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**Office of Healthcare Inspections**

**Report No. 15-01415-382**

## **Healthcare Inspection**

# **Alleged Transcatheter Aortic Valve Replacement Program Issues VA Palo Alto Health Care System Palo Alto, California**

**September 28, 2017**

**Washington, DC 20420**

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## Executive Summary

The VA Office of Inspector General conducted a healthcare inspection in 2015 to assess allegations of delays in performing transcatheter aortic valve replacement (TAVR) procedures and cardiac patients not receiving TAVR procedures at the VA Palo Alto Health Care System (system), Palo Alto, CA, due to Veterans Health Administration (VHA) national policy requirements. Specifically, we received two separate complaints:

### Complaint #1

- Patient A had a delay in obtaining a TAVR procedure at the system.
- VHA would not approve Patient A's non-VA TAVR procedure on two occasions.

### Complaint #2

- VHA's requirement that TAVR procedures occur in a hybrid operating room (HOR)<sup>1</sup> is too stringent and not the community standard.
- Patients were "affected" by VHA's national requirement for the TAVR procedure to be performed in an HOR.
- The system requested a waiver of the national VHA requirement to perform TAVR procedures in an HOR and the request was denied.
- Timeliness issues associated with construction of the HOR prevented the system from implementing the TAVR Program.
- To avoid delays in patient care, the system enrolled patients in research studies so they could undergo the TAVR procedure at the system.

We did not substantiate that Patient A experienced a delay in obtaining the TAVR procedure. Medical factors unique to the Patient A impacted his ability to successfully undergo the procedure; a determination made by two separate VHA systems. Providers must evaluate a patient's condition and risk when the TAVR procedure is considered and make recommendations accordingly. Once Patient A was recommended for a TAVR, the procedure was completed 48 days later, a timeframe consistent with his medical needs.

We did not substantiate that VHA would not approve Patient A's TAVR procedure to be performed at a non-VA facility. We confirmed that two Non-VA Care Coordination requests for the patient's TAVR procedure had been placed. Both were approved within the required timeframe.

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<sup>1</sup> An HOR must conform to the standards of an operating room as well as those of a cardiac catheterization laboratory. The HOR design incorporates the equipment that is typically required to perform procedures in a cardiac catheterization laboratory with the sterility of an operating room, as well as equipment necessary to provide anesthesia and surgery capabilities.

We substantiated that VHA requires TAVR procedures be performed in an HOR. VHA established this requirement after reviewing best practices and obtaining expert consensus. While we found no regulatory requirements for performing TAVR procedures in an HOR at non-VA facilities, we found that non-VA facilities typically performed TAVR procedures in HORs.

We substantiated that patients were affected by VHA's national requirement that TAVR procedures be performed in an HOR as the system did not have an HOR and was unable to perform non-research TAVR procedures onsite. However, we found that processes were in place to refer patients for care elsewhere and that various other factors influenced the timing of TAVR procedures in the patients' electronic health records we reviewed.

We substantiated that the system requested that the VA National Surgical Office grant a waiver of the national VHA requirement to perform TAVR procedures in an HOR (and to perform the procedure in the cardiac catheterization laboratory) pending completion of an HOR at the system; and that the request was denied. In the absence of a waiver, the system utilized the following options to provide non-research TAVR procedures: system staff could perform the TAVR procedure in the HOR at the San Francisco VA Health Care System; physicians could request a case-by-case exception for non-research TAVR; or the system could use the Non-VA Care Coordination process.

We substantiated that project 1, construction on one of the system's operating rooms, was not completed on the projected date, and the delay affected the implementation of the TAVR Program. We found that patients obtained the procedure through other VA services during that time. Delays in completing project 1 occurred, in part, because project 1 was not originally designed with the intent to meet the HOR requirement for TAVR Program approval. Upon completion of the project, the VHA Principal Healthcare Architect determined the renovation did not meet VHA HOR size requirements. As a result, the system conducted a risk assessment through simulations, mitigated identified issues, and requested a re-evaluation. On December 3, 2015, the request was approved, the renovation passed the re-evaluation thereby meeting the needs of an HOR, and the system implemented the TAVR Program.

We substantiated that system providers enrolled patients in research studies involving the TAVR procedure. We were unable to determine if by doing so, they avoided delays in care that the patient may otherwise have encountered.

We identified lapses in the documentation necessary to maintain accurate clinical records including communication and continuity of care. Nine of 11 electronic health records of the patients we reviewed lacked documentation that made it difficult to determine the course and timing of care between evaluation and outcome.

We recommended that the System Director ensure that providers document clinical judgement, coordination of care, communication with the patient or referring facility, and an accurate plan of care from initial assessment to procedure for TAVR patients.

## Comments

The Veterans Integrated Service Network Director and System Director concurred with the report and provided an acceptable action plan. (See Appendixes B and C, pages 20–22, for the full text of the Directors' comments.) We will follow up on the action plan until completed.



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## Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection in 2015 to assess allegations of delays in performing transcatheter aortic valve replacement (TAVR) procedures and cardiac patients not receiving TAVR procedures at the VA Palo Alto Health Care System (system), Palo Alto, CA due to Veterans Health Administration (VHA) national policy requirements. The purpose of the review was to determine the merits of the allegations.

## Background

The system is part of Veteran Integrated Service Network (VISN) 21 and consists of three inpatient facilities located in Menlo Park, Livermore, and Palo Alto, CA, and seven community based outpatient clinics. The system operates over 800 beds, including three nursing homes and a 100-bed domiciliary.

The system's medical center in Palo Alto provides a range of patient care services including medicine, surgery, mental health, rehabilitation, neurology, oncology, dentistry, and geriatrics and extended care. The system has an academic affiliation with Stanford University Medical School.

**Aortic Stenosis.** Aortic stenosis (AS) is a condition in which the aortic valve<sup>2</sup> does not open fully due to narrowing of the aortic valve, which decreases blood flow from the heart to the body.<sup>3</sup> Many elderly patients have comorbid<sup>4</sup> diseases including diabetes, hypertension, and high cholesterol, which may further predispose them to developing AS. Symptoms of the AS include chest pain, fatigue, shortness of breath, and fainting.<sup>5</sup>

**AS Disease Treatments.** The three most common options available for treating AS are medications, balloon valvuloplasty, or surgical intervention. The first option, and least invasive treatment, is the use of medications to reduce symptoms such as fluid build-up or heart rhythm changes. The second option, balloon valvuloplasty, is a minimally invasive procedure that involves the opening of the aortic valve with a catheter.<sup>6</sup> The third option, surgical intervention, involves a more invasive operation that allows

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<sup>2</sup> The aortic valve separates the left ventricle from the aorta. During the contraction phase of the heart cycle, the aortic valve opens and allows oxygenated blood to flow from the ventricle to the aorta. During the filling phase of the heart cycle, the valve closes, preventing regurgitation of blood flow backwards from the aorta into the heart.

<sup>3</sup> Diseases and Conditions Aortic Valve Stenosis. Mayo Clinic Website. <http://www.mayoclinic.org/diseases-conditions/aortic-stenosis/basics/definition/con-20026329> Published April 21, 2015. Accessed May 9, 2016.

<sup>4</sup> Comorbid conditions are medical conditions that exist simultaneously with and usually independently of another medical condition.

<sup>5</sup> Shah, P., Severe Aortic Stenosis Should Not Be Operated on Before Symptoms Onset, *Circulation*. 2012; 126:118-125, doi.org/10.1161/CIRCULATION.AHA.111.079368. Accessed March 13, 2017.

<sup>6</sup> A catheter with a balloon tip is inserted into the aortic valve; the balloon is inflated stretching open the narrowed valve. This improves blood flow; however, the valve will tend to narrow again over time.

replacement of the failing aortic valve with an artificial one.<sup>7</sup> If not addressed by a valve replacement procedure, more than 50 percent of patients with AS die within 2 years of initial symptoms.<sup>8</sup>

Surgical aortic valve replacement (SAVR) is generally performed during open-heart surgery where the damaged valve is removed and replaced with an artificial one. SAVR decreases symptoms and increases length of survival in patients who are not at high risk for morbidity or mortality around the time of surgery.<sup>9</sup> The median survival rate after SAVR is 6 to 10 years, and is related to the age of the patient.<sup>10</sup> Some patients are not candidates for SAVR because they are at high surgical risk or have comorbid conditions. For these patients, a newer, less common procedure, TAVR is an available option.

**TAVR Procedure.** In 2011, the U.S. Food and Drug Administration (FDA) approved the use of TAVR as a minimally invasive procedure for AS patients who were not SAVR candidates.<sup>11</sup> During this procedure, a catheter is used to wedge a new valve into the aortic valve's place without removing the damaged one. Physicians may use different approaches to complete the procedure. They may access the heart through an artery in the groin (transfemoral approach), through a small incision via the heart muscle (transapical approach), in the upper chest through the aorta (transaortic approach), or through the carotid artery (transcarotid approach).<sup>12</sup> Once the approach is determined, the physician makes an incision and inserts a balloon-tipped catheter. Physicians use advanced imaging to visualize the blood vessels allowing the catheter to be passed to the heart. After the catheter is in the right location, the balloon is inflated to open the old calcified valve. The balloon is deflated and that catheter is withdrawn. A second catheter with a valve apparatus over the deflated balloon is inserted. When that catheter is in place, the balloon is inflated, which wedges the new valve into place. Once the valve is secure, the physician deflates the balloon, withdraws the catheter, and closes the access point.<sup>13</sup> The median survival rate after TAVR is 3.5 years; most

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<sup>7</sup>Diseases and Conditions Aortic Valve Stenosis. Mayo Clinic Website. <http://www.mayoclinic.org/diseases-conditions/aortic-stenosis/basics/treatment/con-20026329>, published April 21, 2015. Accessed March 15, 2017.

<sup>8</sup> Mikkar R, Fontan G, Hasan J, et al. Transcatheter Aortic Valve Replacement for Inoperable Severe Aortic Stenosis *The New England Journal of Medicine* 2012, 366:1686-1695. DOI: 10.1056/NEJMoa1200384. Accessed May 31, 2016.

<sup>9</sup> Bates, R. Treatment Options in Severe Aortic Stenosis, *Circulation*.2011;124:355-359 doi: 10.1161/CIRCULATIONAHA.110.974204. Accessed May 20, 2016.

<sup>10</sup> Brennan M, Edwards F, Zhao Y, et al. Long-term Survival after Aortic Valve Replacement Among High Risk Elderly Patients in the United States, *Circulation*, 2012; 126: 1621-1629 Published online before print August 20, 2012, doi: 10.1161/CIRCULATIONAHA.112.091371. Accessed May 20, 2016.

<sup>11</sup> Ibid.

<sup>12</sup> Vinod H. Thourani, Rebecca L. Gunter, Soumya Neravetla, et al. Use of Transaortic, Transapical, and Transcarotid Transcatheter Aortic Valve Replacement in Inoperable Patients. *The Annals Of Thoracic Surgery*. 2012; 96(4): 1349-1357. DOI: <http://dx.doi.org/10.1016/j.athoracsur.2013.05.068>. Accessed May 23, 2016.

<sup>13</sup> Edward Lifesciences Corporation.(2017). About the TAVR Procedure. <https://newheartvalve.com/hcp/tavr-overview>. Accessed February 24, 2017.



patients die of non-cardiac comorbidities such as chronic pulmonary obstructive disease, chronic kidney disease, and frailty.<sup>14</sup>

**Hybrid Operating Room.** A hybrid operating room (HOR) meets all the standards of an operating room as well as those of a cardiac catheterization laboratory (cardiac cath lab). The design incorporates the equipment that is typically required to perform procedures in a cardiac cath lab with the sterility of an operating room, as well as equipment necessary to provide anesthesia and surgery capabilities.<sup>15</sup> The HOR is equipped with advanced medical imaging devices such as fixed C-arms,<sup>16</sup> computerized tomography (CT) scanners, or magnetic resonance imaging (MRI) scanners. The design of an HOR allows for conversion to an open-heart surgery if complications arise.

The VA Office of Construction Facilities Management established specific criteria for the design of HORs in VHA facilities. Some of the specifications include adequate space (900 net square feet); appropriate ceiling support and height to accommodate the advanced medical imaging systems; positive pressure<sup>17</sup> and laminar airflow<sup>18</sup> for high level sterility; stainless steel heating, ventilation, and air conditioning ductwork; lead-lined walls; and a separate control room.

**VHA TAVR Program.** In November 2012, a panel of subject matter experts comprised of physicians from multiple VHA facilities with cardiac programs, the Chair of the VA Cardiothoracic Surgical Advisory Board, the VA National Program Director (NPD) for Cardiology, and the Acting VA National Director of Surgery developed guidelines that outlined criteria for VHA TAVR Program approval. The guidelines included U.S. FDA indications and Centers for Medicare and Medicaid Services National Coverage Determinations for TAVR. An additional component VHA required was an HOR within the operating suite<sup>19</sup> or within the interventional cardiology suite.

The VHA National Surgery Office (NSO), along with the NPD for Cardiology, provides oversight and guidance to facilities planning to implement a TAVR Program. In early June 2013, the NPD for Cardiology advised VHA and VISN leaders that applications

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<sup>14</sup> Rodes-Cabau J, Webb JG, Cheung A, et al. Long-term Outcomes after Transcatheter Aortic Valve Implantation: Insights on Prognostic Factors and Valve Durability from the Canadian Multicenter Experience. *J AM Coll Cardiol*. 2012 Nov 6, 60(19): 1864-75. Doi: 10.1016/j.jacc.2012.08.960. Epub 2012 Oct 10. Accessed April 22, 2016.

<sup>15</sup> Bashore T, Balter S, Barac A, et al. 2012 American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Expert Consensus Document on Cardiac Catheterization Laboratory Standards Update A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents. *J Am Coll Cardiol*. 2012; 59(24):2221-2305.doi:10.1016/j.jacc.2012.02.010. Accessed April 26, 2016.

<sup>16</sup> A C-arm is a type of radiologic equipment named for its c shaped arc surrounding the table. C-arms have x-ray capabilities although they are primarily used for real-time imaging during surgical, orthopedic, critical care, and emergency care procedures.

<sup>17</sup> Positive pressure is pressure greater than atmospheric pressure.

<sup>18</sup> Laminar airflow helps to minimize contamination by mobilizing uniform and large volumes of clean air. When air flows in a single direction at a specific speed, convection currents are eliminated and re-entrance of particles to the operative field are stopped.

<sup>19</sup> A suite is a group of rooms used for one purpose. A cardiac cath lab may be within an interventional cardiology suite.

submitted for a TAVR Program must follow VHA Directive 2009-001,<sup>20</sup> new program approval process, and that the submission would undergo a joint evaluation by the VHA NPD for Cardiology and NSO that included an evaluation of the HOR design.

**Non-VA Care Coordination Consultation Requests.** Non-VA Care Coordination (NVCC), formerly known as fee basis care, is medical care provided outside of VA to eligible veterans and paid for by VA when VA facilities and services are not reasonably available.<sup>21</sup> Requesting providers can submit an NVCC consult, which NVCC staff review to determine the veteran's administrative eligibility for care.<sup>22</sup> A clinician reviews the consult for clinical appropriateness, and if approved, NVCC staff generate an authorization for non-VA care. NVCC staff then send the consult, authorization, and supporting documents to a community-based provider or medical practice for completion of the consultation and/or evaluation. NVCC case managers and schedulers coordinate the scheduling and follow-up process.

Once a patient completes the NVCC appointment, the community-based provider or medical practice is to send the results of the consultation and further recommendations back to the requesting facility so the documentation can be scanned into the patient's electronic health record (EHR). Requesting providers can then determine the patient's needs for continued treatment.

**Clinical Research.** Clinical research is the study of health and illness in people. Participation in research may provide patients access to new treatments.

Eligibility criteria are the standards used for inclusion/exclusion that precisely define what makes an individual appropriate or not appropriate for participation in a study. Inclusion criteria are those factors that must apply to an individual in order for him or her to participate, while exclusion criteria are those factors that, if they apply to an individual, would prevent him or her from participating. When an Institutional Review Board<sup>23</sup> reviews a research study, the eligibility criteria are carefully scrutinized in an attempt to identify factors that might put an individual at too great a risk by his/her participation in the study. The Institutional Review Board is required to make certain determinations during research study review, including that "risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk."<sup>24</sup>

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<sup>20</sup> VHA Directive, 2009-001, *Restructuring of VHA Clinical Programs*, January 5, 2009. This Directive expired January 31, 2014 and has not yet been updated.

<sup>21</sup> Introduction to Non-VA Care Consult/Referral Review Process. <http://nonvacare.hac.med.va.gov/nvcc/sop-and-guides.asp>. Accessed September 6, 2016.

<sup>22</sup> Review for administrative eligibility includes confirming the patient is eligible for VA care and that the requested care or service is not reasonably available—in terms of time or distance—within the facility or via an interfacility (between facilities) consult to another VHA facility.

<sup>23</sup> An Institution Review Board is a group of people who review and provide oversight of biomedical research involving human subjects. The group's role is to ensure steps are taken to protect the rights and welfare of people participating in research studies.

<sup>24</sup> 45 CFR 46.111(a)(1).

Individuals are considered enrolled in research when an investigator conducting research enters the subject into the study and uses the patient's data through intervention or interaction with individual or identifiable private information for research purposes.<sup>25</sup>

**System TAVR History.** In 2011, system physicians began performing TAVR procedures in the cardiac cath lab as part of various research studies. In June 2013, VHA established guidelines and requirements for TAVR Programs (discussed above in VHA TAVR Program section). System leadership reviewed the guidance and found that, other than the HOR requirement, the system had the established infrastructure to support a TAVR Program. System leadership conferred with VA Central Office staff regarding the need to formally apply for TAVR Program approval given that TAVR procedures had been performed under research for 18 months. VHA leadership responsible for approving TAVR Programs determined that the system must apply for TAVR Program approval to conduct non-research<sup>26</sup> TAVR procedures but could continue performing research TAVR procedures outside of an HOR.<sup>27</sup> The system applied for and received confirmation from VHA leadership that performing non-research TAVR procedures would be allowed with the following condition: "Full completion of the hybrid OR". The system was therefore unable to perform TAVR outside of research studies while awaiting the construction of an HOR.

From April 2011 to August 2014, system physicians participated in research studies that included performing TAVR procedures for all groups of patients, including high- or extreme-risk patients.<sup>28</sup> Between August 2014 and January 2015, research studies for high- and extreme-risk populations were not active. During that timeframe, only patients deemed intermediate-risk and those excluded from the extreme-risk population met criteria for a research TAVR. As the system did not yet have an HOR, non-research TAVR procedures, regardless of risk, could not be performed. In early January 2015, a new research study was activated that again allowed enrollment of high- and extreme-risk TAVR patients. Between April 2011 and January 2015, the system had five unique research studies approved. See Appendix A for details, which include the initiation and termination dates of each study.

**Allegations.** On October 29, 2014, the OIG Hotline Division received a complaint (complaint #1) alleging a delay in a patient (Patient A) obtaining a TAVR procedure and that VHA would not approve a non-VA TAVR procedure on two occasions. On April 22, 2015, a second complaint (complaint #2) was received that alleged cardiac

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<sup>25</sup> System Memorandum No. 00-15-32, *Research Compliance Program*, April 1, 2015.

<sup>26</sup> For the purposes of this report, non-research TAVR procedures refer to procedures in which valves approved by the U.S. FDA are used, and in the VA, must be performed in a HOR. Research TAVR procedures refer to procedures in which valves that are experimental and have not been approved by the U.S. FDA are used and, in the VA, may be performed outside an HOR.

<sup>27</sup> See also, discussion in Issue 7.

<sup>28</sup> The Society of Thoracic Surgery Predicted Risk of Mortality (STS-PROM) is the most commonly used risk model, which calculates the risk of operative mortality (death) and morbidity (incidence of ill health) after adult cardiac surgery. The model is based on demographic, clinical variable, and professional judgement. High-risk patients have scores in the upper decile for mortality or have a 30 day mortality greater than 15 percent.

patients at the system could not receive TAVR procedures due to a VHA national requirement for the TAVR procedure to be performed in an HOR. Complaint #2 also alleged the following:

- VHA's requirement that TAVR procedures occur in an HOR is too stringent and not the community standard.
- Patients were "affected" by the VHA national requirement for TAVR to be performed in an HOR.
- The system requested a waiver of the national VHA requirement to perform the TAVR procedure in an HOR and the request was denied.
- Timeliness issues associated with construction of the HOR prevented the system from implementing the TAVR Program.
- To avoid delays in patient care, the system enrolled patients in research studies so they could undergo TAVR procedures at the system.

## Scope and Methodology

We initiated our review in April 2015 and conducted a site visit June 15–18, 2015. Our general methodology included interviews with:

- Complainants.
- System leadership.
- System staff involved with TAVR procedures.
- System staff involved with TAVR research studies.
- System staff involved with planning and development at the system.
- VA Central Office staff involved with developing VHA's TAVR Program.
- VISN 21 leadership.
- VA Office of Research Oversight staff.

In conjunction with complaint #2, we received the names of 10 patients whom the TAVR Program requirements may have affected. We reviewed each patient's EHR. One of the 10 patients was not evaluated for a TAVR. We excluded this patient from the review. During onsite interviews, we identified two additional patients who may have been affected. We also reviewed the EHRs of 94 patients who had consented to participation in one of the system's TAVR research studies and determined which patients underwent a TAVR via a research study.

We reviewed VHA and system documentation relevant to the issues including VHA directives, memoranda, communications (emails); specific guidelines and requirements for TAVR Program approval; system policies and procedures; construction contracts; and scheduling, access, and performance data. We also reviewed research and patient enrollment studies, scientific research articles, professional society guidelines, and

peer-reviewed journals. We consulted with VA Office of Research Oversight and National Center for Ethics in Health Care.

VHA Directive, 2009-001, *Restructuring of VHA Clinical Programs*, January 5, 2009 cited in this report expired January 31, 2014. We considered the policy to be in effect, as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),<sup>29</sup> the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."<sup>30</sup> The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."<sup>31</sup>

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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

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<sup>29</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

<sup>30</sup> VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document*, June 29, 2016.

<sup>31</sup> *Ibid.*

## Inspection Results

### **Allegation 1: Delay in A Patient's TAVR Procedure.**

We did not substantiate that a patient (Patient A) experienced a delay in obtaining the TAVR procedure. No timeliness standards have been established for TAVR. We found that during an approximately 4-year timeframe, Patient A had five TAVR evaluations and, because of medical factors unique to him, on four occasions he was not deemed a candidate for the procedure. Once Patient A was recommended for TAVR, the procedure was completed 48 days later, a timeframe consistent with his medical needs.

The TAVR procedure is generally reserved for patients older than 70 years of age with other medical problems who are deemed too high-risk for open heart surgery. A physician decides if the patient is a good candidate for the procedure. Some factors that could prevent a patient from being a candidate for TAVR include:

- Blood vessels are not the right size.
- The heart is too weak.
- A severe illness or infection is present.

Patient A, who was in his 70s with a history of chronic obstructive pulmonary disease<sup>32</sup> and AS, had his first assessment with the system cardiothoracic surgery team in mid-2010. Additional tests were recommended and a second assessment took place 3 months later.<sup>33</sup> During the second assessment, a provider informed Patient A that he was “not a candidate for aortic valve replacement based on his echocardiogram<sup>34</sup> and his severe lung disease.”

Between late 2011 and mid-2014, Patient A had three TAVR assessments at the system. On one occasion, Patient A was initially deemed a potential candidate; however, a provider found him to be unsuitable after additional testing. On a second assessment, his aortic valve was not the right size;<sup>35</sup> and on a third assessment, the surgical team was concerned that he would “not tolerate” the procedure.

In late 2014, while an inpatient at the San Francisco VA Health Care System, Patient A had another TAVR assessment. By this time, 4 years and 2 months had passed since Patient A's first TAVR assessment. The inpatient cardiologist who evaluated Patient A documented that “after discussions with Patient A and the TAVR team it has been

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<sup>32</sup> Chronic obstructive pulmonary disease, also known as COPD is a disease that makes it hard to breath. Progressive means it gets worse over time.

<sup>33</sup> This appointment was the first time Patient A was evaluated for TAVR.

<sup>34</sup> An echocardiogram is a special test to find out how well the heart is functioning. An image of the heart is taken using high frequency sound waves and helps the doctor to determine if there are any problems with the heart.

<sup>35</sup> The aorta must be 0.8 mm or less for the candidate to be eligible for the TAVR procedure. This is measured preoperatively. (0.8 mm equals 0.031 inches or approximately 3/100 of an inch).

decided that he will not be a candidate for TAVR during this admission, but he can continue to follow up with the TAVR clinic as an outpatient.”

In late 2014, following a VA inpatient admission, Patient A was recommended for an “alternate access approach TAVR”<sup>36</sup> at a non-VA facility. His TAVR procedure took place 48 days later, in early 2015.

### **Allegation 2: VHA’s Denial of Non-VA TAVR Procedure.**

We did not substantiate that on two occasions VHA would not approve the TAVR procedure to be performed at a non-VA facility. As described below, providers submitted two NVCC requests for a TAVR procedure for Patient A, and each request was approved.

In mid-2014, Patient A asked his primary care provider for a cardiac surgery consult at a non-VA facility. In approximately 3 weeks, the primary care provider submitted an NVCC request, which was approved the next day. The NVCC request was discontinued 21 days later, after Patient A had a discussion with caregivers and decided to be re-evaluated for TAVR at the system.

The system Chief of Cardiology submitted the second request for an NVCC TAVR procedure in late 2014. Although we could not locate documentation of the final approved NVCC request, we obtained evidence that the system approved payment for the procedure, and Patient A underwent a successful TAVR procedure at a non-VA facility approximately 2 months later.

### **Allegation 3: VHA’s HOR Requirement is Too Stringent.**

We substantiated that VHA requires TAVR procedures be performed in an HOR. We did not substantiate that TAVR procedures outside an HOR is the community standard. We found the majority of TAVR procedures occur within an HOR in non-VA facilities, although no regulatory agency has established this as a requirement.

Complainant #2 expressed concerns that VHA’s requirement for an HOR is more stringent than the non-VA practice of using a cardiac cath lab when performing TAVR. VHA has determined that performing the TAVR procedure in an HOR is in the best interest of patients. The VHA National Director of Surgery and NPD for Cardiology reported to us that the HOR requirement was based on subject matter experts’ review of research literature and clinical practice guidelines. These guidelines state that although the HOR is not a prerequisite for TAVR, it is the ideal setting for the procedure. The HOR design promotes a sterile environment and allows the provider to safely convert minimally invasive procedures to more complex ones including an open heart surgery without having to move a patient to a different location.

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<sup>36</sup> As noted in the Background, depending on the patient’s medical condition, approach to the aortic valve may be through an artery in the leg, through an artery in the neck, or through a space between the ribs.

Although non-VA regulatory agencies do not require that TAVR procedures be completed within an HOR, the literature reports that 85 percent of TAVR procedures completed in non-VA hospitals throughout the United States occurred in HORs. The remaining cases were completed in cardiac cath labs.<sup>37</sup>

VHA's requirement for the TAVR procedure to occur in an HOR was based on evidence-based best practices, expert consensus, and was consistent with published practices.

#### **Allegation 4: Patients Affected by HOR Requirement.**

We substantiated that although patients were affected<sup>38</sup> by VHA's national requirement for the TAVR procedure to be performed in an HOR (the system lacked an HOR and providers were not authorized to perform non-research TAVR procedures onsite), processes were in place to refer non-research patients for care.

Complainant #2 provided the names of nine patients potentially affected by the lack of an HOR at the system.<sup>39</sup> Two additional patients were identified during onsite interviews. Complainant #2 did not specify how patients were affected. To assess the potential impact that a lack of an HOR may have had on these 11 patients, we reviewed their TAVR-related course of care as documented in their EHRs.

Lack of an HOR at the system resulted in varied courses of care. Eight patients were referred via NVCC for TAVR. Of these eight, six had the procedure performed at non-VA facilities and one had an alternative procedure at a non-VA facility. The eighth patient returned to the system and had the TAVR performed under a research study. Of the three patients not referred via NVCC, one was not medically stable to tolerate the procedure and died, one used his own insurance to have the TAVR at a non-VA facility, and one patient's EHR had insufficient documentation to determine if the lack of an HOR affected the course of care.

Factors other than the existence of an HOR at the system influenced the timeline in which the patients we reviewed received the procedure, including each patient's comorbidities, geographic location, frequency of hospitalizations, preferences, and medical decisions made based on clinical presentation.

Our review of the EHRs for 10 of the 11 patients indicated that the lack of an HOR did not result in a negative medical outcome. Documentation in the EHR for the remaining patient was insufficient to make a determination. While the final disposition of

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<sup>37</sup> Shunk K, Zimmel J, Carson B, Speiser B, Tseng E, Development of a Veterans Affairs Hybrid Operating Room for Transcatheter Aortic Valve Replacement in the Cardiac Catheterization Laboratory. *JAMA* 2015;150(3):216-222. Doi:10.1001/jamasurg.2014.1404. Accessed May 23, 2016.

<sup>38</sup> As the complainant did not define this term, we interpreted "affected" to mean: influenced or touched by an external factor.

<sup>39</sup> As noted in the Scope and Methodology section, one of the 10 patients provided to the OIG was not evaluated for a TAVR and was excluded.



10 patients was evident in the EHR, we found deficiencies in documentation that are discussed below in the *Other Issue* section.

**Allegation 5: Denial of Waiver to Perform Non-Research TAVR Outside an HOR.**

We substantiated that the system requested a waiver<sup>40</sup> of the national VHA requirement to perform the TAVR procedure in an HOR and that the waiver request was denied. The system's request was not approved because NSO leaders have made it their practice to deny waivers on this matter.

In March 2013, the system initiated an application for approval of a TAVR Program that would allow providers to perform non-research TAVR procedures at the system. The application process included submission of the "Evaluation Form for Restructuring VA Surgical Program". As part of the process, members of the National Cardiology Office and NSO conducted site visits (April and May 2013, respectively). Later that May, the system received notification via a memo from the National Director of Surgery to the Assistant Deputy Undersecretary for Health for Clinical Operations stating the request for a TAVR Program was approved with the following condition: "Full completion of the hybrid OR..." According to this notification, system providers could continue to offer TAVR procedures to patients enrolled in an appropriate research study during construction of the system's HOR but could not conduct non-research TAVRs at the system.

Ten months after the system received notification of conditional approval of the TAVR Program, the System Director sent a memo to VISN 21 leadership to request approval to perform non-research TAVR procedures in the cardiac cath lab pending completion of the HOR. System leadership referred to this document as the waiver request. The VISN Director forwarded the request to the Assistant Deputy Under Secretary for Health Clinical Operations. The system did not receive a formal, written response to this waiver request; however, during subsequent telephone calls between the VISN Director and the NPD of Cardiology; the VISN Director was notified the request for waiver would not be approved.

In the absence of a waiver, the system used the following options to provide non-research TAVR procedures.

- System staff performed TAVR procedures in the HOR at the San Francisco VA Health Care System.
- Physicians requested a case-by-case exception for performing a non-research TAVR procedure at the system.
- The system referred patients via the NVCC process.

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<sup>40</sup> A waiver is an exemption from some aspect of a federal health care statute that gives a facility the right to deliver care in a manner that varies from published standards. Waiver requests are typically written documents that outline the rationale behind the desired exemption and the alternative means for complying with the federal requirement.

**Allegation 6: Delay in HOR Construction Prevented TAVR Program Implementation.**

We substantiated that the operating room construction project (project 1) identified by Complainant #2 was not completed in the projected timeline and impacted the implementation of the TAVR Program; however, patients were able to obtain TAVR procedures through other mechanisms during the timeframe at issue.

In June 2012, the system was awarded funds for project 1, which entailed the renovation of an operating room endosuite. The intent was to update the existing operating room for vascular surgery procedures, with a projected completion date of July 2013. Project 1 was not originally intended to meet the HOR requirement for TAVR Program approval.

As discussed above, the system requested approval in March 2013, for a TAVR Program that would allow non-research patients to undergo TAVR procedures at the system. As part of the approval process, representatives from NSO and National Cardiology Office each conducted a site visit to analyze the existing cardiac cath lab for repurposing into an HOR (project 2). Plans included upgrading the HVAC system to meet air exchange requirements and adding new equipment. During the NSO site visit, system cardiology staff asked one of the inspecting team members, the VHA Principal Healthcare Architect (architect) to visit project 1 to discuss its use as a potential interim TAVR HOR. After visiting the project 1 construction site, the architect said that once renovations were complete, the room could be used for TAVR procedures, but the plans would need to be formally reviewed before granting final approval. Through interviews and document reviews, we learned that a formal review of project 1 plans was not completed during the March 2013 NSO visit; however, staff mistakenly interpreted the informal conversation with the architect as provisional approval that once project 1 was completed, the renovated OR could be used as an interim TAVR HOR.

In July 2015, the architect formally evaluated the plans for project 1 for use as an interim TAVR HOR. He determined that the project 1 “room is insufficient in size” and could not recommend the use of the space as an interim HOR.

Project 1 renovation was finished in October 2015, 2 years and 3 months after the original projected completion date. Upon completion of the renovation, the system conducted a risk assessment through simulations and mitigated identified issues. The facility requested re-evaluation of project 1 for use as an interim TAVR HOR. On December 3, 2015, after discussion regarding the risk assessment, the NSO and National Cardiology Office approved the request; and the system implemented a TAVR Program that allowed providers to perform non-research related TAVR procedures.

As stated previously, the system received approval in late May 2013, for the system TAVR Program, conditional upon “full completion of the hybrid OR...” (project 2). One week later, the system received updated HOR requirements from the VA Office of Construction and Facilities Management. After reviewing the updated requirements, system managers determined that project 2 would not meet these requirements.

System leadership, in conjunction with the system Planning and Development staff, redeveloped project 2 to include an HOR that would meet VHA requirements (project 2a). Project 2a's initial projected completion date was May 2016; after renovations started, the contractor revised the completion date to December 2016.

OIG Update: As of July 27, 2017, project 2a was not yet completed.

### **Allegation 7: Patients Allegedly Enrolled in Research to Undergo TAVR at the System and Avoid Delays in Care.**

We substantiated that the system enrolled patients in research studies for the TAVR procedure. However, we were unable to determine if by doing so, they avoided delays in care that the patient may otherwise have encountered.

Between October 1, 2012 and May 14, 2015, 94 unique patients consented to having an evaluation to determine their eligibility for the TAVR procedure under a research study. Of those who consented, 45 (48 percent) patients met study criteria and had a TAVR procedure performed at the system under one of the five active research studies. Patients who did not meet the research criteria but who were considered by system providers as possible candidates for the TAVR procedure were referred to other VA or NVCC facilities. A few patients underwent a TAVR procedure at a non-VA facility using alternative funding. Other patients were determined to be poor TAVR candidates, in need of a different cardiac surgery, or not medically stable for the procedure. With the exception of two patients, the outcome of the research team's evaluation was evident in the EHRs we reviewed.

Referring patients for evaluation of enrollment into a research study during a time when the system was able to perform only research TAVR procedures provided an avenue for patients to receive care from the system's cardiothoracic surgery team and reduced the need for a non-VA referral for care. The disadvantage to this approach for patients, who would benefit from having a TAVR but did not qualify for a research study, was that an additional step in their course of care, a referral elsewhere, may have been required. We could not determine if those patients who had the TAVR procedure performed at the system as part of a research study received more or less timely care than if they had been referred outside of the system.

During the course of this review, staff we interviewed expressed concerns regarding whether the provision of research TAVR procedures in an environment different from that required for non-research TAVR procedures was appropriate. We referred this issue to the National Center for Ethics in Health Care and the VA Office of Research Oversight for review and action. Subject matter experts in both offices studied the issue and recommended actions that the system agreed to and completed in May 2016.

We could not determine which patients would have been referred to research had the system had an HOR and the TAVR Program was approved to perform non-research TAVR procedures. Given the situation at the time, the system took reasonable steps to arrange care for those patients referred for TAVR evaluation.

### **Other Issue: Communication and Continuity of Care.**

We identified lapses in required EHR documentation of the patients discussed in Allegation 4. Specifically, the lapses related to maintaining a complete and accurate clinical record including communication and continuity of care.

EHRs are the primary means of communication for the purpose of coordinating care between healthcare professionals. This is accomplished through chronologically documenting the complete care of a patient. Guidance for documentation is found in VHA Directive 1907.01, *Health Information Management and Health Records*<sup>41</sup>, requires “health records be timely, relevant, necessary, complete, and authenticated.” Completeness implies that all required data is present; including pertinent facts, findings, and observations about an individual’s health history, examinations, tests, treatments, and outcomes. Documentation standards also require that staff with clinical privileges document opinions involving medical judgement.<sup>42</sup> The healthcare practitioner must enter documentation of each event of a patient’s care into the EHR. In addition, The Joint Commission requires that documentation of communication with the patient, including telephone calls and email, be included in the EHR.<sup>43</sup> Timely and complete entries allow providers to assess, plan immediate treatment, and coordinate the patient’s care.

Documentation in the EHR showed evidence that all 11 patients had been evaluated for the TAVR procedure. In 10 of the 11 cases, documentation reflected when and where the patient received the TAVR, an alternate cardiac procedure, or if the patient was unable to undergo the TAVR procedure. We were unable to determine the outcome of one patient due to insufficient documentation in the EHR.

The course of care between evaluation and disposition was often difficult to ascertain due to lack of documentation. Nine of the 11 records lacked documentation related to one or more of the following: clinical judgement, coordination of care, and communication with the patient or referring facility. Following are brief synopses of sample cases.

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<sup>41</sup> VHA Directive 1907.01, *Health Information Management and Health Records*, July 22, 2014. This Handbook was current during some of the events discussed in this report. It was rescinded and replaced by VHA Directive 1907.01, *Health Information Management and Health Records*, March 19, 2015. Both Handbooks contain the same or similar language regarding requirements cited in this report.

<sup>42</sup> Medical judgement is a clinician’s opinion about the likely diagnosis or best treatment options based on the patient’s history, physical exam findings, laboratory, and/or radiographic results.

<sup>43</sup> The Joint Commission Manual via E-dition Web site. <https://e-dition.jcrinc.com/MainContent.aspx>. Published July 1, 2015, (Updated July 1, 2016). Accessed September 21, 2016. Standard, RC.02.01.01 EP4.

#### Patient A

See patient discussed in Allegation 1 (page 8).

#### Patient B

Patient B received primary care through the system but chose to have specialty care through a non-VA provider. The non-VA provider contacted the system's thoracic surgeon requesting evaluation for TAVR. The EHR reflects that a provider saw Patient B in the system's cardiac surgery clinic in 2014. The system provider documented the plan to review additional tests from the referring non-VA provider and discuss with a system cardiology provider. Patient B had a prior aortic valve replacement (AVR), which limited his options, including qualification for some research studies. Patient B signed consent for a TAVR research study the same day as the cardiothoracic surgery clinic appointment. We found no additional cardiothoracic, cardiology, or TAVR research coordinator documentation in the EHR to indicate further care at the VA. According to non-VA records, Patient B received care by non-VA providers after his system TAVR evaluation and was admitted to a non-VA hospital 4 months later for surgical replacement of his aortic valve; however, he died during induction of anesthesia.

#### Patient C

Patient C was referred from VA Loma Linda Healthcare System (Loma Linda) to the system for evaluation of AS. A system provider saw Patient C in the cardiac surgery clinic in late 2014. The system's EHR note indicated Patient C was a potential candidate for a TAVR procedure, but that a system cardiology provider needed to evaluate Patient C and that the TAVR nurse coordinator would follow up with Patient C to further assess TAVR candidacy. Patient C's system EHR does not contain an evaluation by the system's cardiologist or documentation from the TAVR coordinator regarding follow-up; however, the EHR does contain a NVCC request dated a month later for a TAVR procedure at a nearby community hospital.

Loma Linda staff contacted system staff in late 2014 and documented in Patient C's Loma Linda EHR that the system's TAVR nurse coordinator confirmed that Patient C was still in the queue for the TAVR procedure at the system. Two weeks later, the Patient C's Loma Linda EHR noted that the system could not perform the TAVR procedure in the next month and recommended outsourcing. Loma Linda staff placed an NVCC request for a TAVR procedure at a different community hospital. Ultimately, Patient C received treatment through the system's NVCC process.

#### Patient D

Patient D was referred from Loma Linda to the system for evaluation of AVR. In 2014, a cardiac surgery clinic provider assessed Patient D and deemed Patient D a candidate for TAVR pending further imaging evaluation. Patient D's system EHR does not contain additional notes, studies, or communication between the system and Loma Linda. Documentation in Patient D's Loma Linda EHR indicated the Loma Linda nurse coordinator contacted the system 2 months later to check on the status of Patient D's

TAVR procedure. During the call, the Loma Linda staff was told the system was unable to provide the procedure and recommended referring Patient D to an outside facility. Loma Linda placed an NVCC consult for a TAVR procedure. Patient D received treatment through the Loma Linda NVCC process.

#### Patient E

Patient E was referred from Central California VA Health Care System (Fresno) to the system for evaluation of AVR. In mid-2014, a system pulmonary provider note indicated the plan was for Patient E to complete a course of antibiotics and then return in a week or two for re-evaluation to determine if he was a candidate for a TAVR procedure. Patient E's system EHR does not contain additional notes regarding a course of care although system staff submitted an NVCC request 5 months later for a TAVR procedure at a nearby community hospital. According to Patient E's Fresno EHR, system providers did not contact Fresno providers about the need to submit an NVCC consult for a TAVR procedure for Patient E. Rather, Patient E informed the Fresno providers about the system's evaluation, their inability to provide the procedure and plan to send him to a community hospital near the system. The system's EHR contains no documentation regarding how Patient E became aware of this information. Fresno contacted the system to confirm the need for NVCC. Upon verification, Fresno placed consults. Ultimately, Patient E received treatment through the system's NVCC process.

Our review of the 11 cases identified deficiencies in documentation by the multidisciplinary TAVR team of documenting the complete course of care and communication with the patient or referring facility.

## Conclusions

We did not substantiate that Patient A experienced a delay in obtaining the TAVR procedure. Subject matter experts have not established timeliness standards for TAVR. Medical factors unique to Patient A impacted his risk to successfully undergo the procedure. Providers must evaluate Patient A's condition and risk when the TAVR procedure is considered and make recommendations accordingly.

We did not substantiate that on two occasions VHA would not approve Patient A's TAVR procedure to be performed at non-VA facilities. Providers submitted two NVCC requests for TAVR at a non-VA facility for Patient A and each one was approved.

We substantiated VHA requires TAVR procedures be performed in an HOR. VHA established this requirement after reviewing evidence-based best practices and obtaining expert consensus. While we found no regulatory requirements for performing TAVR procedures in an HOR at non-VA facilities, we found that non-VA facilities typically performed TAVR procedures in HORs; therefore, we made no recommendation.

We substantiated that patients were affected by VHA's national requirement for the TAVR procedure to be performed in an HOR. The system lacked an HOR and

providers were not authorized to perform non-research TAVR procedures onsite; however, processes were in place to refer non-research patients for care. Therefore, we made no recommendation.

We substantiated that the system requested a waiver of the national VHA requirement to perform the TAVR procedure in an HOR. However, in 2014, NSO leadership denied waivers on this matter; therefore, the system's request was not approved.

We substantiated that the operating room construction project (project 1) identified by Complainant #2 was not completed in the projected timeline and, although not originally intended for use to perform TAVRs, was ultimately approved as an interim HOR and subsequently impacted the implementation of the TAVR Program. However, patients obtained the procedures through other VA services prior to approval of the system's TAVR Program. The TAVR Program was implemented at the system in December 2015.

We substantiated that the system enrolled patients in research studies involving the TAVR procedure. We were unable to determine if by doing so, they avoided delays in care that the patient may otherwise have encountered.

Although not an allegation, during the course of the EHR review we identified a failure to consistently document a complete and accurate clinical record. Lack of EHR documentation made it difficult to determine the course of care between a patient's evaluation and outcome. Without complete EHR documentation; including clinical judgement, coordination of care, and communication with the patient or referring facility; providers cannot determine an accurate plan of care.

## **Recommendation**

1. We recommended that the System Director ensure that providers document clinical judgement, coordination of care, communication with the patient or referring facility, and an accurate plan of care from initial assessment to procedure for transcatheter aortic valve replacement patients.

**Table. Approved TAVR Research Studies**

Study	Purpose of Study	Sponsor	Activation Date	Termination Date
Medtronic CoreValve© U.S. Pivotal Trial ( <b>high-risk and extreme-risk patients</b> )	To evaluate safety and effectiveness of the Medtronic CoreValve© System (MCS) in the treatment of symptomatic severe aortic stenosis in subjects who have a predicted high risk for aortic valve surgery. Patients were randomized 1:1 to either TAVI <sup>44</sup> with the MCS or to SAVR. <sup>45</sup>	Medtronic, Inc.	April 13, 2011	August 12, 2014 <sup>46</sup>
Medtronic CoreValve© Continued Access Study ( <b>high risk-and extreme-risk patients</b> )	To evaluate the safety and efficacy of the MCS in the treatment of symptomatic severe aortic stenosis in subjects necessitating AVR, with predicted operative mortality or serious, irreversible morbidity risk of $\geq 15$ percent and $< 50$ percent (high-risk) or $\geq 50$ percent (extreme-risk) at 30 days.	Medtronic, Inc.	April 13, 2013	August 12, 2014 <sup>47</sup>
REPRISE III: Repositionable Percutaneous Replacement of Stenotic Aortic	To evaluate the safety and effectiveness of the Lotus™ Valve System for TAVR in symptomatic subjects with calcific,	Boston Scientific	January 5, 2015	Ongoing

<sup>44</sup> The surgery may be called a transcatheter aortic valve replacement (TAVR) or transcatheter aortic valve implantation (TAVI). [http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/What-is-TAVR\\_UCM\\_450827\\_Article.jsp#.WcF2DqoU1s](http://www.heart.org/HEARTORG/Conditions/More/HeartValveProblemsandDisease/What-is-TAVR_UCM_450827_Article.jsp#.WcF2DqoU1s). Accessed September 19, 2017.

<sup>45</sup> Randomization is a statistical method used to assign study participants to a particular treatment group.

<sup>46</sup> The system was notified on January 17, 2014 that the FDA had approved the use of the CoreValve© in the extreme-risk population. At that time, patients were no longer enrolled in research under this study if they fell into the extreme risk category. The system was notified that the FDA had approved the use of the CoreValve© in the high-risk patient population on June 13, 2014. System providers were instructed to no longer consent patients into the study who met that criteria and to ensure that patients who were already consented at that time were enrolled by August 12, 2014.

<sup>47</sup> The system was notified on January 17, 2014 that the FDA had approved the use of the CoreValve© in the extreme-risk population. At that time, patients were no longer enrolled in research under this study if they fell into that category.



Valve Through Implantation of Lotus™ Valve System <b>(high and extreme risk patients)</b>	severe native aortic stenosis who are considered at extreme or high-risk for surgical valve replacement.			
Medtronic CoreValve© U.S. Expanded Use Study <b>(patients excluded from US extreme risk pivotal trial)</b>	To evaluate the safety and effectiveness of the MCS for the treatment of symptomatic severe aortic stenosis in subjects with significant comorbidities in whom the risk of surgical aortic valve replacement has a predictable operative mortality or serious, irreversible morbidity risk of $\geq 50$ percent at 30 days. The primary objective is to evaluate the safety and effectiveness of the MCS in a subset of subjects <b>excluded from the U.S. Extreme-Risk Pivotal Trial population</b> due to one or more additional comorbidities.	Medtronic, Inc.	December 19, 2012	November 4, 2015
Medtronic CoreValve© SURTAVI Trial <b>(intermediate surgical risk patients)</b>	To investigate the safety and efficacy of TAVI in patients with severe, symptomatic aortic stenosis at intermediate surgical risk by randomizing patients to either SAVR or TAVI with the MCS. The primary objective is to evaluate whether TAVI is non-inferior to SAVR with respect to all-cause mortality and disabling stroke.	Medtronic, Inc.	May 10, 2013	June 15, 2017

Source: VA OIG

## VISN Director Comments

**Department of  
Veterans Affairs**

## Memorandum

**Date:** August 15, 2017

**From:** Director, Sierra Pacific Network (10N21)

**Subj:** Healthcare Inspection—Alleged Transcatheter Aortic Valve Replacement Program Issues, VA Palo Alto Health Care System, Palo Alto, California

**To:** Director, Seattle Office of Healthcare Inspections (54SE)  
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the draft report. I concur with the action plan Palo Alto has provided to correct the finding listed in the report.
2. If you have any questions, please contact the Deputy Quality Manager for V21 at (707) 562-8350.

*(original signed by:)*  
Sheila M. Cullen  
Network Director, V21

## System Director Comments

**Department of  
Veterans Affairs**

## Memorandum

**Date:** August 11, 2017  
**From:** Director, VA Palo Alto Health Care System (640/00)  
**Subj:** Healthcare Inspection— Alleged Transcatheter Aortic Valve Replacement Program Issues, VA Palo Alto Health Care System, Palo Alto, California  
**To:** Director, Sierra Pacific Network (10N21)

1. VA Office of Inspector General (OIG) conducted a healthcare inspection in 2015 to assess allegations of delays in performing transcatheter aortic valve replacement (TAVR) procedures and cardiac patients not receiving TAVR procedures at VAPAHCS, due to Veterans Health Administration (VHA) national policy requirements.
2. My staff and I have reviewed OIG's draft report and recommendation. We concur with the recommendation, and we are providing an action plan to address it.
3. Thank you for the opportunity to review and address the allegations and findings. If you have questions concerning this matter, please contact Stephen Ezeji-Okoye, Deputy Chief of Staff, at (650) 493-5000, extension 65555.

*(original signed by:)*  
Thomas J. Fitzgerald III,  
Director, VA Palo Alto Health Care System

## Comments to OIG's Report

The following Director's comments are submitted in response to the recommendation in the OIG report:

### **OIG Recommendation**

**Recommendation 1.** We recommended that the System Director ensure that providers document clinical judgement, coordination of care, communication with the patient or referring facility, and an accurate plan of care from initial assessment to procedure for transcatheter aortic valve replacement patients.

Concur

Target date for completion: September 15, 2017

System response: Patients referred for TAVR are seen in both Cardiology and Cardiothoracic Surgery clinics. The assessment and evaluation of these patients are captured in their respective clinic notes. The patients are then jointly discussed by Cardiology and Cardiothoracic Surgery in a non-clinic, case conference setting. It is in this setting that the decisions about the suitability of the patient as a TAVR candidate and the need for further evaluation and work-up are discussed and a treatment plan is developed. The discussion and decision making of these case conferences would benefit from a standard note that documents when and where the patient was referred, the clinical evaluation, decision-making process, subsequent actions that are proposed, and the communication plan for the patient and the referring facility. The developed note could then be linked/updated to any actions that occur from the time of the case conference to the performance of the TAVR or when the patient and facility are informed that the patient is not a candidate for TAVR. Standard work for the documentation of care and a standard note will be jointly developed between Cardiology and Cardiothoracic Surgery with assistance from Quality Management and Clinical Applications.

## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the OIG at (202) 461-4720.
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