and adenoma detection rates.

Recommendations to Eastern Kansas

1. Request and schedule a consultative site visit from the National GI program office.

2. Send the case of the Veteran identified as delayed for outside review.

3. Ensure Veterans requiring follow-up endoscopy are seen within the appropriate timeframe.

4. Review the training records of schedulers. Ensure schedulers complete all required VSE training modules.
5. Transition to a GI clinical reminder system and eliminate the use of the Future Care consult to track future GI endoscopy follow-up appointments.

6. Monitor the quality of colonoscopy as required in VHA Directive 1015. Additional quality metrics are also encouraged.[22]

7. Utilize a Nurse Leader or RN Care Coordinator to coordinate screening schedules, procedures, and to ensure that all levels of the program are working together (e.g., review of consults, follow-up on requested information, retrieval of in-house and outside medical records, follow-up of no-shows, follow-up on positive fecal occult blood tests, etc.).

8. Review, update, and reissue Health System Policy Memorandum 111-02. Educate all relevant clinical staff upon renewal.

9. Collaborate with HR and Workforce Development and utilize all available incentives to recruit and hire a full-time gastroenterologist at Topeka.

Recommendation to VHA

1. Advocate and support Eastern Kansas' use of an electronic tracking system which assists in clear documentation of endoscopy reports and facilitates appropriate follow-up of Veterans and procedure quality monitoring.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address OSC's concerns that Eastern Kansas may have violated law, rule or regulation, engaged in gross mismanagement and created a substantial and specific danger to public health and safety. In particular, VHA HR has examined personnel issues to establish accountability, and the National Center for Ethics in Health Care has provided a health care ethics review. We found violations of VA and VHA policy, and note that a substantial and specific danger to public health and safety existed at Eastern Kansas.

[22] Rex DK, Schoenfeld PS, Cohen J, Pike IM, Adler DG, Fennerty MB, Lieb JG 2nd, Park WG, Rizk MK, Sawhney MS, Shaheen NJ, Wani S, Weinberg DS. *Quality Indicators for Colonoscopy.* Am J Gastroenterol. 2015 Jan;110(1):72-90. doi: 10.1038/ajg.2014.385.

Attachment A

Documents in addition to the Electronic Medical Records reviewed.

Colorectal Cancer Prevention 2000: Screening Recommendations of the American College of Gastroenterology. In conjunction with ACG Consumer Brochure: "ACG Recommendations on Colorectal Cancer Screening for Average and Higher Risk Patients in Clinical Practice." Am J Gastroenterology, April 2000, 95 (4); 868-877. Copyright © 2000 by the American College of Gastroenterology, http://www.nature.com/articles/ajg2000237.

American College of Gastroenterology Guidelines for Colorectal Cancer Screening 2008. © 2009 by the American College of Gastroenterology. The American Journal of Gastroenterology 24 February 2009; doi: 10.1038/ajg.2009.104 http://s3.gi.org/media/ACG2009CRCGuideline.pdf.

American Gastroenterology Association, Guidelines for Colonoscopy Surveillance after Screening and Polypectomy: A Consensus Update by the US Multi-Society Task Force on Colorectal Cancer. Lieberman, David A. et al. Gastroenterology, Volume 143, Issue 3, 844 – 857. DOI: https://doi.org/10.1053/j.gastro.2012.06.001, http://www.gastrojournal.org/article/S0016-5085(12)00812-8/abstract.

American Society for Gastrointestinal Endoscopy, Colorectal cancer screening: "Recommendations for physicians and patients from the U.S. Multi-Society Task Force on Colorectal Cancer." Copyright © 2017 by the American Society for Gastrointestinal Endoscopy, the AGA Institute, and the American College of Gastroenterology. Gastrointestinal Endoscopy Volume 86, No. 1: 2017, www.giejournal.org, https://www.asge.org/docs/default-source/education/practice_guidelines/piis0016510717318059.pdf?sfvrsn=0

Eastern Kansas Health Care System, *GI Future Consult Concern* October, November 29, 2017.

Eastern Kansas, *GI Review*, October 27, 2017.

Eastern Kansas, *GI Review*, October 30, 2017.

Eastern Kansas, *GI Review*, April 30, 2018.

Eastern Kansas, *Community Care Referrals - May 2017 to May 2018*, May 30, 2018.

Eastern Kansas, *Examination of GI Processes, Findings, and Recommendations*, August 30, 2017.

Eastern Kansas FYs 2017–2018 GI Incident Reports, May 11, 2018.

Eastern Kansas Health System Policy Memorandum, *Moderate Sedation*, July 21, 2015.

Eastern Kansas Health System Policy Memorandum, *Operation of the Post Anesthesia Care Unit (PACU)*, March 31, 2016.

Eastern Kansas Health System Policy Memorandum, *Ordering and Reporting Test Results*, September 12, 2014.

Eastern Kansas Patient Advocate Tracking System, GI inquiries April 2015 - April 2018, May 9, 2018.

Eastern Kansas Power Point Presentation, Monitored Anesthesia Care vs. Moderate Sedation in GI.

Eastern Kansas Productivity Workgroup 2017, July 2, 2017.

Leavenworth GI Scope Appointments, May 9, 2018.

Memorandum from Acting Principal Deputy Under Secretary for Health, *VA Care in the Community (Non-VA Purchased Care) and use of the Veterans Choice Program*, to VISN Directors, October 1, 2015.

Memorandum from Director, Eastern Kansas Health Care System, *Response to CA/VHA/OCT VA OIG Hotline Referral Case 2018-00568-HL-0569/Leavenworth, KS VAMC; RP06*, December 15, 2017.

"Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement, *JAMA*. 2016; 315(23):2564-2575. doi:10.1001/jama.2016.5989 https://www.uspreventiveservicestaskforce.org/Home/GetFile/1/522/rec-statement-colorectal-cancer-final/pdf

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

VHA Directive 1230, *Outpatient Scheduling Processes and Procedures,* July 15, 2016.

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

VHA Issue Brief, Eastern Kansas, *Curtailment of Operations Unplanned Departure for the Topeka GI Physician*, February 27, 2018.

VHA Issue Brief, Eastern Kansas, *Curtailment of GI Operations*, March 27, 2018.

VHA Issue Brief, Eastern Kansas, *Curtailment of GI Operations*, Updated, March 27, 2018.

VHA National Center for Health Promotion and Disease Prevention (NCP)
http://vaww.prevention.va.gov/CPS/Colorectal_Cancer_Screening.asp
Reviewed/Updated February 15, 2018.

VHA Office of Community Care–Standardized Episode of Care, Medical Specialty Care, Screening Colonoscopy.

VHA Surgical Complexity listing of all VHA Facilities
https://vaww.nso1.med.va.gov/vasqip/DUSHOMembeddedPages/complexity.aspx.