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OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Intraoperative Radiofrequency Ablation and Other Surgical Service Concerns at the Samuel S. Stratton VA Medical Center

Albany, New York

HEALTHCARE INSPECTION | REPORT #17-01770-188 | AUGUST 29, 2018

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Samuel S. Stratton VA Medical Center (Facility), located in Albany, New York, in response to confidential allegations regarding quality oversight of the Facility's Surgery Service including patient communications about surgery complications, the peer review (PR) process, and surgery outcomes for a surgical oncologist (Surgeon A).

The complainant alleged:

- Surgery Service lacked quality oversight to identify events requiring review:
  - The Surgery Service's PR process did not follow Veterans Health Administration (VHA) policy.
  - Surgeon A told a patient there was "a recurrence" of a tumor, after the tumor was "completely missed" during intraoperative radiofrequency ablation (IORFA).[1]
- Surgeon A performed IORFA surgery for hepatocellular carcinoma and "completely missed" the tumor in patients identified by the complainant; performed cancer surgery on patients who did not have cancer; and unexpected adverse events occurred during and after other oncologic surgeries performed by Surgeon A.

VHA requires facilities to identify events that necessitate quality review.[2] The OIG substantiated that the Surgery Service lacked quality oversight to identify events requiring review.

The OIG substantiated the PR process for surgery did not follow VHA policy. The Facility's Morbidity and Mortality Conference, which reportedly functioned as an initial peer reviewer, failed to forward cases to the PR Committee for a second-level review, to ensure there was no conflict of interest in the review process, and to document results of reviews using the required Facility forms that contained all required elements. Reviews done by the Morbidity and Mortality Conference were not included in the Facility's PR processes.

OIG staff found that the Facility did not meet VHA requirements for credentialing and privileging. A lack of documentation of Surgeon A's supervision and competencies during the initial Focused Professional Practice Evaluation period may have contributed to the missed

[1] Radiofrequency ablation (RFA) uses a special type of needle that is inserted directly into the tumor to apply electromagnetic energy, which produces heat to destroy metastatic and small primary tumors. RFA may be performed intraoperatively by a surgeon under ultrasound guidance or percutaneously (under the skin) in radiology by an interventional radiologist using ultrasound or computed tomography guidance.

[2] VHA Directive 2010-025, Peer Review for Quality Management, June 3, 2010.

tumors as this was the time for the Facility to determine initial competencies for practice. The OIG found the surgery manager's usage of Focused Professional Practice Evaluation was an ineffective process for practice evaluation. Surgeon A's Ongoing Professional Practice Evaluation contained inaccurate data and did not address specific competencies for Surgeon A. As such, clinical managers were not aware of the missed tumors. The Chief of Surgery failed to collect sufficient data to evaluate Surgeon A's practice and outcomes of IORFA. The quarterly data used by the Chief of Surgery to evaluate the competency of Surgeon A contained errors over a two-year period.

To respond to the allegations that Surgeon A told a patient there was a "recurrence" of a tumor when it was "completely missed" and that Surgeon A missed patients' tumors, OIG staff reviewed electronic health records for three patients, identified by the complainant, who received IORFA. The OIG substantiated that Surgeon A told Patients 1 and 2 that there was "residual" tumor, although these tumors were "completely missed" during IORFA. OIG staff interpreted the term "completely missed" as a failure to ablate any portion of the tumor during the IORFA procedure and was identified in this report as simply "missed." The OIG also found that Surgeon A mischaracterized the outcomes of IORFA for Patient 3.

The OIG substantiated that Surgeon A missed or partially missed targeted hepatocellular carcinoma liver tumors when performing IORFA in all three patients reviewed. OIG staff considered a tumor partially missed when the RFA procedure failed to ablate a large portion of the tumor (larger than what reasonably could be considered residual tumor). In each of the patients, additional interventions including percutaneous RFA were required. The OIG determined that tumors missed during IORFA met the VHA definition of adverse events and may have required consideration for institutional disclosures.[3]

The OIG found that the Liver Tumor Board's members, in reviewing Surgeon A's post-IORFA procedure magnetic resonance images, were aware of the missed tumors but did not report these to the Facility or quality management leaders. None of the episodes of care involving the three patients with missed or partially missed tumors were reviewed by the Facility's PR process or captured in Ongoing Professional Practice Evaluation records. The Liver Tumor Board's failure to accurately document that tumors were missed in patients' electronic health records also contributed to the Facility and quality management leaders' lack of awareness and failure to provide appropriate disclosures. Facility and quality management leaders have the responsibility to provide those disclosures when Facility staff fail to do so.

[3] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, October 2, 2012. Adverse events are "untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care..."

To evaluate if Surgeon A performed cancer surgery on patients without cancer, or if adverse events occurred in other oncologic surgeries, OIG staff reviewed the electronic health records of 10 patients who received non-RFA oncologic surgeries performed by Surgeon A.[4]

The OIG did not substantiate Surgeon A performed cancer surgery on patients who did not have cancer or that adverse events occurred during and after these non-RFA surgeries. The patients had lesions that were operated on for cancer or suspected cancer, and/or were at high risk for developing cancer.

The OIG made nine recommendations related to quality oversight and quality data for professional practice evaluations; improving peer review programs; including accurate performance data for Surgery Service's professional practice evaluations; developing and implementing processes to document, report, and track discussed patient cases; implementing processes to track, monitor, and report IORFA outcomes; consulting with Office of General Counsel on patients with missed tumors to institutionally disclose if appropriate; assessing Surgeon A's IORFA outcomes; performing external reviews of IORFA process; and evaluating actions for relevant staff.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the OIG recommendations and provided acceptable action plans. (See Appendixes B and C, pages 24–31 for the Directors' comments.) Based on information provided, the OIG considers recommendations 2, 7, 8, and 9 closed. For the remaining open recommendations, the OIG will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.

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[4] Patient names were provided by the complainant or found by OIG staff in PR documents.

Contents

Abbreviations

CT	computed tomography
C&P	credentialing and privileging
ECMS	executive committee of the medical staff
EHR	electronic health record
FPPE	focused professional practice evaluation
FY	fiscal year
HCC	Hepatocellular
IORFA	intraoperative radiofrequency ablation
LTB	liver tumor board
MRI	magnetic resonance imaging
OIG	Office of Inspector General
OPPE	ongoing professional practice evaluation
OR	operating room
PR	peer review
QM	quality management
RFA	radiofrequency ablation
US	ultrasound
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the Samuel S. Stratton VA Medical Center (Facility), located in Albany, New York, to assess a confidential complainant's allegations concerning quality oversight of the Facility's Surgery Service including patient communications about surgery complications, the peer review (PR) process, and surgery outcomes for a surgical oncologist (Surgeon A).

Background

The Facility is part of Veterans Integrated Service Network (VISN) 2. It has 112 operational beds and serves more than 35,000 veterans in 22 counties of upstate New York, western Massachusetts, and Vermont. The Facility provides a wide range of inpatient and outpatient services including surgery, interventional radiology (IR),[5] radiation oncology, computed tomography (CT), and magnetic resonance imaging (MRI).[6] Other VISN 2 facilities refer oncology patients to the Facility for care and treatment. The Facility is affiliated with Albany Medical College and other medical schools.

Surgical Quality Oversight

Veterans Health Administration (VHA) requires medical facility directors to ensure that the functions of the Enterprise Framework for Quality, Safety and Value are in compliance with VHA standards, regulations, and policies, and are integrated under an organizational structure that promotes the exchange and flow of quality information.[7] VHA defines key quality functions as institutional disclosure monitoring, PR, and credentialing and privileging (C&P).[8] Oversight of the quality of care occurs through these facility-wide functions. Services, such as Surgery

[5] For the purposes of this report, OIG staff use IR interchangeably for an Interventional Radiologist and the Interventional Radiology Department.

[6] VHA Directive 2010-018, *Facility Infrastructure Requirements to Perform Standard, Intermediate, or Complex Surgical Procedures*, May 6, 2010. This directive expired May 31, 2015 and has not yet been updated or replaced. VHA requires each facility with an inpatient surgical program to have a surgical complexity designation of standard, intermediate, or complex based on its equipment, workload, and staffing. Facilities assigned a complex rating require special services, equipment, and employees who have expertise for difficult operations, such as cardiac and neurosurgery.

[7] VHA Directive 1026, VHA Enterprise Framework for Quality, Safety, and Value, August 2, 2013.

[8] VHA Directive 1026.

Service, may have additional separate and distinct requirements,[9] but must adhere to minimum VHA and facility quality requirements.

Adverse Events and Disclosures

According to VHA, adverse events are untoward incidents or other occurrences of harm or potential harm directly associated with care or services to veterans.[10] Disclosure is warranted for "adverse events that cause death or disability, lead to prolonged hospitalization, require life-sustaining intervention or intervention to prevent impairment or damage (or that are reasonably expected to result in death or serious and/or permanent disability), or that are sentinel events."[11]

Disclosure of adverse events is a forthright discussion between providers or other VHA personnel and patients or patients' representatives of clinically significant facts about the occurrence of a harmful adverse event. VHA requires that facilities adopt strategies to encourage and advocate for identification and reporting of adverse events and close calls, even if it appears to be a result of practitioner error, as even the most conscientious, knowledgeable, and competent professional can make mistakes.[12] The goal is to improve care.[13] Disclosing adverse events to patients is consistent with VHA core values of trust, respect, excellence, commitment, and compassion.[14] Providers are ethically obligated to be honest with their patients.

PR

A PR is a confidential, non-punitive process for evaluating health care provided by an individual provider.[15] PRs are part of a facility's Quality Management (QM) program and results cannot be used for personnel actions such as reassignment, changes in privileges, performance pay determinations, or disciplinary actions.[16]

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[9] VHA Handbook 1102.01, *National Surgery Office*, January 30, 2013.

[10] VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients,* October 2, 2012. This handbook expired October 31, 2017 and has not yet been updated.

[11] VHA Handbook 1004.08.

[12] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook expired March 2016 and has not yet been updated.

[13] VHA Handbook 1050.01.

[14] VHA Handbook 1050.01.

[15] VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. The directive expired June 30, 2015 and has not yet been updated; A peer is a health care professional who has similar or more advanced education, training, experience, licensure, or clinical privileges or scope of practice to the provider being reviewed

[16] VHA Directive 2010-025.

The basic steps of the PR process, required by VHA Directive 2010-025,[17] *Peer Review for Quality Management*, include

1. Initial review: Evaluation of a provider's selected episode of care conducted by a peer reviewer who makes an initial Level of Care decision:
    - Level 1 – The most experienced, competent providers would have managed the case in a similar manner.
    - Level 2 – The most experienced, competent providers might have managed the case differently.
    - Level 3 – The most experienced, competent providers would have managed the case differently.

The Facility required the reviewer to use standardized forms that included required elements of justification for the outcome, identification of the aspect of care involved, and identification of any system issues that may be referred for further review.[18]

2. Secondary review: The PR Committee (PRC) is a multidisciplinary group of senior clinical staff who meet to discuss and reconsider a sample of cases done by an initial peer reviewer to identify professional practice issues for individuals and for trending issues for a VISN and facility. PRC responsibilities include reconsidering initial PR decisions to ensure the validity and reliability of the findings and to evaluate the PR process itself. A Risk Manager tracks and reports outcomes of PR for improvement purposes.

The PRC reviews any confidential recommendations and specific actions for the individual provider to improve practice.

Responsibilities of the peer reviewer include abstaining or withdrawing from participation in a case review if

- The reviewer had direct involvement with the care in question,
- The specialized knowledge required exceeds the reviewer's expertise or when the reviewer feels uncomfortable about evaluating the care,
- A conflict of interest exists, or for any other reason, the reviewer is unable to conduct an objective, impartial, accurate, and informed review, or
- Confidentiality or anonymity of the reviewer cannot be achieved.

[17] VHA Directive 2010-025.

[18] Facility Memorandum SL-PM-04, *Peer Review Policy*, April 2014.

PR reviewers are required to exercise autonomous clinical judgment. The Facility PR policy states the Risk Manager prepares the case for the PRC keeping the identity of the initial reviewer confidential and the initial review itself is not shared with the involved providers.

Program Directors and Service Chief PR Requirements

VHA requires that program directors and service chiefs assist with identifying peer reviewers and participate in the PRC.[19] VHA Risk Management staff stated that service chiefs should not be involved in PR discussions prior to presentation to the PRC.

C&P

Credentialing is the process used by a facility to determine if the physician has the required licenses, education and training, and experience to practice at the facility. Privileging is the definition of what that practice will be, meaning what the physician is allowed to do based on competency. Privileging refers to the process of approving the procedures and services a provider can provide independently. These privileges must be specific to the facility, service, and provider.[20]

VHA requires monitoring and surveillance of professional competency to evaluate if the provider is meeting acceptable levels of performance.[21] Focused Professional Practice Evaluation (FPPE) is used for the new provider and the provider who requests new privileges, as well as when professional practice concerns are identified. Ongoing Professional Practice Evaluation (OPPE) includes review of relevant provider data over time, at a minimum of every six months.

VHA requires service chiefs to evaluate the quality of a provider's practice by gathering and analyzing provider-specific practice data based on the individual's privileges. The service chief is required to review this data at a minimum of every six months to determine competency.[22] The data comes from a variety of sources that can include work done by QM staff, VHA national program data collection processes, or by local committees and groups who meet to review and discuss patient care activities. One such committee is the Liver Tumor Board (LTB).

[19] Facility Memorandum SL-PM-04.

[20] VHA Directive 2010-025.

[21] VHA Handbook 1100.09, *Credentialing and Privileging*, October 15, 2012. This directive expired October 30, 2017 and has not yet been updated.

[22] VHA Handbook 1100.09.

Hepatocellular Carcinoma

Hepatocellular carcinoma (HCC) is a primary malignancy of the liver, typically occurring in the setting of chronic liver disease and cirrhosis.[23] The size of the HCC tumor(s), the extension of the tumor(s) into adjacent structures, and the presence of metastasis(ses) are important determinants of patients' survival and stage of HCC. Providers formulate treatment plans to destroy the tumor(s) based on the HCC stage.[24]

Radiofrequency Ablation

Radiofrequency ablation (RFA) uses a specialized needle to apply electromagnetic energy, which produces heat, to destroy primary or metastatic tumors no larger than 3 centimeters (cm) (about an inch). When used to treat HCC, RFA may be performed intraoperatively by a surgeon under ultrasound (US) guidance[25] or in radiology by an interventional radiologist using US or CT guidance.[26] The needle is guided through a percutaneous route[27] using US or CT, and placed in very close proximity to the tumor. RFA done by a surgeon in an OR (intraoperative RFA or IORFA) setting allows for the additional option of creating a larger incision, inserting both the ultrasound and needle in very close proximity to the targeted tumor. Some patients with HCC are not recommended for surgery but may undergo percutaneous RFA, a less invasive approach to tumor destruction. Percutaneous RFAs are performed by an IR.[28]

The goal of RFA in treating HCC tumors, whether performed surgically or percutaneously, is to destroy the tumor.[29] Physicians determine effectiveness of RFA through MRI, which is performed approximately two months after ablation. If the MRI reveals that some of the targeted tumor remains, this is called a residual. A tumor that regrows in the same area as a removed tumor is called a recurrence. The OIG interpreted "completely missed" as a failure to ablate any portion of the tumor during the IORFA procedure and identified it in this report as simply

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[23] Cirrhosis is a condition of the liver caused by prior liver disease(s) where normal tissue is replaced with scar tissue.

[24] For the purposes of this report, the medical terms tumor, mass, and lesion are used interchangeably.

[25] Guidance with CT scanning was not available in the Facility's operating room.

[26] A CT scan combines a series of X-ray images taken from different angles and uses computer processing to create cross-sectional images or slices of bones, blood vessels, and soft tissues in the body for more detailed information than is obtainable with plain X-rays. http://www.mayoclinic.org/tests-procedures/ct-scan/basics/definition/prc-20014610. (This website accessed June 20, 2017.)

[27] Percutaneous means to perform through the skin http://medical-dictionary.thefreedictionary.com/percutaneous. (This website accessed August 21, 2017.)

[28] An IR is a physician who performs minimally invasive procedures using image guidance.

[29] RFA yields complete tumor ablation on imaging of approximately 90 percent in tumors 3 cm or less. Lu DS, Yu NC, Raman SS, et al., (2005) Radiofrequency Ablation of Hepatocellular Carcinoma: Treatment Success as Defined by Histologic Examination of the Explanted Liver. *Radiology,* 234:954–960.

"missed." The OIG considered a tumor "partially missed" when the RFA procedure failed to ablate a large portion of the tumor (larger than what reasonably could be considered residual tumor).

LTB

The LTB is a multidisciplinary group who reviews patients diagnosed with hepatobiliary (liver, gallbladder, and bile duct) and pancreatic cancers, and makes treatment recommendations. The Facility's LTB is comprised of Surgeon A, an IR, a medical oncologist, a gastroenterologist, and a nurse practitioner liver cancer coordinator.[30]

Allegations

On January 30, 2017, the OIG received allegations from a confidential complainant regarding surgical patients' quality of care and patient safety. This review focused on the following allegations

- The Surgery Service lacked quality oversight to identify events requiring review:
  - The Surgery Service's PR process did not follow VHA policy.
  - Surgeon A told a patient there was "a recurrence" of a tumor, after the tumor was "completely missed" during IORFA.
- Surgeon A performed IORFA surgery for HCC and "completely missed" the tumor in patients, identified by the complainant, performed cancer surgery on patients who did not have cancer, and unexpected adverse events occurred during and after other oncologic surgeries performed by Surgeon A. During the course of the inspection, OIG staff received additional allegations that were outside the scope of this review. OIG staff forwarded these additional allegations to the OIG Hotline Division for further review.

[30] The Facility employs more than one medical oncologist and more than one interventional radiologist. These specialists take turns attending the LTB meetings.

Scope and Methodology

The OIG initiated the review on February 9, 2017, and conducted four onsite Facility visits on February 15, April 3–7, April 17–20, and June 6, 2017.

OIG staff interviewed the VHA Director of Risk Management and the VISN 2 QM Officer and Risk Manager. OIG staff interviewed the Facility's Director, Chief of Staff (COS), chiefs of surgery and radiology, faculty from the surgical oncology fellowship program,[31] QM staff, chairs and members of the LTB, the complainant, and other staff. OIG staff reviewed VHA policies and The Joint Commission Standards. OIG staff reviewed relevant VHA and Facility policies, and procedures, the Facility's Medical Staff Bylaws, and PRC and surgical committee meeting minutes and attendance.

To evaluate possible missed tumors in RFA patients, OIG staff reviewed electronic health records (EHR), MRI images and reports, LTB records, and operative reports.

The OIG reviewed relevant VHA data from October 1, 2012, through December 31, 2016, which included Facility risk management and PR data, surgical occurrence reports, and committee reviews. OIG staff also reviewed Surgeon A's C&P files and FPPE and OPPE records.

To evaluate surgical services program concerns

- The OIG conducted in-depth case reviews of 13 patients, obtained from the complainant and through PR documents, by reviewing EHR and radiology images from October 1, 2012, through December 31, 2016; and
- The OIG sent the Facility five additional IORFA patients for clinicians' review of outcomes and evaluation of actions needed.

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

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

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

[31] Faculty members are from the City of Hope Medical Center, Duarte, CA.

Case Summaries

Patient 1

Patient 1 is a male in his 60s with cirrhosis of the liver. In late 2015, an MRI revealed a 2.5 cm tumor in segment 6 of the liver.[32] A biopsy later confirmed HCC and the LTB recommended IORFA.

In 2016, Surgeon A performed the recommended IORFA procedure. Post operatively, Surgeon A documented that Patient 1's liver was "very cirrhotic," and Surgeon A created a larger incisional opening to improve visualization. With ultrasound as a guide, Surgeon A documented placing the ablation probe in segment 6 of the liver. Surgeon A cited difficulty seeing the mass well, and ablated the "entire area" several times "from lateral to medial" to help ensure complete ablation of the tumor.

A radiologist interpreted Patient 1's follow-up MRI and noted an "ablation cavity," but the previously identified tumor remained. Specifically, the radiologist noted the following impression

> Ablation cavity in segment 6 at the inferior liver tip. Separate from this cavity, a 2.8 cm lesion corresponding to the previously described segment 6 HCC appears slightly increased in size and now demonstrates mild arterial enhancement.[33]

The LTB reviewed Patient 1's post-ablation MRI report. The LTB copied and pasted the MRI results into his EHR, which indicated an ablation cavity separate from the previously identified tumor. Directly below the copied MRI interpretation, the LTB also noted the tumor was "residual/recurrent disease," which had increased in size. The LTB recommended Patient 1 undergo percutaneous RFA. Specifically, the LTB noted

> … intraoperative RFA [IORFA] of segment 6 HCC now with residual/recurrent disease increased in size. Now recommended for percutaneous RFA by IR [interventional radiology]. Remains a candidate for liver transplant.

[32] The Couinaud classification of liver anatomy divides the liver into eight functionally independent segments. Pauli, Eric M., MD; Staveley-O'Carrol, et al., A Handy Tool to Teach Segmental Liver Anatomy to Surgical Trainees. *Arch Surg,* August 2012. 692-693. National Institute of Health Public (This website accessed on August 2, 2017.)

[33] Ablation cavity, as defined in this report, is the tissue destruction and subsequent anatomical void created by the RFA needle. A lesion demonstrating arterial enhancement is consistent with the expected findings in a malignancy.

The next day, Surgeon A called Patient 1 and documented the following conversation

> Called and discussed with pt [patient] over the phone the finding of his most recent MRI **showing residual HCC** as well as the tumor board's recommendation for perc [percutaneous] RFA. Pt indicated that he understood….[34]

Four months after the initial ablation procedure performed by Surgeon A, an IR performed the percutaneous RFA and documented it was for the same tumor. The follow-up MRI from the patient's second ablation procedure revealed that the tumor was effectively ablated, as the tumor was gone.

Five months after the second ablation procedure, the LTB noted in Patient 1's EHR that repeated MRIs showed he had a new HCC tumor, which was unrelated to the first tumor and in a different location. The LTB recommended management with transesophageal echocardiogram and percutaneous RFA by IR, both of which occurred within a month.[35] The follow-up MRI revealed the second tumor was effectively treated.

As of late 2017, Patient 1 continued to have regularly scheduled MRIs to assess any further progression of the HCC. He was on the liver transplant list at a VHA transplant center.[36]

Patient 2

Patient 2 is a male in his 60s whose diagnoses include coronary artery disease, diabetes mellitus, hypertension, and cirrhosis. In 2015, a single 1.8 cm mass, suggestive for HCC, was found on MRI of the liver.

The LTB recommended Patient 2 have IORFA and Surgeon A attempted to perform IORFA laparoscopically. Because the tumor was difficult to access, the procedure was converted to an open abdominal surgery to locate the tumor and complete the ablation.

An abdominal MRI two months later revealed a liver tumor adjacent to the post-RFA cavity "concerning for progression of residual tumor." Of note, the post-ablation cavity was anatomically above the location of the target tumor and the ablation appeared to miss the tumor.

The LTB noted that due to the (now) large size of the mass "approximately four cm," it was no longer amenable to IORFA. For this reason, Transarterial Chemoembolization (TACE) was

[34] The OIG bolded the text for emphasis.

[35] A transesophageal echocardiogram is an ultrasound that produces pictures of the heart and uses a thin tube into the esophagus.

[36] Liver transplantation is an operation that replaces a patient's diseased liver with a whole or partial healthy liver from another person. http://transplant.surgery.ucsf.edu/conditions--procedures/liver-transplant.aspx. (This website accessed August 2, 2017.)

recommended to be performed by IR prior to percutaneous RFA.[37] On the day following the LTB meeting, Surgeon A, who had performed the IORFA, telephoned Patient 2 and described the findings of the post-surgical MRI as showing "residual tumor" and citing the need for further treatment.

Three months after the initial ablation procedure performed by Surgeon A, IR performed a staged procedure with TACE of the HCC lesion done first and a percutaneous CT-guided RFA performed a week later. The follow-up MRI demonstrated effective ablation for a "large part" of the HCC lesion that had been seen in the imaging study of the prior month.

Patient 2 subsequently developed a new 2 cm tumor in another section of the liver, which was treated by IR with percutaneous RFA. A follow-up MRI, two months later, showed the lesion effectively ablated. In 2017, Patient 2 was listed for liver transplant by the VHA regional transplant Facility. As of late 2017, he continues to be monitored by the Transplant Surgery Case Manager.

Patient 3

Patient 3 is a male in his 60s whose diagnoses included hepatitis C and cirrhosis. In 2015, a 2.7 cm mass was found in segment 8 of the liver suggestive of HCC. The LTB recommended IORFA, which was performed by Surgeon A within two months of the diagnosis of the tumor. Surgeon A's operative report documented ablation in segment 6. A follow-up MRI, performed two months after the IORFA, revealed a substantial portion of the target HCC tumor was missed with the large remnant approximating a 1.5 cm mass.

Patient 3's case was again considered by the LTB who noted an HCC "residual" tumor was present and advised that another MRI be done in three months. The MRI was conducted four months later at another VA facility and showed the previously described HCC "with progressive tumor, now measuring 2.5 cm," increased in size compared to initial imaging.

The other facility's oncology staff discussed Patient 3's tumor progression, but no definitive care plan was established at that time. A gastroenterology consultant at the other facility documented being "alerted to the possibility that Patient 3 may be falling through the cracks," noted the MRI evidence of tumor progression, and asked him to call back in one week if he was "still in limbo." The next day, Surgeon A, who performed the IORFA seven months earlier, evaluated Patient 3 and documented that he was "now with recurrent [tumor] superior to the ablation zone."

[37] Transarterial Chemoembolization (TACE) involves direct injection of chemotherapy into the liver via a catheter, sparing the patient the side effects of chemotherapy given to the whole body. Following chemotherapy, the physician will cut off the blood supply to the tumor. http://www.hopkinsmedicine.org/liver_tumor_center/treatments/intraarterial_therapies/tace.html. (This website accessed August 2, 2017.)

The Facility LTB again discussed Patient 3's case and recommended that the previously missed tumor, now larger, be treated by percutaneous RFA by IR. IR performed TACE and a percutaneous RFA due to the previous non-targeted procedure. Two months later, an MRI at a non-VA facility, which was reviewed by the Facility IR, indicated successful RFA with no findings of residual/recurrent HCC.

Inspection Results

Issue 1: Lack of Surgical Quality Oversight

The OIG substantiated that the Surgery Service lacked quality oversight to identify events requiring review:

- **PR Process Deficiencies** – The OIG substantiated the Surgery Service's PR process did not follow VHA and Facility policy.
- **C&P** – The OIG determined that the Facility did not meet VHA requirements for FPPE or OPPE.
- **Patient Communications – Failure to Disclose** – The OIG substantiated that Surgeon A told Patients 1 and 2 there was "residual" tumor although these tumors were missed during IORFA. OIG staff also found that Surgeon A mischaracterized the outcomes of IORFA for Patient 3. The Facility had one surgeon, Surgeon A, who performed IORFA.

PR Process Deficiencies

The OIG substantiated that the Surgery Service's PR process did not follow VHA policy. If VHA and Facility PR requirements are not met, the PR process may not be objective.

Service-Level Committees Conducting Initial PRs

OIG staff heard conflicting information from Facility leaders about the role of the Surgical Morbidity and Mortality Conference (M&M) in performing PRs. The Chief of Surgery stated that he screens all events for PR and that M&M conducted the PRs for surgery service. The Risk Manager stated that M&M was doing PR as an educational process for the staff.[38]

VHA and Facility policies allow committees or other groups to function as initial peer reviewers, provided that VHA requirements are met.[39] Specifically, VHA and the Facility required that committees and groups who function as initial peer reviewers send cases to the PRC for further review.[40] This allows the PRC to perform its duties of ensuring validity and reliability of the

[38] Morbidity is a complication or undesirable side effect following surgery or medical treatment. http://www.merriam-webster.com/dictionary/morbidity. Mortality is the number of deaths that occur in a particular time or place. http://www.merriam-webster.com/dictionary/mortality. (This website accessed May 23, 2017.)

[38] M&M reviews are discussions among clinicians about the care provided to individual patients who die or experience complications. Historically, they are the core meetings for education, quality assurance, and training of surgical residents. http://www.sciencedirect.com/science/article/pii/S0002961006000687. (This website accessed May 23, 2017.)

[39] VHA Directive 2010-025.

[40] VHA Directive 2010-025.

findings, evaluating the PR process, and identifying providers' professional practice issues and trending issues for the VISN and Facility. OIG staff did not find M&M cases assigned a Level 2 or Level 3 forwarded for PRC review either on the PRC tracker or in committee minutes. A sample of M&M cases assigned a Level 1 was not sent to PRC for secondary review as required.

The OIG also found the Facility failed to comply with VHA PR requirements regarding cases forwarded to the PRC, PR documentation, and confidentiality of the peer reviewer.

Cases Forwarded from Initial Peer Reviewer Committees to the PRC for Secondary Review

VHA requires that the Facility PRC review all cases where variation (Level 2 or Level 3 findings) from the standard of care was found by the initial PR and recorded by any committees or groups who function as initial peer reviewers.[41] Cases were assigned a Level 1 by the M&M. OIG staff did not find documentation that samples of these cases were forwarded to the PRC for oversight as required. The Risk Manager stated that all Level 1 cases were reviewed in the PRC. M&M assigned Levels 2 and 3 to cases. OIG staff did not find evidence of these cases going to the PRC for review, tracking, and action as required.

In addition, OIG staff found M&M conducted PR with those who were involved in the care under review present for the M&M discussion and an instance where a subordinate provider completed a PR on a supervisor. These were instances of conflicts of interest that could inappropriately bias the outcome of the review. VHA requires that a peer reviewer with a conflict of interest, or who for any other reason, is unable to conduct an objective, impartial, accurate, and informed review should abstain from participation in a case review.[42] Local PR policy restricts subordinate staff from conducting initial PR of a case that involved a service chief or supervisor and requires individuals with direct involvement in the patient's care under review withdraw from participating in the case review.[43]

PR Documentation

VHA policy outlines essential elements of protected PR[44] and Facility policy requires the use of specific forms that contain all required elements such as levels, aspects of care associated with the case, naming the involved provider, and any actions recommended. These forms are for use

[41] VHA Directive 2010-025.
[42] VHA Directive 2010-025.
[43] Facility Memorandum SL-PM-04.
[44] VHA Directive 2010-025.

anywhere PR is done.[45] OIG staff found no evidence that the M&M members used these forms when conducting PR.

In addition, VHA requires PRC attendance by the Associate Director of Patient Care Services and senior members of key disciplines.[46] OIG staff reviewed M&M meeting minutes for 2015. The M&M committee functioned as the PRC, but the minutes did not show attendance by the Associate Director of Patient Care Services as required.

Confidentiality of the Peer Reviewer

VHA and Facility policies require confidentiality of the identity of the peer reviewer.[47] The M&M members failed to protect the confidentiality of the peer reviewer. The M&M members conducted the PRs with the reviewer and the provider under review present at the same time.

C&P

The OIG determined that the Facility did not meet VHA C&P requirements.

Credentialing and Competency

The OIG determined that Surgeon A did not have adequate documentation of supervision and competencies required for his/her initial credentialing. OIG staff could not determine if Surgeon A received senior staff supervision to ensure Surgeon A was competent to perform IORFA procedures on HCC tumors at the beginning of practice at the Facility. OIG staff found no written evaluation of these procedures by the supervisor in the FPPE. Surgeon A completed training in a general surgery residency program and a surgical oncology fellowship with an accredited fellowship program.[48] As required by VHA,[49] during Surgeon A's initial hiring and credentialing process, Facility staff requested and received evidence of training and current licensure and peer references that were documented as excellent or good for professional knowledge and skill, and received no concerns related to licensing or professional conduct. OIG staff interviewed a surgical oncologist (Surgeon B), a faculty member of Surgeon A's fellowship program, who on Surgeon A's initial hire reference form recommended *"supervision from the senior partner in the beginning for all major cases."* Surgeon B clarified this statement during

[45] Facility Memorandum SL-PM-04.

[46] VHA Directive 2010-025.

[47] VHA Directive 2010-025.

[48] VHA Handbook 1400.01, *Resident Supervision*, December 19, 2012. This handbook expired December 31, 2017 and has not yet been updated. The Surgical Oncology Fellowship Program was accredited by the Accreditation Council for Graduate Medical Education (ACGME).

[49] VHA Handbook 1100.09.

the interview and said it takes at least two years to become competent and comfortable doing complex liver/pancreatic surgeries independently.[50]

In addition, Surgeon B had extensive experience in performing IORFA procedures. Surgeon B stated that having an IR during the procedure is helpful as they are usually better at locating the tumor with ultrasound. For this reason, Surgeon B anticipated needing intraoperative IR assistance every time. While this was not required, OIG staff did not find this same team approach utilized at the Facility. A Facility IR was not scheduled for IORFA patients as described above. Several staff members stated that IRs and surgeons were often at odds on treatment options and best approaches to care, and the relationship was perceived to have challenges in reaching agreed-upon treatment plans.

Surgeon A began performing IORFA at the Facility in 2013, and the Chief of Surgery arranged for another surgeon (Surgeon C), who practiced at another VHA Facility, to be present during Surgeon A's procedures. The Chief of Surgery stated he assigned Surgeon C as a proctor or supervisor for Surgeon A from the beginning. The Chief of Surgery also said that Surgeon C was a mentor, assisted in procedures, and was "like an attending physician."

However, OIG staff learned that Surgeon C did not have experience in RFA and did not perform RFA. During the OIG interview, Surgeon C stated the understanding was to actively participate in Surgeon A's surgeries, not to supervise Surgeon A's procedures.

At the time of Surgeon A's hire in 2012, the Chief of Surgery implemented an FPPE. Surgeon A's FPPE contained documents from the Chief of Surgery showing five procedures were observed. While Surgeon A was given privileges to practice independently, OIG staff found the FPPE signed by the Chief of Surgery indicated that Surgeon A was supervised. OIG staff found no competency evaluation information from Surgeon C, who was identified by the Chief of Surgery as a proctor, in either the FPPE or OPPE.

Privileging

The OIG found Surgeon A's OPPE did not address specialty-specific competencies and contained incorrect/inaccurate data. Criteria defining expectations and quality outcomes for independent practice of complex surgical oncology cases was not specified or measured in Surgeon A's OPPE. OIG staff found data in Surgeon A's OPPE on the number of procedures, on-time starts for surgery rates, infection rates, EHR completion, malpractice claims, and use of antibiotics. While these types of data are important for general practice, it does not effectively monitor specialty practice outcomes. OIG staff did not find data specific to Surgeon A's oncology procedures.

[50] VHA Handbook 1400.01. A fellow is a resident physician who has completed residency training and the qualifications for independent practice, and is in training for an additional certification program.

In addition, the FPPE/OPPE documents showed Surgeon A was performing poorly based on data from indicators related to timeliness of antibiotics and EHR reviews. Data for these indicators from FYs 2012–2014 noted between 93–100 percent per quarter were not timely, and all five of the EHRs listed in the OPPE as reviewed were not compliant with Facility requirements every quarter for two years.

The Chief of Surgery did not make a notation in the OPPE of the poor performance data although he reviewed and signed the quarterly evaluation noting "excellent provider." OIG staff spoke to the Chief of Surgery who said the percentage was calculated inaccurately (number of compliant was used instead of number of noncompliant as noted on the form), so it did not trigger a focused review. The documents contained incorrect quarterly data calculations over a period of two years, and there was no documentation of the data as being inaccurate. The Chief of Surgery did not complete further analysis. As a result, the Facility could not monitor and identify concerns pertinent and specific to Surgeon A.

It is unclear how clinical managers were able to determine competency of Surgeon A when using a process with unreliable performance data. Because of data unreliability, OIG staff could not determine how the required FPPE/OPPE process confirmed the quality of care delivered or identified trends that impacted quality of care and patient safety.

The OIG found no VA guidelines, standards, or quality metrics related to outcomes of IORFA. The surgical quality nurse stated that the data she collected, that was required nationally for surgical oversight, was primarily general surgery. However, OIG staff reviewed relevant medical literature to identify measures that could have been used to evaluate Surgeon A's performance of RFA and determined that quality measures that could have been used included technique effectiveness and benchmarks for complications.

Patient Communications – Failure to Disclose

The OIG substantiated that Surgeon A told Patients 1 and 2 there was "residual" tumor, although these tumors were missed during IORFA. OIG staff also found that Surgeon A mischaracterized the outcome of IORFA for Patient 3.

Clinical and Institutional Disclosures

According to VHA Handbook 1004.08, *Disclosure of Adverse Events to Patients*, a clinical disclosure is a process by which the patient's physician meets with the patient or patient's representative to share that a harmful or potentially harmful adverse event occurred during the patient's care. An institutional disclosure is a formal process by which Facility leaders, together with physicians and others, as appropriate, inform the patient or the patient's personal representative that an adverse event occurred during the patient's care that resulted in, or is

reasonably expected to result in, death or serious injury, and provide specific information about the patient's and next of kin's rights and recourse.[51]

Clinical Disclosures

Facility Medical Staff Bylaws require providers to collaborate with patients in matters regarding personal health care and provide information necessary for patients to make care decisions that reflect their wishes.[52] The OIG determined that Surgeon A failed to provide Patient 1, Patient 2, and Patient 3 accurate IORFA outcomes. For example, although Patient 1's post-RFA MRI interpretation noted an ablation cavity and the previously identified tumor remained in its entirety after surgery, LTB members documented in Patient 1's record that the tumor identified on the MRI was "residual/recurrent disease." This was inaccurate. The targeted tumor was missed by IORFA. This documented inaccuracy enabled Surgeon A to misrepresent tumor information to Patient 1. Accurate information was necessary for Patient 1 to have a full understanding of the actual outcomes, ongoing risks, and benefits, and the option to select another provider or Facility for cancer care.

Institutional Disclosures

The OIG determined that tumors missed during IORFA met the VHA definition of adverse events and required consideration for institutional disclosures in the three patients reviewed, because Surgeon A's failure to ablate the tumors potentially harmed the patients and each patient required further interventions.[53]

Facility and QM leaders were unaware of these missed tumors and the misinformation given to patients. The LTB failed to accurately document in the EHR that tumors were missed. In these events, Surgeon A did not initiate or provide patient disclosures. The lack of documentation of the missed tumors was a contributing factor in the Facility and QM leaders' lack of awareness of patient care information necessary to provide appropriate institutional disclosures. Facility leaders and QM staff must ensure that staff understand what constitutes an adverse event and that there is a culture in which disclosures of adverse events is routine practice, ensuring they are performed openly and promptly.

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[51] VHA Handbook 1004.08.

[52] Facility Medical Staff Bylaws, Revised May 22, 2014. The Bylaws outline rules for the medical staff, and it includes the expectation that providers collaborate with patients in matters regarding personal health care and provide information necessary for patient to make care decisions that reflect their wishes.

[53] VHA Handbook 1004.08. Adverse events are "untoward incidents, diagnostic or therapeutic misadventures, iatrogenic injuries, or other occurrences of harm or potential harm directly associated with care…"

Issue 2: Surgical Oncologist Outcomes

The OIG substantiated that Surgeon A missed or partially missed HCC tumors in all three of the IORFA patients OIG staff reviewed. Two patients had missed tumors and one patient had a partially missed tumor. For 10 non-RFA oncologic surgeries performed by Surgeon A (that OIG staff reviewed), the OIG did not substantiate Surgeon A performed cancer surgery on patients who did not have cancer. The OIG did not substantiate that adverse events occurred during and after these 10 non-RFA surgeries done during 2015–2016.

Review of Patients' IORFA Procedures

OIG staff reviewed EHRs for three patients provided by the complainant, which included MRI images and reports and operative reports. Below are summaries of care for the three patients.

Patient 1

The OIG substantiated that Surgeon A missed Patient 1's targeted HCC liver tumor when performing IORFA in early 2016. Two months later, the post IORFA MRI showed a surgically created ablation cavity separate from the previously identified tumor, and the original tumor remained and had grown in size. This indicated Surgeon A missed the targeted tumor.

During interviews with the OIG, Surgeon A reported missing Patient 1's HCC tumor when performing IORFA in early 2016. Surgeon A described not being a "sharpshooter" and stated some tumors were difficult to visualize. Facility staff stated that liver tumors could be missed during IORFA because patients with HCC have "too small" or "lumpy livers," which can make visualizing the tumor by ultrasound more difficult.

Post operatively, Surgeon A documented that Patient 1's liver was "very cirrhotic" and that a larger opening was made to improve visualization. Because Surgeon A could not see the mass well, Surgeon A ablated the "entire area" several times "from lateral to medial" in an attempt to ensure complete ablation of the area.

Ablation cavities are expected to be at the target tumor site, not separate from it.[54] The post-IORFA MRI interpretation revealed an ablation cavity and separate from the ablation cavity was a 2.8 cm lesion that corresponded to the site of the previously identified tumor. The MRI interpretation also noted that the tumor had increased in size and "now demonstrated mild arterial enhancement." The MRI results indicated that Surgeon A missed the target tumor. Surgeon A told the patient the tumor was residual.

In spring 2016, an IR performed the percutaneous RFA and documented it was for the same tumor. Two months later, an MRI revealed that the tumor was effectively ablated, as the tumor

[54] Ablation cavity, as defined in this report, is the tissue destruction and subsequent anatomical void created by the RFA needle.

was gone. Patient 1 developed a new tumor at a different site several months later. OIG staff were unable to determine if Patient 1's HCC would have spread to additional sites if Surgeon A had accurately eliminated the initial tumor using IORFA in early 2016.

Patient 2

The OIG substantiated that Surgeon A missed Patient 2's target HCC liver tumor when performing IORFA in early 2016. OIG staff found results of an MRI, regularly scheduled after IORFA, which did not demonstrate effective ablation. The MRI showed that the ablation cavity extended above the tumor and did not ablate it. In addition, the MRI showed a tumor nearly doubled in size from the original description, a finding inconsistent with a successful procedure. Surgeon A told the patient that this missed tumor was residual.

Patient 2 developed another tumor at a later date. The OIG could not determine from the available evidence whether the patient would have subsequently developed additional site(s) of HCC had the initial single tumor been successfully ablated in early 2016.

Patient 3

The OIG substantiated that Surgeon A partially missed Patient 3's targeted HCC liver tumor when performing IORFA in early 2016. Patient 3 underwent IORFA, which was described in Surgeon A's operative report as directed to segment 6 of the liver. However, the MRI preceding the IORFA specified the tumor as being in segment 8, a different area of the liver. Results of the post-IORFA MRI did not coincide with effective ablation, which noted that a significant portion of the tumor remained post procedure. Later MRIs documented the tumor continued to grow. Patient 3 was seen at another VA Facility for routine care, where a provider noted that he was "lost to follow-up," referring to the RFA procedure follow-up.[55] After seven months, Surgeon A noted in the record that Patient 3 had a recurrent tumor.

The OIG determined that Patient 3's care was not coordinated following the unsuccessful IORFA ablation, which contributed to a delay in timely effective care, because the Facility did not have an accurate administrative tracking system to help coordinate the care of complex liver disease patients, particularly those with logistical challenges due to multiple points of care. Timeliness is essential for maximizing treatment when surgically managing a dynamic malignant process. The logistics of Patient 3's care were complicated by the involvement of multiple VA facilities, as well as receiving portions of care outside of VHA, which was not effectively tracked by the Facility.

[55] "Lost to follow-up" indicates that a patient was recommended for a follow-up appointment, but it was not completed and/or there was no documentation in the EHR regarding next steps for treatment or appointments.

Review of Patients' Non-RFA Procedures

For the 10 patients' non-RFA oncologic surgeries performed by Surgeon A that OIG staff reviewed, the OIG did not substantiate Surgeon A performed cancer surgery on patients who did not have cancer. The OIG did not substantiate that adverse events occurred during or through the three-month follow up after these non-RFA surgeries. The patients had lesions that were operated on for cancer or suspected cancer. Surgeries that were performed included

- Pancreatic lesions that increased in size under imaging surveillance,
- Pancreatic lesions in patients with a strong family history of cancers,
- Breast cancer removal close to the chest wall muscle,
- Revision to a previous pancreatic surgery to prevent further complications, and
- Metastatic neuroendocrine tumor of the pancreas.

OIG staff found that prior to all 10 procedures, Surgeon A documented discussions with patients that included rationale, potential complications, and alternatives prior to initiating a pre-operative evaluation for surgery. OIG staff found that seven surgeries had biopsies prior to surgery. Of the three that were not biopsied, one surgery was for a revision (no biopsy needed); one was a pre-surgical biopsy, which was offered but the patient declined; and one patient had an expanding pancreatic mass, and the recommendation for surgery would not have changed based on biopsy results.

OIG staff found that for four of the 10 surgeries, the removed tumors had positive margins, that is, the edges of the tumor revealed the presence of cancer cells. In three of the four surgeries, Surgeon A documented a discussion with the patient regarding the positive margins. In one case, OIG staff did not find specific reference to a discussion between Surgeon A and the patient regarding the positive margin. However, all four patients with positive tumor margins received further treatment with either chemotherapy or radiation therapy.

Conclusion

The OIG found that the Facility and the Surgery Service lacked oversight to identify events that required quality review, did not adequately monitor outcomes of patients with HCC managed with IORFA, and that there was limited awareness of patients who had tumors that were missed. These events were also not considered for clinical and/or institutional disclosures.

The OIG substantiated the Surgery Service's PR process did not follow VHA or Facility policy. The M&M failed to properly report, forward, and document accurate PR information to the PRC. The confidentiality of the peer reviewers was not protected as required.

The OIG found a lack of effective oversight of IORFAs for Surgeon A. A fundamental goal for clinical managers is to provide physician oversight that sustains and improves quality of care for patients. In order to effectively meet this goal, clinical managers must recognize deficiencies that may arise when clinical providers are underperforming in specific or broad categories. The Chief of Surgery was not fully aware of the shortcomings in Surgeon A's clinical performance (as demonstrated in patients discussed in this report).

The OIG found deficiencies in the Facility C&P, FPPE, and OPPE processes. The OIG could not determine if Surgeon A received senior staff supervision to ensure Surgeon A was competent to perform IORFA procedures on HCC tumors at the beginning of practice at the Facility. OIG staff found no written evaluation in the FPPE or OPPE by Surgeon C, who was identified by the Chief of Surgery as the proctor. OIG staff found no documentation of competency to perform IORFA on HCC tumors when Surgeon A began this practice at the Facility.

The OIG found data in Surgeon A's OPPE indicating poor performance and further internal analysis was not done. In addition, OPPE records did not contain specific data or analysis of information beyond general surgical data. As a result, the OIG could not determine how the required FPPE/OPPE process confirmed the quality of care delivered or identified trends that impacted quality of care and patient safety.

The OIG substantiated that Surgeon A told Patients 1 and 2 there was "residual" tumor, although these tumors were missed during IORFA. The OIG also found that Surgeon A mischaracterized the outcomes of IORFA for Patient 3.

The OIG found the Facility did not use an interdisciplinary approach to IORFA that could have improved visualization of tumors and possibly prevented poor outcomes. The OIG could not determine if the tumors in the three reviewed IORFA patients would have been successfully ablated had an IR been present; however, failing to employ IRs' expertise in the three patients reviewed may have contributed to Surgeon A's failure to successfully locate and ablate the HCC liver tumors.

The OIG substantiated that Surgeon A missed or partially missed HCC tumors in all three of the IORFA patients reviewed. While OIG staff acknowledge that liver tumors may be difficult to

visualize, the necessary interventions and oversight were not implemented to identify problems or improve outcomes. The OIG did not substantiate Surgeon A performed oncologic surgeries for patients who did not have cancer in the 10 non-RFA patients reviewed. These patients had lesions that were operated on for cancer, suspected cancer, or were at risk for cancer. The OIG did not substantiate that adverse events occurred during or after these 10 non-RFA surgeries.

Clinical managers had not documented their defined expectations for quality outcomes of IORFA or reviewed patients with missed tumors. Baseline performance measures are reported to VHA for every VA surgeon. However, this baseline data does not include more specific factors that may be necessary in assessing surgical quality of care competencies for specialty procedures performed. Had clinical managers specifically defined and measured RFA outcomes and addressed potential risks when implementing IORFA, they may have been able to prevent the poor outcomes listed in this report. This added leadership support may have helped Surgeon A succeed proactively.

Recommendations 1–9

1. The Veterans Integrated Service Network Director ensures that the Facility's credentialing and privileging program is reviewed for integration of key functions of quality oversight, including the use of quality data for Focused Professional Practice Evaluation and Ongoing Professional Practice Evaluation processes and surgical Peer Review program.

2. The Facility Director ensures that the Facility Peer Review program meets all Veterans Health Administration requirements.

3. The Facility Director ensures that Surgery Service's professional practice evaluations include performance data to support provider privileges and contain accurate data.

4. The Facility Director ensures that a process is developed and implemented to document, report, and track patient cases discussed in the Liver Tumor Board and that meeting minutes are completed and forwarded to oversight groups.

5. The Facility Director ensures that a process is implemented to track, monitor, and report intraoperative radiofrequency ablation outcomes to Facility and Quality Management leaders.

6. The Facility Director ensures that the Office of General Counsel is consulted on the three patients with missed or partially missed tumors after intraoperative radiofrequency ablation to determine if institutional disclosure might be appropriate.

7. The Facility Director ensures that the five additional intraoperative radiofrequency ablation patients the Office of Inspector General referred to the Facility, and any other patients who had intraoperative radiofrequency ablation done by Surgeon A, are reviewed by clinicians with qualifications to assess the outcome of these procedures and actions taken as appropriate.

8. The Facility Director ensures an external review of intraoperative radiofrequency ablation processes is obtained to identify possible causes of missed tumors and methods to improve practice and outcomes.

9. The Facility Director ensures that Human Resources and the Office of General Counsel are consulted to determine the appropriate actions, if any, including consideration for ethics review, for staff who were not forthcoming with patients on outcomes of intraoperative radiofrequency ablation.

Appendix A: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: April 25, 2018

From: Director, New York/New Jersey VA Healthcare Network (10N2)

Subj: Healthcare Inspection—Intraoperative Radiofrequency Ablation and Other Surgical Service Concerns, Samuel S. Stratton VA Medical Center, Albany, New York

To: Director, Denver Office of Healthcare Inspections (54DV)
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the OIG report, Healthcare Inspection—Intraoperative Radiofrequency Ablation and Other Surgical Service Concerns, Samuel S. Stratton VA Medical Center, Albany, New York. I concur with the report findings and recommendations.
2. If any additional information is needed, please do not hesitate to contact Pam Wright, VISN 2 QMO, at 718-741-4143.

(Original signed by:)
Joan E. McInerney, MD, MBA, MA FACEP
Director, New York/New Jersey VA Healthcare Network (10N2)

Comments to OIG's Report

Recommendation 1

The Veterans Integrated Service Network Director ensures that the Facility's credentialing and privileging program is reviewed for integration of key functions of quality oversight, including the use of quality data for Focused Professional Practice Evaluation and Ongoing Professional Practice Evaluation processes and surgical Peer Review program.

Concur.

Target date for completion: June 30, 2018

Director Comments

A comprehensive review is being conducted by Veterans Integrated Service Network Quality Management of the Facility's credentialing and privileging program to include integration of key functions of quality oversight, including the use of quality data for Focused Professional Practice Evaluation and Ongoing Professional Practice Evaluation processes and surgical Peer Review program. Review results will be reported to the Veterans Integrated Service Network Quality, Safety and Value Committee with any identified needed improvements followed until closure.

Appendix B: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: April 25, 2018

From: Director, Samuel S. Stratton VA Medical Center (528A8/00)

Subj: Healthcare Inspection—Intraoperative Radiofrequency Ablation and Other Surgical Concerns, Samuel S. Stratton VA Medical Center, Albany, New York

To: Director, New York/New Jersey VA Health Care Network (10N2)

I have reviewed and concur with the findings and recommendations in the OIG report, Healthcare Inspection—Intraoperative Radiofrequency Ablation and Other Surgical Service Concerns, Samuel S. Stratton VA Medical Center, Albany, New York.

(Original signed by:)

Darlene Delancey, MS
Medical Center Director

Comments to OIG's Report

Recommendation 2

The Facility Director ensures that the Facility Peer Review program meets all Veterans Health Administration requirements.

Concur.

Target date for completion: Completed November 30, 2017

Director Comments

To ensure that the Facility Peer Review program meets all Veterans Health Administration requirements, Surgery Service cases considered for review are identified by the Risk Manager or Service Chief and discussed with the Chief of Staff at a weekly meeting. The Risk Manager will notify the Service Chief if the case will be peer reviewed internally or externally. If the case is peer reviewed externally, the case may be presented to the Morbidity and Mortality conference at the next meeting. If the case is reviewed internally, the Risk Manager will notify the Service Chief when the internal peer review is completed, so that it can then be placed on the Morbidity and Mortality conference agenda.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 3

The Facility Director ensures that Surgery Service's professional practice evaluations include performance data to support provider privileges and contain accurate data.

Concur.

Target date for completion: June 1, 2018

Director Comments

The service chiefs have worked with the credentialing and privileging office to update privileges for all providers in the Facility to create Core + privileges to meet Joint Commission requirements. The privileges will include core/specific privileges and also special privileges. The Focused Professional Practice Evaluation (FPPE) and Ongoing Professional Practice Evaluation (OPPE) of the surgeons that have special privileges were updated to include case reviews and quality data. The changes were made to the privileges and FPPE/OPPE information and will be voted on during the April 25, 2018 Executive Committee of the Medical Staff (ECMS) meeting

for concurrence. For providers that do not have a like provider in the Facility, the OPPE and FPPE will be sent to a like provider in the VISN.

Recommendation 4

The Facility Director ensures that a process is developed and implemented to document, report, and track patient cases discussed in the Liver Tumor Board and that meeting minutes are completed and forwarded to oversight groups.

Concur.

Target date for completion: June 1, 2018

Director Comments

A process has been developed and is being implemented to document, report, and track all cases presented to the Liver Tumor Board. Stratton VAMC has hired two registered nurses for positions as Cancer Care Case Managers to track all liver tumor board cases from diagnosis on. The process to be used has been adopted from the VISN 2 Regional Liver Tumor Board which has been recognized as the source of best practices for such regional tumor boards within the VA nationally. Cancer Care Case Managers or a Quality Management representative will attend all Liver Tumor board meetings and refer any cases which might meet the need quality review to the Risk Manager.

Recommendation 5

The Facility Director ensures that a process is implemented to track, monitor, and report intraoperative radiofrequency ablation outcomes to Facility and Quality Management leaders.

Concur.

Target date for completion: August 31, 2018

Director Comments

All radiofrequency ablations will be discussed in Liver Tumor Board. If the consensus of the board is for an intraoperative radiofrequency ablation, the case will be sent to the VISN chief surgical consultant for review to determine if he or she concurs that intraoperative radiofrequency ablation is preferable to image-guided radiofrequency ablation. The tracking, monitoring and reporting intraoperative radiofrequency ablation outcomes will be presented at the Comprehensive Cancer Committee quarterly which reports to the Local Leadership Council.

Recommendation 6

The Facility Director ensures that the Office of General Counsel is consulted on the three patients with missed or partially missed tumors after intraoperative radiofrequency ablation to determine if institutional disclosure might be appropriate.

Concur.

Target date for completion: May 30, 2018

Director Comments

The Office of General Counsel was consulted on the three patients identified. Management Review of the cases resulted in findings of two of the three cases where the target lesion was missed during intraoperative ablation. The two patients will be contacted by the Risk Manager to facilitate Institutional Disclosure to be completed by Facility leaders.

Recommendation 7

The Facility Director ensures that the five additional intraoperative radiofrequency ablation patients the Office of Inspector General referred to the Facility, and any other patients who had intraoperative radiofrequency ablation done by Surgeon A, are reviewed by clinicians with qualifications to assess the outcome of these procedures and actions taken as appropriate.

Concur.

Target date for completion: Completed November 30, 2017

Director Comments

A full management review was conducted by the VISN chief surgical consultant in November 2017. There were 11 cases reviewed. As a result of these reviews, the VISN Chief Surgical Consultant recommended the Liver Tumor Board process regarding decisions needs to be changed so that any recommendation for intraoperative radiofrequency ablation would have a second level review by the VISN Chief Surgical Consultant and that no intraoperative radiofrequency ablation would be undertaken without their concurrence.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 8

The Facility Director ensures an external review of intraoperative radiofrequency ablation processes is obtained to identify possible causes of missed tumors and methods to improve practice and outcomes.

Concur.

Target date for completion: Completed November 30, 2017

Director Comments

The VISN Chief Surgical Consultant review recommended that the Liver Tumor Board establish a process regarding decisions so that any recommendation for intraoperative radiofrequency ablation would have a second level review by the VISN Chief Surgical Consultant and that no intraoperative radiofrequency ablation would be undertaken without their concurrence.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

Recommendation 9

The Facility Director ensures that Human Resources and the Office of General Counsel are consulted to determine the appropriate actions, if any, including consideration for ethics review, for staff who were not forthcoming with patients on outcomes of intraoperative radiofrequency ablation.

Concur.

Target date for completion: Completed July 31, 2018

Director Comments[56]

The recommendation for intraoperative radiofrequency ablation verses image guided radiofrequency ablation was made at Liver Tumor Board. A management review was completed by the VISN Chief Surgical Consultant and determined that image guided ablation is the preferred approach; two cases where intraoperative radiofrequency ablation missed a target lesion were identified.

The Facility requested their local Consultative Ethics team review the cases. Local Consultative Ethics consulted with National Ethics who concluded the matter was beyond their scope. The

[56] The OIG received the Facility Director's response to Recommendation 9 on July 30, 2018.

Office of General Counsel was then consulted for an ethics review; the matter was assigned to local General Counsel. An in-depth review was completed by local General Counsel in collaboration with Human Resources. The conclusion was there is no evidence of intentional or negligent misrepresentation of the clinical condition to the patients, and no basis for further ethical or disciplinary referral.

A process change has been implemented and requires any recommendation for intraoperative radiofrequency ablation have a second level review by the Chief Surgical Consultant for concurrence before this procedure may take place. Staff were re-educated about the fact that consideration for Institutional Disclosure was warranted in relationship to these cases, along with the proper channels to assure this occurs. Following the investigation, Institutional Disclosure was conducted to one of the two Veteran's involved; one Veteran's family declined.

OIG Comment

The Facility provided sufficient supporting documentation, and the OIG considers this recommendation closed.

OIG Contact and Staff Acknowledgments

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