

July 12, 2018

The Honorable Johnny Isakson Chairman Committee on Veterans' Affairs United States Senate Washington, DC 20510

Dear Mr. Chairman:

In response to your letter dated February 28, 2018, in which you requested all Veterans Health Administration (VHA), Office of the Medical Inspector (OMI) unredacted reports, OMI is providing you with our findings from an investigation at the Manchester Veterans Affairs Medical Center, Manchester, New Hampshire.

The enclosed information is disclosed to the Committee pursuant to its oversight authority. The report contains sensitive information that is protected under the Privacy Act, 5 United States Code § 552a. VHA requests that the Committee keep this document in a secure location, limit use to those purposes consistent with the Committee's oversight, and ensure no further disclosure.

Thank you for your continued support of our mission. A similar response has been sent to the Ranking Member of your committee, as well as the Chairman, House Committee on Veterans' Affairs and the Ranking Member.

Sincerely,

Carolyn M. Clancy, M.D.

Executive in Charge



July 12, 2018

The Honorable David P. Roe, M.D. Chairman
Committee on Veterans' Affairs
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

In response to your letter dated April 18, 2018, in which you requested all Veterans Health Administration (VHA), Office of the Medical Inspector (OMI) unredacted reports, OMI is providing you with our findings from an investigation at the Manchester Veterans Affairs Medical Center, Manchester, New Hampshire.

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Sincerely,

Carolyn M. Clancy, M.D.

Executive in Charge



July 12, 2018

The Honorable Jon Tester Ranking Member Committee on Veterans' Affairs United States Senate Washington, DC 20510

Dear Senator Tester:

In response to your letter dated February 28, 2018, in which you requested all Veterans Health Administration (VHA), Office of the Medical Inspector (OMI) unredacted reports, OMI is providing you with its findings regarding the investigation at the Manchester Veterans Affairs Medical Center, Manchester, New Hampshire.

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Executive in Charge



July 12, 2018

The Honorable Tim Walz Ranking Member Committee on Veterans' Affairs U.S. House of Representatives Washington, DC 20515

Dear Congressman Walz:

In response to your letter dated April 18, 2018, in which you requested all Veterans Health Administration (VHA), Office of the Medical Inspector (OMI) unredacted reports, OMI is providing you with our findings from an investigation at the Manchester Veterans Affairs Medical Center, Manchester, New Hampshire.

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Sincerely,

Carolyn M. Clancy, M.D.

Executive in Charge



July 12, 2018

The Honorable Maggie Hassan Committee on Veterans' Affairs United States Senate Washington, DC 20510

Dear Senator Hassan:

This letter is in response to your staff's concerns regarding two recent investigations at the Manchester Veterans Affairs (VA) Medical Center, Manchester, New Hampshire. Enclosed is a redacted copy of the Office of the Medical Inspector's VA report.

Thank you for your continued support of our mission.

Sincerely,

Carolyn M. Clancy, M.D.

Executive in Charge

Department of Veterans Affairs Veterans Health Administration Washington, DC



Department of Veterans Affairs (VA) Manchester Wa Medical Center Manchester, New Hampshire

Veterans integrated Service Network 1 Released to the

Report Date: June 26, 2018

TRIM 2017-D-3072

Executive Summary

Introduction

The Secretary (SecVA), Department of Veterans Affairs (VA), through the Under Secretary for Health (USH), requested that the Office of the Medical Inspector (OMI) assemble and lead a VA team to complete a thorough review of the Manchester VA Medical Center (the Manchester VA), Manchester, New Hampshire, in response to allegations published by the *Boston Globe* on July 15, 2017. The whistleblowers seeme self-identified and some anonymous, reported to the paper that there are several problems at the Manchester VA regarding Veteran care, management issues scope of services offered, and the Veterans Choice Program (VCP). The VA team conducted site visits there on July 20–23, July 26–29, and October 10–12, 2017.

Background on the Scope of Services provided at the Manchester VA

VA determines which types of services each Veterans Health administration (VHA) facility is able to provide based upon its resources. Each facility is assigned a complexity level, the intent of which is to group similar produizations for operational reports, performance reviews, research studies, outcome comparison, and budgeting under the Veterans Equitable Resource Allocation (VERA). There are five levels: 1a, 1b, 1c, 2, and 3. Level 1a facilities are the most complex and those designated at level 3 are the least complex with the lowest Veteran volumes, clinical acuities, and physician specialist ratios. They tend to have little proo research activities.

The Manchester VA is classified as a complexity level 3 facility, but it is an unusual one. Most level 3 VA medical centers (NAMC) are devoted to inpatient MH and long-term care, but the Manchester VA has no inpatient beds apart from its CLC. The Manchester VA closed its acute inpatient care beds in November 1999. It provides acute inpatient care through a contract with a local hospital, Concord Hospital, and by referral to the Boston and White River (MRJ) VA medical centers.

VHA assigns surgical programs an "operative complexity" level of Standard, Intermediate, or Complex, and each of its ambulatory (outpatient only) surgery centers an operative complexity level of either Basic or Advanced. The Manchester VA's operative complexity level is Ambulatory Basic. The requirements for this surgical complexity designation include:

Access to basic pre-operative and postoperative diagnostic evaluation, A Post Anesthesia Care Unit,

- Pharmacy and Blood Bank services available within the hour during weekdays, and
- Protocols to transfer Veterans within 60 minutes to VHA or community acute care facilities.

The Manchester VA provides an array of outpatient services in urgent, primary and specialty care, ambulatory surgical care, mental health (MH), geriatrics and extended care, and has a 41-bed Community Living Center (CLC) with 6 beds dedicated to palliative care. It does not provide any inpatient medical services. The decision to limit the type of services provided in Manchester, which was made 19 years ago, continues to have an impact on the care provided to New Hampshire Veterans today. The lack of a full-service VA medical center in the state of New Hampshire also substantially affects the percentage of Veterans who are eligible for participation in the VCP in that over 93 percent of the state's Veterans are eligible to seek care under its eligibility rules, the fiscal year (FY) 2016, the Manchester VA incurred a \$6 million spending deficit related to the provision of inpatient care in community hospitals. The establishment of VCP and changes in eligibility rules has made its implementation difficult for clinicians as they have tried to provide comprehensive care for Veterans.

Along these same lines, when a new Chief of Surgery was hired string FY 2016, he thought that his charge included expanding the scope of surgical services described above. He proceeded to hire new surgical staff members and requested new surgical equipment to support this expansion; however, he became trustrated with the bureaucracy involved in what he believed to be his mission, but nevertheless continued to persevere. Ultimately, the limited scope or surgical services dictated by the Basic Ambulatory Surgical Complexity in place limited his expansion capabilities.

Specific Allegations Abstracted from the Boston Globe Article

A. VA Care in the Community

Allegation 1. Providers alleged that the Chief of Staff (hereafter, CoS 2) restricted their ability to refer Veterans for Care in the Community (CITC) outside of the Veterans Choice Program (VCP).

Allegation 2. The Manchester VA's program for setting up appointments with outside specialists has broken down and thousands of Veterans, some with life-threatening conditions, struggleto get any care at all.

B. Scope of Services provided at the Manchester VA

Allegations. Surgical Services have allegedly been stymied by a failure to replace obsolute equipment and there is a lack of space for new diagnostic equipment.

Allegation 4. Rust or blood stained surgical instruments that were supposedly sterile have been delivered to the operating room (OR).

Allegation 5. There is an ongoing fly infestation that has closed an OR since October 2016.

Allegation 6. The Manchester VA lacks a reliable Nuclear Medicine (NM) camera; this impairs its ability to diagnose certain conditions in a timely fashion.

C. Veteran Quality of Care Concerns

Allegation 7. A Veteran alleged to the investigative team a 6–9 month delay in his prostate cancer diagnosis.

Allegation 8. A Veteran's daughter contacted the investigative team and alleged father received substandard care while he resided in the Community Living Contact (CLC).

D. Manchester VA Leadership

Allegation 9. Providers alleged that Manchester VA leadership is unresponsive to their concerns.

Allegation 10. Manchester VA leadership appointed an unsualified person as the Acting Chief of Primary Care (PC).

Allegation 11. Providers alleged that nursing leading hip exercised an unusual amount of decision making authority.

Allegation 12. High-ranking doctors at the Manchester VA have given up leadership positions or plan to leave the hospital, and other physicians are indignant on their behalf, citing frustration with management.

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

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

A. VA Care in the Community (CITC)

Conclusions and Recommendations regarding VA CITC

- We do not substantiate that CoS 2 restricted providers' abilities to refer Veterans for CITC outside of using the VCP.
- Prior to the establishment of VCP in 2014, the Manchester Spinal Cord Injury and Disease (SCI/D) service referred the majority of Veterans needing neurosurgical

evaluation to one non-VA provider in Boston, Physician 1, via the traditional CITC process.

- After the enactment of the Veterans Access, Choice, and Accountability Act (VACAA) of 2014, the Manchester VA appropriately referred eligible SCI/D Veterans needing neurosurgical care to VCP, based on the guidance provided by VHA's Hierarchy for Purchased Care. Per the guidance, VCP is the primary mechanism used when Veterans are eligible for Choice care. This includes Veterans in New Hampshire who reside more than 20 miles from the WRJ VA.
- Physician 1 chose not to participate in VCP, and therefore Veterans could not be referred to him for the provision of Choice care without an established provider Agreement with the Manchester VA.
- Throughout his tenure, CoS 2 strictly followed the guidance outlined in the Hierarchy for Purchased Care, as required by VHA Central Office in the October 1, 2015, VA memorandum, and faced pressure from Veterans Integrated Service Network (VISN) 1 that strongly discouraged the use of local funding for OFTC when other options were available.
- CoS 2 individually evaluated each CITC request to purchase non-VA care, and made decisions based on the Hierarchy of Furchased Care guidance. In FY 2016 he authorized 11 of 38 requests to be referred to Physician 1 using CITC funding, and, in the first 5 months of FY 2017, authorized 2 more.
- Due to a confluence of factors, including growth in utilization by Veterans and decreased CITC funding, the Manchester VA ran a \$6 million deficit in FY 2016. We found evidence that VISN's assisted in the management of this deficit before the end of the FY.
- External third-party seer reviews determined 95 episodes of care for Veterans with SCI/D who were receiving nonsurgical care at the Manchester VA received services that met the standard of care, and six episodes of care for Veterans with SCI/D who were receiving honsurgical care at the Manchester VA did not.
- The MSD and CoS 2 were actively engaged in addressing concerns that had been raised and were wholly committed to providing Veteran-centric solutions. They attempted to work within the existing VCP laws, rules, and regulations as they evolved from 2014–2017 to provide a scope of services at the Manchester VA in accordance with its designation as a level 3 facility with basic ambulatory surgical services.
- The Manchester VA leadership worked diligently to maximize their budget, including obtaining funds for additional options under the CITC program, to ensure that they could provide care.

- The MCD and CoS 2 were extremely engaged, transparent, and supportive of exploring options to further develop programs, all signs of their commitment to open communication and psychological safety to ensure that Veterans receive the highest quality of care.
- The VERA funding model does not provide adequate funding to support the realtime needs and actual productivity of the Manchester VA.

Recommendations to the Manchester VA

- 1. Request additional funding as needed for traditional CITC, and continue to scrutinize requests for non-VA purchased care to ensure that each is the most appropriate for the eligible Veteran's needs and cost effective for the American tax payer.
- 2. Ensure that Manchester and Boston VA leadership review each their respective cases that did not meet the standard of care and take appropriate action in accordance with VHA Handbook 1004.08, Disclosure of Appress Events to Patients.

Recommendations to VHA

- 1. Ensure that all the SCI/D cases pending external third-party peer review are completed. These reviews should address whether myelopathy was diagnosed in a timely manner and whether the treatment surgical and nonsurgical) was appropriate.
- 2. Reevaluate the VERA funding moder and its implementation at the Manchester VA in view of the unique limitations imposed by implementation of VACAA in New Hampshire.

Conclusions and Recommendations related to Consultation Management

- We substantiate that the third party administrator (TPA) serving the Manchester VA, Health Net Cailed to meet its contractual obligations to provide services in connection with the VCP, which resulted in the Manchester VA's inability to ensure that Veterans received timely medical care. During the course of this investigation, we identified six Veterans whose care had been referred to a third-party external reviewer to determine if delays in care resulted in harm or adverse outcomes. The provided to these six Veterans is discussed in this report under the relevant vections.
- The Manchester VA's Business Office lacked necessary resources to adequately handle its workload and became seriously overwhelmed as it attempted to address Health Net's failures. The VISN 1 Business Implementation Manager did not completely understand the challenges facing the Business Office or its need for increased staffing. The VHA Office of Community Care (OCC) did not adequately respond to the quality of care concerns raised by the MCD and CoS 2.

- The MCD and CoS 2 consulted with the VHA OCC for guidance and made appropriate decisions to coordinate the care needs of Veterans through other CITC options.
- The Manchester VA Business Office staff failed to make administrative changes to community care consults for VCP referrals as they moved through the consultation process, which resulted in inaccurate community care consult data, violating VHA, Directive 1232, Consult Policies and Processes. Over 3,000 open community care consults for VCP referrals had not been moved from pending to completion status until late July 2017. All of these consults were reviewed for relative adverse events and none were found.
- We found a lack of follow up by VISN and VHA leadership regarding their knowledge of the VHA Support Service Center (VSSC) data and ability to access the data. While VSSC data are available on community care consultations, they are not included in the SAIL reports that VA medical facilities and VISNs automatically receive. The weekly National Consultation Performance improvement teleconference is not mandatory, and while the data are available on the Consultation SharePoint site, there had not been any follow up with the Manchester VA regarding the upward trend of open and pending community care consultations reported on the call in September 2016.
- We have requested an external third-garty review of the Veteran diagnosed with lung cancer. Until this review has been completed, we cannot determine whether the Veteran received appropriate medical care.

Recommendations to the Manahester VA

- 3. Ensure that all Business Office staff members are trained on VHA Directive 1232.
- 4. Implement a monthly audit process for community care consults for VCP referrals to ensure compliance with VHA Directive 1232.
- 5. Depending on the results of the external third-party review, take action if necessary in accordance with VHA Handbook 1004.08.

Recommendation to VISN 1

1. Review the Manchester VA's budget and ensure that the Business Office has adequate staff and resources to address workload.

Recommendations to VHA

3. Consider including very specific accountability expectations and resulting actions if a new contract is awarded to a TPA. Prior to award, VA should gain reasonable

- assurance that the proposed TPA has the clinical and administrative resources necessary to schedule appointments for requested care.
- 4. In addition to VHA Recommendation 1, develop means to provide real-time funding to support the real-time needs and productivity of the Manchester VA. Trace the history of Issue Briefs submitted by the MCD to determine whether or not the process as outlined in the VHA Guide for Issue Briefs was followed.
- 5. Ensure Community Care Support Center (CCSC) and VSSC create their months reports to distribute to VHA facilities with their individually trended data.
- Monitor the newly established CCSC to ensure community care consultation data are provided to every VHA facility and VISN, and that VHA OCC field support staff members are documenting corrective action plans and progress for the VHA facilities that have difficulty meeting consult management metods defined in VHA Directive 1232.
- 7. Ensure that each VHA facility participates in the VHA OCC monthly teleconference and receives the monthly national report on CCSC. Consultation data are occurring, including VISN and VAMC corrective action plans and progress reports.
- B. Scope of Services provided at the Manahester VA

Conclusions and Recommendations related to Surgical Services

- We do not substantiate that the Manchester VA's Surgical Services are stymied. This VHA facility is a Basic Ambulatory Surgical Complexity medical center, which is limited in the complexity of OR cases it can perform due to a lack of inpatient care and other acute care services needed to support more complex surgeries.
- Because of budgetary constraints, neither the Manchester VA nor VISN 1 was able to purchase the equipment requested by the Chief of Surgery until FY 2017. However, order the equipment was received in July 2017, the Chief of Surgery indicated to be returned because it could not be used due to the Manchester VA's designation as a Basic Ambulatory Surgical Complexity facility.

Recommendation to the Manchester VA

 Confirm whether the high-cost, high-tech equipment procured in FY 2017 is needed by Urology or can be utilized by surgical services elsewhere within the Manchester VA or VISN 1.

Recommendations to VISN 1

- Informed by recommendations received from the VA New Hampshire Vision 2025
 Task Force, the MCD should determine which surgical services are feasible for the
 Manchester VA to provide. Once determined, take the appropriate steps for
 implementation.
- 3. Review the Manchester VA's budget to ensure sufficient financial resources are allocated to meet the clinical needs of the increasing number of unique Veterarish being served by the Manchester VA and to address the unique demand for health care services in the State of New Hampshire.

Conclusions and Recommendations related to Stained Surgical liestruments

- Small amounts of particulate matter, not rust or blood, were found on surgical instruments and inside of the packaging. These benign particulates resulted from the city of Manchester's water supply, which is high in heavy metal content. These instruments never came in contact with Veterans.
- The Manchester VA OR nurses were appropriate to take immediate action "to stop the line" of surgical cases in the OR, their actions and the Manchester VA's actions that followed were proactive and appropriate to ensure safety of Veterans, and no Veterans were rescheduled or cancelled following the initial report.

Recommendation to the Manchester V

7. Continue to collaborate with the National Program Office for Sterile Processing (NPOSP) to ensure Veteran safety in surgical care, and complete corrective action plan accordingly.

Conclusions and Recommendations related to Cluster Flies

- We found no documented evidence of surgeries, endoscopies, or colonoscopies being cancelled or rescheduled as a result of flies in OR #2.
- The Marchester VA continues to have flies in OR #2, so it continues to take all recommended actions to monitor OR #2 for flies and to mitigate infiltration.

Recommendations to the Manchester VA

- 8. Continue to implement the recommendations made by VHA's Pest Management Program Manager and the pest management company.
- 9. Ensure that OR staff members continue to check for flies in each room, each morning, prior to the start of the first scheduled case.

Conclusions and Recommendations related to Nuclear Medicine (NM)

- Due to a confluence of factors, including changes in the National Acquisition Center (NAC) process to prepare sites for new equipment installation and associated construction funding, the NM suite renovations were not funded in FY 2017, leading to a delay in construction, and subsequent delivery and installation of the new NM camera.
- The MCD and CoS 2 appropriately decided to temporarily pause NM services and refer Veterans to the Boston or WRJ VAs, and Catholic Medical Center on after considering multiple factors including the construction project delay, technician retirement, cardiologist resignation, and a concern for Veteran safety from excess radiation exposure from repeated cardiac NM stress tests. There was no intention to permanently stop offering NM services, and there was an appropriate plan in place to provide care to Veterans in need of NM testing.
- The MCD and CoS 2 intended to fill the vacant cardiologist position, and hire an intermittent NM technologist. Human Resources (HR) appropriately posted the vacant cardiologist and NM technology positions to the workload demand. However, HR documented the selecting official chose not to interview four applicants that met qualifications in late March for unspecified reasons.
- External third-party peer reviews are trefog completed. We have not determined
 whether any of the three cases identified by the Cardiology Nurse Practitioner (NP)
 as having a delay in care received madequate care.

Recommendations to the Manahester VA

- 10. Continue ongoing efforts to ensure Veterans receive NM studies and testing in a timely manner.
- 11. Informed by recommendations received from the VA New Hampshire Vision Task Force, the MSD should ensure renovation and construction funds are available and the NM project is completed on time to take delivery of the new NM camera on December 30, 2018.
- 12. Petering external third-party peer reviews results for the three cases identified by Cardiology NP as having a delay in care, take appropriate action, if indicated, in accordance with VHA Handbook 1004.08.

Recommendation to VISN 1

 Continue to work with MCD and the VA New Hampshire Vision 2025 Task Force to ensure renovation and construction projects are funded and completed on time to take delivery of the new NM camera on December 30, 2018.

C. Veteran Quality of Care Concerns

Conclusions for Veteran Quality of Care Concerns

- We have requested an external third-party peer review of the first Veteran's medical care related to the diagnosis of prostate cancer and are awaiting the results. Until then, we cannot determine whether the Veteran received appropriate care.
- The external third-party peer review of the second Veteran's CLC care has been completed and it has been determined that it met the standard of care

Recommendation to the Manchester VA

13. Depending on the results of the external third-party review of eare for the Veteran with prostate cancer, take actions if necessary in accordance with VHA Handbook 1004.08.

D. Manchester VA Leadership

Conclusions related to Manchester VA Leadinship

- We do not substantiate that the Manchester VA leadership that was in place at the
 time of this investigation was unresponsive to provider concerns; however, the Office
 of Accountability and Whistleblower Protection (OAWP) will make a determination in
 a separate report of whether and senior leader misconduct occurred.
- We do not substantiate that an unqualified person was appointed as Acting Chief of PC. According to the Bylaws of the Medical Staff, a clinical leader is appointed by the MCD upon the recommendation of the CoS; the appointment of a Physician Assistant (PA) as a clinical leader is not prohibited. The MCD appointed a physician as the Acting Street of PC 1 month after the PA's appointment upon the receipt of complaints from several physicians.
- We do not substantiate that nursing leadership at the Manchester VA exercised an unusual amount of decision-making authority.
- exploring options to further develop programs: all signs of their commitment to open communication and psychological safety to ensure that Veterans receive the highest quality of care.

Recommendation to VHA

8. Consider a National Center for Organizational Development (NCOD) consultation to assist Manchester VA staff members in uniting and moving forward.

Analysis of Findings

Significant challenges faced the Manchester VA leadership and staff members as they attempted to provide care to New Hampshire's Veterans. Specifically, its' status as a complexity level 3 facility without any acute inpatient medical services, as well as the lack of any other VHA facilities within the state designated for this level of care, resulted in 93 percent of New Hampshire's Veterans being eligible for CITC through the VCP. This unique situation, along with Health Net's inability to provide timely CITC consultation management, significantly contributed to the untenable state of care. In the midst of this turmoil, Manchester VA clinicians, some of whom though that their mission was to improve and expand the scope of care within the facility, attempted to add services despite a lack of VHA's prior authorization and approval to do so.

The VCP, established in 2014, changed the business rules that the Manchester VA leadership team was required to follow in providing CITC, for Veterans. Several clinicians became concerned about clinical quality of care due to limited services and an inability to refer patients for care using the former referral rules. Despite leadership's efforts to both improve communication and psychological safety in an effort to provide timely care for Veterans, several clinicians became distrustful and frustrated. When they felt as if their clinical concerns were not addressed by their leadership, several chose to voice them publicly.

While there were several confounding factors contributing to significant challenges, we found that Manchester VA clinical staff members involved in direct patient care are very engaged and appropriately conformed about the clinical care of Veterans.

Summary Statement

We have developed this report in consultation with other VHA and VA offices to address concerns that the Manchester VA had problems with Veteran care, management issues, scope of services offered, and the VCP. In particular, the Office of General Counsel has provided a legal review, and OAWP has reviewed the report to determine whether it makes findings against senior leaders requiring OAWP action, and the National Center for Ethics in Health Care has provided a health care ethics review. We found one violation of VHA policy, no violations of law, rule or regulation, and no evidence of gross mismanagement or a gross waste of funds.

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I. Introduction

The Secretary (SecVA), Department of Veterans Affairs (VA), through the Under Secretary for Health (USH), requested that the Office of the Medical Inspector (OMI) assemble and lead a VA team to complete a thorough review of the Manchester VA Medical Center (the Manchester VA), Manchester, New Hampshire, in response to allegations published by the *Boston Globe* on July 15, 2017. The whistleblowers, some self-identified and some anonymous, reported to the paper that there are several problems at the Manchester VA regarding Veteran care, management issues, scope of services offered, and the Veterans Choice Program (VCP). The VA team conditioned site visits there on July 20–23, July 26–29, and October 10–12, 2017.

II. Facility Profile

The Manchester VA, part of Veterans Integrated Service Network (VSN) 1, is a Joint Commission accredited, complexity level 3 medical center service 33,198 enrolled Veterans in southern and eastern New Hampshire at its main campus and its four Community Based Outpatient Clinics (CBOC) in Conway, Portsmouth, Somersworth, and Tilton, New Hampshire. The Manchester VA initially operated as a 28-bed full-service hospital; however, inpatient services halted in 1999, and it now refers Veterans in need of inpatient services to the Boston VA Medical Center (Boston VA) in Massachusetts, the White River Junction (WR II VA Medical Center in Vermont or to a contracted Community Hospital in Concord, New Hampshire.

Background on the Scope of Services provided at the Manchester VA

VA determines which types of septices each Veterans Health Administration (VHA) facility is able to provide based upon its resources. Each facility is assigned a complexity level, the intent of which is to group similar organizations for operational reports, performance reviews, research studies, outcome comparisons, and budgeting under the Veterans Equipole Resource Allocation (VERA) model. There are five levels: 1a, 1b, 1c, 2, and 3. Level 1a facilities are the most complex and those designated at level 3 are the least with the lowest Veteran volumes, clinical acuities, and physician specialist ratios. They tend to have few or no research activities.

The Manchester VA is classified as a complexity level 3 facility, but it is an unusual one. Most level 3 VA medical centers are devoted to inpatient mental health (MH) and long-term care, but the Manchester VA has no inpatient beds apart from its Community Loring Center (CLC). The Manchester VA closed its acute inpatient care beds in November 1999. It provides acute inpatient care through a contract with a local hospital, Concord Hospital, and by referral to the Boston and WRJ VA medical centers.

VHA assigns surgical programs an "operative complexity" level of Standard, Intermediate, or Complex, and each of its ambulatory (outpatient only) surgery centers an operative complexity level of either Basic or Advanced. The Manchester VA's

operative complexity level is Ambulatory Basic. The requirements for this surgical complexity designation include:

- Access to basic pre-operative and postoperative diagnostic evaluation.
- A Post Anesthesia Care Unit,
- Pharmacy and Blood Bank services available within the hour during weekdays, and
- Protocols to transfer Veterans within 60 minutes to VHA or community acute facilities.

The Manchester VA provides an array of outpatient services in urgent, primary and specialty care, ambulatory surgical care, MH, geriatrics and extended care and has a 41-bed CLC with 6 beds dedicated to palliative care. It does not provide any inpatient medical services. The decision to limit the type of services provided the Manchester VA, which was made 19 years ago, continues to have an impact of the care provided to New Hampshire Veterans today. The lack of a full-service VA medical center in the state of New Hampshire also substantially affects the percentage of Veterans eligible for participation in the VCP in that over 93 percent of the states Veterans are eligible to seek care under its eligibility rules. In fiscal year (FY) 2016, the Manchester VA incurred a \$6 million deficit related to the provision of impatient care in community hospitals. The establishment of VCP and changes in eligibility rules has made its implementation difficult for clinicians as they have tried to provide comprehensive care for Veterans.

Along these same lines, when a new Chief of Surgery was hired during FY 2016, he thought that his charge included expanding the scope of surgical services described above. He proceeded to hire new surgical staff members and requested new surgical equipment to support this expansion; however, he became frustrated with the bureaucracy involved in what he believed to be his mission, but nevertheless continued to persevere. Ultimately, the limited scope of surgical services dictated by the Basic Ambulatory Surgical Complexity in place limited his expansion capabilities.

III. Background of the Boston Globe Article

Jonathan Salizman and Andrea Estes of the *Boston Globe* Spotlight Team contacted the Manchester VA on May 30, 2017, with questions about problems ranging from more than 3,000 Veterans having their referrals to the VCP returned to the Manchester VA so far this year, to a lack of medical equipment at the hospital. The Manchester VA's Public Affairs Officer (PAO) immediately notified the Manchester VA Director (MCD) and the VISN 1 PAO. To keep leadership at all levels informed of the *Boston Globe* interview scheduled for June 14, the MCD sent an Issue Brief to the VHA Central Office through the VISN, updating it nine times before the *Globe* article was published on July 15. In preparation for the interview, the MCD and her senior staff met several times with VHA subject matter experts (SME) in the areas of the media inquiry. On June 14, the

Medical Center Issue Brief and updates submitted to VHA Central Office through VISN 1, June 14-16, 2017.

journalists interviewed the MCD and Chief of Staff (CoS 2, who served from November 2015 until July 2017), who were assisted by the SMEs, VHA and VISN Communications, and the North Atlantic District Office of Public Affairs personnel, the Deputy Under Secretary for Health (DUSH) for the Office of Community Care (OCC), the Deputy Executive Director, Provider Relations and Services, VHA, and the Manchester VA's Office of Public Affairs.²

Immediately after the interview, the MCD debriefed the Principal Deputy Under Secretary for Health (PDUSH), the Assistant DUSH (ADUSH) for Clinical Operations, the DUSH for Organizational Excellence, VHA's Deputy Executive Director, Office of Communications, the Directors of Management Review Service and Network Support, the ADUSH for Integrity, and VISN 1's Director and CoS.³ She also briefed the local Congressional delegation and worked with VISN leadership to formulate a response plan. The MCD and senior staff arranged Town Hall meetings to inform staff and provide opportunities for questions and answers related to the uponning article and media attention.⁴

The Boston Globe article described an "extraordinary rebellion led by [Manchester VA] doctors" who felt that they had almost no say in how the bespital was run. The article emphasized that only one of the four top administrators there is a doctor, and asserted that nursing leadership exercised most of the decision-making authority. In most private sector hospitals, physicians in private practice apply for privileges and are appointed to an affiliated medical staff distinct from the hospital administration. Although a separate entity with its own leadership structure, this medical staff holds great influence over the scope of services and other aspects of oligical practice at the facility, because the hospital depends on its physicians for referrals, admissions, and, ultimately, revenue.

Unlike the private sector, all stant members at government hospitals, including physicians, are salaried employees. The typical structure of the senior leadership team at a VHA facility consists of a quadrad or pentad of executives: the MCD (CEO), Associate Director (COO), CoS 2 (Chief Physician Executive), Associate Director for Patient Care Services (ADPCS: Chief Nurse Executive), and sometimes an Assistant Director. MCDs may come from any professional community; most are career health care administrates, but some are nurses, physicians, or allied health professionals. All quadrad members report to the MCD, and it is common for the CoS to be the only physician of a VA leadership team.

Mentions of the medical staff are appointed by the MCD and ultimately report to him or her brough a hierarchy of leadership. Senior physicians hold leadership positions with significant management responsibility, such as Service Chiefs (e.g., Chief of Anesthesia, Chief of Emergency Medicine) and heads of entire divisions (e.g., Chief of Medicine, Chief of Primary Care (PC), or Chief of Surgery). The entire medical staff works under the supervisory control of the CoS. A similar leadership hierarchy exists

 $^{^{\}rm 2}$ Manchester VA Issue Briefs submitted to VHA Central Office through VISN, June 14-16, 2017. $^{\rm 3}$ Ihid.

⁴ Ibid.

within the nursing staff. Mid-level and upper-level nurse managers work under the supervision of the ADPCS, who in turn reports to the MCD. In addition to overseeing nursing practice, the ADPCS usually has management responsibility for ancillary hospital services such as the laboratory and pharmacy.

In July 2017, the quadrad at the Manchester VA consisted of the MCD, a nurse who also holds a Master of Business Administration degree, appointed in May 2015; the CoS, an internal medicine physician appointed in November 2016; the ADPCS, in that role since 2004; and the Associate Director, a health care administrator appointed in January 2017.

IV. Specific Allegations Abstracted from the Boston Globe Article

A. VA Care in the Community

Allegation 1. Providers alleged the CoS 2 restricted their ability to refer Veterans for Care in the Community (CITC) outside of the VCP.

Allegation 2. The Manchester VA's program for setting appointments with outside specialists has broken down and thousands of Veterars, some with life-threatening conditions, struggle to get any care at all.

B. Scope of Services provided at the Manchester VA

Allegation 3. Surgical Services have allegedly been stymied by a failure to replace obsolete equipment and there is a lagric of space for new diagnostic equipment.

Allegation 4. Rust or blood stained surgical instruments that were supposedly sterile have been delivered to the opporating room (OR).

Allegation 5. There is an ongoing fly infestation that has closed an OR since October 2016.

Allegation 6. The Manchester VA lacks a reliable Nuclear Medicine (NM) camera; this impairs its about to diagnose certain conditions in a timely fashion.

C. Vetetary Quality of Care Concerns

Atlegation 7. A Veteran alleged to the investigative team a 6–9 month delay in his prostate cancer diagnosis.

Allegation 8. A Veteran's daughter contacted the investigative team and alleged her father received substandard care while he resided in the CLC.

D. Manchester VA Leadership

Allegation 9. Providers alleged that leadership is unresponsive to their concerns.

Allegation 10. Manchester VA leadership appointed an unqualified person as the Acting Chief of Primary Care (PC).

Allegation 11. Providers alleged that nursing leadership exercised an unusual amount of decision making authority.

Allegation 12. High-ranking doctors at the Manchester VA have given up legislariship positions or plan to leave the hospital, and other physicians are indignant on their behalf, citing frustration with management.

V. Conduct of Investigation

The VA team conducting the investigation consisted of Gerard Cox, M.D., MHA, Assistant DUSH for Integrity; Erica Scavella, M.D., FACP, FACHE, the Medical Inspector; Marcia Bowens, MSN, RN, Clinical Program Manager, all of OMI; Natacha de Silva, Office of Veterans Access to Care (OVAC), David Douglas, M.D., Chie, Health Informatics Officer, Portland VA Medical Center, and Erin VanVorst, VHA OCC. The Office of Accountability and Whistleblower Protection's OAWP) Acting Director, Investigations Division, Kurt Martin and Michael Doucette Investigator were also present conducting a concurrent investigation; OAWP will issue a separate report. We conducted 47 formal interviews of employees, 6 telephone interviews with Veterans, and provided 36 listening sessions onsite for staff numbers requesting to speak with us. We reviewed at least 363 documents, including relevant policies, procedures, professional standards, reports, memorandums, etc., fieted in Attachment A. On July 19, 2017, a catastrophic pipe failure occurred on the seventh floor causing significant flooding and damage on the four floors below. As a result, we limited our tour to the OR.

We held entrance and exit briefings with the following:

VISN 1 leadersbip:

Deputy Network Director

Quality Management (QM) Officer

Retwork Communications Officer

Manchester VA leadership:

- Acting MCD
- Associate MCD
- Acting CoS (CoS 3)
- ADPCS
- Acting ADPCS
- Chief of QM
- Executive Assistant (EA) to the MCD
- EA to the Acting MCD
- Congressional Liaison

We interviewed the following employees:

From VHA Central Office:

- Members of the OCC Staff
- Members of the OVAC Staff

From VISN 1:

- Network Director
- Chief Medical Officer (CMO)
- QM Officer
- Chief Financial Officer (CFO)
- Business Office Director

From the Manchester VA:

- Manchester VA Leadership Team
- Acting Members of the Executive Leadership Team
- Chief of Medicine and Service Line Manager for Medicine and Specialty Care
- Members of the Administrative Staff
- Members of the Medical Staff
- Members of the Nursing Staff
- Members of the Business Office Staff
- Members of the QM Staff

Windings, Conclusions, and Recommendations

A. VA Care in the Community

The following two allegations fall under this section:

Allegation 1. Providers alleged that CoS 2 restricted their ability to refer Veterans for Care in the Community (CITC) outside of the VCP.

Allegation 2. The Manchester VA's program for setting up appointments with outside specialists has broken down and thousands of Veterans, some with life-threatening conditions, struggle to get any care at all.

Background of VA Care in the Community

Background on Veterans Choice Program

In August 2014, President Obama signed into law the Veterans Access, Choice, and Accountability Act (VACAA).⁵ Among other things VACAA required VA to establish a program, known as VCP, to temporarily expand the availability of hospital cate and medical services from community providers for eligible Veterans. VA implemented this authority by publishing an interim final rule on November 5, 2014.

In order to provide care under VCP VA modified the existing Patient Centered Community Care (PC3) contract which had been set up the provides year to create a network of community providers for VA to use when care could not feasibly be provided within VA. The modified contract required a third party administrator (TPA) to create a network of eligible providers eligible to provide care under VCP.

In instances where VA was unable to acquire the necessary services through the PC3/Choice contract, VACAA, as amended on January 15, 2015, provided VA with authority to enter into agreements, known with VA as Choice Provider Agreements, directly with individual providers. These agreements could only be entered into when VA's existing contracts and acquisition authorities were not sufficient to procure the necessary care.

To be eligible to receive care under VCP, Veterans must be enrolled in VA health care and meet at least one of the receive care under vCP, Veterans must be enrolled in VA health care and meet at least one of the receive care under vCP.

The Veteran pages care that his or her local VA medical facility does not offer;

The VA Medical Center medical facility is not able to schedule an appointment for the Veteran Ceare within the wait- time goals of VHA or, with respect to care and services that are clinically necessary, the period VA determines necessary for such care or services if such period is shorter than the wait-time goals of VHA.

WHA defined its wait-time goals as "a date not more than 30 days from

either: (1) the date that an appointment is deemed clinically appropriate by a VA health care provider. In the event a VA health care provider identifies a time range when care must be provided (e.g., within the next 2 months), VA will use the last clinically appropriate date for determining

⁵ Amendments to VACAA were made on September 26, 2014, by the Department of Veterans Affairs Expiring Authorities Act of 2014 (Pub. L. 113-175); on December 16, 2014, by the Consolidated and Further Continuing Appropriations Act of 2015 (Pub. L. 113-235); on May 22, 2015, by the Construction Authorization and Choice Improvement Act (Pub. L. 114-19); and on July 31, 2015, by the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 (Pub. L. 114-410; and on April 19, 2017 by an act to amend the Choice Act to modify the termination date for the VCP, and other purposes (Pub. L. 115-26).

whether or not such care is timely. (2) Or, if no such clinical determination has been made, the date that a veteran prefers to be seen for hospital care or medical services."

- The Veteran lives more than 40 miles driving distance from the closest VA medical facility with a full-time PC provider; The Veteran lives in a state or territory without a full-service VA medical facility and more than 20 miles from such a facility in another state; this includes approximately 93% of Veterans in New Hampshire because they reside more than 20 miles from the White River Junction (Vermont) VA Medical Center (WRJ).⁷
- The Veteran resides in a location other than Guam, American Samoa, othe Republic of the Philippines and needs to travel by air, boat, or ferry to be nearest VA medical facility;
- The Veteran faces an unusual or excessive burden in traveling to a VA medical facility based on geographic challenges, environmental factors or a medical condition that affects the ability to travel, or other factors as determined by VA.

VA has implemented VCP in part, through the PC3/Choice centract which uses two contractors to act as TPAs that manage regional networks of providers for VA. These contractors are Health Net, the TPA for the Medical Center, and TriWest Healthcare Alliance. In order to participate in the VCP networks managed by the TPAs, non-VA providers must accept VCP's terms of participation agreement and join the TPA's network of providers. In a state where approximately 93 percent of Veterans are eligible to use this program, the Medical Center experienced numerous difficulties implementing the VCP. Health Net was unable to schedule many Veterans in a timely manner or provide access to some of the specialty pare needed; it subsequently returned numerous referrals to the Medical Center for action. We will address these challenges in detail later in this report.

Veterans Choice Program Fimeline⁸

As stated above, in Access, Choice, and Accountability Act (VACAA). Among other things VACAA

³⁸ CFR §17,1505 Defintions.

⁽https://www.sporgov/fdsys/search/pagedetails.action?sr=7&originalSearch=&st=Access+List+IS&ps=10&na=&se=&sb=re&tine=FalateBrowse=&collection=&historical=false&packageId=CFR-2015-title38-vol1&bread=frue&fromState=&granuleId=CFR-2015-title38-vol1-sec17-

¹⁵⁰⁵⁵ MectionCode=CFR&browsePath=Title+38%2FChapter+I%2FPart+17%2FSubjgrp%2FSection+%26sect% 3B 1.1505&collapse=true&fromBrowse=true).

Fact Sheet, Veterans Access, Choice and Accountability Act of 2014, Title I: Choice Program and Health Care Collaboration. Updated December 1, 2015. (https://www.va.gov/opa/choiceact/documents/choice-program-fact-sheet-final.pdf.

⁸ https://www.va.gov/opa/choiceact/.

Amendments to VACAA were made on September 26, 2014, by the Department of Veterans Affairs Expiring Authorities Act of 2014 (Pub. L. 113-175); on December 16, 2014, by the Consolidated and Further Continuing Appropriations Act of 2015 (Pub. L. 113-235); on May 22, 2015, by the Construction Authorization and Choice Improvement Act (Pub. L. 114-19); and on July 31, 2015, by the Surface Transportation and Veterans Health Care Choice Improvement Act of 2015 (Pub. L. 114-410; and on April 19, 2017 by an act to amend the Choice Act to modify the termination date for the VCP, and other purposes (Pub. L. 115-26).

required VA to establish a program, known as VCP, to temporarily expand the availability of hospital care and medical services from community providers for eligible Veterans. VA implemented this authority by publishing an interim final rule on November 5, 2014.

In order to provide care under VCP VA modified the existing (PC3) contract which had been set up the previous year to create a network of community providers for VA to use when care could not feasibly be provided within VA. The modified contract required a third party administrator (TPA) to create a network of eligible providers eligible to provide care under VCP. This network would be the primary method for VA to will its statutory requirements to provide care under VCP. In instances where VA was unable to acquire the necessary services through the PC3/Choice contract, VAC as amended, provided VA with authority to enter into agreements, known within VA as Choice Provider Agreements, directly with individual providers. However, these agreements could only be entered into when VA's existing contracts and acquisition authorities were not sufficient to procure the necessary care.

On April 24, 2015, VA issued another interim final rule modifying how VA measures the distance from a Veteran's residence to the nearest VA intedical facility from straight-line to driving distance. In December 2015, VA published whird interim final rulemaking to implement additional amendments to VACAA, which among other things, defined additional criteria for determining when a Veteran's travel to VA is unusual or excessive, removed the 60-day limitation on an episode scare, and revised what constitutes a qualifying VA medical facility for purposes of determining eligibility based on residence. The change in how VA measures distance and revision to the definition of VA medical facility impacted some Veterans in New Hampshire, many of whom are eligible based on residence due to the fact that there is no full-service VA medical facility in the state. A memorandum dated October 2015, entitled, VA Care in the Community (Non-VA Purchased Care) and use of the Veterans Choice Program, created a hierarchy of care that was required to be followed by medical centers when determining the appropriate way to provide care in the community. VA expected the Hierarchy for Purchased Care to be strictly enforcement, and indicated VISNs/facilities that do not follow the guidance and incur costs for CITC outside of the guidelines will be required to use operating funds from the rhedical services account to cover the expense. Additionally, the October 1, 2815 memorandum instructed VISN Directors not to implement any new agreement for renewals for existing local contracts and local sharing contracts for the purchase of services covered by VCP or national contracts. The following Hierarchy for Purchased Care was included in the October 1, 2015, memorandum and remained in effect until June 2017.

<u>Hierarchy for Purchased Care¹⁰</u>: must be used when the Veteran's primary VA medical facility cannot readily provide needed care to a Veteran, either because the care is unavailable at the facility or because the facility cannot meet VHA's timeliness standard based on the clinically indicated date. When care cannot be

¹⁰ Acting Principal Deputy Under Secretary for Health Memorandum, VA Care in the Community and the Use of the Veterans Choice Program, October 1, 2015.

provided within required timeliness standards, the Veteran's primary medical facility will follow the below guidance as it applies:

- a) Refer to another VA medical facility using usual interfacility referral patterns, or Department of Defense (DoD), Indian Health Service (IHS), or Tribal Health Facility in accordance with the terms of the applicable agreement, if that facility can accommodate the Veteran within the specified timeliness standards. If the VA medical facility can schedule the referred service within VHA's timeliness standard, the Veteran is not eligible for VA CITC. A "referral facility means that the VA medical facility is the primary location for this type of care, is staffed to accommodate the referrals, and the primary medical facility usually sent this service to the referral medical facility prior to VCP;
- b) Facilities may make exceptions to this referral rule when the service is not offered in the primary facility and it was normally sent out in the community prior to VCP or there is a wait list at the referral medical facility. The primary facility should refer the Veteran to CITC using VCP;
- c) If the Veteran's primary medical facility caption secure care from another VA medical facility as specified in 2a, the primary medical facility will refer the Veteran to VCP when the needed services are covered by the program.
- d) If the Veteran is not eligible or the needed services are not covered by VCP, the primary facility may utilize of the VA CITC options, pending availability of local funds. Local facility teachership must make this determination;
- e) If the Veteran is eligible for VCP, but elects not to use the program, then the facility should either schedule an appointment in VA, use the recall reminder system, or place the Veteran on the electronic wait list (EWL), consistent with VHA policy, in the circumstances, the facility may use CITC options to secure care, pending availability of local funds, when the Veteran elects not to use VCP Local facility leadership must make this determination;
- f) If VQB care is authorized, but the VCP contractor returns the authorization, this primary facility may use other VA CITC options, pending availability of Cocal funds, until the VCP provider agreement option is available later in FY 2016;
- g) Medical facilities may continue to use radiation oncology services acquired through an existing contract or sharing agreement where those services are integral to the oncology program at the VA medical facility. If no existing contract or sharing agreement that are integral to the VA medical facility oncology program exists, these services should continue to be referred to VCP.

In January 2017, the VA determined that the remaining VCP funds were sufficient to finance the program through the end of the FY. However, as the year progressed, the agency realized there may not be enough funds after all. On June 7, 2017, VA sent out a memorandum rescinding the October 1, 2015 memorandum. On June 12, 2017, however, the June 7, 2017 memorandum was rescinded by another memorandum titled "Options for Providing Community Care" to VISN Directors which similarly rescinded the October 1, 2015, memorandum, but also included the following measures to be implemented across VA as a means to optimize VCP funds.

 Continue to send Veterans with VCP eligibility based on residence (40 miles from their residence to the closest VA medical facility), wait times (30 days from the clinically indicated date), or other special criteria for the residents of Alaska, Hawaii and New Hampshire, to VCP contractors.

Medical facilities must now follow their usual referral patterns and refer Veterans
to other VA medical facilities, DoD medical facilities, or to other traditional
community care providers when services are not available at their facility and the
Veteran does not qualify for VCP under eligibility identified above.

 VA is realigning internal resources to ensure community care funding through the end of FY 2017.

In August of 2017, the President signed the VA Choice and Quality Employment Act authorizing \$2.1 billion in additional funds in August 2017 as a temporary funding solution for VCP, enabling VA to increase the pumber of appointments scheduled and ensure payments to community providers. These additional funds were projected to be exhausted by January 2018, but the President signed a Continuing Resolution on December 22, 2017, which appropriates another \$2.1 billion into the Choice Fund. The additional funds allowed VA to continue to administer the Choice program into 2018. VCP will expire when the funds in the Choice Fund are exhausted.

Background on SCI/D Care

The spine, also known as the vertebral column, helps support the upper body's weight, supports posture while allowing for movement and flexibility, and protects the spinal cord, the continuation of the brain and brainstem, a bundle of nerve fibers and nerve cells that extend from the brain to the lower back. The spine consists of 33 vertebrae that stretch from the base of the skull to the pelvis through five regions, the neck (cervical) (chest (thoracic), lower back and trunk (lumbar), gluteal region (sacral), and the tailbone (coccygeal). The vertebrae are aligned so that there is a central tubular canal the spinal canal, through which the spinal cord passes. The surrounding bony vertiberae protect the spinal cord from external forces and damage. In the healthy condition, the diameter of the canal is large enough that the spinal cord takes up only 50 to 75 percent of the cross-sectional space, allowing ample room so that the spinal cord is not compressed during movement or while at rest. Intervertebral discs made of thin cartilage separate each vertebra, and small spaces between each adjacent vertebra. the intervertebral canals, allow nerves to pass from each level of the spinal cord to various regions of the body. Nerve cell bodies within the spinal cord have important sensory, motor, and integrative functions. Spinal cord nerve fibers carry sensory

information (e.g., temperature, pain, touch, vibration) from the body up to the brain, and motor impulses from the brain to muscles to control movement.¹¹

SCI/Ds may lead to a spectrum of neurologic deficits collectively referred to as myelopathy. Spinal cord injury can result from violent traumatic events, such as motor vehicle collisions, falls, violence, sports or recreational activities. Spinal cord disorders may be caused by illnesses and processes that lead to spinal cord injury, such as tumors, infections, degenerative neurological disorders such as Amyotrophic Laterat Sclerosis (also known as Lou Gehrig's Disease) and Multiple Sclerosis, and musculoskeletal diseases that produce narrowing (stenosis) of the spinal canada resulting in compression of the spinal cord. An SCI/D may cause disruption movement, sensation, and/or function, resulting in weakness, impaired coordination, numbness, or pain. After an SCI/D occurs, nerve impulses are impeded or cannot travel from the brain beyond the level at which the spinal cord is damaged: the higher the level of injury, the more of the body below that level that is affected. SCI/D treatment requires ongoing management of existing impairments and prevention of secondary problems.

The seven vertebrae of the cervical spine are small in comparison with other regions of the spine, and allow for significant neck flexibility and povement as well as greater vulnerability to injury. Spinal injury or disease below the cervical region results in paraplegia, which produces loss of motor and sensory function of the trunk and lower body including the legs, bladder, and bowel. Cetraplegia, formerly referred to as quadriplegia, results from injury to the upper cervical spinal cord and causes impairment of motor and sensory function in both the arms and lower body.

Spinal stenosis results from wear and tear changes of the vertebral column and is typically found in older adults; resulting in narrowing of the spinal canal. Osteoarthritis of the joints between the bony vertebrae is the most common cause of spinal stenosis. ¹⁵ Arthritic changes cause narrowing of the spinal canal and the space between each vertebra. The signs and symptoms of cervical myelopathy may include loss of hand function, such as clumpiness, difficulty with fine motor skills, and problems with activities of daily living, and problems in the lower body including difficulty with walking, balance, and bladder or bewel control manifested as include leakage of urine and/or stool, difficulty urinating, or constipation. ¹⁶ Clinicians evaluate spinal stenosis and the possibility of accompanying myelopathy by performing a physical examination and

¹¹ Vergorae of the Spine. http://www.innerbody.com/image/skel05.html#full-description; https://www.cedars-strait.edu/Veterans/Programs-and-Services/Spine-Center/The-Veteran-Guide/Anatomy-of-the-Spine/Vertebrae-of-the-Spine.spinal.cord. http://www.merckmanuals.com/home/brain,-spinal-cord,-and-nervedis-of-the-Spine-Indiana-Ind

Myelopathy. American Journal of Neuroradiology. May 2008, Volume 329 (5) 1032-1034. http://www.ainr.org/.
 United Spinal Association. https://www.unitedspinal.org/about/what-is-spinal-cord-injurydisorder-scid/; American Spinal Injury Association (ASIA). http://imperial.networkofcare.org/veterans/library/article.aspx?id=1687).

VA and Spinal Cord Injury. (http://imperial.networkorcare.org/veterans/library/article.aspx?id=1687).
 NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases. Questions and Answers about Spinal Stenosis. August 2016. (https://www.niams.nih.gov/Health_Info/Spinal_Stenosis/#spine_d).

⁶ Cervical Stenosis and Myelopathy. http://www.rushcopley.com/rcmg/services/neurosurgery/conditions-and-procedures/cervical-stenosis-and-myelopathy/.

assessing the Veteran's current symptoms, past medical history, diagnostic studies, and relevant imaging findings from plain x-rays, computed tomography (CT), or magnetic resonance imaging (MRI) scans.

The management of spinal stenosis focuses on symptomatic relief and prevention of neurologic sequelae via both nonsurgical and surgical interventions. Nonsurgical, or conservative, treatment is directed at symptomatic relief of pain, stiffness, muscle spasticity, and functional problems. This typically involves a combination of therapeutic modalities, medications, and rehabilitation such as strengthening exercises, endurance training, activities to improve balance, and exercises to improve flexibility in the reck, arms, trunk, and legs.¹⁷

If symptoms are severe or progressive, or fail to respond to nonsurgical treatment, the clinician may refer the Veteran for evaluation by a neurosurgeon or orthopedic surgeon. Surgery may be indicated when severe or chronic symptoms are present, including pain that interferes with quality of life, and the symptoms correlate with the radiologic evidence of spinal stenosis. The decision to seek surgical intervention should only be made if the likelihood of improvement with nonoperative measures is low. ¹⁸ The goal of surgery may not necessarily be to restore normal function but to stabilize the spine so as to prevent further decline and relieve neck pain and neurological symptoms such as weakness or numbness. ¹⁹ Surgical treatment involves removing pressure from the spinal cord and spinal nerves, known as surgical decompression, and often includes some form of stabilization of the affected area via spinal fusion. The surgeon may place metal implants to support the vertebrae while they heal and fuse together. ²⁰

Although a nonsurgical provider can diagnose myelopathy and refer the Veteran for a surgical evaluation, the orthopedic or neurosurgeon will determine what, if any, surgery is appropriate, based on a physical examination and the Veteran's presentation, history, diagnostic studies, and preferences. The surgeon must weigh the risks and benefits when determining whether surgery is best for the Veteran. There are significant risks from cervical decompression surgery, including complete paralysis and death. The overall incidence of significant complications varies in the literature, depending on the specific surgical procedure, age of the Veteran, and comorbidities. Reported complications from surgical decompression include infection, cerebrospinal leak, epidural hematoma, venous thrombosis, respiratory and cardiac complications, and iatrogenic spinal cord injury. Further impairments following decompressive surgeries have also seen reported including worsened neck pain, decreased neck range of motion and increased neck stiffness. The risk of death following surgery has been reported to be as high as 1 percent in some reviews. The evidence base for when to

¹⁷ Spinal Stenosis Treatment and Management. February 13, 2017.

⁽http://emedicine.medscape.com/article/1913265-treatment).

Spinal Stenosis Treatment and Management. February 13, 2017.

⁽http://emedicine.medscape.com/article/1913265-treatment).

Cervical Spondylotic Myelopathy: Surgical Treatment Options. The American Association of Orthopaedic Surgeons. (http://orthoinfo.aaos.org).

Cervical Stenosis and Myelopathy. http://www.rushcopley.com/rcmg/services/neurosurgery/conditions-and-procedures/cervical-stenosis-and-myelopathy/ North American Spine Association.

perform surgery versus nonsurgical management is unclear because there are varied cervical decompression surgical techniques and the lack of well-designed prospective randomized controlled studies. Advanced Veteran age has been reported as a risk factor for higher rates of complication that lead to unexpected critical care, increased length of hospital stay, and the necessity to be discharged to a nursing facility. Finally, severe spinal degenerative and anatomic changes do not necessarily correlate with an unfavorable prognosis or a mandate for surgery.²¹

Background on VA's SCI/D System of Care

The primary mission of VHA is to provide complete medical and hospital services for the care and treatment of Veterans, as provided in section 7301(b) of Title 38 United States Code (U.S.C).²² When SCI/D care is delivered within the VHA system VHA Handbook 1176.01 requires that it be delivered through VHA's SCI/D System of Care (SoC). Per this Handbook, the mission of VHA's SCI/D SoC is to support, provide, and maintain the health, independence, quality of life, and productivity of includials with SCI/D throughout their lives.²³ The VHA provides a full range of services and care for all enrolled Veterans who have sustained an SCI or have a stable neurologic disease of the spinal cord, and is the largest single network of SCIO care in the nation, integrating medical, functional, vocational, psychological, and social services within a continuum of care that addresses changing needs throughout the Veteran's life. These services include acute and sustaining, primary, specialty preventive, long-term, hospice, and end-of-life care, as well as preventive health caluations, assistive technology, environmental control units, prosthetics, supplies, medications, education for these Veterans, and the maintenance of their durable medical equipment.

The SoC consists of an integrated retwork of care, based on the hub and spoke model. Facilities with advanced SCI/D Services serve as hubs, receiving Veterans with SCI/D from the spokes of local medical centers or community hospitals. The hub addresses the unique aspects of delivering primary and specialty health care, rehabilitation services, home and long term care to those Veterans. In addition to PC, the provided services include orthotics, prosthetics, sensory aids, assistive technology, chronic pain management, mental health, geriatrics, medical nutritional therapy, environmental modifications, and respite care. Veterans living in the geographic area of the hub generally receive their PC from a provider embedded in that SCI/D Service. The hub provides comprehensive preventive health evaluations, focusing on preventive or early identification of complications related to SCI/D. Annual evaluations must be offered to Veterals and performed at SCI/D Services.

The hub's SCI/D Center accepts Veterans from the spokes, coordinating and providing care and services that the spokes are unable to provide, in order to ensure the Veterans have access to the full range of services that they need. Veterans with SCI/D

Cervical Stenosis and Myelopathy. http://www.rushcopley.com/rcmg/services/neurosurgery/conditions-and-procedures/cervical-stenosis-and-myelopathy/ North American Spine Association.
 38 U.S.C. §7301(b).

²³ VHA Handbook 1176.01, Spinal Cord Injury and Disorders (SCI/D) System of Care. February 8, 2011.

experiencing complex problems or in need of complex procedures requiring specialized knowledge must be referred to the SCI/D Service as indicated in the referral guidelines in VHA Handbook 1176.01.²⁴

Background on VA's Initial Investigation at the Manchester VA in Response to a Referral from the Office of Special Counsel

Whistleblowers at the Manchester VA originally contacted members of the New Hampshire Congressional delegation on September 6, 2016, through their attorney who in turn encouraged them to raise their concerns to the U.S. Office of Special Counsel (OSC), the independent agency within the Executive branch of government responsible for receiving disclosures of alleged wrongdoing from Federal Employees and protecting whistleblowers from retaliation. After collecting and verting the information provided by several whistleblowers, OSC formally referred three specific allegations to then-SecVA Robert McDonald on January 10, 2017, OSC's referral letter required the SecVA to investigate the allegations and submit a formal written report, and indicated that the whistleblowers wished to remain anonymous. The allegations that OSC referred to VA for investigation were related to:

the care of Veterans at the Manchester VA suffering from SCI/D, a large
percentage of whom were said to have developed myelopathy due to improper
diagnosis or delayed referral for additional treatment;

improper copy and pasting of the content of electronic health records by the former Chief of SCI/D; and

• repeated infestations of flies in the CR that were alleged to have impacted access to surgical procedures at the Manchester VA.

Citing the standard statutory language contained in 5 U.S.C. §1213(d), OSC's referral letter states that the Special Counsel had concluded that "there is a substantial likelihood that the information in instellation of law, rule or regulation; an abuse of authority; gross mismanagement; and a substantial and specific danger to public health. The "substantial likelihood" phrase does not indicate that the allegations have been proven, but rather that they are of sufficient potential concern that further investigation by the Agency is required to determine whether the allegations are, or are not, substantiated.

The SecVal assigned OMI to assemble an investigative team, including VA SMEs in SCI/D and employee/labor relations, to conduct an initial site visit to the Manchester VA in February 2017. VA submitted its report of investigation to OSC in June 2017 substantiating that the former SCI/D Chief there had improperly copied and pasted clinical information from at least 2006 to 2012, but found that the facility had taken adequate steps to ensure that Veterans had not suffered adverse outcomes as a result

The processes that OSC uses to address whistleblower disclosures are outlined in 5 U.S.C. §1213(d). OSC did not disclose the whistleblowers' identities to VA.

²⁴ Ihid

OMI conducts independent internal investigations of matters related to the quality of Veterans' health care on behalf of the Under Secretary for Health. OMI has performed 78 investigations of whistleblower disclosures requested by OSC since 2014.

of this activity, and to discipline the physician prior to his transfer to another VA facility in 2012. The longstanding problem with the seasonal appearance of cluster flies in one of the ORs, which dated back at least a decade, was also substantiated. The fly infestation had proven resistant to extensive and repeated pest control measures, leading to the MCD's decision in late 2016 to close the OR in question. However, we determined that there had been no adverse impact on access to operative services due to low surgical volume and facility complexity.

We were not able to determine conclusively whether Veterans with SCI/D had suffered adverse outcomes, including myelopathy, as a result of delayed diagnosis, treatment, or referral. The SCI/D SME reviewed the records of 97 Veterans on a list provided by the current SCI/D Chief, and determined that the Veterans' worsening symptoms were due to the natural progression of disease in 74 of the 97 cases. As the evidence was inconclusive in the other 23 cases, we recommended that they should be referred to external, non-VA experts for additional review.

VA submitted its report of investigation to OSC on June 20, 2017. In accordance with its standard procedures, OSC shared the Agency's response with the whistleblowers who remained anonymous at that point. At about the same time, VA began to receive inquiries from the investigative reporters with the Boston Globe Spotlight Team about similar allegations at the Manchester VA, as well as other issues that had not been included in OSC's January 2017 referral to the SecVA. The Boston Globe's Spotlight report appeared on its front page Sunday, June 16, 2017. VA issued a press release that evening announcing that the SecVA had ordered OMI and the OAWP to immediately conduct a top-to-bottom review of conditions there, and that he would remove the MCD and CoS 2 from the release positions pending the review.

Subsequently, OSC submitted a list of additional questions to VA in late July based on comments it had received from whistleblowers, and requested a formal supplemental report, which VA submitted on October 7, 2017. On January 25, 2018, the Special Counsel determined the VA's report met all statutory requirements but determined the VA's findings did not appear reasonable. While the matter is closed, VA will provide OSC supplemental reports detailing the status of clinical reviews referenced in this report.²⁷

Issue Brieß

Accepting to the VHA Guide entitled VHA Issue Briefs, dated May 2017, an Issue Brief is an internal document used and reviewed by senior leaders within our organization, up to and including the SecVA. They provide specific information to leadership within the organization, working through the appropriate chain of command, regarding a situation, event, or issue. VHA facilities submit Issue Briefs to their VISN leadership, who in turn submit them to their assigned VHA Central Office VISN Support Team via an "Automated Issue Brief Tracker." The VISN Support Team is responsible for informing

U.S. Office of Special Counsel, The Special Counsel's letter to Secretary Shulkin: OSC File Nos. DI-16-5687, DI-16-5688, DI-16-5689, and DI-16-5690. January 25, 2018.

VHA leadership and maintaining their situational awareness through the ability to access information, anticipate critical information requirements, and determine necessary follow-up actions for the facility, VISN, VHA Central Office, and/or senior leaders by sharing information regarding situations, untoward events and issues of potential interest to the SecVA.²⁸

Allegation 1. Providers alleged that CoS 2 restricted their ability to refer Veterans for Community Care outside of the Veterans Choice Program (VCP).

Findings

Concerns raised by a physiatrist

According to the *Boston Globe* Spotlight Team article, a physiatrist at the Manchester VA alleged that CoS 2, who arrived in May 2016, restricted his ability to send advanced myelopathy Veterans to private practice neurosurgeons for care that he felt the Manchester VA could or would not provide. This physiatrist had concerns about both the quality of care that the Manchester VA could provide and this lack of ability to refer patients to the community. Prior to the implementation of VOP, this physiatrist was able to refer these types of patients to community providers using traditional CITC funds. The *Boston Globe* article indicated the rationale for using VCP and not the traditional CITC funding was financially motivated and was based on the hospital's projected deficit of \$6 million in 2016.

From 2012 until the establishment of VCR in 2014, the Manchester VA's SCI/D service referred most Veterans needing an evaluation for surgery to one non-VA neurosurgeon in Boston, Physician 1. The referrals went through the traditional CITC process, also known as non-VA purchased care or fee basis care. During FY 2015, the SCI/D department made 38 requests for non-VA purchased neurosurgical CITC. The former, now retired, CoS (hereafter CoS 1) served prior to CoS 2 from 2012–2015. During his tenure he authorized 26 referrals to Physician 1 using CITC funding and the remaining 12 referrals to the Boston VA for care.

Because New Handshire is a state without a full-service VA medical facility, Veterans living more than 20 miles from WRJ are eligible to receive care in their community under VCP. The Medical Center appropriately referred Veterans to VCP to give them the opportunity to obtain neurosurgical care locally. CoS 2 invited Physician 1 to join the VCP network, however he chose not to participate in VCP, and therefore Veterans could not be referred to him.

VA applies the VERA model to fund its medical facilities. VERA funding is based on data that are nearly 2 years old, resulting in funding based on utilization patterns in prior years rather than a projection of future demand. In FY 2016, the Manchester VA experienced a 3.4 percent increase in utilization of its services without receiving

Deputy Under Secretary for Health for Operations and Management (DUSHOM) Guide: VHA Issue Briefs, May 2017

comparable operational funding increases. As a result of this and many other factors, it had incurred a \$6 million deficit by mid-2016. Given these funding challenges, it was required to closely scrutinize where Veterans were sent for care VA was unable to provide within the Manchester VA.

VA implemented the Hierarchy for Purchased Care on October 1, 2015, but the Manchester VA's CoS at that time (CoS 1) did not immediately enforce the use of VCP. CoS 2, who was initially appointed as the Acting CoS in November 2015 and later appointed permanently in May 2016, did try to enforce the new rules. Upon his arrival, he communicated his and VA's expectations and provided clear guidance to clinical staff that the VCP should be the primary mechanism available when Veterart are in need of care that VA could not provide. In the event that the required service under the PC3/Choice contract is not available or the Veteran is not eligible for VCP, the Hierarchy for Purchased Care would be strictly enforced for determining the most appropriate option for providing CITC. According to the Hierarchy to Purchased Care, it is the local leadership's decision to use facility funds for traditional CITC when the Veteran is not eligible for VCP or the needed services are not severed by that program. Providers who agree to participate in VCP agree to accept vedicare reimbursement rates, or when there is no Medicare rate, payment detainined in accordance with VA's payment regulations.

CoS 2 invited Physician 1 to join the VCP network, but since he chose not to participate, the Manchester VA could no longer refer patterns to him for care since the same care was available at two other VHA facilities within Manchester's VISN. Although Manchester VA leadership could approve traditional CITC on a case-by-case basis, the VISN strongly discouraged the use of local funding for CITC when other options were available. Because it does not provide inpatient care, the Manchester VA relies upon community hospitals in New Idampshire to provide inpatient services at VA's expense. In FY 2016, the Manchester VA spent approximately \$36 million of its CITC budget for Veterans requiring local hospitalization, as well as outpatient medical and dental care. The VISN CFO testified that the VISN expected the Manchester VA to "redirect more CITC requests to the VCP, and he was flabbergasted it did not."

In addition to the Hierarchy of Care, CoS 2 based his decisions on the nature and urgency of the individual needs of each Veteran, and the availability of timely neurosurgical access at the Boston VA. Despite the pressure to avoid using CITC funds when other options were available, in FY 2016, the SCI/D department made 32 requests for purchased neurosurgical CITC. CoS 2 authorized 11 of them to be referred to Physician 1, using CITC funding, and referred the remaining 21 to the Boston VA. During the first 5 months of FY 2017, there were two requests for purchased neurosurgical CITC, both of which CoS 2 authorized to be referred to Physician 1.

External Case Reviews

Department of Veterans Affairs, Acting Principal Deputy Under Secretary for Health Memorandum on VA Care in the Community (Non-VA Purchased Care) and use of the Veterans Choice Program, October 1, 2015.

Following the publicity of the *Boston Globe* article, VA determined that it would obtain independent, external reviews of 100 percent of the cases that the Manchester physiatrist had raised concerns about, not just the 23 cases that VA's SCI/D SME had identified. The total number of cases sent for external third-party review included 97 Veterans and 143 episodes of care. As of March 30, 2018, external third-party peer reviews are complete for 101 episodes of care for Veterans with SCI/D who were receiving nonsurgical care at the Manchester VA. Of these episodes of care, 95 met the standard of care and six (5.9 percent) did not. Of these six, two lacked appropriate documentation about the nonsurgical care provided and the subsequent treatment plan; one lacked a timely initial diagnostic evaluation; two lacked timely follow-up care, and one lacked adequate and appropriate findings to support a diagnosis of certical myopathy. These six episodes of care remain under review to determine whether the Veterans were harmed. If there is any evidence of patient harm, the Manchester VA will be advised to take actions in accordance with VHA Handbook 1004 08, *Disclosure of Adverse Events to Patients*, October 2, 2012.³⁰

One of the whistleblowers alleged that some SCI/D Veterans were adversely affected because they were referred to the Boston VA for neurosurgical care, instead of to Provider 1. We identified 40 cases that Manchester reliefed to the Boston VA for surgical care. All of these cases have been included in the third-party external review and are ongoing. Any cases that do not meet the candard of care will be addressed in accordance with VHA Handbook 1004.08.

Findings related to Complementary and integrative Medicine 31

Complementary medicine includes a group of medical and health practices that are not considered part of conventional or allogathic medicine. Integrative medicine refers to complementary practices such as acupuncture and massage that can be used in addition to conventional or allogathic medicine. Specific VA-approved complementary and integrative approaches are authorized as part of the medical benefits package, as addressed in. VHA Directive 1137, Provision of Complementary and Integrative Health (CIH), May 18, 2017, Lifevise, certain identified CIH approaches are provided by community providers in accordance with the VA Hierarchy of Care.

During the course of the investigation we found some Veterans who are eligible for VCP but who did not want to invoke this option for care, and instead had requested that CoS 2 authorize traditional CITC with providers they have specifically chosen for acupuncture or massage therapy. The CIH providers that qualified to be part of the VCP retwork were invited to join, but declined the invitation. In March 2017, CoS 2 did not allow Veterans to seek care from their preferred community providers in accordance

VHA Handbook 1004.08, requires clinical or institutional disclosures of adverse events as a formal process by which facility leaders, together with clinicians and other appropriate individuals, inform the patient or the patient's personal representative that an adverse event has occurred during the patient's care that resulted in or is reasonably expected to result in death or serious injury.

Complementary and integrated medicine includes acupuncture and massage therapy. Complementary medicine is a group of different medical and health practices that are not considered part of conventional or allopathic medicine. Integrative medicine refers to complementary practices such as acupuncture. https://www.warrelatediliness.va.gov/education/factsheets/complementary-and-integrative-medicine.pdf.

with the Hierarchy for Purchased Care guidance that states "if the Veteran is eligible for VCP, but elects not to use the program, then the medical facility should either schedule an appointment in VA, use the recall reminder system, or place the Veteran on the electronic wait list (EWL), consistent with VHA policy. In rare circumstances, the facility may use CITC options to secure care, pending availability of local funds, when the Veteran elects not to use VCP. Local facility leadership must make this determination."

On March 10, 2017, CoS 2 subsequently informed three Veterans in writing that the fact that their preferred non-VA provider for specifically requested complementary and integrative health services did not wish to participate in the VCP is not sufficient reason to justify authorization of non-VA care. If a Veteran does not want to come to the VA for these types of services, they have the opportunity to opt into VCP, and receive the care from a provider who has elected to be part of the VCP and accepts Madisare reimbursement rates. At the time, massage services were not available through the VA or the PC3/Choice contract, so CoS 2 informed the Veterans that he would authorize traditional CITC only when a VA provider determines massage services are warranted. As of August 3, 2017, massage services are covered by the CIM services approved by the USH, and available to Veterans when clinically indicated.

Conclusions regarding VA Care in the Community

- We do not substantiate that CoS 2 restricted providers' abilities to refer Veterans for CITC outside of using the VCP.
- Prior to the establishment of VCP in 14, the Manchester SCI/D service referred the majority of Veterans needing neurosurgical evaluation to one non-VA provider in Boston, Physician 1, via the traditional CITC process.
- After the enactment of VACAA in November 2014, the Manchester VA appropriately referred eligible SCI/D Veterans needing neurosurgical care to VCP, based on the guidance provided by VHA's Hierarchy for Purchased Care. Per the Hierarchy's guidance, VCP is the primary mechanism used when Veterans are eligible for Choice care. This includes Veterans in New Hampshire who reside more than 20 miles from the WRJ VA.
- Physician 1 chose not to participate in VCP, and therefore Veterans could not be referred to him for the provision of Choice care without an established Provider Agreement with the Manchester VA.
- Throughout his tenure, CoS 2 strictly followed the guidance outlined in the Hierarchy for Purchased Care, as required by VHA Central Office in the October 1, 2015, VA memorandum, and faced pressure from VISN 1 that strongly discouraged the use of local funding for CITC when other options were available.
- CoS 2 individually evaluated each CITC request to purchase non-VA care, and made decisions based on the Hierarchy of Purchased Care guidance. In FY 2016,

he authorized 11 of 38 requests for referral to Physician 1 using CITC funding, and in the first 5 months of FY 2017 authorized 2 more.

- Due to a confluence of factors, including growth in utilization by Veterans and decreased CITC funding, the Manchester VA ran a \$6 million deficit in FY 2016. We found evidence that VISN 1 assisted in the management of this deficit before the end of the FY.
- External third-party peer reviews determined 95 episodes of care for Veterans with SCI/D who were receiving nonsurgical care at the Manchester VA received services that met the standard of care, and six episodes of care for Veterans with CI/D who were receiving nonsurgical care at the Manchester VA did not.
- The MCD and CoS 2 were actively engaged in addressing concerns that had been raised and were wholly committed to providing Veteran-central solutions. They attempted to work within the existing VCP laws, rules, and concerns as they evolved from 2014–2017 to provide a scope of services at the Manchester VA in accordance with its designation as a level 3 facility with basic ambulatory surgical services.
- The Manchester VA leadership worked diligently to maximize their budget, including obtaining funds for additional options under the CITC program, to ensure that they could provide care.
- The MCD and CoS 2 were extremely engaged, transparent, and supportive of exploring options to further develop programs, all signs of their commitment to open communication and psychological safety to ensure that Veterans receive the highest quality of care.
- The VERA funding model does not provide adequate funding to support the real-time needs and actual productivity of the Manchester VA.

Recommendation to the Manchester VA

- 1. Request additional funding as needed for traditional CITC, and continue to scrutinize requests for non-VA purchased care to ensure that each is the most appropriate for the digible Veteran's needs and cost effective for the American tax payer.
- 2. Ensure that Manchester and Boston VA leadership review each of their respective cases that did not meet the standard of care and take appropriate action in accordance with VHA Handbook 1004.08.

Recommendations to VHA

 Ensure that all the SCI/D cases pending external third-party peer review are completed. These reviews should address whether myelopathy was diagnosed in a timely manner and whether the treatment (surgical and nonsurgical) was appropriate.

2. Reevaluate the VERA funding model and its implementation at the Manchester VA in view of the unique limitations imposed by implementation of VACAA in New Hampshire.

Allegation 2. The Manchester VA's program for setting up appointments with outside specialists has broken down and thousands of Veterans, some with life-threatening conditions, struggle to get any care at all.

Background on Consultation Management

Consultations are requested by clinicians when a patient's medical or subsical care needs exceed the expertise or capabilities of the clinician who is currently providing care. VHA Directive 1232, Consult Processes and Procedures, August 23, 2016, provides guidance on the mechanisms by which requests for consultative services are handled. The requestor includes pertinent clinical information in the consultation request so that the accepting consultant is able to make a sound clinical assessment and plan. As consultations move from pending to completed status, the status of the consultation should be updated.

Consult Status Definitions

The receiving service must update the states of pending as soon as possible and no later than 7 calendar days of receiving the request.

Pending: This status designates requests that have been sent, but not yet acted on by the receiving service.

Active: This status occurs when a consult is "received" and efforts are underway to fulfill it.

Scheduled: This indicates that an appointment has been made and linked to the consult request scheduled status automatically sends an alert to the requesting clinician. The consult status should not be manually changed to "scheduled" in the consult package, but should be linked to appointments so that the consult status changes when the appointment status is changed.

Partial Result: This status designates partial but not complete resolution of the consult request.

Complete: This status designates completion of the requested service.

In 2008, VHA began to require that all consultations with the exception of consultations for Prosthetics and Future Care be moved from pending status to active within 7 days. These directions apply to consultations that are requested for what is now known as

VHA Directive 2008-056, VHA Consult Policy, September 16, 2008 and VHA Directive 1232, Consult Processes and Procedures, August 23, 2016.

Care in the Community (CITC). As of June 5, 2017, VHA policy requires all pending consultations be moved from pending to active status within 2 business days. The Office of Veterans Access to Care (OVAC) hosts a weekly National Consultation Performance Improvement teleconference to discuss process management and to review pending consultation requests. All VHA facilities are expected to be compliant with these consultation management requirements.

Findings related to Consultation Management

Overview

Over 90 percent of Veterans in New Hampshire are eligible to use the VCP because they reside in a state without a full-service VA medical facility and also live more than 20 miles from the WRJ VA. We reviewed FY 2016 and 2017 consultation requests for over 500 Veterans who sought medical care from the Manchester VA who were referred to the VCP. These eligible Veterans did not receive appointments because the TPA for the VCP, Health Net, was unable to meet its contractual obligation to refer and schedule appointments for these patients with non-VA providers. We reviewed several email exchanges for the same two FYs between the Manchester VA leadership and Health Net that reported a lack of sufficient staff members on Health Net's staff to scheduling requests for consultation, and a lack of community providers for particular medical services. Veterans responded by complaining to their Congressional representatives, who often passed the concerns on to the Manchester VA with the expectation that the problems would be addressed.

Several Veterans also contacted the Manchester VA's Patient Advocate and the MCD to lodge a variety of complaints against Health Net, including unanswered telephones, excessive on hold telephone wait times exceeding an hour, experiences with reporting to community providers for appointments that had never been scheduled, and interactions with providers who were not being paid for their services. If Veterans were able to speak with a Health Net employee, they then faced significant challenges to provide the clinical information Health Net requested. The MCD reported that her own father, a Veteran in self, had complained to her that his telephone calls to Health Net went unanswered.

In FY 2017, in response to these concerns, the MCD and CoS 2 authorized Business Office staff members to intervene with the management of VCP referrals for Veterans who were eligible based on their mileage from the WRJ VA, even though these specific Veterans could self-refer to the VCP. Unfortunately, despite having open access, Veterans were unable to successfully communicate with Health Net in order to schedule appointments. This additional workload further overloaded an already understaffed Business Office.

DUSHOM Memorandum, Scheduling and Consult Policy Updates, June 5, 2017.

³⁴ Health Net Federal Services PowerPoint/Manchester VA Veteran-Centered Community Care and Veterans Choice Program, March 2015—June 2017.

Health Net's Contractual Obligations

In FY 2017, Health Net's contractual obligation was to schedule appointments within 5–10 days of receipt of a consultation request or to return the request to the Manchester VA indicating that it could not schedule the appointment. Health Net returned an average of 36 percent of the Manchester VA's referrals between October 2016 and February 2017. The rate of returns for January through May 2017 was 65 percent, with the rate peaking in April and May 2017 at 85 percent (over 2,500 consultations). This volume of returned consultations was nearly impossible for the Manchester VA to manage. In response, the Manchester VA assembled a team of medical, nursing and administrative staff members after May 2017 to prioritize appointments based upon clinical needs. Staff members notified Veterans and offered them options to receive care at the Manchester VA or through the VCP as they had initially requested. In some cases, the Manchester VA was able to arrange care using previously-established Provider Agreements. Staff members after May 2017 to prioritize appointments based upon clinical needs. Staff members notified Veterans and offered them options to receive care at the Manchester VA or through the VCP as they had initially requested. In some cases, the Manchester VA was able to arrange care using previously-established Provider Agreements.

According to our review of documents from Health Net, the high volume of returned consultations was due to their failure to anticipate the volume of referrals received from the Manchester VA combined with a lack of adequate resources to schedule appointments within 5–10 days, per the contract. The second largest reason for returning consultation requests to the Manchester VA was due to missing clinical information for Veterans who were eligible for the VSP based upon their residence. In response to their own deficiencies to meet contractual obligations, Health Net identified three action items: (1) gain a better understanding of the anticipated volume of consultation requests to ensure that they have the proper resources in place to schedule appointments; (2) increase the solume of Health Net scheduling agents to increase productivity; and (3) focus on the categories of care that generate the most returns.

These processes created a substantial increase in the Business Office's workload, which was untenable, and according to the VHA OCC, was not the Manchester VA's responsibility. In response to this increased workload, the Business Office reported the issues and resulting interventions to the VISN and VHA OCC and arranged teleconferences directly with Health Net in an attempt to resolve them.

Patient Preferences

We found that several Veterans who needed subspecialty care preferred to invoke their VCP eligibility rather than receive a referral to Boston or WRJ VA, most often due to the distarce they would have been required to travel to get care at either of these VA facilities. In January 2017, the Manchester VA altered its VCP consultation process to

³⁵ Ibid.

Between January and May 2017, 3,142 of 4,857 consultations were returned to the Medical Center by Health Net. During the last 2 months of this time period (April and May 2017), the Medical Center received the highest volume of returned consultations at 85 percent (over 2,500 consultations).

Manchester VA Email and Health Net Returns Triage Spreadsheet.

³⁸ Health Net Federal Service Power Point/Manchester VA Patient Centered Community Care Veterans Choice Program, July 24, 2017.

Statement from K. Matthews, Deputy Executive Director, Provider Relations and Services.

include options based upon mileage eligibility in order to ensure that individual Veterans' preferences for where they wanted to receive care were included in the request to Health Net. The Manchester VA referred to these as "Choice Mileage" consultations. While Health Net initially accepted these consultations, after a few months they reviewed their contract and realized that it does not allow VA to initiate any VCP consultations based upon mileage eligibility. We found at least 1,400 of these Choice Mileage consultation requests that were returned to the Manchester VA. In July 2017, the Manchester VA modified the process to allow Veterans to refer themselves to Health Net by providing Veterans with a Choice Mileage letter. The letter provided detailed instructions for Veterans when making self-referrals to Health Net, including the telephone number for Health Net's schedulers and reminding them to provide relevant clinical information to ensure timely, Veteran-centric care.

VISN 1 and VHA Central Office – Awareness of Health Net's Faitures
Beginning in August 2016, the Manchester VA engaged with VHA OCC on numerous occasions via telephone and email to report the challenges it was having with the VCP and Health Net. After Health Net began to return large quantities of consultation requests in 2017, the MCD submitted two Issue Briefs through VISN 1 to VHA Central Office to highlight the issues she was having and to raise concerns about quality of care as a result of Health Net's inability to schedule appointments as requested. The MCD submitted the following two Issue Briefs and updates:

- May 15, 2017 the MCD submitted an issue Brief to VISN 1 reporting the high rate of consultation returns from Health Net and the Manchester VA's plans to mitigate risk⁴¹
- June 7, 2017 the MCD submitted a second Issue Brief to VISN 1 regarding
 Health Net consultation returns and quality of care concerns due to delayed care
- June 9, 2017 the MCD potented the June 7 Issue Brief
- June 20, 2017 the MSD updated the June 7 Issue Brief a second time⁴²

Although the MCD following the VHA Guide to Issue Briefs and submitted timely Issue Briefs to VISN 1 leadership, the perception of Manchester VA leadership was that this process did not result in any assistance with managing VCP consultations.⁴³

Through this communication, VHA OCC leadership became aware of Health Net's failures and the Manchester VA's efforts to coordinate care for Veterans. During our investigation, the VHA OCC informed us that they were confident that Manchester VA leadership was proactive in their attempts to address this demand for services. While the VEN CFO attested to the investigative team that the Manchester VA should be reducing its number of employees, the Business Office was not adequately staffed to handle its workload. In response to the increased demand to manage CITC referrals, the MCD restructured the Business Office and assigned additional staff members to manage Health Net returns, but the workload became overwhelming. The MCD and CoS also requested that the VHA OCC and VISN 1 Business Implementation Manager

⁴³ DUSHOM Guide: VHA Issue Briefs, May 2017.

Medical Center Issue Brief, dated May 15, 2017.

⁴² Medical Center Issue Brief, dated June 7 and updated on June 9 and 20, 2017.

(BIM) include them in a pilot program to develop a local OCC within the Manchester VA; however, they were not selected for participation and were unable to attain staffing models to develop their own OCC until completion of the pilot program. On July 30, 2017, the reorganized Business Office implemented a local OCC within the Manchester VA with 17 additional full-time employee equivalent staff members.

National Health Net Deficiencies

By May 2017, significant concerns had been raised across VHA about Health Net's inability to meet its contractual obligations. By May 5, 2017, the VHA OCC had is pied at least 25 Letters of Correction addressing Health Net's failure to meet the following contract performance standards:

Appointments must take place within 30 days

- Medical documentation must be returned to VHA upon the completion of appointments
- The average speed to answer telephone calls
- The telephone call abandonment rate
- Urgent appointments must be scheduled within 2 business days

There are insufficient networks of community previders

 Several returned consultation authorizations lie within the control/responsibility of the contractor (Health Net).⁴⁴

The VHA OCC was also aware of the high volume of returned consultations from Health Net, citing it as a national problem, due to the company's inadequate staff to process consultations, and in some cases insufficient networks of providers.⁴⁵

VISN 1's involvement

On November 10, 2015, VISN Ritained Manchester VA staff members on VISN-specific consultation management metrics, including pending consultations, and best practices for managing community care consultations. As of July 2017, only one of the trained staff members remained an staff at the Manchester VA in a consultation-management capacity. Since November 2015, the Manchester VA has participated in several national consultation initiatives focusing on closing open consultation requests, reviewing those pending more than 7 days, and dispositioning consultations more than 90 and 180 days old as part of standard consultation management processes.

In addition to OVAC resources, the VHA Support Service Center (VSSC) makes a variety of consultation data reports available on its website where VHA staff members who have been granted access can drill down to specific data on each individual consultation. The Consultation Trigger Tool that exists for in-house consultations includes metrics for those pending more than 7 days; however, CITC consultations do not trigger notification when wait times exceed the allowed time frame. In order to facilitate the management of consultations for CITC, OVAC has requested that CITC

https://vssc.med.va.gov/VSSCMainApp/.

OCC Updates PowerPoint, April 25, 2017.

⁴⁵ VHA OCC, FY 2017 Letter of Correction Report, May 5, 2017.

consultations be included in the tool. Training on the VSSC reports is available, but not required. Furthermore, VSSC data on community care consultations must be actively retrieved, as they are not included in the Strategic Analytics for Improvement and Learning (SAIL) reports that VHA facilities and VISNs receive automatically.

In December 2016, the VISN 1 BIM conducted a site visit to the Manchester VA to examine processes surrounding CITC. However, she did not write a report documenting any findings from the site visit and did not seem to initially have any concerns about the Manchester VA's ability to manage consultation requests for the VCP. The VISN 1 BIM did not completely understand the challenges facing the Business Office or its need for increased staffing to manage the VCP. She informed us that it was not until April 2017, that she became aware of problems with VCP referrals through attempts to individually manage initial referrals and returned consultations for some Veterans. The BIM admitted that she was unaware of any VSSC data that indicated both the upward trend in the number of consultations as well as a substantial increase in the number of open consultations beginning in September 2016. The VISN 1 Director also indicated during his interview that he was unaware of these VSSC consultation data.

Mitigation of Risk - The Consultation Stand Down

On July 29 and 30, 2017, the Manchester VA held a Consultation Stand Down to review open consultations for the VCP. In some instances, consults remain open despite the fact that the required service has been provided. Thirty-two staff members participated in the stand down and were able to successfully close a high volume of consultations because care was being, or had already been, provided. This was reflected in the VSSC data by a precipitous drop in open consultations. We reviewed a sample of staff comments related to these closures, which supported the information provided during interviews in support of ongoing or completed care. The Manchester VA and VISN 1 staff members assigned to review these consultations were also required to identify any instances of Veteran hand or adverse events related to delays in care. They recommended 13 cases or review by the Chief of QM. She found no adverse events or evidence of harm; CoS3 concurred.

On October 17, 2017, the Manchester VA had only 37 consultations for the VCP pending more than 7 days. During this review they identified a Veteran who had not received an appointment to see an oncologist more than 4 weeks after a diagnosis of lung career. This case has been referred for a third party review, and we await completion of this review for any evidence of Veteran harm.

Care in the Community Consultation Data

During the course of the investigation we discovered a system-wide lack of knowledge and awareness related to CITC consultation data. We found that over 500 VHA staff members participate in OVAC's weekly national teleconference; however, this meeting is not mandatory so participation is not tracked. Presentations from these meetings,

which include individual VISN- and facility-specific consultation data, are available on the Consultation SharePoint site that is accessible by all VHA staff members.

On July 24, 2017, immediately after our first site visit, the Acting MCD informed us that there were over 10,000 open consultations for the VCP that had not been properly managed. He added that this information had just been identified and had not been investigated. The following day, he informed us that this was erroneous as the information was retrieved from an incorrect data source. He clarified his previous statement, informing us that he believed there were approximately 3,900 such open consultations and that he had assigned the Acting Manager of the Business Office to investigate the matter further. The Acting Manager of the Business Office, solely responsible for all of the office's operations, retracted an initial statement that "thousands of Veterans were waiting for care," instead offering that "there were a lot of consultations that needed to be completed for administrative reasons. By moving them from pending and completing the consultations [because] a lot of them had already received the care."

VSSC data show that the Manchester VA had an upward trend in community care consultations starting in September 2016, and with this come a substantial increase in open consultations. This trend plateaued in March 2017, which coincided with consultation closing initiatives. The data then showen upward spike of approximately 2,700 open consultations in June 2017 with a precipitous drop at the end of that month.

Additionally in the fall of 2017, in support cleach VHA facility, the VHA OCC created a Community Care Support Center (CCSC) to provide and explain facility-specific CITC data. The CCSC distributes data to each VHA facility and its VISN leadership on a monthly basis and holds monthly toleconferences with the VISN BIMs to review the reports. The VHA OCC field support staff members assigned to each facility assist with challenges that they may experience related to meeting the metrics defined in VHA Directive 1232, Consult Processes and Procedures, August 24, 2017. The CCSC is currently collaborating with the VSSC on a monthly report to VAMCs with their individually trended data. Once that report is up and running, CCSC will have monthly calls to discuss data trends and help challenged VAMCs develop and implement action plans for improvement.

Conclusions related to Consultation Management

• We substantiate that Health Net failed to meet its contractual obligations to provide vices in connection with the VCP, which resulted in the Manchester VA's inability to ensure that Veterans received timely medical care. During the course of this investigation, we identified six Veterans whose care has been referred to a third-party external reviewer to determine if delays in care resulted in harm or adverse outcomes. The care provided to these six Veterans is discussed in this report under the relevant sections.

- The Manchester VA's Business Office lacked necessary resources to adequately
 handle its workload and became seriously overwhelmed as it attempted to address
 Health Net's failures. The VISN 1 BIM did not completely understand the challenges
 facing the Business Office or its need for increased staffing. The VHA OCC did not
 adequately respond to the quality of care concerns raised by the MCD and CoS 2.
- The MCD and CoS 2 consulted with the VHA OCC for guidance and made appropriate decisions to coordinate the care needs of Veterans through other CITC options.
- The Manchester VA Business Office staff failed to make administrative changes to community care consults for VCP referrals as they moved through the consultation process, which resulted in inaccurate community care consult data violating VHA Directive 1232. Over 3,000 open community care consults for VCP referrals had not been moved from pending to completion status until late July 2017. All of these consults were reviewed for relative adverse events and none were found.
- We found a lack of follow up by VISN and VHA leadership regarding their knowledge of VSSC data and ability to access the data. While VSSC data are available on community care consultations, they are not included in the SAIL reports that VA medical facilities and VISNs automatically receive. The weekly National Consultation Performance Improvement to conference is not mandatory, and while the data are available on the Consultation harePoint site, there had not been any follow up with the Manchester VA regarding the upward trend of open and pending community care consultations reported on the call in September 2016.
- We have requested an external third-party review of the Veteran diagnosed with lung cancer. Until this review has been completed, we cannot determine whether the Veteran received appropriate medical care.

Recommendations to the Manchester VA

- 3. Ensure that all Business Office staff members are trained on VHA Directive 1232.
- 4. Implement a monthly audit process for community care consults for VCP referrals to ensure compliance with VHA Directive 1232.
- 5. Depending on the results of the external third-party review, take action in accordance with VHA Handbook 1004.08.

Recommendation to VISN 1

1. Review the Manchester VA's budget and ensure that the Business Office has adequate staff and resources to address workload.

Recommendations to VHA

- Consider including very specific accountability expectations and resulting actions if a new contract is awarded to a TPA. Prior to award, VA should gain reasonable assurance that the proposed TPA has the clinical and administrative resources necessary to schedule appointments for requested care.
- 4. In addition to VHA Recommendation 1, develop means to provide real-time funding to support the real-time needs and productivity of the Manchester VA. Trace the history of Issue Briefs submitted by the MCD to determine whether or not the process as outlined in the VHA *Guide for Issue Briefs* was followed.
- 5. Ensure CCSC and VSSC create monthly reports to distribute to What facilities with their individually trended data.
- 6. Monitor the newly established CCSC to ensure community care consultation data are provided to every VHA facility and VISN, and that VIXVOCC field support staff members are documenting corrective action plans and progress for the VHA facilities that have difficulty meeting consult management metrics defined in VHA Directive 1232.
- 7. Ensure that each VHA facility participates in the VHA OCC monthly teleconference and receives the monthly national report on CCSC. Ensure that VHA OCC field support staff members' oversight activities of CITC and VCP consultation data are occurring, including VISN and VAMO corrective action plans and progress reports.

B. Scope of Services provided at the Manchester VA

The following four allegations fell under this section:

Allegation 3. Operating from (OR) Surgical Services have allegedly been stymied by a failure to replace obsolete equipment and there is a lack of space for new diagnostic equipment.

Allegation 4. Rust or blood stained surgical instruments that were supposedly sterile have been delivered to the OR.

Allegation 5. There is an ongoing fly infestation that has closed an OR since October

Allegation 6. The Manchester VA lacks a reliable Nuclear Medicine (NM) camera; this impairs its ability to diagnose certain conditions in a timely fashion.

The Manchester VA is an Ambulatory Basic Surgical Complexity facility, which limits the complexity of OR cases due to lack of an inpatient intensive care unit and other acute care services needed to support more complex surgeries, such as joint replacement.

An OR suite typically consists of individual rooms where procedures are performed, as well as areas where sterile supplies are stored and others where dirty instruments are placed for pick up. ORs are generally windowless and feature controlled temperature and humidity. Special air handlers filter the air and maintain a slightly elevated pressure to ensure a sterile environment.

On August 4, 2017, the SecVA announced a VA New Hampshire Vision 2025 Task Force that will develop a future vision of what VA must do to best meet the needs of New Hampshire's Veterans. This comprehensive review will include input from Veterans and other key stakeholders and will develop recommendations on the to best configure future VA services in the state. Members of the task force are multidisciplinary subject matter experts from the local medical community, Veterans and VA. including a staff member from the Manchester VA who brought forward concerns to New Hampshire's Congressional delegation as well as the media Special Medical Advisory Group, which includes prominent leaders in U.S. health care, will review the Task Force recommendations. Final recommendations are expected to be forwarded to the SecVA in May 2018.

Allegation 3. Surgical Services have allegedly been stimled by a failure to replace obsolete equipment and there is a lack of space locknew diagnostic equipment.

Background on Surgical Services

The Manchester VA's surgical suite consists of four ORs, three for surgical procedures and one for endoscopies and colonoscopies. The Manchester VA uses a small room inside the adjoining Post Anesthesia Bare Unit (PACU) for minor procedures. Prior to early FY 2013, a contracted ophth@mology practice group performed cataract surgeries there. In 2013, the Manchester A started a major heating, ventilation and air conditioning (HVAC) renovation project which required the closure of the entire OR in order to gain access to the building's HVAC system, and the Manchester VA's OR remained closed until July 2014. 47 Thereafter, 84 cases were performed in the OR during the remainder of the FY.

Findings related to Surgical Services

A urologist recruited by CoS 1 to be the Chief of Surgery began his employment in June 2015. He provided testimony that he thought he could develop a robust surgery center in Manchester for Veterans. The complexity of surgical cases is limited due to a lack of inpatient intensive care and other acute care services available at the Manchester VA. In order to provide a wider variety of surgical care, the Chief of Surgery recruited two nurse anesthetists, one anesthesiologist, one otolaryngologist (Ear, Nose, and Throat (ENT) surgeon), and one urologist.

He also requested additional high-cost, high-tech surgical equipment valued at \$239,358. The Manchester VA submitted this request to VISN 1 for purchase in FY

Once the OR re-opened, the Manchester VA contacted the practice group to resume cataract surgery, but the group declined. Leadership is exploring other options for providing cataract surgery.

2016. The VISN prioritizes all such equipment requests from all of its facilities, and this one was prioritized as third for purchase. Based on available funding, the VISN was only able to purchase equipment for the two highest priority requests in FY 2016. The Manchester VA resubmitted the request to VISN 1 in FY 2017, at which time the purchase was approved, but the equipment was not delivered by the vendor until late in the year. The Manchester VA's Chief Logistics Officer reported that on July 12, 2017, the Chief of Surgery told him, "he would not be using the equipment here for some time up to a year or longer," and then on July 19, 2017, told him "we are going to have to return it, because we cannot use it here; it has to do with the complexity of the place." While the MCD and CoS 2 were supportive of the expansion of surgical services and the subsequent hiring and equipment purchasing actions, these requests were not aligned with the scope of services provided at the Manchester VA.

Conclusions related to Surgical Services

- We do not substantiate that the Manchester VA's Surgical Services are stymied. This VHA facility is a Basic Ambulatory Surgical Complexity medical center, which is limited in the complexity of OR cases it can perform due to a lack of inpatient care and other acute care services needed to support more complex surgeries.
- Because of budgetary constraints, neither the Manchester VA nor VISN 1 was able to purchase the equipment requested by the Chief of Surgery until FY 2017. However, once the equipment was received in July 2017, the Chief of Surgery indicated it would have to be returned because it could not be used due to the Manchester VA's designation as a Basic Ambulatory Surgical Complexity facility.

Recommendation to the Manchester VA

6. Confirm whether the high cost, high-tech equipment procured in FY 2017 is needed by Urology or can be utilized by surgical services elsewhere within the Manchester VA or VISN 1.

Recommendations to VISN 1

- 2. Informed by ecommendations received from the VA New Hampshire Vision Task Force, the MCD should determine which surgical services are feasible for the Manchester VA to provide. Once determined, take the appropriate steps for indifferentiation.
- 3. Review the Manchester VA's budget to ensure sufficient financial resources are allocated to meet the clinical needs of the increasing number of unique Veterans being served by the Manchester VA and to address the unique demand for health care services in the State of New Hampshire.

Allegation 4. Rust or blood stained surgical instruments that were supposedly sterile have been delivered to the OR.

Findings related to Stained Surgical Instruments

On June 8, 2017, Manchester VA OR nurses informed their leadership that they discovered discoloration or questionable particulate matter in a surgical instrument pack as they were preparing for a surgical case. The nurses opened a second instrument pack and discovered the same issue. The discoloration was suspected to be water stains, possibly iron residue, and the Manchester VA responded immediately by temporarily closing the OR to conduct a thorough investigation. Two OR surgical cases were canceled as a result, one was deemed urgent and the patient had surgery performed on June 9 at the WRJ VA. The second case was not urgent and was rescheduled for a later date. There were no surgical cases scheduled for June 9. All instruments required for scheduled surgeries during the week of June 12 –16 were sterilized at the WRJ VA, and no surgeries had to be canceled or rescheduled as a result.

Manchester VA leadership consulted the National Program Office for Sterile Processing (NPOSP) on June 12 to discuss plans to address process over the discoloration, which was suspected to be water stains or heavy metal residue related to the heavy metal content of water in Manchester. The leadership team restarted sterilization operations at the facility and validated that the equipment used to sterilize scopes was in compliance with manufacturing guidelines and the correct water filtration system was in place. Additionally, Sterile Processing Service (SPS) staff members began to perform a final rinse of all instruments with deprized water after the sterilization process. The Chief of SPS modified operating procedures to reflect this change and all SPS staff members were trained accordingly. The steam sterilizer manufacturer, Steris, was onsite June 14 for a consultative visit. Steris indicated that staining problems often are a result of impurities in the steam and recommended replacing steam filters as a preventive measure. The Boston VA SPS leadership also conducted a consultative visit on June 14 to provide additional input on SPS procedures. In addition, the Manchester VA replaced many surgical instruments and sterilizer trays on June 13, and has since purchased an additional \$60,000 of surgical instruments.

In follow up to the above concerns, NPOSP conducted a site visit to the Manchester VA on June 20–22, 2017. Discoloration identified as water stains, possibly from iron residue, was found on the majority of the peel packages sampled, and a small amount of particulate material was found inside the majority of the surgical instrument sets, but not on the instruments themselves. NPOSP reported the facility has developed and implemented a corrective action plan to address the concerns. The facility engineering service purged and flushed both steam and water lines the weekend of June 24–25 to remove suspected sediments. The steam autoclave chambers had been professionally cleaned and appeared in good working condition.

The Manchester VA's boiler plant has been under construction as part of a large utility plant upgrade. As a result, steam pressures have varied and a steam "surge" occurred in June. The heavy metal content of Manchester water becomes particulate matter when subjected to steam. Approximately 50 percent of the steam traps from the original construction of the 1950s have been addressed or replaced. NPOSP found no nonconformities in the sterilization processes and procedures, determined the discoloration and particulate matter found was neither blood nor rust, and identified the overall risk as negligible due to the quality assurance audits completed by OR staff.

Following publication of the *Boston Globe* article, the NPOSP Director led another site visit to the Manchester VA on July 19–20, 2017, and reviewed SPS Decontamination and Preparation Areas and the OR, and inspected a number of sterilized packages from the storage areas. Discoloration identified as water stains, possibly iron residue, were found on some stainless-steel instruments and instrument containers, and also on a sample of peel-packaged items. There continued to be small pieces of particulate, not rust or blood, found on surgical instrument packaging, identified as benign particulates resulting from multiple construction projects and the use of temporary boilers. These instruments never came in contact with Veterans. The sterilized items sampled had fewer particulates noted inside the packaging compared to those sampled 4 weeks earlier. SPS staff continues to utilize the bottled deionized water as a final rinse for reprocessed reusable medical equipment.

The Boiler Efficiency Institute, LLC, completed a steam analysis on September 11, 2017. The tests conducted onsite reveal that this condition is not impacting steam quality at the sterilizers. Essentially, the building itself acts as a steam-filter, removing impurities and excess liquid from the steam flow prior to its reaching the sterilizers. The water quality in the processing area is a known problem that produces similar issues at other facilities. While the boiler condition must be addressed, the consultants concluded that the domestic water quality issues in the processing area are the most likely cause of the observed defects in packaged, sterilized instruments.

NPOSP continues to collaborate with the Manchester VA that has moved forward with the installation of in-line steam filters and deionized water to effectively mitigate SPS reprocessing challenges. Two additional Manchester VA construction improvement projects may also be a contributing factor related to steam and water problems. Two temporary boiler units were mounted in August 2017, but are not expected to be operational until the entire project is complete in June 2018.

Conclusions related to Stained Surgical Instruments

Small amounts of particulate matter, not rust or blood, were found on surgical
instruments and inside of the packaging. These benign particulates resulted from
the city of Manchester's water supply, which is high in heavy metal content. These
instruments never came in contact with Veterans.

• The Manchester VA OR nurses appropriately took immediate action "to stop the line" of surgical cases in the OR. Their actions and the Manchester VA's actions that followed were proactive and appropriate to ensure safety of Veterans, and no Veterans were rescheduled or cancelled following the initial report.

Recommendation to the Manchester VA

7. Continue to collaborate with NPOSP to ensure Veteran safety in surgical care, and complete corrective action plan accordingly.

Allegation 5. There is an ongoing fly infestation that has closed an OR since October 2016.

Background on Cluster Flies

Cluster flies are common in many countries around the world, including the northern parts of the United States. They feed on flower nectar, are parasites to earthworms, and breed in fields and lawns during the spring and summer months. Their complete life cycle from egg to adult is 27 to 39 days, and they usually produce four generations per year.

Adults are attracted to the sunny side of buildings in the fall, looking for access to the inside before the onset of winter. As temperatures drop, the flies enter buildings through cracks and small openings, including gaps under windows, eaves, roof lines, and siding. They hibemate in wall voids these flies become active on warm days and crawl out of the wall voids in an attempt to return to the outside. On sunny days throughout autumn, winter, and each spring, the flies become active if the surrounding temperature rises above 54 degrees Fahrenheit. Some find their way outside, while others are trapped indoors, and can be seen flying near lights or windows, as they are attracted to light.

Cluster flies do not breed or nest in buildings. They usually cause no structural damage and pose no know health problems to humans. Physical barriers to access are the best method to keep cluster flies from entering homes and buildings. Cracks around windows, downs siding, utility pipes, and other openings should be sealed with silicone or silicone latex caulk. Exterior applications of insecticides may offer some relief from infestations where the task of completely sealing the exterior is difficult or impossible. The optimum time to treat for cluster flies is late August or early September. Sunlight attend the chemical make-up of insecticide and can render them less effective, thus, the residual effect of the material will be greatly decreased and may not kill the flies much beyond several days or a week. 48

Findings related to Cluster Flies

Penn State College of Agricultural Sciences, Department of Entomology (http://ento.psu.edu/extension/factsheets/cluster-flies.

In our earlier investigation, we found that in the fall of 2014, OR staff members began noticing flies in OR #2, while preparing the room for the first scheduled case of the day. The insects were identified as the cluster flies common to the area. The staff notified OR leadership and then prepared for and completed the procedure in one of the other ORs. An Environmental Management Services (EMS) employee terminally cleaned OR #2, and the room remained closed for 6 consecutive days, during which time staff members saw no flies there. They saw no cluster flies after a Veteran was brought into OR #2 or while surgery was in process, but did see some throughout the remainder of the fall of 2014 and the following winter.

Staff members began seeing cluster flies again in OR #2 late in the summer of 2015. Some sprinkler heads were resealed and Engineering Service checked the new HVAC system, and found it was 100 percent air tight. As a result of the repeated insect sightings, the use of OR #2 was discontinued until the issue could be resolved. The room remained closed from September 2015 until January 2016, in April 2015, the Manchester VA contracted a new pest management company that installed flying insect lights with glue boards for surveillance and capture of insects. The contractor installed these lights in OR #2 and the mechanical room above it. All windows in the OR were sealed as part of the renovation. However, because of a miscommunication with the Manchester VA about safety concerns and weather conditions, the company did not spray insecticides outside the building in August of September 2016, the optimum time to prevent these infestations.

In August and September 2016, the pest control contractor applied exterior pesticide treatments in an attempt to eradicate the lies. In October, the contractor treated the outside roof line above the OR with a chemical to repel and eradicate various pests including cluster flies. It was difficult to determine the success of the treatment since some flies may already have penetrated the building before the treatment began. The Manchester VA obtained a second opinion regarding cluster fly mitigation options from a different pest management company. These recommendations, which the Manchester VA has implemented include:

- Treating exterior walls with pesticide, specifically in the areas of the OR suite and roof line three times in the fall during August, September, and October.
- Sealing all vents and other suspected areas of interior and exterior entry points in OR 22.
- Seating the holes or openings in the ceiling lights in OR #2 to reduce light Catraction between ceiling and mechanical room floor.

OR staff members saw no additional flies throughout calendar year 2016 until that autumn. During VA's site visit in February 2017, the VA team, which included the VHA's Pest Management Program Manager, toured the entire OR suite and the mechanical room above the OR. We did not identify any obvious visible entry points, though several OR staff acknowledged multiple sightings of cluster flies in OR #2. We reviewed recent pest control surveillance logs: staff members documented five sightings of flies in OR #2 between January 3 and 27, 2017. There were none present

during our tour, nor were any flies in the insect light or glue traps in OR #2; however, there were a few flies of various types in one of the insect light traps in the mechanical room above the OR. The Pest Management Program Manager determined that while the Manchester VA had taken the actions recommended by the third-party consultant, flies were still entering OR #2 on an intermittent basis. During our visit in July 2017, we toured the OR, including OR #2, and found no evidence of flies; however, the room remains closed.

The Pest Management Program Manager revisited the Manchester VA again on the 24 and 25, 2017, to evaluate the continued presence of cluster flies. He determined that the facility was continuing to implement all previously recommended actions and was monitoring OR #2 for flies. He discovered several small openings in the ceiling of OR #2 associated with installation of the new HVAC system, and recommended:

That the openings be sealed,

That the ceiling of OR #2 be enclosed with a plastic barrier of at least 3 months to determine whether the ceiling lights are the access points for the flies.

That electrical panels and windows in OR #2 be correct for the next 3 to 4 months.

That the room be monitored daily for the presence of flies,

 That OR #2 be closed with continued monitoring until there are no fly sightings for 3 to 4 consecutive months, beginning in September 2017, and

 That the Manchester VA treat the exterior wall of the third to fifth floors with longacting pesticides in early August.

As of March 2018, the Manchester VA(has completed all recommended actions and plans to block all windows in the OR to reduce the portals of entry for flies.

The whistleblowers cited in the Boston Globe article alleged that the fly infestation led to delays and cancellations of surgical procedures. Only one staff member stated that the flies in the OR had caused the Manchester VA to cancel cases and delay care to Veterans, a conclusion based on an incorrect assumption that since OR #2 was closed, cases must have been cancelled. We reviewed the OR scheduling and surgical reports and found no doscopiented evidence of surgeries, endoscopies, or colonoscopies cancelled or rescheduled as a result of flies in OR #2. We found that as of early 2017, endoscopies were scheduled up to 6 months from the time they were requested because of issues with the scheduling system, not because OR #2 was closed. After the OR team addressed the scheduling system issues, staff members were able to schedule endoscopies within 6 weeks of the time requested instead of 3 to 6 months.

During FYs 2015 and 2016, the Manchester VA was only able to use three ORs instead of its full capacity of four, because of a lack of sufficient staff in the Anesthesia and SPS, not because OR #2 was closed. Additionally, during FY 2016, there was a delay in the completion of orthopedic cases because the surgeon was not available for an extended period of time. When he returned to duty, he gradually resumed his workload. These three reasons for delays in care were unrelated to the closure of OR #2 due to the presence of flies. No OR cases have been scheduled for OR #2 since the decision

was made to close it in the fall of 2016, and it will remain closed until the Manchester VA can confirm that flies are no longer gaining access to the room. According to surgical and OR staff members, Veteran surgeries are only scheduled to take place in the open OR rooms. The Manchester VA did not cancel or send any patients to community providers because of OR#2's closure.

In July 2017, a large pipe burst at the Manchester VA, resulting in extensive damage to many areas, including the PACU. The damage to the PACU resulted in the closure of the OR until the Manchester VA remediates the water damage in the PACU, since a fully functional PACU is vital for immediate postoperative care. As of March 2018, all surgical cases are referred to other VAMCs or non-VA community hospitals, and the OR remains closed for an issue unrelated to fly sightings in the OR. Although the OR remains closed, the Manchester VA continues to monitor for the presence of flies in the OR, noting the last fly sighting was 8 months ago in November 2017.

Conclusions related to Cluster Flies

- We found no documented evidence of surgeries, endoscopies, or colonoscopies being cancelled or rescheduled as a result of flies in \$10.00 #2.
- The Manchester VA continues to have flies in \$\text{\pi}\pi^2, so it continues to take all recommended actions to monitor OR #2 for the and to mitigate infiltration.

Recommendations to the Manchester

- 8. Continue to implement the recommendations made by VHA's Pest Management Program Manager and the pess management company.
- 9. Ensure that OR staff mentoers continue to check for flies in each room, each morning, prior to the start of the first scheduled case.

Allegation 6. The Manchester VA lacks a reliable Nuclear Medicine (NM) camera; this impairs its ability to diagnose certain conditions in a timely fashion.

Background on Nuclear Medicine

NM imaging uses small amounts of radioactive material called radiotracers that are injected into the bloodstream, inhaled, or swallowed. The radiotracers travel through the acta being examined and gives off energy in the form of gamma rays which are detected by a special NM camera and processed by a computer to create images of the inside of the body. NM imaging provides unique information that often cannot be obtained using other imaging procedures and offers the potential to identify disease in its earliest stages.⁴⁹

American College of Radiology https://www.acr.org/Advocacy/Economics-Health-Policy/Imaging-3/PEC-Resources/radiologyinfo Accessed August 24, 2017.

NM Bone Scans offer the potential to identify disease in its earliest stages and to help diagnose and evaluate a variety of bone diseases and conditions.⁵⁰

Cardiac Nuclear Medicine imaging evaluates the heart for coronary artery disease and cardiomyopathy. Initially the patient receives an injection of a radiotracer while they are resting. Approximately 20 to 40 minutes after the radiotracer is injected, the Veteran will lie on a moveable imaging table with their arm(s) over their heads for about 15 to 20 minutes while images are recorded.⁵¹

Cardiac NM Stress Testing occurs after the initial cardiac nuclear imaging. A stress test requires the Veteran to exercise either by walking on a treadmill or pedating a stationary bicycle. If unable to exercise, the Veteran is given a drug that increases blood flow to the heart. Throughout the exercise period, an electrocardiogram (ECG) monitors the electrical activity of the heart and the Veteran's blood pressure is also monitored. When blood flow reaches its peak, the radiotracer is administered. Approximately 20 to 40 minutes after the stress test portion is completed, the Veteran will have a second series of images recorded with an ECG to trage the motion of the heart. Total time in the NM department will be from 2 to 4 hours. ⁵²

Findings related to Nuclear Medicine

The Manchester VA provided full-service imaging until January 2017, when a NM technologist retired. Bone scans and cardiac press tests made up the majority of NM imaging studies completed prior to that time. In FY 2016, they averaged approximately 150 such tests per year. The Manchester VA does not have an emergency room, an intensive care unit, or the ability to maintain advanced cardiac life support. As a result, it cannot perform stress tests on Voterans who are symptomatic and transfers any Veteran in urgent need of a stress test to a community hospital affiliate.

The Boston Globe article reported that the Manchester VA "ordered a \$1 million NM camera in 2015 to replace a balky one, but never installed it because it was too big for the examination room. Without a reliable camera, the hospital in February stopped offering nuclear stress tests for heart disease risk, and bone scans that detects tumors. The building is expected to be remodeled for the new camera in 2018. A cardiology Nurse Practitioner (NP) has been especially worried about Veterans with potential heart conditions waiting weeks for nuclear stress tests, which have been referred to providers outside the Manchester VA since NM was shut down. A cardiologist claims the cardiology program has been in free fall since officials closed the NM program in February. Not only does he have to send his Veterans to other facilities for nuclear cardiologist left several months ago and the hospital hasn't replaced him, though

⁵⁰ American College of Radiology https://www.acr.org/Advocacy/Economics-Health-Policy/Imaging-3/PEC-Resources/radiologyinfo Accessed August 24, 2017.

American College of Radiology https://www.acr.org/Advocacy/Economics-Health-Policy/Imaging-3/PEC-Resources/radiologyinfo Accessed August 24, 2017.

[&]quot; Ibid.

⁵³ Nuclear Camera Purchase Meeting Minutes Amendment, January 17, 2017.

hospital officials say they are now sharing a second cardiologist with a sister facility." The remaining cardiologist is quoted in the article "Since I've been here, there's been a gradual deterioration in the quality of care, not the quality of care I deliver, but the quality of care I'd like to deliver."

The end of the projected lifespan of the facility's current NM camera is 2018. In FY 2014, the National Acquisition Center (NAC) authorized the purchase of a new NM camera and allocated funds. The size of the new camera required renovations to the existing NM suite, which was well known at the time of the purchase. Once the size is ready, delivery of the new camera will be scheduled, and it will be the most current model of the camera available. A modification to the original purchase contract on March 30, 2016, added plans for a Turnkey Installation. Leadership believed the Turnkey Installation would include the architectural, engineering, and construction services necessary to renovate the existing NM Suite, including the reception desk, waiting area, restrooms, and office to accommodate the new camera. The vendor estimated the construction duration would be approximately 5 weeks.

In October 2016, the Manchester VA planned for construction to begin in April –May 2017. In January 2017, the NM technician retired and shortly thereafter, one of the two cardiologists resigned. In light of the impending construction and renovation required to install the new camera, the retirement of the NM technologist, and resignation of a cardiologist, leadership decided to temporarily fold off on hiring a new technologist and pause NM studies for 6 to 9 months until the penovation, construction, and installation of the new camera could be completed. The penovation minutes indicate that CoS 2, the ADPCS, and the Chief of Medicine discussed this matter with key staff on January 9, 2017, including plans to hire a new NM technologist and a new cardiologist and resume full NM operations at Manchester. Once the project was complete.

In the meantime, Manchester, A leadership planned to meet the demand for NM services by referring patients for care in accordance with the Hierarchy of Care guidelines. They referred patients in need of NM studies to the Boston or WRJ VA, and Catholic Medical Center, a participating Choice provider located 2.3 miles from the Manchester VA. COS 2 verified that all three of these medical centers had capacity to meet this temporary need. While the Cardiology NP voiced concerns about referring nuclear studies but to the community, his workload decreased and he was given responsibility for coordinating the care of these Veterans to ensure they received the appropriate level of care. The ST As clinically indicated, Veterans are scheduled within 30 days of the clinically indicated date at any of the referral facilities. The NP reported an are tage wait time prior to the pause of nuclear stress testing of 11 business days.

The National Acquisition Center (NAC) is responsible for supporting the health care requirements of VA as well as the needs of other Government agencies. The NAC solicits, awards, and administers VA's Federal Supply Schedule and National Contract Programs including the acquisition of high technology medical equipment.

Turnkey installation is when a vendor is responsible for providing both the equipment and construction services required to make imaging equipment and space fully functional. This incorporates renovations to the rooms such as construction of walls; electrical power runs; additional cooling; lighting; flooring; wall finishes; ceiling tiles; and other work needed for the equipment.

Nuclear Camera Purchase Meeting Minutes, January 9, 2017.
 Clinic Workload Report Cardiology NP October 2014–July 2017

On January 11, 2017, the Manchester VA was informed that the NAC was changing the Turnkey Installation process, and only approving funding for work required to install new equipment. This new process became effective on January 25, 2017. In the past, the NAC has funded relevant renovation and construction projects related to new equipment installations. The Manchester VA planned to swap the room where the existing nuclear camera is located with the existing waiting room because of the size of the camera, which would also improve patient flow and patient confidentiality. However, this plan was not within the scope of installation and the Manchester VA now must use local funds to pay for renovation and construction. The Manchester VA requested \$250,000 of additional funding from the VISN to cover renovation and construction costs. However, the VISN High Cost High Tech Equipment Committee did not provide funding in FY 2017, a decision that the VISN Executive Leadership Board ratified in May 2017. Additionally, on May 19, 2017, the NAC provided official guidance to the field regarding the new process to prepare sites for new equipment installation and associated construction funding. Due to the lack of construction funding, the purchase contract for the new NM camera was modified on May 25, 2017; delaying the delivery date until December 30, 2018.

As a result of the project delay, leadership did advertise a new cardiologist position with an intension to hire on February 23-March 6, 2012 The workload only justified the need for a part-time cardiologist; however, a patitime cardiologist is difficult to hire, so the Manchester VA sought either a full-time opart-time position. In the meantime, the WRJ VA had recently hired a full-time carefologist. According to the Human Resources (HR) Officer, there were two qualified external applicants and one internal applicant. HR issued the Certificate to the Chief Medicine, the selecting official, on March 20, 2017. He returned the certificate to HR on March 28, 2017, without making a selection. HR noted that there was a qualified applicant who applied directly to the local HR office on March 14, 2017; HR also electing official and documented that he expressed no interest in interviewing or selecting this qualified applicant for unspecified reasons.⁵⁹ HR posted a Cardiologist position again from May 11-25, 2017, this time advertising the possibility of 50 percent duty at Manchester VA and 50 percent at another VAMC, and two qualified applicants applied. HR issued the Certificate to the Chief of Medicine, on May 26, 2017. The Chief of Medicine reported on 300 26, 2017, that the Manchester VA would be sharing a Cardiologist with the WRJ VA. 60 The Manchester VA collaborated with the WRJ VA and worked out an agreement for the new cardiologist to work at the Manchester VA during half of the time which satisfied the cardiologist's workload needs. As of July 18, 2017, the plan was for the WRJ VA cardiologist to begin working on site at the Manchester VA in September 2017. In the meantime, some remote sharing of work is occurring. Additionally, leadership evaluated the need to hire an NM technician and based on the low workload determined an intermittent technician would be most appropriate. An

USAJOBS Manchester VA Non-Invasive Cardiologist Postings, February 23, 2017

HR Specialist Email to HR Officer regarding Physician – Non-Invasive Cardiologist, July 12, 2017.
 HR Specialist Email to HR Officer regarding Physician – Non-Invasive Cardiologist, July 12, 2017.

announcement was posted for an intermittent NM Technologist from June 26–July 6, 2017.⁶¹

We received testimony that over the course of the last few years there have been consistency problems with the operation of the NM camera: it had broken down on numerous occasions, and at times Veterans have had to have repeat stress tests as a result. The Chief of Medicine reported that in some months the camera was down 50 percent of the time, leading to appointment cancellations. The Patient Safety Officer (PSO) told the investigative team that he received verbal reports of concerns from the Cardiology NP regarding the reliability of the camera in late December 2016 of early January 2017. The Cardiology NP reported that the camera had broken down a number of times in the middle of tests, which required repeat testing and to sequently exposed Veterans to additional radiation. The PSO rightfully reported this information to the MCD and CoS, and this Veteran safety concern was a key factor in their decision to temporarily pause NM services. Months later, the PSO discovered that there was only one Veteran who required repeat testing as a result of the camera breaking down in the middle of testing. A chart review confirms the event occurred in June 2015, and the repeat test was in October of that year.

Since the Manchester VA began referring NM studies to the Boston VA, WRJ VA, or Catholic Medical Center, the Manchester VA's Chief of QM, Risk Manager, and PSO have found no evidence of adverse outcomes of delays. However, the Cardiology NP identified three cases he believed had a delay in care. We have referred these cases for external, non-VA peer reviews to determine whether the care received was appropriate. As of March 30, 2018, external third-party peer reviews are pending.

Conclusions related to Nuclear Medicine

- Due to a confluence of factors, including changes in the NAC process to prepare sites for new equipment installation and associated construction funding, the NM suite renovations were not funded in FY 2017, leading to a delay in construction and subsequent delivery and installation of the new NM camera.
- The MCD and CoS 2 appropriately decided to temporarily pause NM services and refer Veteral to the Boston VA, WRJ VA, and Catholic Medical Center only after considering multiple factors including the construction project delay, technician retirement, cardiologist resignation, and a concern for Veteran safety from excess retirement, cardiologist resignation, and a concern for Veteran safety from excess retirement, cardiologist resignation, and a concern for Veteran safety from excess retirement, cardiologist resignation, and a concern for Veteran safety from excess retirement, cardiologist resignation, and there was an appropriate plan in place to provide care to Veterans in need of NM testing.
- The MCD and CoS 2 intended to fill the vacant cardiologist position, and hire an
 intermittent NM technologist. HR appropriately posted the vacant cardiologist and
 NM technology positions to meet the workload demand. However, HR documented

⁶¹ USAJOBS Manchester VA Intermittent -- Nuclear Medicine Technologist, June 26, 2017.

the selecting official chose not to interview four applicants that met qualifications in late March.

 External third-party peer reviews are being completed. We have not determined whether any of the three cases identified by the Cardiology NP as having a delay in care received inadequate care.

Recommendations to the Manchester VA

- 10. Continue ongoing actions to ensure Veterans receive NM studies and testing in a timely manner.
- 11. Informed by recommendations received from the VA New Hampshire Vision Task Force, the MCD should ensure renovation and construction funds are available and the NM project is completed on time to take delivery of the new NM camera on December 30, 2018.
- 12. Pending external third-party peer reviews results for the three cases identified by Cardiology NP as having a delay in care, take appropriate action, if indicated, in accordance with VHA Handbook 1004.08.

Recommendation to VISN 1

4. Continue to work with the MCD and the VA New Hampshire Vision 2025 Task Force to ensure renovation and construction projects are funded and completed on time to take delivery of the new NM camera on December 30, 2018.

C. Veteran Quality of Care Concerns

The following two allegations fall under this section:

Allegation 7. A Veteral alleged to the investigative team a 6–9 month delay in his prostate cancer diagnosis.

Allegation 8. A Veteran's daughter contacted the investigative team and alleged her father received substandard care while he resided in the CLC.

The concal vignettes provided here to explain the medical care received by these Valerans will be concluded upon together, along with the requisite recommendations. Allegation 7. A Veteran alleged to the investigative team a 6–9 month delay in his prostate cancer diagnosis.

Findings related to a Veteran's Prostate Cancer Diagnosis

A Veteran decided to change his PC Provider to the Manchester VA, which is closer to his home. This Veteran was evaluated for the first time on April 20, 2016, by his new Primary Care provider (PCP) at the Manchester VA. His laboratory test results included

an elevated prostate specific antigen (PSA) of 6.3, which was an increase from the value obtained 3 years ago of 4.48. The Veteran's PCP documented the elevated PSA in the electronic health record (EHR), but that this was not uncommon for a man this age. The PCP added that he planned to recheck the Veteran's PSA in 6 months. The PCP entered a consultation request for Boston VA Urology on April 24, 2016, since they had been following him for a few years for other urologic conditions. The Veteran received appointments for Boston VA Urology on May 19, 2016, and June 20, 2016, but he later canceled these appointments. He was evaluated by the Boston VA Urology service on June 23, 2016, and his prostate examination was abnormal, prompting them to order a biopsy on August 11, 2016. They diagnosed him with prostate cancer of August 25, 2016. We have referred this case for external, non-VA peer review to determine whether the care received was appropriate. As of March 9, 2018, the external third-party peer review is pending.

Allegation 8. A Veteran's daughter contacted the investigative team and alleged her father received substandard care while he resided in the CLC

Findings related to a Veteran's Care in the CLC

The Manchester VA received a telephone call from a Veteran's daughter who had concerns regarding the geriatric care her father received while he resided in the CLC. The Veteran was a 98-year-old male with a history of multiple chronic medical illnesses including hypertension, anemia, peripheral vascular disease, congestive heart failure, chronic kidney disease, prostate and bladder cancer, and chronic obstructive pulmonary disease. He was initially admitted to the CC on August 10, 2011, for rehabilitation after hospitalization for injuries sustained after a fall. On September 16, 2011, the CLC discharged him to his home in a senior community with his daughter providing assistance at his home as needed. The Home Telehealth program began coordinating and providing his care.

Between September 2011 and September 2016, the Veteran was seen numerous times for the evaluation and treatment of issues with his hand, knee, anticoagulation monitoring, coronary arteriosclerosis, and other health issues. In September 2016, the Veteran requested calliative care for his declining health; however, since there were no beds available in the CLC, he was admitted to a community nursing home for hospice care on October 18, 2016. The Veteran determined that he did not want to be resuscitated in the event that his heart stopped or he stopped breathing. His family was aware. While at the community nursing home, the Veteran's blood pressure became elevated, and in mid-December 2016, the nursing home transferred him to a community hospital where he received treatment. During this hospitalization he was also diagnosed with pneumonia and treated with an antibiotic. The Veteran improved; however, his family expressed concerns about his ability to care for himself. The Veteran was admitted to the CLC on December 28, 2016, for rehabilitation.

During his CLC admission, the Veteran developed decompensation of both his chronic kidney disease and congestive heart failure. His health declined over the course of the month of January, and he was transferred to a local emergency room at a community

hospital for evaluation. The Veteran was diagnosed with septic shock and due to the fact that the physicians providing his care did not know his wishes related to resuscitation, he was placed on a mechanical ventilator and prescribed medications to sustain his blood pressure.

Later that same day, the Veteran's daughter spoke with the Manchester VA CLC staff members to relay her concerns related to his care, stating that he had been complaining of urinary symptoms for several weeks. The Veteran's condition continued to decline and he died on January 22, 2017, as a result of a complication of the urinary traction and the development of septic shock.

We requested an external third-party peer review of this Veteran's medical care, which has been completed and determined to have met the standard of care.

Conclusions for Veteran Quality of Care Concerns

- We have requested an external third-party peer review of the first Veteran's medical care related to the diagnosis of prostate cancer and are awaiting the results. Until then, we cannot determine whether the Veteran received appropriate care.
- The external third-party peer review of the second Veteran's CLC care has been completed and determined that it met the standard of care.

Recommendation to the Manchester VA

13. Depending on the results of the external third-party review of care for the Veteran with prostate cancer, take actions if necessary in accordance with VHA Handbook 1004.08.

D. Manchester VA Leadership

The following folicallegations fall under this section:

Allegation Providers alleged that Manchester VA leadership is unresponsive to their concerns.

Attendation 10. Manchester VA leadership appointed an unqualified person as the Acting Chief of Primary Care (PC).

Allegation 11. Providers alleged that nursing leadership exercised an unusual amount of decision making authority.

Allegation 12. High-ranking doctors at the Manchester VA have given up leadership positions or plan to leave the hospital, and other physicians are indignant on their behalf, citing frustration with management.

The concerns provided here are addressed individually, but concluded upon under Manchester VA Leadership together, along with the requisite recommendations.

Background on Manchester VA Leadership

Allegation 9. Providers allege that Manchester VA leadership is unresponsive to concerns.

One now-retired physician alleged that he could not get things addressed through his chain of command; however, he provided no evidence during his destimony to support this allegation. However, we found that the MCD, while ultimately accountable for approving management decisions, encouraged collaborative decussion and decision making by the entire quadrad. Similarly, various multidisciplinary hospital committees responsible for recommending management decisions the so by routing meeting minutes for endorsement to the pertinent member of the quadrad (e.g., via CoS 2 for clinical practice matters, or the Associate Director to administrative issues) before obtaining final approval by the MCD. This approach ensured that input from leaders at multiple levels, including service chiefs and leads of the Medicine and Surgery divisions, was incorporated into management decision making.

As noted above, a physiatrist alleges that Veterans were getting substandard spinal care at the Manchester VA. He had even organized a conference of doctors and administrators, including the MCD in September 2015 to discuss this concern, but felt that nothing had changed. Several attendees told us that the MCD only gave opening remarks for the September 2015 conference and was not present for the remainder of the meeting. They further indicated that the physician presenting the program used profanity and went of the topic of the agenda. Someone notified the MCD who instructed the September 2015 to direct that doctor to get the conference back on topic in order to meet the requirements of Continuing Education. The MCD neither returned to the conference, nor was the doctor asked to leave the stage. Other than this physician's testimony, we found no evidence to substantiate or refute these allegations.

Adjustion 10. Manchester VA leadership appointed an unqualified person as the Acting Chief of PC.

Findings related to the Appointment of an Acting Chief of PC

The Boston Globe article indicated "the Administration named a low-ranking employee, a Physician Assistant (PA), rather than a physician, to serve as the Acting Chief of PC. In fact, CoS 2 incorrectly thought that he possessed sole authority to make this temporary duty assignment, but he did not. Ultimately, the MCD is responsible for all

personnel actions at VHA facilities. In addition to being considered unqualified by the physicians in PC, the PA also had a record of two arrests for driving while intoxicated. Within 2 weeks of his temporary assignment, the MCD downgraded him to Acting Associate Chief of PC. Hospital officials said they wanted someone with additional qualifications." We discovered that CoS 2 intended to recommend the PA to serve temporarily as Acting Chief of PC during the recruitment and hiring process for a new Chief. According to the Bylaws of the Medical Staff, the MCD selects or appoints a clinical leader upon recommendation of the CoS. Clinical leaders must be board certified or have equivalent experience in comparable training as vetted through the credentialing process. 62 Although the Director never appointed the PA as Acting Chief of Primary Care, the bylaws do not prohibit the appointment of a PA to clinical leadership. Despite the information reported in the Boston Globe article, the PA is a high performing, well-respected, senior PC provider who holds an unrestricted PA license.

Allegation 11. Providers alleged the nursing leadership at the Marchester VA exercised an unusual amount of decision making authority.

Findings related to the Nursing Leadership

The ADPCS has been a member of the leadership team considerably longer than the other quadrad members. It is not unusual for an ADPCS to be involved in hiring and promoting mid-level and senior nurse leaders working under his or her supervisory authority. We found that some medical staff members perceived that the ADPCS had disproportionate influence at the Manches TA because of her longevity in her leadership role and the number of other dursing leaders that were viewed as being loyal to her. The fact that the MCD trained as a nurse before becoming a health care executive may also have led to the perception that nurses "ran the hospital."

Allegation 12. High-ranking distors at the Manchester VA have given up leadership positions or plan to leave the hospital, and other physicians are indignant on their behalf, citing frustration with management.

Findings related to Physician Attrition

The 2016 All Employee Survey (AES) results after the MCD's first year showed a marked imprevement, and also compared favorably to facility average improvement at all other VIO sites. However, physicians did have significantly lower scores on most items. And of the whistleblowers, a former Manchester VA physician, provided a list of five physicians who, he believed had resigned, transferred to other VHA facilities, or retifed, rather than continuing to work at the Manchester VA. We reviewed exit interview information for these physicians and were unable to attribute this attrition to their concerns with leadership.

In October 2015, the MCD actively engaged with the National Center for Organization Development (NCOD) to help create an Executive Team Development (ETD) program to facilitate team building, and help her improve employee engagement, psychological

⁶² Manchester VA Bylaws, Rules & Regulations of the Medical Staff, March 2016.

safety, and organizational health within the facility. In August 2016, NCOD assisted the ETD in creating and executing a plan to enhance organizational health facility wide through AES action planning at the workgroup level. The ETD created and executed a communication plan to help staff understand the purpose and benefits of AES action planning, and NCOD provided four virtual training sessions on this planning for supervisors with active involvement from the ETD. Following the training, NCOD provided survey feedback to the EDT and discussed methods to support AES action planning implementation over time. In June 2017, with knowledge of the impending Boston Globe article, the MCD reached out to NCOD for a plan to support staff in coping with the aftermath of the negative publicity. Staffers agreed that the MCD was very proactive and responded to service-level requests to meet with front-line staff regarding the article.

We interviewed nearly 50 employees of the Manchester VA, 8 of whom identified themselves as whistleblowers, and met with an additional 36 employees who requested an opportunity to speak with us. Six different physicians have thinktioned as appointed or acting CoS at the Manchester VA since June 15, 2015. CoS 1, who retired in 2015, allowed each service line chief to manage autonomously. His successor, who served in the position for approximately 18 months, was immediately required to conduct a disciplinary process recommended by the OAWP for the Chief of Medicine, initiate an Administrative Investigative Board that resulted in removal of some staff in leadership positions, and shortly thereafter, enforce the VACO Hierarchy of Care guidelines related to care in the community. The combination of these enforcement actions, problems with the VCP, the additional workload caused of Health Net's inability to meet its contractual obligations, budgetary constraints, the CoS new leadership style, and his emphasis on increased accountability led to a breakforwn of working relationships between CoS 2 and some providers. We also found that space constraints, the age of the facility, the inability to obtain high-tech equipment expeditiously, and the arduous acquisition process in general also dispatisfied some staff.

Several employees, including service chiefs, told us that the MCD and CoS 2 have been extremely engaged, approachable, visible, and supportive of further developing programs. One service line chief stated, "I can't say enough about [CoS 2] and I have nothing negative to say about [the MCD]." Several recognized the MCD's implementation of the *Red Button* on the Manchester VA website as a huge improvement for staff members to easily communicate Veteran safety, compliance, and ethical epiderns, as well as general concerns and complaints. The ability to send an email directly to "Ask the Director," and to subsequently receive a personal response, served as a way to open new lines of communication and improve transparency at the facility. Many mentioned that the MCD had open forums to which all staff members were invited.

Conclusions related to Manchester VA Leadership

⁶³ NCOD Email Correspondence regarding Manchester, July 18, 2017.

- We do not substantiate that the Manchester VA leadership that was in place at the time of this investigation was unresponsive to provider concerns. OAWP will make a determination in a separate report of whether any senior leader misconduct occurred...
- We do not substantiate that an unqualified person was appointed as Acting Chief of PC. According to the Bylaws of the Medical Staff, a clinical leader is appointed by the MCD upon the recommendation of the CoS; the appointment of a PA as a 🛴 clinical leader is not prohibited. The MCD appointed a physician as the Action this of PC 1 month after the PA's appointment upon the receipt of complaints from several physicians.
- We do not substantiate that nursing leadership at the Manchester V unusual amount of decision-making authority.
- The MCD and CoS 2 were actively engaged, transparent, and supportive of exploring options to further develop programs: all signs whiteir commitment to open communication and psychological safety to ensure that Veterans receive the highest quality of care.

Recommendation to VHA

8. Consult NCOD to assist Manchester VA staff members in uniting and moving forward.
 VII. Analysis of Findings

Significant challenges faced the Manchester VA leadership and staff members as they attempted to provide care to New Hampshire's Veterans. Specifically, its' status as a complexity level 3 facility without any acute inpatient medical services, as well as the lack of any other VHA facilities within the state designated for this level of care, resulted in 93 percent of New Hampshire's Veterans being eligible for CITC through the VCP. This unique situation, along with Health Net's inability to provide timely CITC consultation an agement, significantly contributed to the untenable state of care. In the midst of this turmoil, Manchester VA clinicians, some of whom thought that their mission was to improve and expand the scope of care within the facility, attempted to add services despite a lack of VHA's prior authorization and approval to do so.

The VCP, established in 2014, changed the business rules that the Manchester VA leadership team was required to follow in providing CITC for Veterans. Several clinicians became concerned about clinical quality of care due to limited services and an inability to refer patients for care using the former referral rules. Despite leadership's efforts to both improve communication and psychological safety in an effort to provide timely care for Veterans, several clinicians became distrustful and frustrated. When they felt as if their clinical concerns were not addressed by their leadership, several chose to voice them publicly.

While there were several confounding factors contributing to significant challenges, we found that Manchester VA clinical staff members involved in direct patient care are very engaged and appropriately concerned about the clinical care of Veterans.

VIII. Summary Statement

We have developed this report in consultation with other VHA and VA offices to address concerns that the Manchester VA had problems with Veteran care, management is sues, scope of services offered, and the VCP. In particular, the Office of General Counsel has provided a legal review, and the Office of Accountability and Whistleblower Protection (OAWP) has reviewed the report to determine whether it makes findings against senior leaders requiring OAWP action, and the National Center for Ethics in Health Care has provided a health care ethics review. We found one vide policy, no violations of law, rule or regulation, and no evidence of stops mismanagement or a gross waste of funds. Health Care has provided a health care ethics review. We found out violation of VHA

Attachment A

Department of Veterans Affairs Memorandum: VA Care in the Community (Non-VA Purchased Care) and use of the Veterans Choice Program. Versions: May 12, 2015, and October 1, 2015.

Department of Veterans Affairs Memorandum: Options for Providing Community Care. June 12, 2017.

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Choice Referral Template

Communications from Manchester VA to VISN related to Status of Mid-Year Supplemental from VACO and Concerns About funding.

Communications from the Manchester VA with the VACO Office of Care in the Community

Computations from the Manchester VA with the VISN related to Manchester Radiology Equipment Issue.

Documentation of NCOD's Guidance to the Manchester VA.

Emails from the Manchester VA Director to the VISN Director Related to Concerns with Veterans Choice Program and Veteran Safety Concerns.

Executive Leadership Board Meeting Record during which the previous Medical Center Director report about Health Net's Response.

Executive Leadership Board Retreat Presentation: Community Care Operating Model and VA Community Care Updates.

Health Net's Communications to the Manchester VA.

Health Net Federal Services/VA Veteran-Centered Community Care and Veterans Choice Program, March 2015–June 2017.

List of Durable Medical Equipment Requested for SCI Veterans.

Manchester VA Issue Briefs for the previous 3 years.

Manchester VA's Actions Tracker.

Manchester VA's Administrative Executive Board Meetings (47 2015, 2016 and 2017 through August 2017.

Manchester VA's Adverse Events Tracker.

Manchester VA's Administrative Investigative Board related to MH Leadership.

Manchester VA's All-Employee-Survey Results for the Past 3 years.

Manchester VA's Analysis of Neurosingical Single Source Referrals from FY 2015 through FY 2017.

Manchester VA's Cardiology WWW Workload 2013-2017.

Manchester VA's Care Coordination Cell Organizational Chart.

Manchester VA's Chief of Staff Choice Clarification Memorandum.

Manchester (2) Choice First Nuclear Medicine Consultations January 15, 2017 through July 18, 2017.

Manchester VA's Choice Hierarchy Flow.

Manchester VA's Choice Mileage Master Spreadsheet.

Manchester VA's Choice Mileage Returns Triage Sheet.

Manchester VA's Choice Referral Updates.

Manchester VA's Choice Return's Process.

Manchester VA's Choice Returns Action Steps.

Manchester VA's Choice Update Memorandum (June 2, 2017).

Manchester VA's Clinic Management Committee Meeting Minutes April 2016 through June 2017.

Manchester VA's Clinic Management Committee-Consultation Steering Meeting Minutes January 2017 through April 2017.

Manchester VA's Daily Data for Manchester Community Care Office for August 2017.

Manchester VA's Documentation for Choice Delay FY 2017, Quarter

Manchester VA's Documentation of Discussions with VACO Community Care Office Related to CHOICE Issues Unique to Manchester.

Manchester VA's Documentation Related to Acquisitions of Prology Equipment Requested by Dr. Chibaro.

Manchester VA's Documentation related to Health-Net's Failure to Answer Phones, Make Appointments, High Volume of Returns, and Vendor Payment issues.

Manchester VA's Documentation Requesting Guidance for Realignment of the Manchester CITC Office.

Manchester VA Email and Health Net Returns Triage Process.

Manchester VA HR NM Technician Vacancy Documents.

Manchester VA HR Cardiologist Physician Vacancy Documents.

Manchester VA's Enrollment and Unique Veteran Workload for FYs 2014 through 2017.

Manchester (A) Equipment Management and Board Meeting Minutes.

Manchester VA's Executive Decision Memorandums for:

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- Whole Health Partners
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- Mental Health, Primary Care (PACT), Home Based Primary Care, Same Day access
- Dermatology and Cardiology Access Improvement
- Pain Clinic Support Enhancement

- MyVA Access Improvement Project
- Patient Care

Manchester VA's Fact Finding Documents Related to OR Narcotic Discrepancy.

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Attachment B



Stephen E. Borofsky Andrea Amodeo-Vickery Christopher A. Bandarian

September 6, 2016

Senator Jeanne Shaheen 2 Wall Street, Suite 220 Manchester, NH 03101

Dear Senator Shaheen,

Please be advised that I represent several doctors currently employed at the Manchester VA Clinic in New Hampshire. These doctors have come to me as 'Whistleblowers' and as such, they should be protected under the Federal Whistleblower Protection Law. With that as a caveat, as their representative and advocate, I herein summarize serious and tragic issues currently extant at not just the Manchester facility, but the Boston, Massachusetts, VA Hospital as well. These doctors came to me after numerous attempts to effect remedial action by the VISN, as well as the administration in Manchester, have fallen on deaf ears. Veterans are dying and becoming paralyzed because of the failures that these doctors have tried, in vain, to remedy.

As you are aware, there are numerous issues interfering with the proper care of Veterans who are patients of the VA Center in Manchester, New Hampshire. Each of these issues is serious on its own, but the real issue is the Administration's unwillingness or inability to correct systemic problems. The Center is "governed" by a Quadrad.

The leadership style adopted by the Quadrad is both insular and not focused on patient care. There are no treating clinicians represented on the Quadrad, and the four members ignore the views of the physicians, even those who have worked at the Center for many years. The VA Center is run solely by an Administration whose main goal is to put on a good face for the various entities who review their facility. The members of this foursome have a vested interest in covering up issues that would shine a negative light on the actual serious lapses in patient care resulting from the above behavior.

The Quadrad measures problems in the VA Center with a yardstick of how they can provide cover for themselves. The results of this behavior have been actions or better yet, inactions, which have endangered patients and have ruined many lives. What follows is a litany of the many issues that have caused substandard treatment of our Veterans. The recent example in the medical malpractice action brought in US District Court in Concord, New Hampshire, where a judge rendered a verdict in excess of \$21 million in 2015, illustrates just how poorly this facility operates. The doctors named in that lawsuit were unfairly blamed by



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the judge for actions that were not of their making. I can certainly flesh out the specifics of what was wrong with the conclusion of the presiding Justice, if need be.

The most troublesome example of the disconnect between the bureaucrats and the clinicians is the situation involving Myelopathy, a condition that became preventable twenty (20) years ago. However, despite this, there is a list of approximately seventy (70) Manchester Veterans who were patients at the Center who have suffered quadriplegia or quadra paresis, through clinical neglect as well as the lack of effective neurosurgical intervention. These conditions, as indicated above, were all but eradicated twenty (20) years ago, when patients were given the proper neuro-surgical intervention. This shocking number will in fact grow at the current time because of the Administrative decisions that have recently been enacted by the Quadrad at the Manchester VA.

The facility in Manchester, New Hampshire does not have a neurosurgeon on staff and so patients must be referred to the Boston VA for stenosis of the cervical spine. The Boston VA was not treating these patients appropriately and so the former Chief of Staff of the Manchester VA, Dr. Andrew Breuder, agreed to fund private "fee care" in the community for these Veterans. Dr. W. E. Kois, a pain specialist, who became employed at the Manchester VA in 2012, is the physician who discovered these seventy (70) cases of paralysis. For more than three years under Dr. Kois and Dr. Breuder, these Veterans were sent to New England Baptist Hospital in Boston to be treated by a reknowned neurosurgeon. This neurosurgeon was shocked at the condition that he found Veterans to be in. His letter, attached herein, illustrates his opinion on the substandard care provided to spinal stenosis Veterans at these facilities. (See Attachment "A" attached hereto).

When these Veterans were seen at the Boston and West Haven VA's they were referred to physical therapy instead of to a neurosurgeon. In some instances these Veterans were seen by a Chiropractic Resident instead of a Neurosurgeon, which is beyond the pale. One such patient drove his own vehicle to the Manchester VA and was able to walk into the hospital. He was subsequently transferred to the Boston VA, at the conclusion of his surgery this patient was rendered severely quadriparetic and was forced to use a motorized wheelchair. He was limited in the use of his right hand to work the controls on his wheelchair. Sadly, he has expired from complications. As stated above, this result would never occur in the private treatment setting. Why is it acceptable for our Veterans to be subjected to such low quality treatment?

One of the doctors who met with you is the Chief of Medicine, Dr. Stewart Levenson, and is directly involved in securing treatment of these Veterans, but, under the current Manchester Administration and the new Chief of Staff, Dr. Schlosser, he has been thwarted. He has been told that there is no money in the budget to fund "fee care" in the community and that Veterans must be referred to Veterans Choice. As you know, this is a new program which has numerous problems, not the least of which is the refusal of many community based doctors to accept this plan. In addition, the HealthNet telephones are answered by unqualified persons with no medical training. This has resulted in many Veterans being referred to inappropriate specialists. In addition, the use of Veterans Choice cuts off the

Veteran from his actual treating physicians at the Manchester VA and they are, therefore, unable to follow up on their patients to assure that they are receiving the appropriate care.

Tragically, there are few if any participating neurosurgeons in this program that will see Veterans on a timely basis. And when they are seen there are significant problems with follow up and carry through. Unfortunately many providers have had difficulty getting their fees paid under this program and refuse to see Veterans until this situation is resolved.

Although some providers have agreed to come back into the system, their stay is tenuous and wholly dependent on the payment status. This has left many patients at the Manchester VA languishing in pain and without care. The previously cited neurosurgeon in Boston, who is part of the neurosurgeon practice at New England Baptist, as well as a professor at Harvard Medical School, has agreed to see these patients on a priority basis, but the Manchester Quadrad refuses to authorize this.

The decisions about patient care at the Manchester VA are made by Administrators without input from the treating physicians or the Chief of Medicine or other Specialists. This is not a situation that exists in the private sector. The corporate structure of the Manchester VA is an inverted pyramid. The Chief of Medicine in Manchester has attempted on numerous occasions to educate Dr. Mayo Smith on these serious issues and has asked for his assistance, all to no avail.

In addition to the Administrations' refusal to consider the doctor's input on treatment, the equipment at the Manchester VA is substandard and is known to be so by the Quadrad. Although the cost of a new nuclear medicine scanner had been expensed well over a year ago, the build out for the new scanner has been delayed to an unknown time in the future. The old scanner is so out of date that it is off line as much as 50% of the time and it is so old that parts are no longer being manufactured for it. Again, this impacts directly on the care available to our Veterans.

This past winter there was an instance where dirty surgical instruments were reused without sterilization. The instruments were placed in bags to be autoclaved, but instead were placed on the supply table. OR techs then picked up the bags and brought them for reuse to another OR. Each bag has not one, but two indicators, to demonstrate sterility, yet no one picked up on this error. When Administration was informed of this serious lapse, their only concern was damage control and did nothing to investigate how and why this had occurred or take any steps to assure it didn't happen again. In addition, many instruments are used beyond their useful life. The Surgery Chief discovered that the bladder curettes were so dull that they would not cut out tumors in the bladder. When he asked for replacements he was told by Administration that this would have to wait to be purchased until next year when a new budget cycle started! The building is so old that flies come into the OR through gaps in the bricks and the surgeons have had to cancel surgeries frequently because of this unsanitary issue. The director hired the lowest bidder to eradicate the flies but the company has been totally ineffective in solving this situation.

Another example of the low regard in which physicians are held at the Manchester VA facility has to do with the safety and security of its doctors. There is no screening apparatus, security guard or locked doors at the entranceway or in the hallways, which would prevent patients from walking into a doctor's office without notice. This became an issue subsequent to 2012 when Dr. Kois became the only Specialist in Pain Management at the Center. Prior to his employment at the Manchester VA, Dr. Kois was in private practice for 25 years. He was shocked to discover the rampant use of opioids in the treatment of our Veterans in the Manchester facility. Sadly, it had been the prior Administrations policy to start pain patients on opioids because they were cheap to buy at the VA Medical Center when compared to definitive surgical treatment. At one point, Dr. Kois tried to prescribe topical non-steroid gels or oral Cymbalta, but was denied and told to use opioids first, because they were cheaper. Fortunately he refused to do this and has been successfully weaning Veterans off said opioids. However this has come with a personal cost to Dr. Kois.

In the past six months several unhappy Veterans, not the majority of pain Veterans, but a small group, who are at high risk for overuse or diversion of the drugs, threatened the life of Dr. Kois when he cut them off. They did this in writing as well as verbally and specifically mentioned using guns and aluminum baseball bats to kill him. This was reported to the Security personnel at the VA and a meeting was held by the Quadrad to address this issue and a decision was made to install a secure door for his office. The security door has just been installed. This event occurred more than five months ago. Meanwhile, when a threat was made against some Administrators, a security door was installed within a week.

The treating physicians and clinicians at the Manchester VA are woefully understaffed. They lack Physician's Assistants, nurses and secretarial help. Oftentimes nurses must assist four or more physicians. The doctors must type their own reports and they must wait for more than a week for their dictated chart notes to be transcribed. Unfortunately this lag time has resulted in numerous instances where the lack of continuity of care has negatively impacted the patient. Again, complaints about these issues fall on deaf ears.

While hiring a needed clinician is woefully difficult, if not impossible, adding new layers of ineffectual bureaucrats happen routinely. In the past, new hires have been made for data safety officers, patient safety officers, compliance officers, research compliance officers, privacy officers and most recently, an attorney was hired for Risk Management.

At the Manchester VA, the Quadrad has a complete distrust of the clinician to the point of total exclusion from decision-making processes that directly involve patient care. A prime example of this is in the decision made two years ago by Administration to purchase a \$1.4 million dollar cardiology camera without consultation with the Cardiologists. When said camera arrived at the Manchester VA facility the Administration discovered that it did not fit into the space that the old camera was occupying. To this date this \$1.4 million dollar camera remains in a warehouse waiting for a larger room to be built in Cardiology to house it. Meanwhile the Manchester VA is left with an old camera that only functions half the time and as a result, once again, the Veterans suffer.

An easy illustration of these priorities is demonstrated by a look at the employee parking lot. A former chief of surgery characterized that out of the 800 vehicles parked in that lot, approximately 80 belong to clinicians who provide direct patient care. As I stated to you during our meeting with the doctors currently employed at the Manchester VA, these doctors are greatly concerned about the substandard care that the VA in Manchester provides to our Veterans, and they have failed in all attempts to have their voices heard or to find a person above them who will take corrective action. Each of them became VA physicians because of their deep commitment to the care of our Veterans and each are totally frustrated with their ability to provide care. The Administration in Manchester has failed and continues to fail to provide these physicians with the necessary resources to do their jobs.

These doctors have asked me to assist them in being heard by Dr. Shulkin. If needed, the Chief of Medicine as well as the Pain Management Specialist and a Cardiologist are happy to come to Washington, DC for a personal meeting with Dr. Shulkin.

Thank you for your attention to this matter and the doctors truly appreciate your time and input and concern about these important issues. I will be happy to provide any other documentation which you feel is needed to move this forward.

Sincerely

Andrea Amodeo-Vickery aamodeovickery@aol.com

(603) 625-6441

AAV/tmb

cc: Dr. William Kois

Attachment"A"

From: Ohaegbulam, Chima O., MD (Neurological Surgery) < cohaegbu@nebh.org>

Date: Tuesday, May 6, 2014 Subject: Cervical Myelopathy

To: William Kols <wekois@amail.com>

Ed

Thank you for the recent referrals, it is sad to see the large number of significantly disabled patients that have come my with conditions that could have been treated more successfully earlier in their clinical course.

As you know, and as we have frequently discussed, the diagnosis of cervical myelopathy is a clinical one rather than radiographic. Most clinicians (certainly most surgeons) would agree that there is enough variability to presentation, and enough patients with progressive deficits in spite of seemingly unconcerning MRI reports, that the trigger for surgical intervention is usually derived the history and exam, and not primarily the MRI report. If I screened patients based on a specific measurement of the spinal canal, I would be doing several patients a disservice, putting them at risk of permanent deficits.

It is said to see 21st century patients in the US progressing to wheelchair dependence for cervical myelopathy, when this could be treated. This has been a treatable cause of gait disorder for several decades. Only in 3rd world countries is it common to see patients end up as disabled from myelopathy as the ones who have been showing up after referral from you. I see such patients on visits to Nigeria, and really only see them in Boston when they show up from the VA!

I would be willing to help in any way that I can to facilitate care for patients as early as possible in their clinical course, which would greatly enhance their outcome and decrease disability, if such treatment is not available/possible in the VA system. The cost of caring for these individuals when they decline to the extent that I have recently seen is far greater than what the costs to the system would be with early treatment- and more importantly, the individual would be given a much better quality of life than they are currently ending up with.

Best wishes,

Chima

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