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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Ophthalmology Equipment and Related Concerns at the James A. Haley Veterans' Hospital

Tampa, Florida

HEALTHCARE INSPECTION | REPORT #19-07095-253 | NOVEMBER 7, 2019

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess a number of allegations involving ophthalmology equipment-related maintenance and repair issues and other concerns at the James A. Haley Veterans' Hospital (facility) in Tampa, Florida. Specifically, it was alleged software updates had not been completed; preventive maintenance had not been done; equipment was not repaired; work orders for repairs were not addressed in a timely manner; procedures were canceled due to equipment failures; productivity decreased in the Eye Clinic resulting in increased consults in the community; patients had to wait four to six weeks for eyeglasses; and facility leaders had not responded satisfactorily to complaints for at least 15 years.

Ophthalmology equipment is often expensive and delicate, and maintenance and repair actions require detailed precision. Veterans Health Administration (VHA) requires all medical facilities to follow manufacturers' recommended procedures for medical equipment preventive maintenance and has established timeliness standards for completing preventive maintenance based on the frequency of the required maintenance. The facility has a Medical Equipment Management Program (MEMP) to ensure operational reliability, assess and minimize risks, and respond to failures of medical equipment systems that support the patient care environment. In VHA facilities, equipment maintenance activities, including preventive maintenance, are the responsibility of the Biomedical Section.

The OIG did not substantiate allegations related to four specific pieces of ophthalmology equipment referenced by the complainant. The team found that the potentially outdated high-resolution camera software did not affect the accuracy of measurements or that patients were placed at risk for incorrect lens implants. The OIG found no evidence that the facility's optical coherence tomography (OCT) equipment was nonfunctional for an extended period such that patient injections were delayed or care was otherwise compromised. Preventive maintenance was performed on the high-resolution camera, OCT equipment, ophthalmic cryosurgery system, and the ophthalmic microscope according to the manufacturers' recommendations and the facility's MEMP plan. The team did not identify, nor was the team told about, adverse patient outcomes.

The OIG did not substantiate that the Biomedical Section had not conducted preventive maintenance on ophthalmology equipment. The OIG team learned that preventive maintenance requirements had changed over time and Eye Clinic staff were not always familiar with the maintenance strategy being employed. The Biomedical Section managed ophthalmology-related equipment and repairs in accordance with facility protocols and manufacturers' instructions.

The OIG did not substantiate that Biomedical Section staff were unable to provide service logs verifying preventive maintenance, or that they could not explain the lack of preventive

maintenance stickers on equipment. New preventive maintenance stickers were in use; however, clinical staff had not been formally notified of the new process.

The OIG team did not substantiate that Biomedical Section staff were routinely unable to repair equipment. If unable to complete the required repairs in-house, a purchase order was requested such that repairs could be completed through other avenues. The team found no evidence that biomedical support specialists lacked competencies to perform their assigned tasks.

The OIG was unable to determine whether Eye Clinic work orders took a week before Biomedical Section staff would call the manufacturer for maintenance. Incomplete work order documentation precluded the OIG from fully evaluating the timing of in-house repairs or tracking parts requests and referrals to vendors.

The OIG was unable to determine whether Eye Clinic procedures were canceled due to equipment issues. Available documentation did not include the reason a community referral was made rather than providing the service in the facility's Eye Clinic. A variety of factors could have resulted in a community care referral, not just equipment failure.

The OIG substantiated an increase in eye care-related community care consults; however, the increased volume of community care referrals was largely the result of changes in access to ambulatory surgery services and in Eye Clinic scheduling practices (not equipment failure). The team did not substantiate that Eye Clinic equipment issues resulted in over 1,000 patients waiting for (eye-related) community care consults to be scheduled.

The OIG substantiated that Prosthetic and Sensory Aids Service (PSAS) took four to six weeks to issue a purchase order to the optical shop vendor, resulting in patients waiting six to eight weeks for eyeglasses. The two facility purchasing agents designated to process purchase orders for eyeglasses retired. Two purchasing agents were subsequently hired to fill the positions.

The OIG was unable to determine if facility leaders had not responded satisfactorily to complaints for at least 15 years. The team did not interview previous facility leaders going back that far, and the adequacy of leadership responsiveness was subjective. However, OIG found that facility leaders made management decisions in consideration of financial priorities and the availability of an alternate means to address preventive maintenance and repairs, which excluded preventive maintenance contracts. Communication between Eye Clinic and Biomedical Section staff was not consistently effective or collaborative. Efforts were underway to improve communication and resolve the most pressing ophthalmology equipment concerns. These efforts included development of a third-party routine maintenance agreement for select pieces of equipment and increased Biomedical Section support specialist staffing to meet the demand for preventive maintenance and work order requests.

The OIG made four recommendations related to Biomedical Section staff work order documentation; equipment corrective maintenance timeliness and communication; timeliness of eyeglass purchase order processing; and resolution of the open eyeglass purchase order requests.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A and B, pages 24–28). The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

CBOC	community based outpatient clinic
EOC	environment of care
MEMP	Medical Equipment Management Program
OCT	optical coherence tomography
OIG	Office of Inspector General
PSAS	Prosthetic and Sensory Aids Service
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted an inspection to assess allegations involving ophthalmology equipment-related maintenance and repair issues and other concerns at the James A. Haley Veterans' Hospital (facility) in Tampa, Florida.

Background

The facility provides comprehensive services including medical, surgical, and mental health care, and is classified as Level 1a—High Complexity.[1] From October 1, 2017, through September 30, 2018, the facility had 499 beds and served more than 97,000 patients.[2] The facility, part of Veterans Integrated Service Network (VISN) 8, consists of the main hospital in Tampa, and community based outpatient clinics (CBOCs) in New Port Richey, Zephyrhills, Lakeland, and Brooksville, Florida.

Eye Care

Ophthalmology is a branch of medicine dealing with the structure, functions, and diseases of the eye. Ophthalmologists are physicians who diagnose and treat eye diseases and perform eye surgery. Optometrists are health care providers who examine, diagnose, and manage visual changes in the eye. Ophthalmologists and optometrists use a variety of sophisticated, sensitive equipment to evaluate and treat eye conditions. For example, cameras with high-powered lenses capture images of the eye, and optical coherence tomography (OCT), an imaging test, helps with the diagnosis and treatment of glaucoma, age-related macular degeneration, and diabetic eye disease. Ophthalmology equipment is often expensive and delicate, and maintenance and repair actions require detailed precision.[3]

Medical Equipment Management Program

The facility's Medical Equipment Management Program (MEMP) is "designed to ensure the operational reliability, assess and minimize the special risks, and respond to failures of medical

[1] Veterans Health Administration's Facility Complexity Model categorizes medical facilities based on patient population, clinical services offered, educational and research missions, and administrative complexity. Complexity Levels include 1a, 1b, 1c, 2, or 3, with Level 1a facilities being the most complex and Level 3 facilities being the least complex.

[2] The facility had 402 inpatient hospital beds, 33 domiciliary beds, and 64 Community Living Center beds.

[3] DS Walia, Jane Huria, and Ismael Cordero, "Equipment Maintenance and Repair," *Community Eye Health*, Vol. 23 no. 73 (September 2010): 26-29. https://www.cehjournal.org/article/equipment-maintenance-and-repair/. (The website was accessed on May 31, 2019.)

equipment systems that support the patient care environment." The biomedical engineering section (Biomedical Section) of the Facilities Management Service is required to identify equipment to be included in the MEMP based on several factors including inherent risk to patients, visitors, or employees; equipment function, clinical application, and maintenance requirements; and incident history.[4] Facilities Management Service is required to develop operational plans, policies, and procedures for the testing, inspection, and maintenance of equipment in the program. Veterans Health Administration (VHA) requires all medical facilities to follow manufacturers' recommended procedures for medical equipment preventive maintenance and has established timeliness standards for completing preventive maintenance based on the frequency of the required maintenance.[5] Maintenance strategies used by the facility included

- Predictive maintenance, which is designed to measure and track data significant to the piece of equipment so that specific repairs are completed before the equipment fails;
- Metered maintenance, which is based on the number of hours of run time, the number of times the equipment is used, or the number of images processed;
- Corrective maintenance, which restores a piece of equipment to operational status after equipment failure; and
- Interval- or calendar-based maintenance, which is completed at specific intervals. (End users tend to be most familiar with this traditional type of preventive maintenance as it occurs on a regular schedule that is easily followed and understood.)

Biomedical Section Staffing

In VHA facilities, equipment maintenance activities, including preventive maintenance, are the responsibility of the Biomedical Section. The supervisory biomedical engineer is responsible for financial management of budget resources supporting quality assurance and maintenance activities to ensure that the facility medical equipment inventory is available for patient care activities.[6] Biomedical equipment support specialists, also called technicians, install, maintain, safety test, calibrate, troubleshoot, and support medical technologies such as endoscopic systems, dental imaging, and clinical laboratory equipment. Biomedical engineering support specialists have an associate's or a bachelor's degree in biomedical electronics technology or a related

[4] Facility Policy Memorandum No. 138-19, *Medical Equipment Management Program*, June 2016.

[5] VHA allows exceptions to preventive maintenance schedules in some cases.

[6] VA Handbook 5005/104, Part II, Appendix G38, March 25, 2019, refers to the supervisory biomedical engineer (clinical) position on p.8.

technical field or have completed a military training program in biomedical equipment and have two years of experience. Licensure or certification is desired, but not required.[7]

From 2014 through 2018, Biomedical Section staffing remained static although the number, complexity, and value of medical devices at the facility increased. The staffing level of one supervisory biomedical engineer (the Biomedical Section Chief) and 10.8 to 12 biomedical support specialists was substantially below VHA facilities of similar size and complexity.[8]

Allegations

On February 8, 2019, the OIG's Hotline division received the following allegations:

1. The Biomedical Section did not manage ophthalmology-related equipment and repairs properly as it
    - Had not completed software updates on Pentacam HR® equipment, which caused inaccurate (lens) implant measurements, and would not allow a service repair contract for the Spectralis® OCT, which placed patients at risk for vision loss due to the possibility of delayed injections;[9]
    - Had not performed preventive maintenance on ophthalmology equipment, could not provide service logs verifying completed preventive maintenance, and could not explain the lack of preventive maintenance stickers on equipment;
    - Could not repair equipment; and
    - Did not address Eye Clinic work orders timely, with Biomedical Section staff (often) taking a week before they would call the manufacturer for maintenance, resulting in additional time for repairs.
2. Eye Clinic equipment issues had resulted in
    - Patient procedures being canceled and not rescheduled due to no scheduling capacity;
    - Decreased productivity in the Eye Clinic;

[7] VHA Handbook 5005/95, Part II, Appendix G49, Biomedical Equipment Support Specialist, Qualification Standard, GS-1601, February 7, 2018. At the GS-11/12/13 level, certifications are highly desirable; however, at the GS-5/7/9 entry level, nothing beyond basic educational requirements is expected.

[8] The Biomedical Section Chief provided a facility comparison with VHA facilities located in Houston and Dallas, Texas; Orlando, Florida; and Los Angeles, California. The Biomedical Section Chief told the OIG team that as of March 26, 2019, four vacant biomedical support specialist positions were approved and awaiting announcement by the Human Resource Management Service. However, the positions were reportedly difficult to recruit and fill because of the specialized education and experience required.

[9] Pentacam HR® is a high-resolution, rotating camera system.

- Increased consults to community care providers for eye-related care, which had increased the cost of care; and
- Care delays as over 1,000 patients were waiting for (eye-related) community care consults to be scheduled.

3. Prosthetic and Sensory Aids Service (PSAS) did not issue purchase orders to the optical shop vendor for four to six weeks, resulting in patients waiting six to eight weeks for eyeglasses.
4. Facility leaders had not responded satisfactorily to complaints for at least 15 years.[10]

The complainant subsequently told the OIG about a malfunctioning ophthalmic cryosurgery system probe and an ophthalmic operating room microscope that was allegedly repaired with duct tape.

Scope and Methodology

The OIG initiated the inspection on February 22 and conducted a site visit March 26–28, 2019.

Prior to the site visit, the OIG team interviewed the complainant, Chief of Ophthalmology, Eye Clinic Administrative Officer, Patient Safety Manager, Risk Manager, and Patient Advocate. During the site visit, the OIG team interviewed the Facility Director and Chief of Staff; the Chiefs of Surgery Service, Facilities Management Service, the Biomedical Section, and PSAS; Eye Clinic providers and technicians; as well as other individuals with knowledge of ophthalmology, optometry, and the preventive maintenance processes. The OIG team also toured the Eye Clinic.

The OIG team reviewed relevant VHA directives and handbooks; facility policies and procedures; a list of ophthalmology-specific equipment, associated work orders, and preventive maintenance records; patient advocate data; quality management and performance improvement documents; and surgery schedules. The OIG team also reviewed relevant organizational charts, staffing, and competencies, as well as eyeglass purchase order processing data and eye care-related community consults.

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

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the

[10] During the week of February 4, 2019, the OIG conducted a Comprehensive Healthcare Inspection Program (CHIP) review at the facility and advised the complainant of the process to file a formal OIG complaint at that time. CHIP reviews provide a focused evaluation of the quality of care delivered in the inpatient and outpatient settings and covers key clinical and administrative processes that are associated with promoting quality care.

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.

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 Equipment

This section of the review focuses on the specific allegations related to the primary pieces of ophthalmology equipment initially identified by the complainant—the Pentacam HR® (high resolution camera) and the Spectralis® OCT. This section also includes the ophthalmic cryosurgery system probes and the operating room ophthalmic microscope concerns, although the complainant did not specifically allege that the Biomedical Section failed to meet preventive maintenance requirements related to these two items.

Pentacam HR® Software Update

The OIG did not substantiate that outdated software was causing inaccurate (lens) implant measurements. This high-resolution, rotating camera system is used for anterior eye segment analysis that allows for early detection of changes in the eyes and takes measurements for an intraocular (artificial) lens after the cloudy natural eye lens is removed during cataract surgery. The camera manufacturer recommended biannual preventive maintenance and had a "built in" courtesy notification that alerted the user about 90 days prior to the service due date. An Eye Clinic technician told the OIG of an "error message" that started appearing on the high-resolution camera in October 2018, although the camera was still operable. The notification read, "Upcoming service: 02/2019. Please contact your local distributor." The notification did not specify that high-resolution camera software needed updating.[11]

An Eye Clinic employee reportedly told the Eye Clinic Preventive Maintenance Liaison (an optometry technician who coordinates with the Biomedical Section on work orders and repairs) about the issue and believed a work order was submitted at that time. However, the Eye Clinic Preventive Maintenance Liaison told the OIG of not being aware until February 2019 that the high-resolution camera needed service, and a work order was submitted at that time. The OIG found only one work order, which was submitted in February 2019.

Pending completion of the needed service, the facility received a loaner high-resolution camera with updated software from the manufacturer on or around March 14, 2019.[12] The OIG team was unable to determine the exact date in February 2019 that would have represented the two-year preventive maintenance due date; the preventive maintenance was delayed between two and six

[11] It was unclear why the complainant alleged the camera's software was outdated. However, an Eye Clinic employee told the OIG about a conversation with an "outside" technician (referring to outside of the facility's Eye Clinic). The outside technician reportedly told the Eye Clinic employee that a newer software version for the high-resolution camera incorporated new formulas and details for surgeries.

[12] Three weeks later, the Eye Clinic's high-resolution camera was returned with software updates completed.

weeks. The manufacturer told the OIG that this delay was not "overly concerning," and that measurements would not have been affected.[13] Therefore, the OIG determined that the potentially outdated software did not affect the accuracy of measurements for the two- to six-week period or that patients were placed at risk for incorrect lens implants.

The OIG interviewed multiple Eye Clinic providers about the high-resolution camera service update delay. While there appeared to be some frustration and confusion surrounding the issue, none of the providers reported concerns about inaccurate measurements or potential patient harm.[14]

Spectralis® Service Contract

The OIG did not substantiate that because there was no service contract for the OCT equipment, patients were at increased risk of permanent vision loss due to the possibility of delayed injections (because of equipment failure).[15] A service contract would not have definitively prevented equipment breakdowns. Further, the potential risk to patients as suggested by the complainant was largely theoretical, as harm would generally occur only if the provider failed to exercise good judgement and not make other arrangements should the OCT equipment not be functional when needed.

An OCT machine is a diagnostic imaging device used to view the posterior segment of the eye and to perform measurements of ocular anatomy and ocular lesions. OCT can be used to assess the status of macular degeneration and diabetic retinopathy, which helps to guide treatment. For example, rather than give anti-new blood vessel growth agents (vascular endothelial growth factor) on a set timed (for example monthly) regimen, the ophthalmologist could use a detailed picture of the retina to accurately assess the progression of the disease process. If there was no active disease, the anti-vascular endothelial growth factor injection could be held. If there was disease progression, the injection could be given.

The OIG found no evidence that the facility's OCT equipment was nonfunctional for an extended period such that patient injections were delayed or care was otherwise compromised. From October 1, 2016, through March 31, 2019, Biomedical Section staff addressed OCT equipment-related work orders multiple times and documented preventive maintenance in November 2018 for two Eye Clinic OCT machines. A new OCT machine was received in

[13] The Pentacam®/Oculus representative said a two- to three-month preventive maintenance delay was like getting a car oil change at 4,000 miles rather than 3,000 miles.

[14] Cataract surgery is elective in nature. Eye care providers with concerns about the accuracy of the high-resolution camera implant measurements during the two to six weeks in February and March 2019 could have made alternate arrangements.

[15] Despite the complainant's suggestion that the Biomedical Section would not *allow* service contracts in general, there was a service contract in place for the LenStar® laser optic measurement equipment, which is used to determine the power and type of lens for implantation.

November 2018 at the New Port Richey CBOC. If the OCT equipment was not functional when needed to assess the status of a patient's macular degeneration and diabetic retinopathy, the patient could be sent to the facility's New Port Richey location, or the patient could be referred to a community provider. The Chief of Ophthalmology was unaware of patient harm related to nonfunctional OCT equipment.

Ophthalmic Cryosurgery System

The OIG team determined that an ophthalmic cryosurgery system probe had malfunctioned. During the site visit, the OIG team heard that the probe attached to the cryosurgery system would "pop off" of the machine during use, requiring an operating room staff member to hold the probe in place to maintain the connection to the machine. The ophthalmic cryosurgery system is a nonelectric, low-pressure system that uses nitrous oxide gas applied via a handheld probe to freeze and destroy tissue. Ophthalmic cryosurgery is used for extraction of cataracts, and treatment for glaucoma, retinal detachment, and tumors.

The OIG team was told that three weeks prior to the OIG visit, there were several instances when the probe to the cryosurgery system spontaneously disconnected. No concerns with probe functionality were noted prior to the initial disconnect in early March. These events occurred in the operating room while the surgeon was using the device and had the potential to harm patients. None of the clinicians interviewed, however, identified cases of harm resulting from the spontaneous probe disconnects.[16]

A work order was submitted on March 7, 2019, referencing the spontaneous probe disconnect. Although the biomedical support specialist was unable to duplicate the problem, the manufacturer suggested the issue was not within the machine but with the worn attachable probes. The OIG team could not determine with certainty whether biomedical support specialists could have or should have identified the worn probe connections prior to the spontaneous disconnections. The OIG was notified while on-site that new probes were purchased and tested, and the problem was resolved. The OIG team was told that the facility implemented a process to determine the age of probes and for educating staff about identifying deteriorating probe connectors.

Ophthalmic Operating Room Microscope

The OIG team was unable to determine whether duct tape had been used to repair an ophthalmic operating room microscope. The operating room ophthalmic microscope uses high-resolution images, which aid in surgical procedures such as cataract and retinal surgeries. By using the term

[16] The probe could pop off and injure a patient or staff member. Also, depending on how long it took to reconnect a suitable probe, the patient may have required refreezing of the eye.

"repair," the complainant implied that the microscope was subsequently put back into service and was being used in the operating room.

The complainant was unable to provide information that would allow the OIG to fully evaluate the concern, and the OIG was unable to validate the timeframe, technician, or circumstances surrounding the allegation due to the absence of a work order. The Chief of Surgery heard duct tape was discovered "inside" the microscope. However, none of the interviewees reported first-hand knowledge about duct tape being used to repair an operating room microscope, nor could the team find evidence that such a microscope was being used in the operating room. The team confirmed that a new ophthalmic microscope was installed in May 2017.

Preventive Maintenance, Service Logs, and Stickers

Preventive Maintenance

The OIG did not substantiate that the Biomedical Section had not conducted preventive maintenance on ophthalmology equipment. The OIG team learned that preventive maintenance requirements had changed over time and Eye Clinic staff were not always familiar with the maintenance strategy being employed.

The Biomedical Section Chief told the OIG team that the facility followed the respective equipment manufacturer's preventive maintenance recommendations. The team reviewed preventive maintenance logs from October 1, 2016, through March 31, 2019, and found that preventive maintenance was being performed on the high-resolution camera, OCT equipment, ophthalmic cryosurgery system, and the ophthalmic microscope according to the manufacturers' recommendations and the facility's MEMP plan.

VHA's Biomedical Engineering Performance Monitoring and Improvement program uses a scorecard to measure business processes. One key indicator, on-schedule completion for non-high-risk medical devices, calculates the percentage of compliant non-high-risk medical device preventive maintenances.[17] VHA's target for non-high-risk device preventive maintenance is 100 percent. For the four consecutive reporting quarters from January 1, 2018, through December 31, 2018, the facility's compliance with non-high-risk medical device preventive maintenance was 99–100 percent for all biomedical equipment.[18]

[17] Value is calculated by the number of non-high-risk medical device preventive maintenances with a Passed, Corrective Action Taken, Could Not Locate, In Use, or Out of Service status divided by the total number of non-high-risk medical device preventive maintenances scheduled. High-risk medical equipment is medical equipment for which there is a risk of serious injury or death to patients or staff should the equipment fail. This equipment is identified in the inventory and includes life-support equipment. By this definition, ophthalmology equipment is considered non-high-risk. HPM 138-19, *Medical Equipment Management Program*, June 2016.

[18] HPM 138-19.

Service Logs

The OIG did not substantiate that Biomedical Section staff were unable to provide service logs verifying preventive maintenance.[19] Preventive maintenance logs were provided to the Chief of Surgery, who forwarded them to the Chief of Ophthalmology prior to the OIG's site visit. The OIG team also received copies of the preventive maintenance logs as requested.

Preventive Maintenance Stickers

The OIG did not substantiate that Biomedical Section staff could not explain the lack of (preventive maintenance) stickers on equipment. VHA requires that facilities have a mechanism to assure users that the equipment they are using is safe and functional. Although not required, stickers are a traditional and easy method to indicate that inspection is complete, and equipment is safe to use. Facilities may use a sticker or tag to provide the user with information on when the last preventive maintenance or inspection was done, and when the next preventive maintenance or inspection is due.[20]

The Biomedical Section Chief told the OIG about a change in one-time-only equipment inspection stickers, which was rolled out "within the past year." The additional stickers denoted equipment had been inspected and approved by Biomedical Section staff and that no further inspections were required. Examples of the new stickers showing pending due date and no further inspection are shown below.

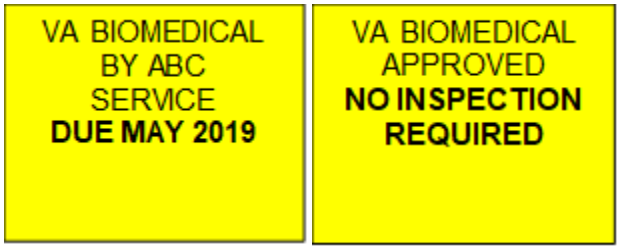

Figure 1. New biomedical inspection stickers by the facility. "ABC" in the first graphic is the biomedical engineer's initials.
Source: Facility MEMP 2018 Annual Report

The 2018 MEMP Annual Report reflected that formal training for clinical staff had not been performed relative to the new stickers because staff were already accustomed to the use of preventive maintenance stickers. Reportedly, clinical staff were questioned about stickers during environment of care (EOC) rounds and explanations (about sticker changes) were provided on

[19] The complainant told the OIG of requesting, but not receiving, preventive maintenance logs. The Biomedical Section Chief told the OIG that the preventive maintenance logs were being reformatted to make them easier to understand.

[20] VHA Center for Engineering & Occupational Safety and Health (CEOSH), *Environment of Care Guidebook,* January 2019.

the spot. However, Eye Clinic staff whom the OIG interviewed uniformly denied having been told about the new preventive maintenance sticker process.

During a tour of the facility's Eye Clinic, the OIG team spot-checked eight ophthalmology-related devices for preventive maintenance stickers. One piece of equipment, a keratometer, did not have a preventive maintenance sticker. The other items had valid preventive maintenance stickers indicating that inspection was completed or that preventive maintenance was due on a future date.

Equipment Repair and Work Orders

Repairs

The OIG team did not substantiate that Biomedical Section staff could not repair equipment.[21] According to the Biomedical Section Chief, upon receipt of a work order, biomedical support specialists first assessed whether an item could be repaired in-house or if service needed to be provided outside of the facility.[22] If facility Biomedical Section staff were unable to complete the required repairs in-house, a purchase order was requested to either allow an external source to complete repairs on-site, or the equipment would be mailed out for repair. It appeared that biomedical support specialists followed the facility's process for completing the "first look" assessment of the problem and then determining next steps.

According to the Biomedical Section Chief, biomedical support specialists were initially evaluated for competencies consistent with the position description and the assigned workload at the time of hire. Daily technician work assignments were evaluated for accuracy, completeness, and proper documentation by the Biomedical Section Supervisor. Annual performance evaluation competencies were assessed by direct observation and monitoring of work order and preventive maintenance completion. The OIG found no evidence that biomedical support specialists lacked competencies to perform their assigned tasks, which included equipment assessments and repairs.

Work Orders

The OIG was unable to determine whether Biomedical Section staff did not address work orders timely, often taking a week before calling the manufacturer for maintenance, which resulted in delays. Work orders had been submitted for each of the four biomedical devices included in this

[21] The OIG interpreted this allegation to be that Biomedical Section staff could not consistently repair equipment, implying that staff did not possess the necessary skills to do so. The OIG acknowledges that, more likely than not, there were occasions when Biomedical Section staff could not repair equipment; however, the team did not find this to be a routine occurrence.

[22] Facility Policy Memorandum No. 138-02, *Facilities Maintenance Management*, August 2016.

review; however, incomplete work order documentation precluded the OIG from fully evaluating the timing of in-house repairs or tracking parts requests and referrals to vendors. VHA requires facilities' Biomedical Engineering programs to document all work and services in a timely fashion. Work order data entry fields include responsible technician, equipment location, equipment identifiers, work type, vendor support, start date, finish date, and a summary of work performed.[23]

VHA's Biomedical Engineering Performance Monitoring and Improvement program data reflected that the facility's corrective maintenance turnaround times exceeded the VHA target. One key indicator, average corrective maintenance work order turnaround time, reflects the time, in days, to repair medical equipment.[24] VHA's target for corrective maintenance completion is nine days or less. For the eight consecutive reporting quarters from January 1, 2017, through December 31, 2018, the facility's corrective maintenance work order completion times ranged from 16 days to more than 30 days for all biomedical equipment.

Overall, the OIG found that the Biomedical Section Chief appropriately monitored performance measures and reported relevant data to the EOC Committee at regular intervals as required by the facility.[25] The OIG reviewed EOC meeting minutes from January 1, 2017, through December 31, 2018, and noted that Biomedical Section staff provided all required quarterly MEMP reports.

The OIG concluded that the Biomedical Section was largely following guidance and facility process related to preventive maintenance and repair. However, the Biomedical Section appeared to have limited communication and interaction with clinical staff about preventive maintenance-related changes and equipment repairs, which may have contributed to the perception that preventive maintenance was not occurring or that repairs were delayed.

2. Eye Clinic Cancellations and Community Care Consults

The complainant's allegations initially centered around the premise that nonfunctional eye care equipment resulted in clinic cancellations and an increase in community care consults. Subsequent contacts revealed that the concerns were more general to Eye Clinic access and capacity.

The OIG was unable to determine whether Eye Clinic procedures were canceled due to equipment issues, primarily because available documentation did not support a more granular

[23] SB2018-002 Healthcare Technology Management Service Bulletin – Maximo, *Documentation of Biomedical Engineering Services*, August 2018.

[24] Value reflects time from when the corrective maintenance service was requested through the equipment's return to clinical operation, including elapsed time that may be beyond the control of Biomedical Engineering (for example, waiting for parts to be ordered and delivered).

[25] Facility Policy Memorandum 138-19, 2016. Ongoing performance measure results of annual MEMP evaluations will be reported quarterly to the EOC Committee.

view of the possible reasons for cancellations and referrals to community care. Further, the reason for the community care request for high-risk cases did not state that the referral was made because of inoperable or unavailable equipment. Specifically, documentation available through work orders did not consistently include a complete description of the problem needing repair, whether the problem rendered the equipment completely or partially inoperable, or how long the equipment was unavailable.[26] As such, any number of factors could have resulted in a community care referral, not just equipment failure. The Chief of Ophthalmology was unaware of patients being referred to the community care program as a result of nonfunctional equipment.

While the OIG could not determine whether a relationship existed between inoperable equipment, clinic cancellations, and community care consults, the team found that changes in Eye Clinic scheduling practices had impacted clinic access, thereby decreasing clinic capacity and increasing the volume of eye care-related community care consults. The team did not find this to be problematic because this improved patient access and satisfaction as discussed below.

Eye Clinic Capacity and Productivity

The OIG substantiated that Eye Clinic patients were being referred to community care providers due to reduced scheduling capacity and that Eye Clinic productivity was impacted.

Prior to 2018, Eye Clinic patients were given appointments with the first available optometrist or ophthalmologist. Multiple patients were scheduled for a single appointment time, resulting in complaints about extensive wait times. The Chief of Ophthalmology told the OIG that beginning in 2018, the Eye Clinic restructured the appointment scheduling process to decrease appointment wait times and increase patient satisfaction.[27] The Chief of Ophthalmology told the OIG team that after implementation of the new scheduling system, clinic patients "seemed to like the new appointment scheduling system," the number of patients complaining about appointment wait times appeared to be declining (from a high of 14 in April 2018 to a low of two in February 2019). Although fewer appointments were available, resulting in less patients being seen by Eye Clinic providers, the OIG team found that the decrease in productivity and resulting increase in referrals to community care providers was reasonable to improve patient access and satisfaction.

[26] The OIG team compared ophthalmology and optometry community care consults to work orders for the four ophthalmology equipment items included in this review for October 1, 2016, through March 26, 2019. While the OIG team found no clear pattern suggesting a possible relationship between community care consults and work orders for specific ophthalmology equipment, the team acknowledges the limitations of this approach. For the purposes of this review, high-risk ophthalmology cases would potentially include patients with diagnoses of macular degeneration, diabetic retinopathy, glaucoma, retina tears or detachment, and trauma. The team selected high-risk consults for review due to the possibility of those patients experiencing adverse outcomes. The OIG team determined high-risk cases based on the frequency of consults containing ophthalmic disease management procedure codes. Routine optometry screening exams were excluded.

[27] Implementation of the new Eye Clinic scheduling processes began in August 2018.

Community Care Consultations and Cost

The OIG substantiated an increase in the number of patients being referred for ophthalmology (surgical, disease management) community care as these consults more than tripled from October 1, 2016, through Sept 30, 2018.

VHA's goal is to schedule patient appointments within 30 days of the desired or clinically indicated date. If scheduling capacity is reached and the appointment cannot be scheduled timely, patients are to be offered the option of receiving the requested care from a community (non-VA) provider.[28] The Chief of Ophthalmology explained that in August 2017, the facility's arrangement with the University of Florida's Ambulatory Surgery Center (where facility ophthalmologists performed some surgeries) was discontinued. As a result, presurgery evaluations and eye surgery consults to community providers increased. This change, coupled with the Eye Clinic's new scheduling practices, resulted in more patients being referred to community care providers.

The OIG did not substantiate that over 1,000 patients were waiting for (eye-related) community care consults to be scheduled. As of March 26, 2019, there were 203 active eye-related community care consults.[29] The earliest was dated January 15, 2019, and nearly half were submitted in March.[30] As of June 11, 2019, more than 750 ophthalmology-specific consults had been processed since October 1, 2018.

With the increased community care consults, the OIG concluded that higher costs would likely result. Changes in Eye Clinic appointment scheduling practices and the closing of a community ambulatory surgery center contributed to the increased use of community care consults. However, in the context of a finite number of eye care providers, clinic space, equipment, and operating room time, combined with a new, more patient-centric appointment scheduling process, the OIG determined that the use of community care resources to ensure timely access to eye care to be appropriate. Therefore, the OIG team did not attempt to quantify the costs associated with eye care-related community care consults.

3. Eyeglass Procurement

The OIG substantiated that PSAS took four to six weeks to issue purchase orders and that, in many cases, patients waited six to eight weeks for eyeglasses.

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[28] VHA Directive 1230(1), *Outpatient Scheduling Processes and Procedures*, July 15, 2016, amended July 12, 2019.

[29] An active consult is one that has been received and efforts are underway to address the requested services.

[30] There were also five pending consults that were requested March 13 to March 26, 2019, and were not reviewed further as they were not delayed.

VHA requires that quality patient care be provided by furnishing properly prescribed prosthetic equipment, sensory aids, and devices in an economical and timely manner.[31] For eyeglasses, the optometrist completes an eye examination and writes an eyeglass prescription, and the Eye Clinic technician submits a consult to PSAS to complete a purchase order for the eyeglasses.[32] The patient then visits the optical shop vendor to be fitted for eyeglasses. The PSAS purchasing agent must complete the purchase order, which authorizes the vendor to process the eyeglass order.

The Chief of PSAS told the OIG that two purchasing agents, who were designated to process purchase orders for eyeglasses, retired in December 2017 and October 2018, respectively. Prior to the purchasing agents' retirements, the standard time to process a purchase order for eyeglasses was reportedly five to seven days. After October 2018, no purchasing agent was assigned specifically to process purchase orders for eyeglasses. The average number of days for processing eyeglass purchase orders steadily increased from 13.2 days in October 2018 to 39.1 days in March 2019. Patient Advocate Tracking System data from November 29, 2016, through March 14, 2019, reflected that of the 33 eyeglass delay complaints, 73 percent were received since November 2018.

The Chief of PSAS told the OIG that as of late May 2019, five purchasing agents had been hired, with two of the new staff dedicated to processing the more than 2,400 eyeglass purchase orders that were open as of mid-June.

4. Leadership Knowledge and Responsiveness

The OIG was unable to determine if facility leaders responded inadequately to reported concerns for at least 15 years. This was largely because (1) the OIG did not interview previous facility leaders dating back 15 years, and (2) the adequacy of leadership responsiveness was a matter of perspective.

According to The Joint Commission, "It is the leaders who can together establish and promulgate the organization's mission, vision, and goals. It is the leaders who can strategically plan for the provision of services, acquire and allocate resources, and set priorities for improved performance." The current Facility Director, who began the position in 2015, told OIG that the complainant brought ophthalmology-related concerns forward at that time. The Chief of Surgery also reported being aware of the complainant's concerns for several years. The Chief of Staff,

[31] VHA Directive 1173, *Prosthetic and Sensory Aids Service*, June 27, 2008. VHA Handbook 1173.1 Prosthetic appliances include "[all] aids, devices, parts or accessories which patients require to replace, support, or substitute for impaired or missing anatomical parts of the body. The items include artificial limbs, terminal devices, stump socks, braces, hearing aids and batteries, cosmetic facial or body restorations, optical devices, manual or motorized wheelchairs, orthopedic shoes, and similar items."

[32] PSAS is responsible for ordering prosthetic items that cost less than $3,500. Orders exceeding that amount must be placed through a VHA Contracting Official.

who had been in the role for about a year as of March 2019, was generally aware of the complainant's concerns but denied having any first-hand knowledge of the issues.

Preventive maintenance and service contracts were central to the complainant's concerns. According to the Facility Director, who was a former VHA Chief of Engineering, as well as the Biomedical Section Chief, preventive maintenance contracts requested by the Eye Clinic were not always necessary. Facility leaders made management decisions in consideration of financial priorities and the availability of an alternate means to address preventive maintenance and repairs, which excluded preventive maintenance contracts. The OIG found no evidence that leadership decisions were improper or fell outside of normal protocol.[33]

The OIG noted that communication between Eye Clinic and Biomedical Section staff was not always effective or collaborative. In an effort to improve communication and resolve the most pressing ophthalmology equipment concerns, in January 2019, the Chief of Surgery, along with Eye Clinic and Biomedical Section leaders, came to an agreement for a third-party ophthalmologic technician group to provide routine maintenance for select pieces of equipment identified by Eye Clinic leaders.[34] Specifically, the Chief of Ophthalmology was tasked with providing a list of ophthalmologic equipment needing maintenance agreements and the ophthalmic companies capable of providing the service. The requested information was provided to the Biomedical Section Chief in April 2019. Additionally, to ensure that staffing levels were sufficient to meet the demand for preventive maintenance and work order requests, the Biomedical Section was actively recruiting to fill vacant biomedical support specialist positions.

Conclusion

The OIG did not substantiate the concerns related to four pieces of ophthalmology equipment. The team found that the potentially outdated high-resolution camera software did not affect the accuracy of measurements for the two- to six-week delay or that patients were placed at risk for incorrect lens implants. The OIG found no evidence that the facility's OCT equipment was nonfunctional for an extended period such that patient injections were delayed or care was otherwise compromised. Preventive maintenance was performed on the high-resolution camera, OCT equipment, ophthalmic cryosurgery system, and the ophthalmic microscope according to

[33] The OIG team found that a new service contract for the OCT equipment was requested through the budget hearing process on January 31, 2018. The request was not funded, reportedly because only "prior service contracts were approved." Per the facility's stated process, funding decisions were made in the context of limited resources and benefit to the patient population. The facility's Chief Financial Officer reported that new service contracts would have to meet business and patient care needs, including frequency of repair, cost, down time, and harm criteria. The request was submitted again in January 2019.

[34] Biomedical Section staff told the OIG that only the mechanical equipment or parts to instruments were serviced; software and technical pieces of the instruments were not included in the service agreement.

the manufacturers' recommendations and the facility's MEMP plan. The team did not identify, nor was the team told about, adverse patient outcomes.

The OIG did not substantiate that the Biomedical Section had not conducted preventive maintenance on ophthalmology equipment. The OIG team learned that preventive maintenance requirements had changed over time and Eye Clinic staff were not always familiar with the maintenance strategy being employed. The Biomedical Section managed ophthalmology-related equipment and repairs in accordance with facility protocols and manufacturers' instructions.

The OIG did not substantiate that Biomedical Section staff were unable to provide service logs verifying preventive maintenance, or that they could not explain the lack of preventive maintenance stickers on equipment. New preventive maintenance stickers were in use; however, clinical staff had not been formally notified of the new process.

The OIG team did not substantiate that Biomedical Section staff were routinely unable to repair equipment. Biomedical section staff were not expected to be able to repair every piece of medical equipment. If unable to complete the required repairs in-house, a purchase order was requested such that repairs could be completed through other avenues. The team found no evidence that biomedical support specialists lacked competencies to perform their assigned tasks.

The OIG was unable to determine whether Eye Clinic work orders took a week before Biomedical Section staff would call the manufacturer for maintenance. Incomplete work order documentation precluded the OIG from fully evaluating the timing of in-house repairs or tracking parts requests and referrals to vendors.

The OIG was unable to determine whether Eye Clinic procedures were canceled due to equipment issues. Available documentation did not include the reason a community referral was made rather than providing the service in the facility's Eye Clinic. A variety of factors could have resulted in a community care referral, not just equipment failure.

The OIG substantiated an increase in eye care-related community care consults; however, the increased volume of community care referrals was largely the result of changes in access to ambulatory surgery services and in Eye Clinic scheduling practices (not equipment failure). The team did not substantiate that Eye Clinic equipment issues resulted in over 1,000 patients waiting for (eye-related) community care consults to be scheduled. Because the use of community care resources to ensure timely access to eye care was appropriate, the OIG team did not attempt to quantify the costs associated with eye care-related community care consults.

The OIG substantiated that PSAS took four to six weeks to issue a purchase order to the optical shop vendor, resulting in patients waiting six to eight weeks for eyeglasses. The two facility purchasing agents, designated to process purchase orders for eyeglasses, retired; subsequently two purchasing agents were hired to fill the positions.

The OIG was unable to determine if facility leaders had not responded satisfactorily to complaints for at least 15 years. The team did not interview previous facility leaders, and the

adequacy of leadership responsiveness was subjective. However, OIG found no evidence that facility leaders' decisions, made in the context of financial considerations, facility priorities, and the availability of alternate means to address preventive maintenance and repairs, were outside of normal protocol.

The OIG found that communication between Eye Clinic and Biomedical Section staff was not consistently effective or collaborative. Efforts were underway to improve communication and resolve the most pressing ophthalmology equipment concerns. These efforts included development of a third-party routine maintenance agreement for select pieces of equipment and increased biomedical support specialist staffing to meet the demand for preventive maintenance and work order requests.

Recommendations 1–4

1. The James A. Haley Veterans' Hospital Director ensures that Biomedical Section staff complete work order documentation accurately as required by facility policy and in accordance with Veterans Health Administration guidelines.

2. The James A. Haley Veterans' Hospital Director enhances efforts to improve equipment corrective maintenance completion times and that Biomedical Section staff communicate the status of repairs with end users.

3. The James A. Haley Veterans' Hospital Director takes action to improve the timeliness of eyeglass purchase order processing.

4. The James A. Haley Veterans' Hospital Director ensures that Prosthetics and Sensory Aid Service resolves the open eyeglass purchase order requests.

Appendix A: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: October 11, 2019

From: Director, VA Sunshine Healthcare Network (VISN 8)

Subj: Office of the Inspector General Draft Report, Ophthalmology Equipment and Related Concerns at the James A. Haley Veterans' Hospital, Tampa, Florida

To: Director, Rapid Response, Office of Healthcare Inspections (54RR00)

I have reviewed the OIG's findings and recommendations concerning the Healthcare Inspection at the James A. Haley VA Medical Center, Tampa, Florida, in response to Ophthalmology Equipment and Related Concerns. I concur with the recommendations as written in the report.

Additionally, I have reviewed the action plans and timeline for completion as submitted by the Medical Center Director and concur. VISN 8 will assist the Healthcare System in ensuring timely and sustained compliance.

(*Original signed by*:)

Miguel H. LaPuz, M.D., MBA
Network Director, VISN 8

Appendix B: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: September 30, 2019

From: Director, James A Haley Veterans' Hospital (673)

Subj: Healthcare Inspection—Ophthalmology Equipment and Related Concerns at the James A. Haley Veterans' Hospital, Tampa, Florida

To: Director, VA Sunshine Healthcare Network (VISN 8)

1. I have reviewed the VA OIG's draft report of the Ophthalmology Equipment and Related Concerns review conducted at the James A. Haley Veterans Hospital of Tampa, Florida. I concur with the OIG's recommendations.
2. I am submitting my plan to comply with the recommendations to include timeline for completion and sustainment of improvements.
3. I appreciate the OIG's partnership in our continuous improvement efforts.

(*Original signed by*:)

Joe D. Battle
Director

Facility Director's Response

Recommendation 1

The James A. Haley Veterans' Hospital Director ensures that Biomedical Section staff complete work order documentation accurately as required by facility policy and in accordance with Veterans Health Administration guidelines.

Target date for completion: January 31, 2020

Director Comments

Action Plan – Biomedical staff will receive refresher training on HTM Service Bulletin 2013-001, *Biomedical Engineering Uniform Work Actions*, HTM Service Bulletin 2014-004, *Documentation of Biomedical Engineering Services*, and Documentation of Services Advisory Board Guidance Document dated August 14, 2014. All work orders will be reviewed by the Biomedical Engineer prior to closing to ensure required information has been entered. Incomplete or unclear documentation shall be returned to the responsible Biomedical Support Specialist for correction or clarification. Facility Management Service (FMS) will perform audits of 20 work orders per month for November 2019, December 2019, and January 2020 to assess compliance with required information to be entered. The target for this review is 100%. If compliance is not 100%, FMS will continue the audits until 3 consecutive months of compliance. Monthly audits are to be reported to the Environment of Care Committee during the Quarterly Medical Equipment Management Report.

Recommendation 2

The James A. Haley Veterans' Hospital Director enhances efforts to improve equipment corrective maintenance completion times and that Biomedical Section staff communicate the status of repairs with end users.

Target date for completion: November 30, 2019

Director Comments

Action Plan – All Ophthalmology work order requestors will receive training on reviewing the work order status in AEMS/MERS (Automated Engineering Management System/Medical Equipment Reporting System, the computerized work order system currently in use); a written guide shall be provided and will be available to all work order users. Continue recruitment efforts to fill remaining vacant Biomedical Equipment Support Specialist positions (two of four have been filled to date and these employees began new employee orientation August 5, 2019). Communication with customers and work order requestors has already been discussed during Biomedical Shop huddles and best practices have been shared with staff. Corrective maintenance

turnaround time is monitored quarterly as a national Key Performance Indicator (KPI) and will continue to be reported. Maintenance turnaround time status will be reported to the Environment of Care Committee during the quarterly Medical Equipment Management Report.

Recommendation 3

The James A. Haley Veterans' Hospital Director takes action to improve the timeliness of eyeglass purchase order processing.

Director Comments

The current number of pending eyeglass consults has been reduced by 50% since the OIG visit in May 2019. Executive Leadership and Prosthetics & Sensory Aids Service (PSAS) Chief developed an action plan to improve timeliness of eyeglass purchase order processing, including:

1. Chief PSAS has changed the internal process to now assign consults within 2 days to be completed by the purchase agents. The PSAS Chief daily monitors completion and follows the PSAS National timelines guidelines to ensure ordering is completed within 5 days.
   Status: Since September 1, 2019, 75% of eyeglass orders (those complete and require a purchase order) are completed within the 5-day National Prosthetics Guidelines standard. We recommend closure once 3 consecutive months of 100% is achieved with periodic auditing as a follow up.
2. Develop new process to notify patients whose glasses have been ordered but still need to be seen by the optician to complete the consult. Status: The new process will be fully implemented by November 1, 2019.
3. Leadership has approved 4 additional purchasing agents to improve timeliness of all purchases.
   Status: Currently these positions are being advertised for recruitment. Expected onboarding is planned for the end of the calendar year.
4. All current Purchasing Agents (PA's) have been cross trained to order eyeglasses so there are no interruptions if PA's are on leave.
5. A new VISN-wide Eyeglass Contract went into effect on Sept 1, 2019.
   Status: Complete.

OIG Comment

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

Recommendation 4

The James A. Haley Veterans' Hospital Director ensures that Prosthetics and Sensory Aid Service resolves the open eyeglass purchase order requests.

Director Comments

Four newly hired purchasing agents are ordering eyeglasses full time. Leadership approved overtime as needed to support the prosthetic consult backlog clean-up efforts. As a result, the 2,400 open eyeglass consults have been completed.

Status: Complete.

OIG Comment

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

Glossary

biomedical engineering. The application of engineering principles, practices, and technologies to the fields of medicine and biology especially in solving problems and improving care.[35]

cataract. A clouding of the lens of the eye or of its surrounding transparent membrane that obstructs the passage of light.[36]

cryosurgery system. A nonelectric, low-pressure system that uses nitrous oxide gas to destroy tissue by applying extreme, controlled temperature down to a maximum of -89 centigrade.[37]

diabetic eye disease. A group of eye problems people with diabetes may face as a complication of diabetes such as diabetic retinopathy.[38]

diabetic retinopathy. A growth of abnormal retinal blood vessels due to a lack of blood supply to the eye (ischemia) and is a common complication in patients with diabetes and may have a sudden and debilitating impact on visual acuity, eventually leading to blindness.[39]

glaucoma. A disease of the eye marked by increased pressure within the eyeball that can result in damage to the optic disk and gradual loss of vision.[40]

keratometer. An instrument to measure curvature of the cornea.[41]

macular degeneration. A progressive deterioration of the macula resulting in a gradual loss of the central part of the visual field.[42]

optical coherence tomography (OCT). A non-invasive imaging test that uses light waves to take cross-section pictures of the retina.[43]

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[35] https://www.merriam-webster.com/dictionary/biomedical%20engineering. (The website was accessed on May 30, 2019.)

[36] https://www.merriam-webster.com/dictionary/cataract. (The website was accessed on May 30, 2019.)

[37] https://www.coopersurgical.com/medical-devices/detail/frigitronics-cs-2000. (The website was accessed on May 30, 2019.)

[38] NIH, National Eye Institute, https://nei.nih.gov/health/diabetic. (The website was accessed on June 11, 2019.)

[39] American Diabetes Association, Diabetes Care, http://care.diabetesjournals.org/content/26/9/2653. (The website was accessed on May 30, 2019.); https://www.merriam-webster.com/dictionary/ischemia. (The website was accessed on May 30, 2019.)

[40] https://www.merriam-webster.com/dictionary/glaucoma. (The website was accessed on May 30, 2019.)

[41] https://www.merriam-webster.com/medical/keratometer. (The website was accessed on June 2, 2019.)

[42] https://www.merriam-webster.com/dictionary/macular%20degeneration. (The website was accessed on May 30, 2019.)

[43] American Academy of Ophthalmology, What Is Optical Coherence Tomography? https://www.aao.org/eye-health/treatments/what-is-optical-coherence-tomography. (The website was accessed on May 30, 2019.)

OPMI VISU 210. A microscope using high-resolution images which aid in surgical procedures in the field of ophthalmology such as for cataract and retinal surgeries.[44]

optometry. The health-care profession concerned especially with examining the eye for defects and faults of refraction, with prescribing correctional lenses or eye exercises, with diagnosing diseases of the eye, and with treating such diseases or referring them for treatment.[45]

Pentacam HR® (Oculus/Insight Instruments)**.** A high-resolution rotating camera system for anterior eye segment analysis. This aids in the early detection of changes in the examined area of the eye.[46]

probe. Is usually a small object that is inserted into something.[47]

retinal detachment. A condition in which the retina of the eye is no longer connected to the eye as it should be.[48]

slit lamp. A type of microscope, is a lamp for projecting a narrow beam of intense light that is used in conjunction with a biomicroscope for examining the anterior parts (as the conjunctiva or cornea) of an eye.[49]

Spectralis HRA+OCT® (Heidelberg Engineering)**.** A non-contact diagnostic imaging device. It is intended for viewing the posterior segment of the eye and to perform measurements of ocular anatomy and ocular lesions. The device is indicated as an aid in the detection and management of various ocular diseases, such as age-related macular degeneration, macular edema diabetic retinopathy, and glaucoma.[50]

vascular endothelial growth factor. A protein which stimulates abnormal blood vessel growth in age-related macular degeneration.[51]

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[44] MED, Zeiss OPMI Visu 210 Surgical Microscope, https://med.equipment/zeiss-opmi-visu-210-surgical-microscope.html. (The website was accessed on May 30, 2019.)

[45] https://www.merriam-webster.com/dictionary/optometry. (The website was accessed on May 30, 2019.)

[46] Oculus, Pentacam® HR, https://www.oculus.de/us/products/anterior-segment-analysis/pentacam. (The website was accessed on May 30, 2019.)

[47] https://www.merriam-webster.com/dictionary/probe. (The website was accessed on May 30, 2019.)

[48] https://www.merriam-webster.com/dictionary/retinal%20detachment. (The website was accessed on May 30, 2019.)

[49] https://www.merriam-webster.com/medical/slit%20lamp. (The website was accessed on May 30, 2019.)

[50] U.S. Food and Drug Administration, https://www.accessdata.fda.gov/cdrh_docs/pdf17/K172649.pdf. (The website was accessed on May 30, 2019.)

[51] Cochrane Library, Anti-vascular endothelial growth factor for neovascular age-related macular degeneration (Review), Solomon SD, Lindsley K, Vedula SS, Krzystolik MG, Hawkins BS, https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005139.pub4/epdf/full. (The website was accessed on June 11, 2019.)

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