DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Management of the Ophthalmology Clinic and Patient Safety Reporting Concerns at the VA Central Iowa Health Care System in Des Moines

HEALTHCARE INSPECTION | REPORT #20-01326-08 | NOVEMBER 3, 2020

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess multiple allegations related to Ophthalmology Clinic management, quality of care, oversight, medication management, and facility leaders' response to concerns at the VA Central Iowa Health Care System (facility) in Des Moines.

On December 10, 2019, the OIG received several allegations about the Ophthalmology Clinic including specific allegations related to a recent ophthalmology residency graduate (subject ophthalmologist) and gained additional clarifications during subsequent interviews:

- Facility leaders hired a new physician right out of residency training to be the Chief of Ophthalmology.
- Ophthalmology residents were not appropriately supervised.
- The quality of cataract surgeries had declined while the number of complications had increased, leading to more patients being sent to community providers to address the complications.
- Cataract surgery outcomes were not reviewed by an oversight group.
- A facility audit report of medications in the outpatient clinic exam rooms revealed concerns with inappropriate storage, labeling, and utilization of those medications.
- Surgery managers and facility leaders were told about complications and other concerns but did not take action.
- Staff were being discouraged from reporting documentation errors, dropped orders, or other facility failures.

During the inspection, the OIG also identified issues with the management and impact of ongoing personnel conflicts within the Ophthalmology Clinic.

The OIG did not substantiate that the facility hired a new physician right out of residency training to be the Chief of Ophthalmology. While Veterans Health Administration (VHA) policy and facility bylaws and rules of the medical staff do not preclude hiring a new graduate into the position of chief of a service, a review of hiring documents confirmed that the subject ophthalmologist was not hired as the Chief of Ophthalmology.

The OIG did not substantiate that there was a lack of appropriate supervision of ophthalmology residents. The subject ophthalmologist served as the site director and supervising practitioner for ophthalmology residents. Residents told the OIG that the subject ophthalmologist closely supervised them in the operating room during cataract surgeries and in the Ophthalmology Clinic. The University of Iowa Ophthalmology Residency Director and the residents interviewed

also commented that the facility ophthalmologists, including the subject ophthalmologist, provided an excellent clinical experience by the level of supervision and training provided.

The OIG did not substantiate that the quality of cataract surgeries decreased while the number of complications increased, leading to more patients being sent to providers in the community to address the complications. Complications can occur during, soon after, or weeks after cataract surgery. The OIG evaluation of 26 patient electronic health records provided by the complainant, presumably because they represented examples of poor care or some other deficit, did not identify quality of care concerns or unexpected complications. The OIG determined that necessary referrals to non-VA community providers were appropriate.

The OIG did not substantiate that cataract surgery outcomes were not reviewed by an oversight group. VHA policy does not require the inclusion of ophthalmology procedures in the data that the Veterans Affairs Surgical Quality Improvement Program monitors and tracks due to unlikely significant morbidities or mortalities. The OIG identified facility quality management activities to monitor and evaluate processes that could capture complication data related to ophthalmology. However, the OIG identified deficits in staff members' knowledge and use of the required patient safety event reporting system.

The OIG substantiated that facility audit report findings identified inappropriate storage and labeling of medications; however, facility leaders took actions to resolve the findings. The OIG did not substantiate that audit report findings included inappropriate medication utilization in Ophthalmology Clinic exam rooms. The OIG was not provided with specific instances or identifiers related to alleged improper medication utilization in Ophthalmology Clinic exam rooms. Additionally, when interviewed, facility staff did not identify any concerns with improper medication utilization, including the use of multi-dose ophthalmic medications.

The OIG did not substantiate that surgery managers and facility leaders were told about complications and other concerns and did not take action. The OIG confirmed that the former Chief of Staff, former acting Chief of Surgery, and Associate Director for Patient Care Services met with the subject ophthalmologist to address the concerns. Additionally, the OIG did not substantiate that staff were discouraged from reporting documentation errors, dropped orders, or other facility failures. However, some of the Patient Safety Manager's comments and instructions to staff could have been interpreted as discouraging this type of reporting.

In general, strong, stable leadership correlates positively with the functional status of an organization. The OIG was told that since July 2018, the facility had three Chiefs of Surgery and two Administrative Officers for Surgical Services. The OIG determined that unstable facility leadership may have contributed to the ill-defined oversight and management structure as well as the eroding culture found in the Ophthalmology Clinic, and had the potential to adversely affect patient care.

The OIG made four recommendations to the Facility Director related to training staff on reporting patient safety events and close calls, entering patient safety events and close calls into the Joint Patient Safety Reporting system, addressing the Ophthalmology Clinic culture, and the oversight and management of the Ophthalmology Clinic.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the findings and recommendation and provided an acceptable action plan (see appendixes A and B). The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

EHR	electronic health record
JPSR	Joint Patient Safety Reporting
OIG	Office of Inspector General
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess multiple allegations related to Ophthalmology Clinic management, quality of care, oversight, medication management, and facility leaders' response to concerns at the VA Central Iowa Health Care System (facility) in Des Moines.

Background

The facility, part of Veterans Integrated Service Network (VISN) 23, provides acute medical and surgical services, residential outpatient treatment programs in substance abuse and posttraumatic stress, mental health and long-term care services, sub-acute and restorative rehabilitation services, and a domiciliary. The Veterans Health Administration (VHA) classifies the facility as a complexity level 1c.[1] From October 1, 2018, through September 30, 2019, the facility served 32,301 patients and had a total of 223 operating beds, including 55 inpatient beds, 60 domiciliary beds, and 108 Community Living Center beds. The facility is affiliated with the University of Iowa College of Medicine, Des Moines Area Medical Education Consortium, Inc., and Des Moines University, and provides numerous internship programs for allied health professionals.

Ophthalmology and Ophthalmologist

Ophthalmology is a medical specialty that deals with the structure, functions, and diseases of the eye.[2] An ophthalmologist is a doctor specializing in the diagnosis and treatment of the eyes and visual systems. An ophthalmologist diagnoses and treats all eye diseases, performs eye surgery, and prescribes and fits eyeglasses and contact lenses to correct vision problems. Ophthalmologists complete at least four years of additional specialized training after medical school. For example, some ophthalmologists specialize and offer treatments in focused areas such as retina, glaucoma, or oculo-plastic surgery.[3]

Ophthalmology is one of the residency programs the facility provides in conjunction with the University of Iowa College of Medicine. Ophthalmology is a surgical specialty and requires

[1] "The Facility Complexity Model classifies VHA facilities at levels 1a, 1b,1c, 2, or 3 with level 1a being the most complex and level 3 being the least complex." A level 1c facility has "medium-high volume, medium risk patients, some complex clinical programs, and medium sized research and teaching programs." VHA Office of Productivity, Efficiency, & Staffing, Facility Complexity Level Model Fact Sheet. (This website was accessed on May 4, 2020.)

[2] Merriam Webster Dictionary, *Definition of ophthalmology*. https://www.merriam-webster.com/dictionary/ophthalmology. (The website was accessed on March 11, 2020.)

[3] American Academy of Ophthalmology®, "What is an Ophthalmologist," January 18, 2019. https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist. (The website was accessed on April 2, 2020.)

hands-on experience to perform more complex eye surgeries, such as cataract extractions. During clinical rotation, the facility is responsible for education of fourth-year ophthalmology residents who have previously completed cataract extractions.[4] In a teaching program, oversight of residents is required by an attending ophthalmologist. Based on the resident's strengths and weaknesses, the attending ophthalmologist determines the resident's level of independence. Ultimately, the training should enhance the resident's skills while addressing deficits. Particularly, fourth-year ophthalmology residents are near completion in their training and the ability to independently perform complex eye surgeries prior to entering practice is paramount.

Allegations

On December 10, 2019, the OIG received several allegations about the Ophthalmology Clinic including specific allegations related to a recent ophthalmology residency graduate (subject ophthalmologist), and gained additional clarifications during subsequent interviews:

- Facility leaders hired a new physician right out of residency training to be the Chief of Ophthalmology.
- Ophthalmology residents were not appropriately supervised.
- The quality of cataract surgeries had declined while the number of complications had increased, leading to more patients being sent to community providers to address the complications.
- Cataract surgery outcomes were not reviewed by an oversight group.
- A facility audit report of medications in the outpatient clinic exam rooms revealed concerns with inappropriate storage, labeling, and utilization of those medications.
- Surgery managers and facility leaders were told about complications and other concerns but did not take action.
- Staff were being discouraged from reporting documentation errors, dropped orders, or other facility failures.

During the inspection, the OIG also identified issues with the management and impact of ongoing personnel conflicts within the Ophthalmology Clinic.

[4] University of Iowa and VA Central Iowa Health Care System Ophthalmology Residency Program Rotation Description. During the third year, these residents rotate through the facility for 10 weeks.

Scope and Methodology

The OIG initiated the inspection in January 2020 and conducted a site visit February 4–6, 2020.

The OIG interviewed the Facility Director, acting and former Chief of Staff, Associate Director for Patient Care Services, former acting and current Chiefs of Surgery, Chief of Quality Management, Care in the Community Nurse Manager, ophthalmology staff, other facility staff who had relevant knowledge about the Ophthalmology Department and processes under review, and the University of Iowa Ophthalmology Residency Director.

The OIG reviewed relevant facility policies and surgical procedures, credentialing and privileging documents, hiring documents, focused and ongoing professional practice evaluations, patient safety reports, surgical volume data, staff emails, and pertinent committee meeting minutes from July 1, 2018, through January 23, 2020. To verify the level of resident supervision in the operating room, the OIG reviewed the Surgical Service Attending Surgeon Cumulative Report from July 1, 2018, through January 27, 2020, which identified 713 ophthalmology cases. The OIG also reviewed the electronic health records (EHRs) of 26 patients with alleged ophthalmology quality of care concerns and complications.

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

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

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, § 7, 92 Stat 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

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

Inspection Results

1. Ophthalmology Chief Position and Resident Supervision

The OIG did not substantiate that facility leaders hired a new physician right out of residency training to be the Chief of Ophthalmology. In addition, the OIG did not substantiate that ophthalmology residents were not appropriately supervised.

Ophthalmology Chief Position

The OIG found that the newly graduated subject ophthalmologist was not hired to be the Chief of Ophthalmology. However, VHA policy and facility bylaws and rules of the medical staff do not preclude hiring a new graduate into the position of chief of a service.[5]

The subject ophthalmologist told the OIG that during the interview for the ophthalmology position, the understanding was that the opening was for the facility's Chief of Ophthalmology position.[6] Approximately one month before the start date, the subject ophthalmologist was told that another ophthalmologist had also been hired and the two new hires would be "co-chiefs."

The former Chief of Staff told the OIG that the subject ophthalmologist may have presumed the position was for the Chief of Ophthalmology but that was not the case. The former Chief of Staff further stated that the subject ophthalmologist was hired as an Ophthalmology Department "co-leader." In addition, the former Chief of Staff stated that the Ophthalmology Service was small and it "just didn't make sense to have a Chief of Ophthalmology."

A review of hiring documents confirmed that the subject ophthalmologist was not hired as the Chief of Ophthalmology and was hired along with another ophthalmologist in July 2018.

Resident Supervision

The OIG found that the subject ophthalmologist served as the site director and supervising practitioner for ophthalmology residents.

VHA policy requires the presence of an attending physician when residents are involved in patient care within the outpatient clinic or procedure room.[7] However, the supervising

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[5] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. Facility Policy, *Bylaws and Rules of the Medical Staff of Veterans Health Administration (VHA) VA Central Iowa Health Care System*, November 28, 2017.

[6] During the review, the OIG noted that in a January 2020 email, the subject ophthalmologist's signature block used "Chief of Ophthalmology."

[7] VHA Handbook 1121.01, *VHA Eye Care*, March 10, 2011. This handbook was in effect for the time frame discussed in this report. The 2011 handbook was rescinded and replaced by VHA Directive 1121, *VHA Eye and Vision Care,* October 2, 2019, amended June 19, 2020. The handbook and the directive contained the same or similar language concerning resident supervision.

ophthalmologist can evaluate "a resident's ability to accept responsibility for performing procedures or activities without" an ophthalmologist present.[8] The residency program director must agree with the decision and the level of independence for procedures "must be based on the resident's clinical experience, judgment, knowledge, and technical skills."

During an interview, the OIG was informed that the subject ophthalmologist was not always available to supervise residents in the clinic when providing patient care. Specifically, the subject ophthalmologist was in the operating room instead of in the clinic with the fourth-year ophthalmology residents.

The subject ophthalmologist had full-time responsibility to instruct ophthalmology residents rotating through the facility. The OIG was told that the subject ophthalmologist was responsible for teaching cataract extractions to ophthalmology residents and was "scrubbed in" the operating room as standard practice. To verify the level of resident supervision in the operating room, the OIG reviewed the Surgical Service Attending Surgeon Cumulative Report from July 1, 2018, through January 27, 2020, which identified 713 surgical cases where the subject ophthalmologist was the attending physician of record including:

- 254 cases as the attending physician doing the surgery;
- 456 cases as the attending physician in the operating room, scrubbed;
- Two cases as the attending physician in the operating room, not scrubbed; and
- One case as the attending physician or resident supervisor, code not entered.

When interviewed, the subject ophthalmologist provided details of resident supervision in the operating room, which included increasing resident understanding of potential complications based on a patient's anatomy and medical history, and providing immediate assistance when a resident needed help during patient care. Residents told the OIG that the subject ophthalmologist was always in the operating room when residents performed cataract surgeries. Further, the subject ophthalmologist, or another attending physician, was present in the Ophthalmology Clinic when residents provided patient care.

The OIG found that ophthalmology residents were very satisfied with the facility's education and training program. The University of Iowa Ophthalmology Residency Director and the residents interviewed also commented that facility ophthalmologists, including the subject ophthalmologist, provided an excellent clinical experience by the level of supervision and training provided.

[8] The OIG team noted several terms used for attending or supervising ophthalmologist. For the purposes of this report, the OIG uses both terms interchangeably.

2. Cataract Surgery Quality and Oversight

The OIG did not substantiate, based on available information, that the quality of cataract surgeries had declined while the number of complications increased leading to more patients being sent to community providers to address the complications. The OIG also did not substantiate that cataract surgery outcomes were not reviewed by an oversight group. Although the facility had patient safety reporting processes in place, the OIG found deficits in ophthalmology staff members' knowledge and use of the patient safety event reporting system.

VHA facilities completed over 79,000 ophthalmology surgical procedures in fiscal year 2018 with the majority being cataract surgeries. According to professional literature, cataracts are more common in older patients with "approximately half of all Americans" having some degree of cataracts by age 75.[9] Complications following cataract surgery are uncommon but can include inflammation, infection, bleeding, swelling, and loss of vision.[10]

Cataract Surgery Quality

The OIG found no evidence that the quality of cataract surgeries had declined and complications had increased during a time that coincided with the facility's hiring of the subject ophthalmologist and another ophthalmologist.

For a variety of reasons, a broad retrospective review of cataract surgeries and potentially associated complications would be difficult to perform and unlikely to yield definitive results. For example, complications can occur during, soon after, or weeks after cataract surgery.[11] Further, none of the Ophthalmology Clinic staff interviewed expressed concern about the quality of care delivered by the subject ophthalmologist or about the appropriateness of community care referrals.

For the reasons listed above, the OIG focused on evaluating the quality of care and complications (if any) in the 26 patient cases provided by the complainant, which presumably were provided because they represented examples of poor care or some other deficit. The patient cases included 21 cataract surgeries, two injections, one laser procedure, one patient who decided not to have surgery, and one patient who required ophthalmology interventions not provided by the facility.[12]

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[9] American Academy of Ophthalmology, *Eye Health Statistics*. https://www.aao.org/newsroom/eye-health-statistics. (The website was accessed on April 1, 2020.)

[10] Mayo Clinic, *Cataract Surgery Risks.* https://www.mayoclinic.org/tests-procedures/cataract-surgery/about/pac-20384765. (The website was accessed on May 18, 2020.)

[11] Yu-Chi Liu, Mark Wilkins, Terry Kim, Boris Malyugin, Jodhbir S Mehta, "Cataracts", *Lancet*, 390 (August 5, 2017):600-12.

[12] One of the two patients who did not receive surgical intervention decided not to schedule their second cataract surgery because the cataract was not bothering them. The second patient had an eye injury, was seen in the Emergency Department over a weekend, and by an ophthalmologist in the eye clinic the following Monday. The ophthalmologist sent the patient to a community retina clinic for treatment.

Three different facility ophthalmologists, including the subject ophthalmologist, provided care for these 26 patients.

The OIG evaluated the 26 EHRs for the ophthalmologists' plan of care for each patient's condition, whether complications were addressed timely, whether follow up was completed at intervals commensurate with a patient's condition, and whether subspecialists were consulted when needed. The OIG did not identify quality of care concerns or unexpected complications, including the patients cared for by the subject ophthalmologist. Further, the OIG found that, when complications occurred, they were recognized complications for the types of eye surgeries completed, and providers managed those cases appropriately through a combination of close monitoring, medical and surgical intervention at the facility, or referral to a subspecialist, such as a community retina-related expert. Based on the results of the 26 EHR reviews, the OIG did not conduct a larger retrospective review of quality of care.

Based on interviews, the OIG did not find evidence of quality of care deficits resulting in increased complications and referrals to community providers to correct the complications. However, the Chief of Surgery reported an approximately 165 percent increase in the volume of ophthalmological surgical procedures performed at the facility when comparing July 1, 2016, to January 23, 2018, with July 1, 2018, to January 23, 2020. For this reason, the OIG determined that it is reasonable to assume a proportional increase in complications. Further, the OIG determined that if referral patterns for community care due to the need for outside expertise, equipment, or other factors stayed consistent, there would likely be an increase in the number of consults sent to the community across all procedure types.[13] The OIG did not find that an increase in community referrals reported by the Care in the Community Nurse Manager was problematic.

The OIG found no evidence that the quality of cataract surgeries declined and complications increased during a time that coincided with the facility's hiring of the subject ophthalmologist and another ophthalmologist.

Oversight

The OIG identified facility quality management activities that monitored and evaluated processes and were designed to capture complication and patient safety data related to ophthalmology. However, the OIG identified deficits in staff members' knowledge and use of the required patient safety event reporting system.

VHA policy does not require the inclusion of ophthalmology procedures in the data that the Veterans Affairs Surgical Quality Improvement Program monitors and tracks due to unlikely significant morbidities or mortalities. However, VHA does require the facility to conduct routine

[13] The OIG was told that since the facility did not have a full-time retina specialist, facility ophthalmologists utilized a community retina group for retina-related expertise leading to patients receiving care in the community.

reviews of clinical care to evaluate reported quality of care and provider performance concerns.[14] These review processes include ongoing professional practice evaluations and focused professional practice evaluations, Surgical Work Group, including morbidity and mortality review, peer review for quality management, and patient safety-related activities.[15]

The OIG determined that the facility followed VHA policy to exclude ophthalmology procedures from the Veterans Affairs Surgical Quality Improvement Program monitoring and tracking, which could have led to the complainant's perception that the facility was remiss in monitoring ophthalmology procedure outcomes.[16]

The OIG reviewed the facility ophthalmologists' ongoing professional practice evaluations, Surgical Work Group meeting minutes from July 2018 through December 2019, and peer review meeting minutes where the ophthalmology or optometry peer reviews were discussed, and determined that oversight was conducted.

Further, after the February 2020 on-site visit, the OIG received information that facility leaders conducted further oversight relating to quality of care.

Patient Safety Event Reporting System

While the facility had patient safety processes in place, the OIG identified deficits in ophthalmology staff members' knowledge and use of the facility's patient safety event reporting system. These deficits may have negatively affected the reporting and review of patient safety reported events for quality of care or patient safety events requiring additional review.

Patient safety includes an evaluation of contributing factors, associated actions, and outcome measures to mitigate recurring events within the facility. VHA policy establishes procedures for reporting, analyzing, and addressing patient safety events, which include quality of care concerns, and instructs facility staff to report any unsafe conditions, including patient safety

[14] VHA Handbook 1121.01. This handbook was in effect for the time frame discussed in this report. The handbook was rescinded and replaced by VHA Directive 1121. The handbook and the directive contained the same or similar language concerning ophthalmology care.

[15] VHA Handbook 1100.19, *Credentialing and Privileging*, October 15, 2012. VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018. VHA Handbook 1050.01, VHA *National Patient Safety Improvement Handbook,* March 4, 2011. VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013. This handbook was in effect for a portion of the time frame of the events discussed in this report and was rescinded and replaced by VHA Directive 1102.01 (1), *National Surgery Office*, April 24, 2019, amended May 22, 2019. Both the handbook and the directive have same or similar language related to review of quality of care and patient safety.

[16] The Veterans Affairs Surgical Quality Improvement Program database "is a quality assurance activity-derived database containing information on all patients who undergo surgery within the VA." https://catalog.data.gov/dataset/veterans-affairs-surgical-quality-improvement-program-vasqip. July 2, 2019. (The website was accessed on June 4, 2020.)

events and close calls, to the Patient Safety Manager.[17] The Joint Patient Safety Reporting (JPSR) system is VHA's authorized enterprise-wide electronic patient safety reporting system. In addition to the authorized JPSR system, facility leaders continued use of a previously created SharePoint-based reporting tool.[18] The use of two patient safety reporting systems caused staff confusion since both systems allowed staff to report patient safety or other concerns.

The OIG found that Ophthalmology Clinic staff members did not consistently use the JPSR or the SharePoint-based systems to document and report actual or potential incidents, and some staff appeared unsure of the facility's expectations for reporting patient safety concerns.[19] The OIG found three ophthalmology-related JPSRs from July 2018 through January 22, 2020, one of which was submitted for further review outside of patient safety. The Patient Safety Manager told the OIG that an unreasonable volume of JPSRs had been submitted for review when considering the patient volume of the Ophthalmology Clinic and the number of procedures performed. In addition, the OIG learned that JPSRs were being improperly used as a mechanism to lodge employees' complaints.

The Patient Safety Manager, who is responsible for patient safety activities at the facility, told the OIG that facility staff are expected to attend JPSR training during orientation and annually thereafter, with refresher training provided upon staff request. The OIG determined through interviews with ophthalmology staff that staff were unaware of their responsibilities to report patient safety concerns using the JPSR process. The Patient Safety Manager also stated that JPSR training was the "ultimate responsibility" of the service line. Further, the Patient Safety Manager explained that staff should take patient safety concerns to their supervisors to resolve, that there are multiple options for reporting safety concerns, and that the use of JPSR is not "overly impactful."

The OIG would have expected the Patient Safety Manager to ensure facility staff, including ophthalmology, had knowledge of the patient safety reporting process and would have acted on the low volume of reported ophthalmology patient safety events. The OIG learned through an interview that the Patient Safety Manager did not make efforts to champion patient safety-related incident reporting in the Ophthalmology Clinic.

In summary, Ophthalmology Clinic staff did not consistently follow VHA policy to report patient safety events and quality of care concerns. The OIG determined that facility leaders were

[17] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. The JPSR system is a web-based electronic system that standardizes data management on medical errors and near misses for Department of Defense and Veterans Health Administration systems. VHA National Center for Patient Safety. http://vaww.ncps.med.va.gov/tools.html. (The website was accessed on April 26, 2020.)

[18] SharePoint is a customizable internet tool used to share and manage information that relates broadly to an organization as a whole and to specific teams or projects.

[19] *See Something Say Something* is a SharePoint-based reporting tool that was created locally in 2012 to simplify reporting for staff.

unable to track, respond to, and take actions related to reported patient safety events due to the Patient Safety Manager and Service Line Leaders not ensuring the use of the authorized JPSR system.

3. Ophthalmology Clinic Medication Management

The OIG substantiated that facility audit report findings identified inappropriate storage and labeling of medications; however, facility leaders took actions to resolve the findings. The OIG did not substantiate that audit report findings included inappropriate medication utilization in Ophthalmology Clinic exam rooms.

Audits refer to a variety of in-person inspections including environment of care rounds and other inspections by facility staff. VHA policy provides guidance on appropriate storage and labeling of medications. Specifically, medications used in a clinic must be securely stored with access limited to authorized staff. Further, the policy allows for the use of multi-dose ophthalmic medication drops. However, the bottles must be clearly labeled by staff with an expiration date no later than 28 days from the date of opening.[20] Multi-dose ophthalmic medications, such as eye drops used to dilate the eye, are commonly used during an Ophthalmology Clinic visit.[21]

The OIG was told that Ophthalmology Clinic staff stored multi-dose ophthalmic medication drops in securable medication boxes or drawers in patient care areas. The OIG confirmed through interviews and a review of documents and emails that facility staff performed audits and other reviews that included securable medication boxes in the Ophthalmology Clinic. The audits and other reviews found instances of expired, unlabeled, or inappropriately stored ophthalmic medications. The OIG found similar discrepancies during a tour of the Ophthalmology Clinic.[22]

The OIG reviewed emails between Ophthalmology Clinic and pharmacy staff that addressed the repeat findings associated with expired, unlabeled, or inappropriately stored medications. An Ophthalmology Clinic staff member's email indicated that clinic staff were not intentionally disregarding policy but compliance was challenging due to the volume of appointments and the flow of patients and staff in the clinic.[23] In response, a pharmacy staff member offered to work with the Ophthalmology Clinic to support the appropriate labeling of multi-dose ophthalmic medication drops by supplying "expiration date labels" so that Ophthalmology Clinic staff had them available.

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[20] VHA Directive 1108.06, *Inpatient Pharmacy Services*, February 8, 2017.

[21] University of Florida, Department of Ophthalmology, *What to expect at your appointment for Adults*. https://eye.ufl.edu/patient-care/what-to-expect-at-your-appointment (The website was accessed on April 29, 2020.)

[22] Medications were determined to be expired if the date written on the bottle was prior to the date of the OIG inspection. This means that Ophthalmology Clinic staff opened the medication and wrote an expiration date per policy but failed to discard the medication on or prior to the date written on the label.

[23] In the email the staff member notes "limited resources and space," poor "clinic flow," and the need for multiple staff members to frequently move between patients and clinic rooms.

According to the Chief of Pharmacy, facility leaders were aware of plans by pharmacy staff to conduct monthly Ophthalmology Clinic audits to assess medication labeling and storage, and the first audit conducted in March 2020 did not identify issues. After six months, the need for the pharmacy audits will be reevaluated. If the audits do not have continued findings, pharmacy staff will discontinue their audits and will expect Ophthalmology Clinic staff to maintain compliance with VHA policy.

The OIG was not provided with specific instances or identifiers related to alleged improper medication utilization. The OIG found that two of the six ophthalmology-related patient safety event reports submitted to the facility's Patient Safety Manager between January 1, 2018–January 22, 2020, were medication utilization issues. However, the two patient safety reports occurred before the hiring date of the subject ophthalmologist. Additionally, when interviewed, facility staff did not report concerns with improper medication utilization, including the use of multi-dose ophthalmic medications.

4. Leaders' Response and Reporting Ophthalmology Clinic Concerns

The OIG did not substantiate that surgery managers and facility leaders were told about complications and other concerns but did not take action. Additionally, although the OIG did not substantiate that staff were discouraged from reporting documentation errors, dropped orders, or other facility failures, some of the Patient Safety Manager's comments and instructions to staff could have been interpreted as discouraging this type of reporting.

Leaders' Response

The OIG reviewed emails and interviewed staff to evaluate the details of information presented to nurse managers and facility leaders related to the subject ophthalmologist's surgical complications and concerns about ophthalmology system failures, documentation errors, and dropped orders. The OIG confirmed that the former Chief of Staff, former acting Chief of Surgery, and Associate Director for Patient Care Services met with the subject ophthalmologist to address the concerns.

Staff did not support concerns that the Ophthalmology Clinic's practices negatively affected patient care. The OIG interviewed facility managers and staff who stated that they had no concerns regarding the subject ophthalmologist's quality of care.

Reporting Concerns

As noted above, the OIG determined in interviews with the Patient Safety Manager and Ophthalmology Clinic staff that the JPSR process was not valued, there was confusion on which safety reporting process was acceptable, and staff were encouraged to resolve patient safety concerns at the clinic level.

Based on an interview, the OIG determined that the Patient Safety Manager was not proactive in offering remedial training to Ophthalmology Clinic staff to ensure they understood the JPSR system or its impact on patient safety in the Ophthalmology Clinic because staff were encouraged to resolve patient safety concerns at the clinic level.

5. Ophthalmology Clinic Culture

During the course of the inspection, the OIG determined that leaders at multiple levels had difficulty managing the impact of interpersonal conflicts in the Ophthalmology Clinic that adversely affected the culture of the clinic. Staff told the OIG that this conflict created a tense, uncomfortable work environment. The Joint Commission requires that facility leaders maintain a culture of safety and quality because "disruptive behavior that intimidates others and affects morale or staff turnover can be harmful to patient care."[24]

The departure of the former ophthalmologist in 2018 coincided with the addition of two ophthalmologists, one being the subject ophthalmologist. The transition led to changes in staff responsibilities and clinic processes. Prior to 2018, the OIG was told that ophthalmology technicians had performed a variety of clinical and administrative duties. As the subject ophthalmologist took over clinical duties, the technicians' roles and responsibilities were modified. The OIG learned through interviews that the changes caused frustration, concern, and mistrust in the subject ophthalmologist for some of the technicians. The OIG determined that staff conflicts increased over the next 19 months.

Because facility leaders were aware of the interpersonal issues within the Ophthalmology Clinic, they met with staff on more than one occasion to discuss conduct, professionalism, and expectations. Through interviews, the OIG determined that although facility leaders had taken action, the culture in the clinic continued to decline.

In general, strong, stable leadership correlates positively with the functional status of an organization.[25] The subject ophthalmologist told the OIG that since July 2018, there were three Chiefs of Surgery and two Administrative Officers for Surgical Services. Clinical staff told the OIG that Ophthalmology Clinic staff reported to the Administrative Officer for Surgical Services

[24] Governance Institute. *Leadership in Healthcare Organizations*. San Diego, California, page 20, Winter 2009. Available from: The Joint Commission: https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/wp_leadership_standardspdf.pdf?db=web&hash=86F0223A5C016F833DA3DDB1C62F5D20. (The website was accessed on February 26, 2020.) The Joint Commission Standard LD 03.01.01 "Leaders create a culture of safety and quality throughout hospital." Schyve, Paul M, MD.

[25] Governance Institute. *Leadership in Healthcare Organizations*. San Diego, California, Winter 2009. Available from: The Joint Commission: https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/wp_leadership_standardspdf.pdf?db=web&hash=86F0223A5C016F833DA3DDB1C62F5D20. (The website was accessed on February 25, 2020.)

(now retired). The ophthalmology technicians previously reported to the Administrative Officer for Surgical Services but were aligned under Nursing Service in May 2019.

The OIG was told that ophthalmologists reported to the Chief of Surgery, as there was no Chief of Ophthalmology at the facility. When questioned during interviews, staff had conflicting ideas about the oversight and management structure of the Ophthalmology Clinic.

The fact that optometrists and ophthalmology technicians were reporting to a non-clinical administrative officer was concerning as a lack of clinical knowledge has the potential to adversely affect the quality of care provided to patients. In addition, the OIG determined that unstable facility leadership, such as the Chief of Surgery position, may have contributed to the ill-defined oversight and management structure as well as the eroding culture found in the Ophthalmology Clinic and had the potential to adversely affect patient care.

Conclusion

The OIG did not substantiate that the facility hired a new physician right out of residency as the Chief of Ophthalmology. While VHA policy and facility bylaws and rules of the medical staff do not preclude hiring a new graduate into the position of chief of a service, a review of hiring documents confirmed that the subject ophthalmologist was not hired as the Chief of Ophthalmology.

The OIG did not substantiate that there was a lack of appropriate supervision of ophthalmology residents. The subject ophthalmologist serves as the site director and supervising practitioner for ophthalmology residents. During interviews, the OIG learned the subject ophthalmologist closely supervised residents in the operating room during cataract surgeries and in the Ophthalmology Clinic. The University of Iowa Ophthalmology Residency Director and the residents interviewed also commented that the facility ophthalmologists, including the subject ophthalmologist, provided an excellent clinical experience by the level of supervision and training provided.

The OIG did not substantiate that the quality of cataract surgeries decreased while the number of complications increased, leading to more patients being sent to providers in the community to address the complications. Complications can occur during, soon after, or weeks after cataract surgery. The OIG evaluated 26 EHRs and determined that surgical care, follow up, and management of the patients including necessary referrals to non-VA community providers was appropriate.

The OIG did not substantiate that cataract surgery outcomes were not reviewed by an oversight group. The facility's quality management activities monitored and evaluated processes that could capture complication data related to ophthalmology. However, the OIG determined that Ophthalmology Clinic staff did not consistently follow VHA policy to report patient safety events and quality of care concerns affecting facility leaders' ability to track, respond to, and take action. The OIG determined that the facility should ensure that Ophthalmology Clinic staff

are trained on and report using the patient safety event reporting system as required by VHA policy.

Facility audit report findings identified inappropriate storage and labeling of medications; however, facility leaders took actions to resolve the findings. Facility leaders were aware of the plans for pharmacy staff to conduct monthly Ophthalmology Clinic audits to assess medication labeling and storage. The OIG did not substantiate that audit report findings included inappropriate medication utilization in Ophthalmology Clinic exam rooms. The OIG was not provided with specific instances, and facility staff did not identify medication utilization concerns.

The OIG did not substantiate that surgery managers and facility leaders were told about complications and other concerns but did not take action. Additionally, although the OIG did not substantiate that staff were discouraged from reporting documentation errors, dropped orders, or other facility failures, some of the Patient Safety Manager's comments and instructions to staff could have been interpreted as discouraging this type of reporting.

Unstable leadership may have contributed to the ill-defined oversight and management structure found in the Ophthalmology Clinic. The OIG found that staff had conflicting ideas about the oversight and management structure of the Ophthalmology Clinic.

Facility leaders were aware of the eroding culture in the Ophthalmology Clinic. The OIG determined that unstable facility leadership, such as the Chief of Surgery position, may have contributed to the ill-defined oversight and management structure as well as the eroding culture found in the Ophthalmology Clinic, and had the potential to adversely affect patient care. The OIG determined that although facility leaders had taken action, the culture in the clinic continued to decline.

Recommendations 1–4

1. The VA Central Iowa Health Care System Director ensures Ophthalmology Clinic staff are trained on how to identify, analyze, and report patient safety events and close calls.
2. The VA Central Iowa Health Care System Director ensures that patient safety events and close calls are entered into the Joint Patient Safety Reporting system, and monitors for compliance.
3. The VA Central Iowa Health Care System Director develops an action plan to address the culture within the Ophthalmology Clinic and monitors effectiveness.
4. The VA Central Iowa Health Care System Director reviews the oversight and management of the Ophthalmology Clinic, makes recommendations for improvement, and monitors effectiveness.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 2, 2020

From: Executive Director, VA Midwest Health Care Network (10N23)

Subj: Healthcare Inspection—Management of Ophthalmology Clinic and Patient Safety Reporting Concerns at the VA Central Iowa Health Care System in Des Moines

To: Director, Rapid Response Team, Office of Healthcare Inspections (54RR00)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed and concur with the findings and recommendations in the OIG DRAFT report Healthcare Inspection-Management of Ophthalmology Clinic and Patient Safety Reporting Concerns at the VA Central Iowa Health Care System in Des Moines.

(*Original signed by*:)

Robert P. McDivitt, FACHE
Executive Director
VA Midwest Healthcare Network (VISN 23)

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 2, 2020

From: Director, VA Central Iowa Health Care System (636A6)

Subj: Healthcare Inspection—Management of Ophthalmology Clinic and Patient Safety Reporting Concerns at the VA Central Iowa Health Care System in Des Moines

To: Director, VA Midwest Health Care Network (10N23)

Please see attached the response for the draft report Healthcare Inspection-Management of the Ophthalmology Clinic and Patient Safety Reporting Concerns of VA Central Iowa HCS, Des Moines, IA

(*Original signed by*:)

Gail L. Graham
Director

Facility Director Response

Recommendation 1

The VA Central Iowa Health Care System Director ensures Ophthalmology Clinic staff are trained on how to identify, analyze, and report patient safety events and close calls.

Concur.

Target date for completion: September 15, 2020

Director Comments

All Ophthalmology Clinic staff have completed Talent Management System (TMS) training titled "Reporting Patient Safety Events and Accidents." This training was followed up with additional discussion, including guidance to notify appropriate physician and their supervisor for all patient safety related concerns, i.e. patient safety events and near misses (close calls). In addition, a JPSR job aid was posted near the clinic's huddle board.

OIG Comment

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

Recommendation 2

The VA Central Iowa Health Care System Director ensures that patient safety events and close calls are entered into the Joint Patient Safety Reporting system, and monitors for compliance.

Concur.

Target date for completion: April 1, 2021

Director Comments

The Patient Safety Manager (PSM) will participate in Ophthalmology morning huddles bi-weekly fiscal year (FY) 21 quarter (Q) 1 and Q2 to ensure patient safety events and close calls are entered into JPSR. The PSM will send a daily report, which lists all JPSR submissions, to the Director, Chief of Staff, Nurse Executive, Associate Director, and the Chief and Administrative Officer of Quality & Safety. The PSM will track and notify assigned Handlers of individual JPSR reports on a weekly basis for the previous seven days to ensure appropriate follow up investigation and required documentation is completed. The PSM will provide a monthly Patient Safety Program briefing at the Quality, Safety, and Value Council meeting, which is co-chaired by the Director, to monitor reporting and compliance.

Recommendation 3

The VA Central Iowa Health Care System Director develops an action plan to address the culture within the Ophthalmology Clinic and monitors effectiveness.

Concur.

Target date for completion: April 1, 2021

Director Comments

Functional Statements for each position/staff member in the Ophthalmology Clinic have been reviewed to ensure the proper alignment of duties. All staff were also provided "Expectations of Work Behaviors" and the Code of Conduct policy. One on one reviews of expectations between supervisor and staff members will occur on an ongoing basis during the mid-year performance review cycle. The Director will meet with the Chief of Surgical Services—FY21 Q1 and Q2 to monitor effectiveness of actions taken to improve culture.

Recommendation 4

The VA Central Iowa Health Care System Director reviews the oversight and management of the Ophthalmology Clinic, makes recommendations for improvement, and monitors effectiveness.

Concur.

Target date for completion: April 1, 2021

Director Comments

Daily huddles occur and are attended by all available staff. Opportunities for improvement are identified during this meeting and followed through to completion. Challenges, concerns, and requests for assistance are identified and discussed during first level huddles and are then elevated to supervisory and/or Quad level huddles, as needed. In addition, a Board of Daily Workflow is utilized and monitored each day to ensure and enhance communication with all staff. Clinic operations are reviewed by rotating health technicians weekly to ensure schedules are completed and utilized. Nurse Manager and Clinical Resource Nurse conduct daily rounding. The clinic Nurse Manager and Chief Nurse are involved in biweekly meetings with Surgical Service administration to discuss all clinical issues. The Director will meet with the Chief of Surgical Services—FY21 Q1 and Q2 to monitor effectiveness of oversight and management of the Ophthalmology Clinic.

Glossary

cataract. A clouding of the normally clear lens of the eye.[26]

focused professional practice evaluation. "A time-limited period during which the medical staff leadership evaluates and determines the practitioner's professional performance." The focused professional practice evaluation usually occurs when a provider first begins practicing at a VA medical center.[27]

glaucoma. A condition of the eye that causes increased pressure in the eye and can result in damage to structures responsible for sight.[28]

morbidity and mortality reviews. "Discussions among clinicians of the care provided to individual patients who died or experienced complications."[29]

oculo-plastic surgery. Plastic surgery of the eye and structures around the eye.[30]

ongoing professional practice evaluation. The regular monitoring of a providers practice allowing the VHA facility to identify practice trends that affect the quality of care and patient safety. This data must be reviewed on a regular basis by leaders at the VA medical center.[31]

ophthalmologist. A physician "who specializes in eye and vision care."[32]

ophthalmology. A specialty in medicine that addresses the anatomy, pathology, and functions of the eyes.[33]

peer review for quality management. A critical review to determine whether the clinical decisions and actions of a clinician during a specific clinical encounter met the standard of care.[34]

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[26] Merriam Webster Dictionary, *Definition of Cataract*. https://www.merriam-webster.com/dictionary/cataract. (The website was accessed on May 6, 2020.)

[27] VHA Handbook 1100.19. *Credentialing and Privileging*, October 15, 2012.

[28] Merriam Webster Dictionary, *Definition of glaucoma*. https://www.merriam-webster.com/dictionary/glaucoma. (The website was accessed on April 6, 2020.)

[29] VHA Directive 1320, *Quality Management And Patient Safety Activities That Can Generate Confidential Records And Documents*, July 10, 2020. This reference is out of the date range of the report; however, is only being used as a definition and does not determine a finding or recommendation.

[30] Merriam Webster Dictionary, *Definition of oculoplastic*. https://www.merriam-webster.com/medical/oculoplastic.(The website was accessed on April 6, 2020.)

[31] VHA Handbook 1100.19. *Credentialing and Privileging*, October 15, 2012.

[32] American Academy of Ophthalmology®, *What is an Ophthalmologist?* https://www.aao.org/eye-health/tips-prevention/what-is-ophthalmologist. (This website was accessed on July 17, 2020.)

[33] Merriam Webster Dictionary, *Definition of ophthalmology*. https://www.merriam-webster.com/dictionary/ophthalmology. (The website was accessed on March 11, 2019.)

[34] VHA Directive 1190, *Peer Review For Quality Management*, November 21, 2018.

retina. The portion of the eye responsible for converting light into nerve signals that can be interpreted by the brain to produce sight.[35]

Surgical Work Group. Responsible for oversight and policy for the surgery programs at the facility. The Surgical Work Group oversee surgical outcome data, review surgical deaths, and work to improve practice and patient safety.[36]

[35] Merriam Webster Dictionary, *Definition of retina*. https://www.merriam-webster.com/dictionary/retina. (The website was accessed on April 6, 2020.)

[36] VHA Directive 1102.01(1), *National Surgery Office*, April 24, 2019, amended May 22, 2019.

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