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Office of Inspector General

Healthcare Inspection

Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, Pennsylvania and Other VA Medical Centers

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Executive Summary

Introduction

On May 5, 2008, a patient of Philadelphia, PA VA Medical Center (PVAMC) underwent prostate brachytherapy in treatment for prostate cancer. The patient was inadvertently implanted with radioactive seeds of 0.38 millicurie (mCi)/seed activity when the implanting radiation oncologist had prescribed seeds of 0.509 mCi/seed activity. This error was discovered seven days later and set in motion a chain of events that ultimately led to suspension of PVAMC's prostate brachytherapy program, a review of all PVAMC prostate brachytherapy treatments since PVAMC had begun performing the procedure in February 2002, and reviews by numerous Federal and VA oversight entities, most particularly the U.S. Nuclear Regulatory Commission (NRC).

In June 2009, after two articles in large metropolitan newspapers prominently reported a number of the aforementioned events, a U.S. Senate field hearing was held at PVAMC to examine errors in prostate brachytherapy there. At this time, VA's Secretary and Congress requested a review by VA's Office of Inspector General (OIG) and in July 2009, the U.S. House of Representatives Committee on Veterans Affairs held a hearing in Washington, D.C., to address these same issues.

In response to the above concerns, OIG's Office of Healthcare Inspections (OHI) reviewed specific concerns outlined in Congressional, media, and other reports; PVAMC's performance of prostate brachytherapy in the treatment of prostate cancer during the seven year period of 2002-2008; PVAMC's contractual relationship with the University of Pennsylvania which provided brachytherapy services for PVAMC; and the overarching performance of brachytherapy within VHA. To accomplish this, OHI inspectors visited PVAMC on June 29–July 2, October 13–15, and December 15–16, 2009, and March 15-16, 2010. OHI also visited Brooklyn, NY VAMC on September 3, 2009 and Jackson, MS VAMC on November 3-5, 2009. In addition to these site visits, extensive documentation associated with the performance of brachytherapy at PVAMC and VHA as a whole was reviewed.

Post-implantation CT-based dosimetry is considered an essential component of prostate brachytherapy because it is the only method of assessing the actual dose delivered to the prostate and normal surrounding structures. We assessed the dosimetry outcomes for all VHA prostate brachytherapy programs that were active during any period of FY 2005-2009. We analyzed the clinical outcomes of cancer recurrence, biochemical failure (PSA relapse), and complications (toxicity) after prostate brachytherapy for PVAMC patients and biochemical failure for Jackson VAMC prostate brachytherapy patients.

Results and Conclusions

PVAMC Wrong Seed Case: OHI found that the cause of the May 5, 2008, incident in which a patient received I-125 seeds of 0.38 mCi strength, when the implanting radiation oncologist intended seeds of 0.509 mCi strength was that a *pre-printed computer-generated* template called for 0.38 mCi seeds favored by PVAMC Radiation Oncologist 1, the radiation oncologist who performed most of PVAMC's brachytherapy procedures, when it was Radiation Oncologist 2, who preferred 0.509 mCi seed strength, that performed the May 5 implant. No one at PVAMC or elsewhere revised the pre-printed template accordingly, and 0.38 mCi seeds were ordered from the manufacturer and ultimately implanted. This was an isolated occurrence.

Alleged Medical Records Alteration at PVAMC: OHI did not substantiate the allegation of medical records alteration. We found no evidence of medical record falsification in either electronic or paper medical records.

PVAMC Quality Management: OHI found that quality management (QM) processes pertaining to PVAMC's practice of prostate brachytherapy were deficient. From 2002 to 2006, no peer review or quality assessments took place at PVAMC for prostate brachytherapy. We also did not find any prostate brachytherapy cases that were referred for case conferences or morbidity and mortality conferences in this time period. While PVAMC's radiation oncologists had been appropriately credentialed, at re-privileging we found no specific data that actually demonstrated observation, critique, or statistics that could be evidence of ongoing proficiency in performing brachytherapy. We identified two examples of problems identified by PVAMC's Radiation Safety Committee (RSC) which the RSC failed to track to resolution. Overall, we concluded that QM deficiencies of this nature deprived PVAMC of an opportunity to identify possible problems with its prostate brachytherapy implants prior to May 5, 2008.

PVAMC Computer Systems: We confirmed that for a period of twelve months the VariSeed™ treatment planning system used in prostate brachytherapy could not receive CT images because of a network connectivity issue. There was also a failure at PVAMC to isolate the VariSeed™ computer from other operating systems and inappropriate transfers of information using unsecured media, although we found no evidence that actual patient personal information was compromised or misused. We concluded that relatively simple computer hardware and software problems resulted in 17 PVAMC patients during a 12-month time period not having post prostate brachytherapy dosimetry studies. We concluded that the problem should have been fixed far more expeditiously than was the case.

PVAMC Clinical Outcomes: Recurrence and disease-relapse rates of PVAMC prostate brachytherapy patients appear within the norm. The Kaplan-Meier overall 5-year recurrence-free rate is 90 percent and the 7-year is 86 percent. The 6-year recurrence-

free rate is 91 percent for patients diagnosed with low risk diseases, significantly higher (p=0.0001) than 64 percent for patients diagnosed with intermediate or high risk diseases. The Kaplan-Meier overall 7-year freedom from both recurrence and PSA relapse rate is 82 percent. The 6-year disease-free rate is 88 percent for patients with low risk diseases, compared with 54 percent for patients with intermediate or high risk diseases (p=0.0016). In 2007, Zelefsky et al. reported multi-institutional analysis of 8-year PSA relapse-free survival as follows:

- 74 percent for low-risk patients,
- 61 percent for intermediate-risk patients, and
- 39 percent for high-risk patients.

Our analysis indicates that the dosimetric outcome D90 (a calculated value that reflects the minimum dose of radiation absorbed by 90 percent of the prostate) does not correlate with either recurrence or disease-relapse (recurrence or PSA relapse by nadir +2 criteria) in the population of PVAMC prostate brachytherapy patients. Although some studies (Stock et al. 1998; Potters et al. 2001; and Zelefsky et al. 2007) showed an association between dose and response, this lack of association has been reported by others (Morris et al. 2009; Ash et al. 2006, and Lee et al. 2005). The data does not permit us to analyze the dose and response association by patient risk group at this time.

Complication and adverse event rates for the 114-patient PVAMC prostate brachytherapy patient cohort were not excessive. Four patients of the 114 treated with prostate brachytherapy had died as of December 31, 2009. Our review revealed that none of these four patients died as a result of an adverse event from prostate brachytherapy and none died from prostate cancer. We looked at two additional complications that had clear endpoints: urethral strictures and serious rectal complications causing excessive bleeding and/or requiring an operation. The incidence of urethral strictures was 7.9 percent. This percentage is within the *American College of Radiology's Appropriateness Criteria® [for] permanent source brachytherapy for prostate cancer* published rate of 1 – 12 percent. Of 16 patients with documented radiation proctitis/proctopathy or rectal ulceration, we found that four met the NIH adverse events (AE) classification criteria for serious (NIH Grade 3 or Grade 4) toxicity. The incidence (3.5 percent) of Grade 3 or above rectal AEs is consistent with other data cited in the literature.

<u>PVAMC Medical Events:</u> Employing a D90 metric, PVAMC had reported 97 cases to the NRC as being "medical events" in which patients received either too little radiation to the prostate or excessive radiation to surrounding tissues and organs. In 2009, VHA's Advisory Panel for Prostate Brachytherapy promulgated new medical event criteria. Utilizing these criteria, VHA asserted that of 105 evaluable patient implants, 17 should be considered as medical events. NRC did not accept VHA's proposed new definition of a medical event.

VHA Assessment: Fifteen VA medical facilities had an active prostate brachytherapy program during some period of FY2005-2009. As of March 12, 2010, eight VA medical facilities continue their prostate brachytherapy program. The American Brachytherapy Society (ABS) recommended that post-implantation dosimetry should be performed on all patients undergoing permanent prostate brachytherapy in 2000 (Nag et al. 2000). In particular, it specified that a dose-volume histogram of the prostate should be performed and the D90 (percent) reported by all prostate brachytherapy programs. We found that Jackson and Cincinnati VAMC prostate brachytherapy programs did not follow the ABS recommendation to perform post-implant dosimetry as a component of prostate brachytherapy prior to 2008.

Over the period of FY 2005-2009, average D90s of most VAMCs were in the range of 90-110 percent. Two VAMCs consistently had D90s over 110 percent. However, the average D90s were under 80 percent of the prescription doses for Durham VAMC in FY2005, Philadelphia VAMC in FY 2005-2006 and FY2008, Washington DC VAMC in FY 2006-2008, and Jackson VAMC for all FY 2005-2008.

PVAMC Contract Review: We concluded that from between May 1, 1999 through April 25, 2005, PVAMC paid the University of Pennsylvania for radiation therapy services without a contract or other agreement authorizing payment for these services. From April 26, 2005, through 2009, VA paid for radiation therapy services under an Interim Agreement that violated VA policy.

Jackson, MS VA Medical Center: We had concerns about prostate brachytherapy as practiced at Jackson VAMC (JVAMC). We found substantial problems with JVAMC's QM processes and information-technology systems. JVAMC did not routinely perform post-implantation dosimetric evaluation as a component of prostate brachytherapy treatment. Independent review shows low delivered dose coverage (D90). Overall 4-year PSA relapse-free survival at JVAMC was 92 percent. No further analyses were conducted because of the short follow-up time interval.

Recommendations

Recommendation 1: VHA's National Director of Radiation Oncology Programs should have sufficient resources, to ensure that VHA provides one high quality standard of care for the prostate brachytherapy population. To achieve this end, VHA should standardize, to a practical extent, the privileging, delivery of care, and quality controls for the procedures required to provide this treatment.

Recommendation 2: VHA should take the steps required to ensure that patients who received low radiation doses in the course of brachytherapy be evaluated to ensure that their cancer treatment plan is appropriate.

Recommendation 3: VHA should review the controls that are in place to ensure that VA contracts for healthcare comply with applicable laws and regulations, and where necessary, make the required changes in organization and/or process to bring this contracting effort into compliance.

Recommendation 4: Senior VA leadership should meet with Senior NRC leadership to determine if there is a way forward that will ensure the goals of both organizations are achieved.

Recommendation 5: VHA should work with the OIG to develop a list of documents that should routinely be provided to the OIG when an outside agency is notified of a (possible) untoward medical event.

Comments

The Under Secretary for Health concurred with the findings and recommendations. See Appendix D (pages 96–99) for the full text of his comments.

We will follow up on the corrective actions until all recommendations have been fully implemented.

(original signed by:)
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Assistant Inspector General for
Healthcare Inspections

Introduction

Purpose

On May 5, 2008, a patient of Philadelphia VA Medical Center (PVAMC) underwent a treatment for prostate cancer known as brachytherapy. This procedure entails the implantation of radiation emitting seeds into, and sometimes around, the prostate gland. These implanted seeds are minuscule titanium capsules impregnated with iodine-125 (I-125), a radiation emitting isotope[1] of elemental iodine. Radiation emitting seeds are manufactured in varying strengths (activities), and PVAMC's May 5, 2008, patient was inadvertently implanted with seeds of one activity when the implanting radiation oncologist believed the seeds to be of another activity. This medical error was discovered 7 days later.

This discovery set in motion a chain of events that ultimately led to a review of all PVAMC prostate brachytherapy treatments since PVAMC had begun performing the procedure in February 2002; placement of PVAMC's brachytherapy program on indefinite suspension; and a series of inspections and reviews by numerous Federal and state oversight entities including, but not limited to, the U.S. Nuclear Regulatory Commission (NRC), the Veterans Health Administration's (VHA's) National Health Physics Program (NHPP), VHA's Clinical Risk Assessment Advisory Board (CRAAB), a VHA Administrative Board of Investigation (ABI), and VHA's National Center for Patient Safety (NCPS). Monitoring by these bodies continues to this day.

On June 21, 2009, two articles in large metropolitan newspapers prominently reported the aforementioned events and detailed additional serious allegations about the quality and safety of PVAMC's prostate brachytherapy program. On June 29, 2009, a U.S. Senate field hearing was held at PVAMC to examine errors in prostate brachytherapy there, and at this time VA's Secretary and Congress requested a review by VA's Office of Inspector General (OIG). On July 22, 2009, the Senate field hearing was followed by a U.S. House of Representatives Committee on Veterans Affairs hearing in Washington, D.C., to address these same issues.

The purpose of this report is to review PVAMC's practice of prostate brachytherapy from that institution's start of a prostate brachytherapy program in 2002 through the program's suspension in 2008. Further, this review addresses relevant events after the 2008 program closure to the present. Finally, in that brachytherapy is performed at a relatively small number of VAMCs, we report on system-wide data in an attempt to determine whether problems indentified at PVAMC were systematic in nature.

[1] Atoms of the same element that have different numbers of neutrons. http://www.colorado.edu/physics/2000/isotopes/index.html [11/23/2009]

Background

A. Philadelphia VAMC

PVAMC is a tertiary care facility located in downtown Philadelphia. It serves as one of the ten VAMCs that comprise Veterans Integrated Service Network (VISN) 4, the "VA Stars & Stripes Healthcare Network." VISN 4 covers all or parts of six states: Pennsylvania, West Virginia, Delaware, New Jersey, New York, and Ohio (see Figure 1).[2]

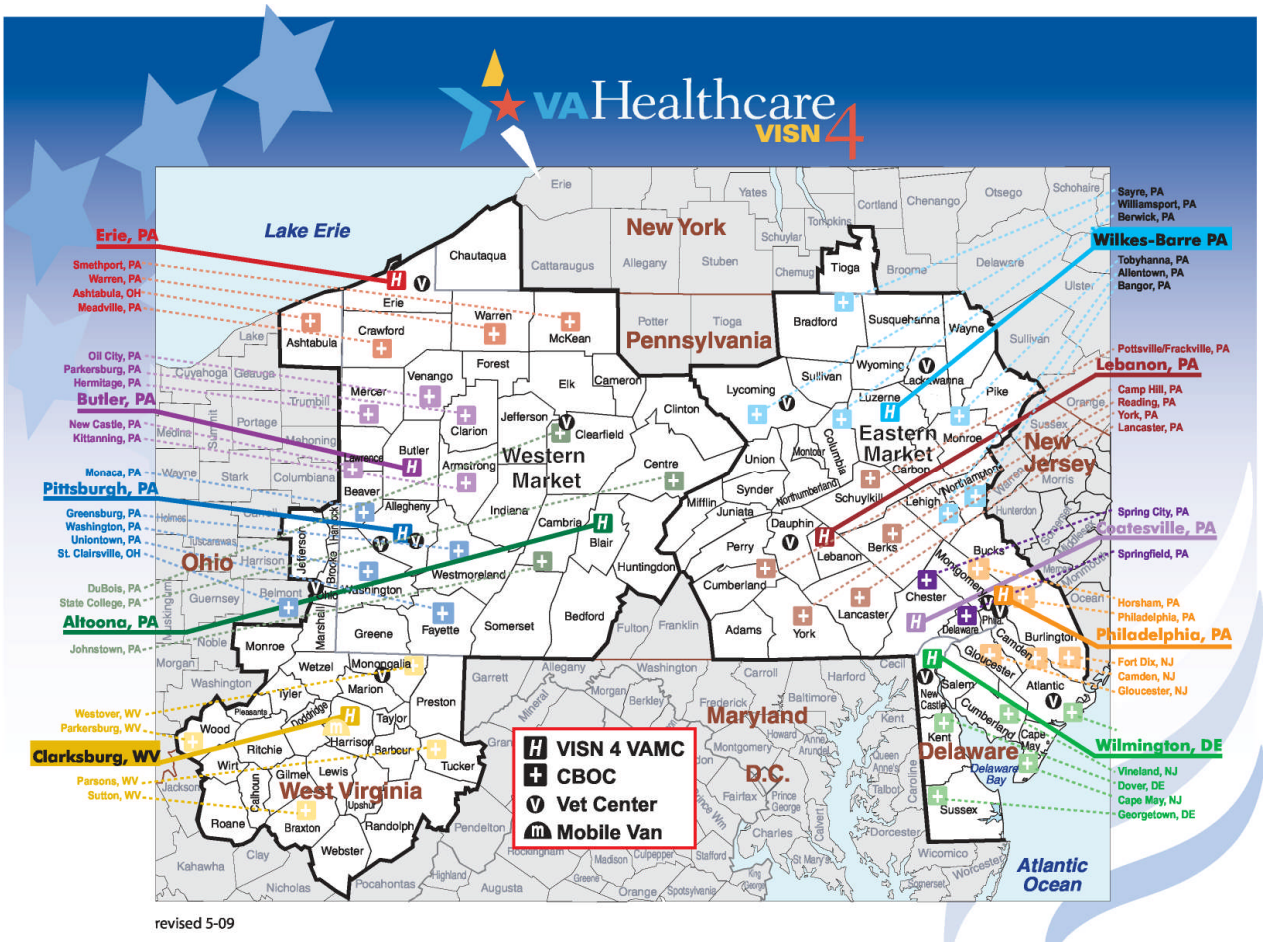


Figure 1: *VISN 4: The VA Stars & Stripes Healthcare Network*[3]

PVAMC was the only VISN 4 facility performing prostate brachytherapy and patients came from a multitude of locations within VISN 4. Those living in the metropolitan Philadelphia area typically received the majority of their care, including the implant procedure and its follow-up, at PVAMC. If referred from another part of VISN 4, the procedure was performed at PVAMC. The procedure was then followed by a one-day

[2] Altoona, Butler, Coatesville, Erie, Lebanon, Philadelphia, Pittsburgh, and Wilkes-Barre, PA VAMCs; Wilmington, DE VAMC; and Clarksburg, WV VAMC. http://www.visn4.va.gov/Who_We_Are.asp [accessed 11/27/2009].
[3] http://www.visn4.va.gov/docs/VISN4_FacilityMap_June09.pdf

overnight stay on PVAMC's Urology Service, performance of a post-operative Day 1 CT scan, and discharge. Long-term follow-up was performed at the referring VAMC, often in conjunction with PVAMC.

PVAMC is located near the University of Pennsylvania and its extensive medical complex. It is affiliated with the University of Pennsylvania's Schools of Medicine, Nursing, and Dental Medicine.[4] According to its web site, it supports 145 acute care beds and a 135-bed nursing home. Additionally, PVAMC serves as the parent center for five VA community-based outpatient clinics (CBOCs) located in Center City Philadelphia; Horsham, PA; Fort Dix, NJ; Camden, NJ; and Gloucester County, NJ. In 2008, PVAMC had 417,018 visits by 48,786 different patients.[5]

B. Prostate Cancer

1. Epidemiology and Diagnosis of Prostate Cancer

Cancer of the prostate is the second most prevalent male cancer in the United States, second only to skin cancer. The National Cancer Institute estimated that in 2009 in the United States there would be 192,280 new cases diagnosed and 27,360 deaths from the disease.[6] VHA medical centers diagnose approximately 12,000 new cases of prostate cancer yearly. The disease is of particular concern to the VA health care system because VA patient demographics embrace the most vulnerable patients for this disease, i.e., older men. Also, the Institute of Medicine has concluded that there is a suggestive (although inconclusive) linkage between exposure to Agent Orange and prostate cancer in Agent Orange exposed veterans which is compensable by VA.[7]

Prostate cancer screening with serum prostate specific antigen (PSA) and digital rectal examination (DRE) commonly detects prostate cancer before the presence of symptoms. When symptomatic, prostate cancer may present as frequent urination during the day or night, and/or burning or bleeding with urination or ejaculation. Rectal discomfort or bleeding may also occur in patients with advanced disease. Symptoms such as bone pain, weakness, or numbness, particularly in the lower back, hips, and legs are suggestive of tumor spread to bone. The diagnosis of prostate cancer is made through the identification of cancer cells on tissue samples (biopsies) obtained from the prostate. Based on the pattern of disease under a microscope the prostate cancer is assigned a Gleason score. Gleason scores are a measure of a cancer's aggressiveness and can range in value from 2 to 10.

[4] http://www.philadelphia.va.gov/
[5] Web site, accessed 4/13/2010, states higher numbers: "More than 90,000 Veterans are enrolled for health care at PVAMC, with nearly 60,000 receiving care in 2008."
[6] 2010 estimates are pending.
[7] Terris MK, "Agent Orange and Prostate Cancer: Fact or Fiction?," Stanford University School of Medicine, Urology: http://urology.stanford.edu/about/articles/agentorange.html [accessed 3/22/2010].

Three major factors are used to estimate the risk of spread and recurrence: PSA, DRE, and Gleason score. A PSA level less than 10 nanograms/milliliter (ng/mL) is low, 10 to 20 ng/mL is intermediate, and greater than 20 ng/mL is high. Extracapsular penetration or seminal vesicle involvement on DRE are signs of advanced disease. A Gleason score of 6 or less is low, 7 is intermediate, and 8-10 is high. Patients are categorized in risk groups using these three factors: low-risk, intermediate-risk, and high-risk. Risk groupings aid physicians in discussing treatment options and prognosis with patients.

The success of treatment may be measured by the response of PSA. PSA values are expected to decline following treatment and can typically continue to decline for a period of approximately 2 to 3 years. During this time, however, benign rises in PSA that later decline and stabilize can occur. These rises can be as large as 2 ng/mL in 15% of patients. PSA levels that continue to rise, however, are worrisome for persistent or recurrent disease and the patient's clinician must carefully consider the possibility of a cancer recurrence.

2. Prostate Cancer Treatment Modalities

A man with newly diagnosed prostate cancer has a variety of treatment options, with generally more options available the earlier the stage of the cancer at diagnosis. Well-established treatment modalities include radiation therapy, surgery, and hormone therapy. Several newer and experimental modalities including cryosurgery and cryotherapy are also available. Furthermore, prostate cancer is unusual among cancers in that one option available, particularly in early-stage prostate cancer, is to monitor the cancer without intervention ("watchful waiting" or "active surveillance"). Overall, a variety of factors can and should influence physician recommendation and patient choice in addressing newly diagnosed prostate cancer.

From the time of Wilhelm Roentgen's discovery of x-rays in late 1895 followed several months later by Henri Becquerel's discovery of radiation emitting radioactive elements in February 1896, it was quickly recognized that both of these forms of radiation damage or kill living tissue. If such radiation could harm normal cells, it stood to reason that diseased cells — such as cancer cells — could also be damaged and killed by radiation.[8] Modern radiation therapy takes advantage of this observation, and thus, both external beams of radiation (EBR) and internally placed sources of radiation (brachytherapy) as cancer therapy trace their early origins to the turn of the twentieth century. In treating prostate cancer, radiation may be delivered as an external beam of radiation to the patient's prostate, or by inserting seeds containing radioactive elements into and around the cancerous prostate (prostate brachytherapy). The two methods may also be used in combination. According to the Office of the VHA National Director of Radiation

[8] One source writes: In July 1903 Alexander Graham Bell ... wrote to a physician who was experimenting with radium treatments, "There is no reason why a tiny fragment of radium sealed up in a fine glass tube should not be inserted into the very heart of the cancer, thus acting directly upon the diseased material. Would it not be worthwhile making experiments along this line?" (Peter Grimm. John Blasko. John Sylvester, editors. *The Prostate Cancer Treatment Book*. McGraw-Hill. 2003.)

Oncology Programs, of the 12,000 cases of prostate cancer diagnosed yearly in VHA, approximately one-fourth (3,000) of patients opt to undergo radiation therapy, of which about one-fourth (750) are treated with prostate brachytherapy.

C. Brachytherapy in VHA

1. Overview

Fifteen VA medical centers have or recently had brachytherapy programs. As best as can be ascertained from interviews and available documentation, the ability to offer brachytherapy as a treatment option for veteran patients with early stage prostate cancer was seen within VAMC radiation oncology units to be a natural progression of available cancer therapies within a field of medicine undergoing constant change and innovation. As such, brachytherapy programs within VHA appear to have developed more at the VISN and at the level of individual VAMCs than through centralized VA headquarters planning. In the late 1990s, medical centers began performing brachytherapy and the earliest sites offering this treatment were the Boston, Cincinnati, Richmond, San Francisco, and Seattle VAMCs. The performance of brachytherapy within VHA then appeared to have spread more or less on a VISN by VISN basis such that, within VHA's overall total of 33 radiation oncology programs, most VISN's have at least one site that performs brachytherapy.

Currently, nationwide oversight of brachytherapy resides with VHA's National Director of Radiation Oncology Programs. However, this is a relatively new full-time position, the current occupant having held it since January 2009. His predecessor held the position in a part-time capacity for approximately one year before January 2009. Prior to that, VACO oversight of radiation oncology was exercised under the auspices of VHA's Chief Consultant, Diagnostic Radiology Services.

Three VA medical centers, Richmond, VA VAMC; Cincinnati, OH VAMC; and Seattle, WA VAMC have performed approximately 75% of all brachytherapy within VHA. Most, but not all, VHA brachytherapy programs are affiliated with a university medical school.

2. Prostate Brachytherapy at Philadelphia VAMC

History

Testimony to OHI indicated an interest in the late 1990s in performing brachytherapy at PVAMC. There is no single document indicating a VISN 4 or VA Central Office directive to implement a brachytherapy program at PVAMC. However, ultimately, in or around early 2001, VISN 4 gave approval to begin such a program. A February 5, 2001, letter from PVAMC's Surgical Care Product Line vice-president to a senior urologist at the University of Pennsylvania Health System indicates that the program was, "apparently recently approved by the VISN [4] director." Also, both NRC and NHPP

inspections from 2001 indicate anticipation that PVAMC will soon begin performing brachytherapy.

In 2001, draft prostate brachytherapy protocols were circulated at PVAMC, on January 14, 2002, a patient underwent transrectal ultrasound in preparation for the procedure, and on February 25, 2002, the first prostate brachytherapy implant at PVAMC was performed.

Process

Patients had a diagnosis of prostate cancer made by screening and biopsy at PVAMC if they received their ongoing primary care at that facility, or at another VISN 4 facility if they lived elsewhere in the VISN 4 catchment area. An initial workup was typically conducted by primary care, internal medicine, and urology physicians. After a biopsy-proven diagnosis of prostate cancer was made, if a patient was a prostate brachytherapy candidate and interested in considering this treatment modality, he was referred to PVAMC's Radiation Oncology Service where a consultation could take place and the patient's options reviewed.

If the patient was a possible candidate for an implant and continued to express interest in the procedure, "sizing" was performed by PVAMC's Urology Service. This "sizing" process allowed for further patient selection and/or pre-treatment. If the prostate was excessively large, the patient might not be a candidate for brachytherapy, or he might be a candidate for several months of neoadjuvant hormone treatment to shrink the prostate down to implant size (approximately 55 grams or less). Selection criteria *guidelines* included:

1. Stage T1, T2 prostate cancer.
2. PSA less than 10.
3. Gleason score ≤ 6, but with some cases Gleason score = 3+4.
4. Prostate size less than 55 gms on transrectal ultrasound.
5. Good performance status.
6. Age 60 years or greater.
7. American Urological Association Prostate Symptom Score of 15 or less.[9]

If the decision to embark upon prostate brachytherapy was made, a pre-plan was prepared using ultrasound images of the prostate. The gland was contoured and the VariSeed™ Treatment Planning System (TPS), a software package that allows the radiation oncologist to delineate the prostate borders, determine its volume, and calculate the number of seeds required for maximum treatment effectiveness, was used.

Patients ultimately determined to be candidates for implant therapy also had a surgical pre-operative clearance performed at either PVAMC or the referring facility.

[9] E.g., Mild BPH = 1 to 7, Moderate = 8 to 19, Severe = 20 to 35. http://individual.utoronto.ca/mgreiver/prostate.htm [accessed 3/25/2010]

On the day of the procedure, patients came through the pre-bed unit at PVAMC and, from there, went to the operating room (OR). In attendance in the OR were, at a minimum, an anesthesiologist, urologist, radiation oncologist, and medical physicist. Housestaff, e.g., residents, from the Urology Service were also often present. The procedure was performed under general anesthesia. The urologist would help with the insertion of a transrectal ultrasound probe, general OR set-up of the patient, guidance with the placement of at least the first guide needle, and a postoperative cystoscopy at the culmination of the procedure. The radiation oncologist would perform the actual seed implantation. The procedure took from 30 minutes to two hours.

The Urology Service admitted the patient after the procedure, generally for a one night stay for observation and management. Discharge occurred the next morning after a CT scan of the prostate was obtained, and the patient was given instructions for follow-up with the urologist and/or hematologist/oncologist at his referring facility. PVAMC's Radiation Oncology Service and Urology Service staff would also usually see the patient in 30 days.

Follow-up included PSA levels obtained at the 30-day appointment, every 3 months for the first year, every 6 months during the second year, and annually thereafter.

D. Oversight of Radiation Therapy Within VA

1. United States Nuclear Regulatory Commission (NRC)

Overview

The NRC is an independent agency created by Congress to license and regulate the civilian use of radioactive materials. In performing this function, NRC issues licenses to facilities for possession and use of radioactive material and provides oversight of entities using radioactive materials. This includes medical facilities, including VA medical centers, that use radioactive substances in diagnosis, therapy, and research.

Prior to March 2003, each VA medical center was an individual licensee with the NRC.

In March 2003, VA was issued a master materials license (MML) to use radioactive materials. Currently, three Federal departments have been granted a MML: the Departments of the Air Force, Navy, and VA. State governments may be granted regulatory authority by NRC for oversight of radioactive materials uses within that state and are referred to as "Agreement States."

Under the MML, the NRC has the expectation that VHA's National Health Physics Program (NHPP) will provide regulatory oversight for VA facilities and ensure that practices meet applicable requirements promulgated in the Code of Federal Regulations (CFR). With this regulatory configuration and with the approval and signing of the MML, VHA became the "licensee" and the previously independently licensed VA medical centers became "permitees." As such, NHPP (which is discussed under a separate heading below) is responsible for issuing permits, conducting inspections,

investigating allegations, investigating incidents, and enforcement for all VA facilities under the aegis of the National Radiation Safety Committee.

Scope

NRC states that it does not regulate the practice of medicine. Its focus is on radiation safety as opposed to quality of care or community standards of medical care. Nevertheless, in the area of radiation oncology, i.e., radiotherapy, NRC ensures that patients receive a physician's intended dose of radiation.

With regard to a prostate brachytherapy, NRC allows licensees to promulgate their own standards as to how and when to measure the radiation dose given to a patient. However, it simultaneously holds the licensee to an established standard which it interprets in relation to the governing provisions of 10 CFR Part 35, a body of regulation addressing the reporting of "medical events." Thus, in a health care setting, NRC is concerned that facilities use safe practices when using radioactive materials, and that patients receive the dose of radiation intended. NRC licensees are required to report medical events, which 10 CFR 34.304, Subpart M—Reports, § 35.3045 *Report and Notification of a Medical Event* describes as follows:

> (a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--
>
> > (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
> >
> > > (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
> > >
> > > (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
> > >
> > > (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
> >
> > (2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following--
> >
> > > (i) An administration of a wrong radioactive drug containing byproduct material;
> > >
> > > (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration;
> > >
> > > (iii) An administration of a dose or dosage to the wrong individual or human research subject;

(iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(v) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

(b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician.

At the time of the events discussed in this report, VHA, including NHPP, had not clearly defined a "medical event" in VA policy. However, VHA believes that "the application of a definition for a medical event for prostate brachytherapy based on current NRC regulations is not clear" and notes that it is currently the subject of NRC rulemaking.

2. VHA

Several VHA entities at a national level have a role or potential role in oversight of prostate brachytherapy. These include NHPP, VA's National Radiation Safety Committee, Nuclear Medicine & Radiation Safety Services, VHA's National Director of Radiation Oncology Programs, and prior to 2009, VHA's Diagnostic Radiology Service, and the VA Radiation Safety Center for Inquiry.

Nationwide programmatic oversight of brachytherapy resides with VHA's National Director of Radiation Oncology Programs. VHA's National Director of Radiation Oncology Programs reports to the VACO Chief, Patient Care Services.

VA National Radiation Safety Committee (NRSC)

This is a VHA national committee that meets quarterly and reports to the Under Secretary for Health. It has "responsibility for providing oversight of the VA's implementation of its [MML] license and associated activities. The Committee has delegated the authority to manage the VA radiation safety program to its National Health Physics Program."

NHPP

As noted, prior to March 2003, each VA medical center was an individual licensee with the NRC. During that period, centralized VA support for oversight was provided to facilities by the NHPP, which was at that time, a unit of the VHA's Nuclear Medicine Program. With the approval and signing of the MML, VHA became the "licensee" with

NHPP providing regulatory oversight under aegis of the National Radiation Safety Committee.

NHPP notes that it "provides regulatory oversight for radiation safety throughout VHA." As such, NHPP serves to regulate the medical, dental, and research use of radioactive materials within VHA. NHPP oversees therapeutic and diagnostic use of radioisotopes as is the case in brachytherapy and has a registration program for linear accelerators used for external beam therapy.[10]

NHPP proactively inspects all VHA brachytherapy programs and reactively performs inspections when possible medical events occur. It conducts inspections of permit sites every two or three years, depending on the scope of the granted permit. Within VHA, NHPP reports to the Chair, VHA National Radiation Safety Committee (which reports to the Under Secretary for Health) and to the Chief, Patient Care Services. Its headquarters is in Little Rock, Arkansas, with field offices in Baltimore, MD; Ann Arbor, MI; and Mare Island, CA.

Radiation Safety Center for Inquiry (RSCI)

Asserting that NHPP's role is "a purely regulatory one," the "RSCI was created to assume the educational and consultative functions of the NHPP." It operates with VA radiation safety officers who volunteer to serve as regional radiation safety consultants and describes itself as "eager to answer questions concerning issues of radiation safety and regulatory compliance."

E. Prostate Brachytherapy at PVAMC Prior To May 5, 2008

In 2002, PVAMC started performing prostate brachytherapy under a contract with the University of Pennsylvania Health System, and as a direct licensee of NRC. PVAMC's first prostate brachytherapy procedure was performed on February 25, 2002. This appears to have occurred after VISN-level approval and development of one or more brachytherapy protocols in 2001. On July 12–13, 2001, prior to the first implant, NHPP had conducted a routine inspection at PVAMC, and no deviations were found in either the physical areas inspected or in the medical center's compliance with various documentation requirements, the one exception being that the issue was raised of PVAMC's documentation of measurement of ventilation rates within its Nuclear Medicine Service.

From July 22–November 25, 2002, seven more prostate brachytherapy procedures were performed, comprising a total of eight procedures in Calendar Year (CY) 2002. These first eight cases are all described in the medical record as "uneventful," or "without difficulty or complication." In three of these eight cases three seeds were extruded from the bladder.

[10] The essential distinction between brachytherapy and EBRT is that only in the former are radioactive sources placed inside the patient's body.

On February 3, 2003, in the first prostate brachytherapy procedure of CY 2003 and the ninth PVAMC prostate brachytherapy overall, 74 I-125 seeds of 0.38 millicurie (mCi)/seed activity were initially intended to be implanted. However, by the procedure's end, 40 seeds had been recovered from the bladder by the urologist performing cystoscopy. PVAMC reported this occurrence to the NHPP and NRC. An NRC reactive inspection was conducted with an NHPP presence. PVAMC also conducted a Root Cause Analysis (RCA) of the incident. NRC reported, "several factors were encountered during the treatment, including, insertion of seeds into a small prostate, suboptimal positioning of the ultrasound probe and the patient, and rectal gas resulting in placement of a rectal tube during the procedure." In the course of this review process, it was found that the written pre-plan had been revised *intraoperatively* (i.e., while the procedure was still ongoing in the OR) to reflect that only 34 seeds were implanted.

On February 19, 2003, NRC found that the occurrence did not constitute a reportable medical event because the written directive was changed intraoperatively to reflect the intended dose. Although the multiple seed extrusions were discovered intraoperatively, the radiation oncologist did not attempt at that time to re-implant the extruded seeds as he was concerned about biological contamination of the seeds. However, on March 31, 2003, 56 days later, the patient had a second implant of 66 I-125 seeds. The medical record notes that during this procedure one seed was recovered from the bladder and the procedure was "completed without difficulty or complications."

A subsequent NRC inspection on August 6, 2003, and NHPP inspections on January 29, and February 26, 2004, identified no violations of Federal regulations.

In October 2005, the medical center again gave notice to the NHPP and NHPP notified NRC of a medical event concerning an October 3, 2005, prostate brachytherapy implant, wherein only 45 of the implanted 90 seeds remained in place. This incident seemed to resemble the reported 2003 case.

A joint site visit conducted by NHPP and NRC on October 13, 2005, determined that this case did not constitute a reportable medical event. Again, this was because the written directive was revised by the radiation oncologist in the OR to reflect the actual number of seeds implanted. Specifically, NHPP wrote:

> During the procedure, 90 Iodine-125 seeds were implanted under ultrasound guidance. At the end of the procedure, 45 seeds were recovered from the patient's bladder. The authorized user physician revised the written directive in the operating room after the seeds were recovered, but before the procedure was completed. The revision to the written directive was made to accurately reflect the actual number of seeds implanted in the patient. A post-implant CT examination was performed the next day and a post-plan was created. The CT revealed 41 seeds were implanted in the prostate, 2 seeds were in the bladder wall, and 2 seeds were recovered in the patient's urine.

NHPP also wrote, "Based on the previous NRC conclusion [i.e., the 2003 case previously discussed], the current circumstances also do not appear to represent a medical event."

The medical center again conducted an RCA. Unlike the February 2003 case, this case was not followed by a second implant. The radiation oncologist wrote, "Initial review of this study indicates excellent placement of the I-125 seeds throughout the prostate. For quality control and full documentation we will perform a thorough dosimetric analysis. Nonetheless, because of the excellent uniformity of the localization of the seeds, I fully expect the final analysis will indicate that no repeat implantation will be required."

Beyond the RCA, no additional QA reviews such as a peer review of the radiation oncologist's overall practice, or re-review of his credentials and/or privileges were performed.

On January 26 and February 28, 2006, NHPP on-site visits found no violations, but several recommendations relating to shielding were made. The first visit was a routine inspection and the second visit was limited to external beam therapy and did not review prostate brachytherapy.

From November 14, 2006, to November 15, 2007, there was an Information Technology (IT) systems failure that resulted in a 12-month time period during which PVAMC brachytherapists were unable to obtain post-operative dosimetry data. Due to a network connectivity issue, postoperative CT scans were unable to be uploaded into the VariSeed™ treatment planning system (TPS). However, ultrasound images used for pre-planning were able to be transferred to the VariSeed™ TPS. Despite this IT problem, prostate brachytherapy continued during this time.

On July 20, 2007, in the midst of the IT problem, the American College of Radiation Oncology conducted a Practice Accreditation Program review of PVAMC's Radiation Oncology Service, and on August 26, 2007, PVAMC was notified that it "has been awarded a Full (three year) accreditation."

On May 5, 2008, a patient was implanted with I-125 seeds of 0.38 mCi strength when the radiation oncologist's written pre-plan directive called for the implantation of seeds of 0.509 mCi strength. This was reported to NHPP and NRC as a medical event. As noted, this incident triggered a process that led to review of all 114 PVAMC prostate brachytherapy patients, as well as review of prostate brachytherapy at all VAMCs performing the procedure. Subsequent events, as well as the etiology of the incorrect seed-strength implantation, are discussed in the Results and Conclusions section of this report.

Scope and Methodology

In this review we assessed PVAMC's performance of prostate brachytherapy in the treatment of prostate cancer during the seven year period of 2002–2008, as well as associated events from 2001 to the present.

A. Onsite Visits and Meetings

OHI inspectors visited PVAMC on June 29–July 2, October 13–15, and December 15–16, 2009, and March 15–16, 2010; Brooklyn, NY VAMC on September 3, 2009; and Jackson, MS VAMC on November 3–5, 2009.

Numerous inspections, investigations, and reviews — some routine, some reactive to the May 5, 2008 incident at PVAMC — were conducted prior to and concurrent with this OIG review. These reviews were performed by entities such as the NRC, VHA's CRAAB, VHA's NHPP, a VHA ABI, VHA's NCPS, the Joint Commission, and the American College of Radiation Oncology. Additionally, a committee was impaneled "at the request of the dean of the University of Pennsylvania School of Medicine and asked "to review the Department of Radiation Oncology's prostate implant brachytherapy program, with a particular focus on quality assurance and quality control measures in the department implemented after learning of problems with the Philadelphia Veterans Affairs Medical Center (PVAMC) prostate implant to brachytherapy program in June 2008." Soon thereafter, in response to refining criteria to define a "medical event," VHA's Acting Principal Deputy Under Secretary for Health directed VHA's Chief Patient Care Services Officer to convene a VHA Advisory Panel for Prostate Brachytherapy.

We obtained and studied these reviews, often interviewing team members from each of these review groups.

We met with VHA's National Director of Radiation Oncology Programs as well as his predecessor, the Chairman of VHA's CRAAB, and most members of VHA's NHPP, the Director of VHA's NCPS, and many of the participants in the aforementioned VHA ABI. We attended two quarterly meeting of VHA's National Radiation Safety Committee

We met with NRC Region III officials, and with an NRC on-site inspection team at PVAMC. We attended the NRC's fall "Advisory Committee on the Medical Uses of Isotopes," meeting, and NRC's December 17, 2009, Predecisional Enforcement Conference concerning the "*Department of Veterans Affairs (DVA) VA Medical Center, Philadelphia, Pennsylvania*."

We conducted multiple interviews at PVAMC with both past and present clinical and administrative staff. We interviewed senior leadership, quality management staff, and individuals involved in the prostate brachytherapy program. We interviewed clinical, managerial, information technology, and contracting staff and officials. One of the two radiation oncologists who performed prostate brachytherapy at PVAMC is no longer employed by the Department of Veterans Affairs and declined to meet with us.

B. Document Reviews

We examined the medical records of all 114 patients PVAMC treated with prostate brachytherapy. Medical records examined included both the electronic medical records found in VA's Compensation and Pension Record Interchange (CAPRI) system and

individual accompanying paper records which contained pre- and post-plan dosimetric data. In addition to notes by the Radiation Oncology and Urology Services, notes by patients' primary care providers and nursing staff were examined as these often provided insight into patients' day-to-day status while at home, often long after the brachytherapy procedure.

We reviewed committee minutes, patient records, QM records, email, and other documentation. We reviewed credentialing and privileging folders of staff performing prostate brachytherapy at PVAMC. We obtained and reviewed the nationwide data analyzed by VHA's CRAAB.

PVAMC maintains a strong affiliation with the University of Pennsylvania's Schools of Medicine, Nursing, and Dental Medicine. Substantial services were contracted for from the University of Pennsylvania and we reviewed the contract under which the University of Pennsylvania provided prostate brachytherapy at PVAMC. In order to examine personnel and contractual issues, we constructed time lines of employment for the two radiation oncologists that performed prostate brachytherapy at PVAMC. We interviewed PVAMC/Human Resources (HR) staff. We developed contractual time lines for professional and technical services for radiation therapy between the University of Pennsylvania and PVAMC that included review of invoices and time sheets. We interviewed the contracting officer and the Contracting Officer's Technical Representative (COTR) for the clinical sharing agreement and reviewed contract extensions. PVAMC's HR Director provided documentation for the principal physicians confirming their VA employment.

Data, for example, PSA and dosimetric data collected and analyzed is discussed in Section II of this report. Our approach to possible complications suffered by PVAMC patients is also discussed in its relevant section.

With regard to Jackson, MS VAMC (JVAMC), on November 3–5, 2009, OHI conducted a site visit to that medical center. We conducted interviews with JVAMC leadership, staff from Information Technology (IT), Biomedical Engineering (Biomed), JVAMC radiation oncologists, its medical physicist, and its dosimetrist. In addition, we reviewed a document from the facility outlining the timeline of events of JVAMC's brachytherapy program.

Despite the detail and complexity of this review, it is not a review of PVAMC's Radiation Oncology Service. Most particularly, this review does not purport to cover external beam radiation therapy (EBRT) in PVAMC's (or other VHA facilities') treatment of prostate or other cancers.

This inspection was performed in accordance with *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Section I

Issue 1: Events Related to Prostate Brachytherapy at PVAMC May 5, 2008 and Subsequently

On May 5, 2008, a PVAMC patient underwent a prostate brachytherapy procedure in which he was inadvertently implanted with I-125 seeds of 0.38 millicurie/seed (mCi/seed) activity when the radiation oncologist's pre-plan had prescribed seeds of 0.509 mCi/seed, resulting in the patient receiving a lower than intended radiation dose. The etiology and circumstances surrounding this error are described later in this report.

Unlike the incidents of 2003 and 2005 in which an excessive number of seeds were extruded into patients' bladders, this incident was not detected intraoperatively. The attending radiation oncologist wrote in the medical record:

> Under general anesthesia [the patient] underwent the insertion of 16 needles containing 41 I-125 seeds. The position of each needle was checked on ultasound [sic] and found to be accurate. The depth of the implant was confirmed by examining a saggital [sic] view of the prostate. There were no seeds recovered at cysto and no seeds were found in the room. He tolerated the procedure well and was transferrred [sic] to PACU [post-anesthesia care unit]. He will have a CT for dosimetry tomorrow.

The patient was discharged the next day and the discharge summary written by the Urology Service indicated, "In summary, this patient is a [age]-year-old gentleman who underwent the uneventful placement of brachytherapy seeds. He was ultimately discharged home in stable and good condition."

Seven days later, on May 12, 2008, in the course of a routine audit, a medical physicist at PVAMC discovered the dosing discrepancy. PVAMC's radiation safety officer (RSO) was notified that same day. The RSO then notified NHPP, again on May 12, of the implanted seed activity discrepancy. Also, on May 12, PVAMC's Chief, Radiation Oncology Service attempted unsuccessfully to notify the patient. On May 14, 2008, the radiation oncologist who performed the procedure was able to notify the patient and was able to tell the patient personally that further recommendations would be forthcoming.

On May 15, 2008, after preliminary assessment of the facts, the incident was formally declared to be a "medical event" and NHPP notified NRC's Operations Center of a "possible medical event."[11] An issue brief was produced for management in VISN 4 headquarters, summarizing the facts as they were then known.

A two-day reactive NHPP inspection began on May 28, 2008, followed by a second NHPP site visit on June 24–25, 2008. In its May 28, through October 16, 2008 inspection, NHPP identified four violations of NRC regulations. At the initial exit

[11] NHPP considered May 15, 2008, as the "date of discovery of the above possible medical event."

meeting on May 29, 2008, NHPP identified two apparent violations based on the one medical event known at that time:

1) "Failure to complete required form at completion of implant and prior to leaving the operating room;

2) Low confidence of procedures in place with [will] ensure radiation dose delivery is within 20% of prescribed dose."

At or about this time, at NHPP's direction PVAMC began reviewing approximately 20 more PVAMC prostate brachytherapy cases. By June 5, 2008, 20 patient cases had been reviewed, and these additional reviews raised the possibility of four more possible medical events characterized by underdosing. Fifty more cases were then reviewed by PVAMC in addition to the initial 20 cases.

These 50 further case reviews likewise showed further problems with underdosing and raised the possibility of further reportable medical events.

The review criterion used to assess radiation dosage to the prostate was a metric (i.e., dose measurement) known as the "D90." In its simplest expression, D90 is a calculated value that reflects the minimum dose of radiation absorbed by 90% of the prostate. D90 may be expressed in at least two ways. As noted earlier, before the prostate brachytherapy implant is performed in the OR, pre-planning is done. In the pre-planning process, the radiation oncologist calculates his or her intended or prescribed dose of radiation based upon ultrasound images of the patient's prostate that were obtained several weeks or months before the procedure. These ultrasound images are transferred into computer treatment planning software, which enables the radiation oncologist to prescribe a dose of radiation and consider where he or she will implant seeds.[12] As such, D90 may be expressed as a *percentage of the radiation oncologist's intended or prescribed dose of radiation*. In this report, other oversight reports, and the medical literature, the reader will often find D90 expressed as this percentage value. However, D90 may also be expressed simply as the absolute number of Gray (Gy) units dosed, without noting what may have been intended or prescribed.[13]

Use of D90 to determine a medical event at PVAMC was directed by NHPP. We were told by NHPP that, "NHPP recommended to the facility use of the D90 metric since our understanding was that NRC considered that metric to be required as the basis to determine if a medical event had occurred." NHPP staff told us that it had come to this conclusion based upon an NRC technical assistance request (TAR) document that NRC had issued based upon an earlier incident at a non-VA facility.

[12] It should be noted that this description of process applies to PVAMC as is discussed in this report. More recent innovations permit real-time calculation of dosages and seed placement, obviating the need for much of the pre-planning imaging and calculations.

[13] Gray (Gy) units are measured in joules/kilogram. 1 gray = "dose of one joule of energy absorbed per kilogram of matter." http://www.unc.edu/~rowlett/units/dictG.html [accessed 3/30/2010].

Specifically, a January 29, 2004, memorandum from the Chief, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NMSS [Nuclear Materials Safety & Safeguards] to the Director, of Nuclear Material Safety, [NRC] Region I states:

> For the "uunderdosing" [sic] events at [a non-VA healthcare system], the appropriate measure for determining if a prostate brachytherapy treatment misadministration/medical event had occurred is D90, the dose received by 90% of the target volume, in comparison to the prescribed dose. A misadministration/medical event occurred if D90 is less than 80% of the intended dose, as specified in the written directive.

However, this document (NRC TAR 1/29/2004) appears to be referring to D90 when measured four weeks postoperatively. The D90s at PVAMC were obtained on Postoperative Day 1. For instance the referenced TAR states:

> 1) The American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 64, in its review of permanent prostate seed implant brachytherapy, states: "For dosimetric evaluation *performed at the optimum imaging time [approximately four weeks postimplant for 1-125]*, [OHI emphasis] it is recommended to use D90 in comparison to the prescribed dose, as an indicator of implant quality in dose coverage." D90 is the dose received by at least 90% of the prostate volume. [NRC] Region I documented the D90 values for each patient reported by the licensee as a misadministration/medical event. The D90 values ranged from 11.52% to 70.7% of the prescribed dose. (Considering 80% of the prescribed dose to be an acceptable D90, all of the events reported by [a non-VA healthcare system] thus far would remain as reportable medical events; i.e., all of the 21 reported misadministrations had 90% of the target organ, the prostrate [sic], receiving less than 80% of the prescribed dose.);

A senior NRC official told OHI, "the NRC did not request nor direct PVAMC to use D90 [as the medical event criterion]."

VHA's National Chief of Radiation Oncology Programs at that time had no objection to it being employed.

Using the D90 metric to assess radiation dosage to the prostate, there appeared to be problematic radiation doses to a total of 45 PVAMC patients. The results of this review were reported on June 11, 2008, by PVMAC's radiation safety officer to NHPP.

On June 11, 2008, in conjunction with the VISN 4 Director's recommendation, on PVAMC's Director suspended prostate brachytherapy at the medical center.

In the ensuing weeks, all remaining patient cases were reviewed. On October 2, 2008, NHPP notified NRC's Operations Center of an additional 37 medical events, bringing the

total number of medical events to 92.[14] NHPP also informed VHA's Chair, National Radiation Safety Committee, and NRC's Project Manager for VHA's MML of this information.

The analysis was performed in two phases. Phase I assessed for low dosage to the prostate. However, as there was concern about seeds not being implanted in the prostate, it stood to reason that these seeds were implanted elsewhere and could be excessively irradiating non-prostatic tissue. Thus, Phase II of the analysis concentrated on identifying overdosing to non-prostatic tissue. A convention in the medical event reporting process is, however, that *a patient can only be considered a medical event once* in an incident. Therefore, if a patient was initially reported as underdosed, while he may have also fit in the overdose to non-prostate tissue category, he would not be reported again as another medical event.

In summary, in Phase I, PVAMC reported to the NHPP 55 underdosed cases; in Phase II, PVAMC reported to the NHPP initially 37 cases of excessive doses to areas other than the prostate. These numbers however were modified as various discrepancies were identified. For example several patients were noted to be duplicates, having both underdosing to the prostate and overdosing to non-prostatic tissues, yet, as noted above, could only be counted once for medical event reporting purposes. This diminished the reporting numbers. However, as various review bodies addressed the matter throughout the latter half of 2008, calculations were done and redone, and, in numerous instances, patients had repeat CT scans. These additional review processes countervailed any subtraction of cases caused by duplicates, and ultimately, added more cases to the total. When all reviews for NRC reporting purposes were finally completed, the final number reported to NRC as medical events was 97.

In about this same time frame, VHA's National Director of Radiation Oncology Programs made a site visit to PVAMC. He wrote a report entitled, *Review of Prostate Brachytherapy Program at Philadelphia VAMC*, and on June 26, 2008, sent the report to PVAMC's Medical Center Director. This report had several observations and made several recommendations. These included:

> a. There is no second check [that the correct seeds are being implanted] in the OR.
> b. It is not clear if pre versus postplan volumes were verified. The doctor was of the impression that there was swelling of the prostate by about 20–30%.
> c. There was no compensation done to account for swelling when performing a preplan.
> d. In some cases the V90 [sic] doses were low. [One of PVAMC's two brachytherapists] was told about this by the physicist [named].
> e. [The aforementioned brachytherapist] acknowledges knowing about the low doses but did nothing as there was no policy in place to handle this situation.

[14] These "medical events" were based on an analysis using D90 criteria. It was widely reported that these 92 medical events were indicative of substandard care.

f. The patient[s], chief of department, and the urologist were not informed of the low dosages.
g. There is no evidence of quality control evaluation.
h. From November 2006 through January 2008 due to the [computer] incompatibility issues post implant CT could not be transferred to the treatment planning system. Thus, these patients had no documentation of what dose was delivered. [The aforementioned brachytherapist] stated that the radiation safety officer, chief, and others knew of the problem. With the exception of seven cases, where there is corrupted data, most plans were run this year.
i. In his experience, [the physicist] stated that in several cases there were issues of cold spots and seeds placed outside of prostate which was not as per the preplan.
j. There is a plan in place to evaluate all 70 patients; 63 with V90 [sic] less that 80% and seven with no data. Under dosed patients will be informed.

VHA's National Director of Radiation Oncology recommend "a complete evaluation with external review on technical aspects of implants in Seattle [i.e., for the cases to be reviewed at the Seattle VAMC], "continued monitoring of patients with serial PSA evaluation and assessment of toxicity and failure," and "keeping the program on hold till all of the investigations and notifications are completed."

At approximately the same time, July 1, 2008, VHA convened a Clinical Risk Assessment Advisory Board (CRAAB), a VHA body that may provide guidance regarding disclosure of adverse events related to clinical care to patients or to their personal representatives.[15] In conjunction with the VHA's National Director of Radiation Oncology's review, the CRAAB decided to request a sample of ten brachytherapy cases from each VAMC performing brachytherapy to be reviewed external to the submitting VAMC. Two and a half weeks later, on July 17, 2008, an Administrative Board of Investigation (ABI) was convened pursuant to the authority of PVAMC's Medical Center Director. This Board was charged "to review the facts and circumstances surrounding the possibility that patients involved in the Brachytherapy program [of PVAMC] may have received radiation doses lower than prescribed strength to their prostate glands."

The first of five NRC site visits to PVAMC took place July 23–25.[16,17]

On October 16, 2008, NHPP issued its report, *RADIATION SAFETY PROGRAM INSPECTION, VA Medical Center, Philadelphia, Pennsylvania*,[18] and NRC concurrently exercised its oversight responsibility, from the perspective of compliance with NRC regulations. On November 12–13, 2008, VHA's National Center for Patient Safety (NCPS) performed a site inspection.

[15] VHA Directive 2008-002.
[16] July 23–25 and September 9–12, 2008, and June 22–26, August 27–28, and October 14–16, 2009.
[17] These inspections ultimately culminated in NHPP report: RADIATION SAFETY PROGRAM INSPECTION, Inspection Report Number 642-08-102, VA Medical Center, Philadelphia, Pennsylvania, May 28–October 3, 2008; and NRC Inspection Reports No. 030-34325/2008-029(DNMS), March 30, 2009; and No. 030-34325/2009-001(DNMS), November 17, 2009.
[18] Inspection Report Number 642-08-102, May 28–October 16, 2008.

NRC, in the course of its formal reports as well as its exit meetings (preliminary and final) at PVAMC, identified nine violations of Federal regulations relating to improper radioactive seed implantation in the prostate.[19]

On May 15, 2009, the medical center underwent an accreditation review and an on-site survey by the American College of Radiology (ACR). ACR's report was issued on August 5, 2009, and it indicated that the ACR was "unable to grant accreditation to the facility due to one or more deficiencies." A corrective action plan was required and accreditation was "deferred pending receipt of satisfactory corrective action plan by November 6, 2009, and re-survey of the facility."

On November 17, 2009, NRC issued *Philadelphia Veterans Affairs Medical Center (PVAMC), NRC Reactive Inspection* Report No. 030-34325/2009-001(DNMS). This report cited eight apparent violations involving the failure to:

> (1) develop adequate written procedures to provide high confidence that each prostate seed implant administration is in accordance with the written directive as required by 10 CFR 35.41(a)(2);
>
> (2) develop procedures that address methods for verifying that the administration is in accordance with the treatment plan and written directive as required in 10 CFR 35.41(b)(2);
>
> (3) develop procedures that address verifying that the administration is in accordance with the written directive as required in 10 CFR 35.41(b)(2);
>
> (4) train supervised individuals regarding identification and reporting requirements for medical events as required in 10 CFR 35.27(a)(1);
>
> (5) instruct a non-supervised individual regarding identification and reporting of medical events as required in 10 CFR 19.12(a)(4);
>
> (6) report by telephone to the NRC the next calendar day numerous medical events as required by 10 CFR 35.3045(c);
>
> (7) record total dose on a written directive as required by 10 CFR 35.40(b); and
>
> (8) provide complete and accurate information in accordance with 10 CFR 30.9 in several 15-day written reports to the NRC as required in 10 CFR 35.3045(d).

NRC wrote that its inspectors "determined that a substantial programmatic breakdown of the prostate brachytherapy program occurred at PVAMC due to the number and significance of the medical events."

On December 17, 2009, NRC held a Predecisional Enforcement Conference concerning its November 17, 2009 report. At that time, VHA contested several of the of NRC's cited apparent violations. Additionally, VHA presented arguments that D90 was an imperfect

[19] Preliminary inspection exit meetings: June 26, August 28, and October 16, 2009, and final exit meeting on November 2, 2009.

criteria for identification of medical events, cited the work of its Advisory Panel for Prostate Brachytherapy, and proposed retractions from its initially reported 97 medical events.

VHA followed the Predecisional Enforcement Conference with letters to the NRC dated January 14 and January 28, 2010. In the January 14 letter, VHA's Acting Under Secretary for Health accepted all but two of the apparent violations cited in the NRC report. However, VHA took issue with employing the D90 to assess for a medical event, writing,

> D90 is not a widely accepted criterion for regulatory evaluation. Furthermore, a blue ribbon panel of external experts [i.e., VHA's Advisory Panel for Prostate Brachytherapy] has recommended medical event criteria for the treatment site, which are derived from an imaging review of seed localization, as compared to the intended treatment volume… Our review of the previously report [sic] medical events under these new criteria better reflects the overall effectiveness of our brachytherapy treatments, since ongoing reviews by clinical experts have not identified an overall increased rate of adverse outcomes for the patients.

In its January 28 letter, VHA proposed retracting 80 medical events from the previously reported 97, "based on the criteria recommended by the external experts." VHA's newly proposed criteria had the central concept that, "For implementing the treatment-site accuracy ME pathway definition, the ME endpoint will be the total source strength implanted in the treatment site, not absorbed dose." It argued that "these criteria follow from the NRC Advisory Committee on the Medical Uses of Isotopes recommendations in 2005 that the D90 absorbed dose criteria, developed for clinical uses, provide dose data which are both imprecise and too subjective for regulatory reviews.

On March 17, NRC notified VHA that it had,

> "considered the information presented by the DVA during the conference as to the number of medical events that occurred. This information was also documented in the January 14, 2010, letter. On January 28, 2010, the DVA submitted a proposal to retract approximately three-fourths of the reported medical events based on a review performed by an external panel. The NRC has reviewed the January 28, 2010, letter and the criteria applied by the DVA for determining whether a medical event occurred, and has determined that the criteria applied by the DVA do not conform to the current regulatory definition of a medical event in Title 10 of the Code of Federal Regulations (10 CFR) 35.2, which references 10 CFR 35.3045(a) or (b). If the DVA desires to deviate from the NRC's regulations, it must file an exemption request pursuant to the requirements of 10 CFR 35.19. Alternatively, if the DVA wishes to request the Commission to change the definition of a medical event, the DVA may file a petition for rulemaking pursuant to 10 CFR 2.802. Accordingly, based on current NRC regulations and requirements, the staff rejects your position regarding medical event retraction as described in the January 28, 2010, letter.

NRC proposed imposition of a civil penalty of $227,500.00.

Conclusions

We concluded that VHA acted expeditiously and promptly in face of the May 5, 2008, wrong seed dose case. At a local level, PVAMC quickly identified the problem and set in motion appropriate reviews. At the national level, VHA's National Director of Radiation Oncology Programs made a timely site visit. Once it became clear that the *underdosage* that characterized this "index case" at PVAMC was not isolated, (although, in fact, the seed strength error that characterized it was an isolated occurrence), PVAMC took steps to review all cases of prostate brachytherapy performed from 2002–2008. VHA's CRAAB quickly became involved and expanded the issue's focus to examine brachytherapy results throughout VHA. An ABI was empanelled. In assessing these several reviews, we found them to be rigorous and thorough.

We found that the use of the D90 metric, as it was calculated at PVAMC, to ascertain medical events was problematic because of technical factors related to its use and aspects that limit its application for quality assurance. From a technical perspective, the proper and accurate use of the D90 metric requires two assumptions that were not met at PVAMC:

1) D90 values are calculated from CT scans obtained more than three weeks post-implant.
2) Assumption of a prescription dose of 145 Gy.

Post-implant dosimetry at PVAMC was calculated from CT scans obtained 1 day after the procedure. At that time, swelling from the procedure enlarges the size of the prostate, which, in turn, produces a lower D90 value than would be the case if the prostate was not swollen, underestimating the prostate D90. D90 values at PVAMC may have been higher if week 3 or 4 CT scans were used.

Second, higher doses of radiation were used at PVAMC where the majority of patients were generally prescribed 160 Gy. Thus, D90 values expressed as a percentage of intended dose may give the impression of a radiation underdose, when if that same implant's radiation dose had been expressed as an absolute number of Gy, D90 might be considered adequate. The prostate D90 > 90% standard was born from treatments in which 145 Gy was used. Ultimately, it is the absolute amount of dose that is important in terms of cancer control. When expressed in absolute terms, 130 Gy is considered an acceptable D90.

Dose escalation at PVAMC may have had the unintended effect of overcoming poorly placed seeds in some PVAMC cases. From the perspective and interest of the patient, cancer control may not have been significantly worse because an adequate amount of radiation was delivered to the cancer.

This leads to the next point, which is that prostate D90 may not be the best suited measure to alert clinicians to a medical event or misadministration that is intended to

represent a serious error that is likely to translate into patient harm. In addition to the technical factors discussed previously, the calculation of the prostate D90 can be variable. Contouring of the prostate volume on post-implant CT scans can be difficult because of the tendency to define the anatomy based on the distribution of the implanted seeds. This phenomena is further complicated by the fact that the seeds themselves cause an artifact in the images making it difficult to discern the boundaries of the prostate. Interobserver variability can be high.

Also, not specific to PVAMC, D90 calculations assume the prostate is a homogeneous gland, when, in fact, prostate cancer is a multifocal disease. Therefore, the cancer may be unevenly distributed in the prostate. Additionally, many brachytherapists welcome radiation to a margin of tissue around the prostate, e.g., 1 centimeter, except posteriorly.

The prostate D90 also does not describe the radiation dose that may have been inadvertently delivered to critical structures such as the rectum or bladder; and injury to the rectum or bladder from intended radiation should be the impetus for monitoring of medical misadminstrations.

Overall, we are concerned that the January 29, 2004, NRC TAR cited as the basis for employing D90 at PVAMC has different facts than were the case at PVAMC in 2008. We do not refute that the prostate D90 may be one quality measure for the field of radiation oncology to help clinicians monitor their performance, and concluded that more research into this subject is needed.

Issue 2: Clinical Care and Outcomes in 114 Patients Treated with Prostate Brachytherapy at PVAMC, 2002 – 2008

A. Overview of PVAMC's Prostate Brachytherapy Population

One hundred fourteen patients were treated at PVAMC, with two implanted twice for a total of 116 PVAMC implants. An additional eight patients had second implants performed at the Seattle, WA VAMC (Puget Sound VA Health Care System).

Thirty-three patients had pretreatment neoadjuvant androgen ablation therapy, also known as hormonal deprivation therapy, in the year prior to their prostate brachytherapy.[20]

The agents employed at PVAMC and other VISN 4 medical centers were a combination of Zoladex® (goserelin acetate), a luteinizing-hormone-releasing hormone agonist; and Casodex® (bicalutamide), a drug that blocks adrenal androgen production.[21] However, in some cases Zoladex® was used as a single pretreatment agent, and in one case, flutamide was used instead of bicalutamide.

[20] Neoadjuvant therapy is "Treatment given as a first step to shrink a tumor before the main treatment, which is usually surgery, is given. Examples of neoadjuvant therapy include chemotherapy, radiation therapy, and hormone therapy." http://www.cancer.gov/dictionary/?CdrID=45800 [accessed 3/17/2010]
[21] http://www.cancernews.com/hrt.htm [accessed 3/7/2010]

Most of the 114 patients had significant comorbidities. However, while often serious, comorbidities were not atypical of an older patient population nor atypical of a veteran population whose median age was 64 years. In some cases, these comorbidities influenced the selection of prostate brachytherapy as a patient's preferred treatment modality. For example, serious cardiac or pulmonary comorbidity contraindicated a major operative procedure such as a radical prostatectomy, thus steering several patient towards a radiation therapy modality such as prostate brachytherapy. In other cases, for geographic or psychosocial reasons, it was not feasible for a patient to undergo the multitude of treatments required with external beam radiation therapy, thus influencing the selection of prostate brachytherapy for treatment.

In the wake of the concern about possible underdosing, all living patients (four patients were deceased as of 12/31/2009) and/or their families were contacted by PVAMC staff. Patients are currently followed at PVAMC, other VISN 4 facilities, and in the private sector. In some cases, patients have opted for simultaneous VA and private sector care.

B. Assessment of Complications

Overview

All radiation therapy has the potential for short and long-term complications. The primary normal tissues of concern in this case are the bladder and urethra that effect urinary function and the rectum that affects bowel function. Radiotherapy to the proximal portion of the penis, or penile bulb, is thought to be responsible for the development of erectile dysfunction, however this is not firmly established as mechanical injury of the neurovascular bundles from the brachytherapy needles is also possible. The great majority or side-effects from prostate brachytherapy are mild, easily treated with common medications, and self-limited. The most common short-term urinary irritative symptoms include dysuria and urgency and obstructive symptoms including daytime urinary frequency, nocturia, weak stream, hesitancy, and intermittency. Long-term, patients may experience continued urinary urgency, frequency, and nocturia.

The most common short-term rectal side-effects include frequent bowel movements, loose stool, and mucus discharge. Rectal bleeding similar to a hemorrhoid that is painless and associated with bowel movements can also occur after one year. This is usually self-limited. Rectal injuries such as fistulas that require surgery are rare.

The urethra and rectum are particularly vulnerable to radiation injury because radiation targets rapidly dividing cells. Both organs are lined by epithelial (surface) cells which have rapid rates of normal cell turnover. Thus, these healthy cells are adversely affected as well as the target cancer cells. Current literature reports that significant rectal complications can occur in 5-10 percent of patients and urethral complications in 0-12 percent.

Rectal Toxicity

In prostate brachytherapy, the rectal lining may sustain either an acute radiation injury or progressive epithelial atrophy and fibrosis. Obliterative endarteritis and chronic mucosal ischemia may result in chronic radiation proctitis. For this reason, the term "radiation proctitis" as is often found in the literature can be misleading as it may inaccurately imply a rectal inflammatory condition when, in fact, the underlying pathology is not inflammation but ischemia and fibrosis. Therefore, many authorities prefer to refer to rectal injury secondary to radiation exposure as a "proctopathy." We agree with this distinction. However, in order to be consistent with the literature and the manner in which PVAMC medical records notes were recorded, we will use both terms, "proctitis" and "proctopathy."

In acute radiation proctitis/proctopathy, symptoms typically occur in the first several weeks after prostate brachytherapy and may include diarrhea and the urgent wish to defecate without the ability to do so. This symptomatology is caused by direct radiation-induced damage to the colonic epithelium. It generally is self-limiting, resolving without treatment over several months. However, if discomfort is excessive the condition may be treated symptomatically with stool softeners and Anusol HC® (hydrocortisone), Azulfidine® (sulfasalazine), or Rowasa® (mesalamine) suppositories.

In contrast to acute radiation proctitis/proctopathy, symptoms of chronic radiation proctitis/proctopathy may develop as early as several months after prostate brachytherapy, though occasionally their onset is delayed, occurring several years after the procedure. Chronic radiation proctitis/proctopathy may develop as a continuation from the acute phase or it may begin spontaneously after a latent period of 90 days or more. Most commonly, the onset is 8-12 months after treatment. Patients with chronic radiation proctitis/proctopathy develop a chronically ischemic (i.e., blood-starved) intestinal segment that becomes susceptible to rectal and anal stricture formation and bleeding. Symptoms of chronic radiation proctitis/proctopathy therefore include diarrhea, bleeding, rectal pain or urgency, and, rarely, fecal incontinence.

The diagnosis of radiation proctitis/proctopathy is challenging. There are no specific radiological features that uniformly characterize radiation proctitis/proctopathy. On endoscopy (e.g., proctoscopy, sigmoidoscopy, or colonoscopy) findings between observers may not be reproducible, and tissue biopsy may be inconclusive. However, symptoms such as irregularity of bowel function, rectal blood loss, and pain may be graded by clinical criteria. Measurement of blood loss for hemorrhagic chronic radiation proctitis/proctopathy may also be used in staging. However, in the presence of inflammatory and gastrointestinal disorders, symptoms and measures of radiation proctitis/proctopathy disease activity may be difficult to attribute. Finally, radiation-induced endoscopic or histologic bowel injury may be seen in patients without symptoms.

As noted, various studies place the incidence of prostate brachytherapy induced radiation bowel injury in the 5-10 percent range. Other data suggests that the reported cases of chronic radiation proctitis/proctopathy may represent only a fraction of its true prevalence. Finally, and in part due to the lack of uniform diagnostic criteria for radiation proctitis/proctopathy, treatment options often vary. Attempts at medical management have included Sitz baths, sucralfate enemas, corticosteroid enemas, Proctofoam-HC®, Azulfidine® (sulfasalazine), Rowasa® (mesalamine) and metronidazole. Argon plasma coagulation is highly effective for painless chronic rectal bleeding. For refractory rectal bleeding or rectal bleeding associated with other irritative symptoms, hyperbaric oxygen therapy may be prescribed and its early use may prevent disease progression, avoiding serious injury such as ulceration and fistulization.

Urinary Toxicity

Due to the anatomy of the radiated area in prostate brachytherapy, as well as the relatively rapid turnover of genitourinary epithelial cells, a variety of urinary tract symptoms and complications are associated with prostate brachytherapy. In fact, following prostate brachytherapy, almost all patients develop urinary irritation or obstructive symptomatology to varying degrees. Wallner wrote:

> Many physicians and prospective patients have a false perception that prostate brachytherapy has fewer side effects and complications than external beam radiation, a perception derived in part from the seemingly logical assumption that the more localized radiation of an implant should lead to fewer problems ... Brachytherapy typically causes *more* [Wallner's emphasis] marked and *more* [Wallner's emphasis] prolonged radiation-related urinary symptoms, at least in the first six to twelve postimplant months.[22]

Alpha blocker drugs such as Uroxatral® (alfuzosin), Cardura® (doxazosin), Rapaflo® (silodosin), Flomax® (tamsulosin), and Hytrin® (terazosin) are widely prescribed to improve symptoms. While most urinary symptoms are self-limited, in some cases, patients develop chronic urinary symptomatology. Urinary incontinence, in particular, is highly distressing but, fortunately, rare. Also, anatomic lesions to the urinary tract such as urethral necrosis and urethral stricture may develop. Hyperbaric therapy in combination with Trental® (pentoxifylline) and Vitamin E is effective for patients suspected to have necrosis. Urethral stricture is treated with dilatation at cystoscopy and/or urethrotomy (a closed surgical incision within the urethra).

OHI Adverse Event and Toxicity Analysis

The cited incidence of urethral strictures varies depending upon study. The American College of Radiology Appropriateness Criteria® [for] permanent source brachytherapy

[22] Wallner, Kent. Blasko, John. Dattoli, Michael J. editors. *Prostate brachytherapy made complicated*. Second edition. Smart Medicine Press. Seattle Washington. 2001.

for prostate cancer cites an incidence of urethral strictures ranging from one to twelve percent.

A variety of instruments and scales exist that attempt to quantify prostate brachytherapy morbidity, with scales for assessment of urinary, rectal, sexual symptomatology, as well as overall quality of life and well-being. The National Institutes of Health (NIH) promulgates an overarching system for grading adverse events (AE) as follows:

> Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.
>
> Grade 2: Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL [activities of daily living].
>
> Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL.
>
> Grade 4: Life-threatening consequences; urgent intervention indicated.
>
> Grade 5: Death related to AE.

Urinary toxicity may be quantified using the National Cancer Institute's (NCI) Common Toxicity Criteria as well as the International Prostate Symptoms Symptom Score; rectal toxicity may be quantified using the Radiation Therapy Oncology Group/European Organization For Research And Treatment Of Cancer (RTOG/EORTC) late radiation morbidity scoring scheme for reporting rectal morbidity; and sexual side effects may be quantified using the Sexual Health Inventory For Men. Finally, a variety of somewhat more subjective health-related quality-of-life instruments exist. We found, in the course of reviewing the medical records of 114 PVAMC prostate brachytherapy patients, that PVAMC progress notes were often not specific enough for us to retroactively quantify symptoms, which by their nature are subjective. Therefore, to assess complications in this review, we selected outcomes that had clear endpoints: patient deaths, urinary strictures, and Grade 3 or greater radiation proctitis/proctopathy.

OHI Chart Review Findings: Patient Deaths

Four PVAMC prostate brachytherapy patients had died as of December 31, 2009. One of these four patients died at PVAMC, and death certificates were obtainable for three of the four patients.

None of these four patients died as a result of an adverse event from prostate brachytherapy (Grade 5 above).

Additionally, review of available medical records as well as discussions with the patients' caregivers who were in contact with the deceased patients' families indicated that none of these deaths were attributable to prostate cancer. We found the following:

Case A: The patient's death certificate stated "possible MI" as the cause of death. While this patient was documented to have biopsy-proven prostate cancer recurrence, after

treatment with androgen ablation therapy his PSA declined. It was recorded at 0.25 ng/mL less than eight weeks before his death. A bone scan obtained two months before death showed no evidence of metastatic disease.

Case B: Another patient's death certificate stated "sepsis, aspiration pneumonia, upper GI bleed." The last PSA in VA medical records was 0.21 ng/mL, although we note that this was obtained one year prior to the patient's death.

Case C: A third patient had metastatic non-small cell lung cancer. He died in hospice and his last PSA on record was 0.57 ng/mL, which was obtained one-half month prior to his death.

Case D: The fourth mortality case was that of a patient who was bedbound for the last several years of his life due to a stroke. The patient's daughter described the patient as becoming progressively more debilitated prior to death. His last PSA in VA medical records was 6.47 mg/mL that was obtained five months prior to death.

In summary, we found no evidence of biochemical activity suggesting metastatic prostate cancer in patients A – C above. For patient D, while his PSA was indeed elevated five months prior to death, we would expect a far higher PSA level than was the case if metastatic prostate disease was the cause of mortality. We therefore concluded that no patient deaths occurred due to prostate cancer.

OHI Chart Review Findings: Urethral Strictures

In the course of reviewing PVAMC patient records, there was insufficient documentation to make the fine discriminations required to use the NCI Common Toxicity Criteria to quantify urinary side effects. Therefore, we elected to assess patient records for the post prostate brachytherapy development of an anatomical lesion, namely urethral stricture, which is known to be a serious side effect of prostate brachytherapy. We were able to locate definite documentation of this diagnosis in patients' medical records. Employing NIH's adverse events grading system, we classified this complication as a Grade 3 AE ("severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL").

We identified nine patients (7.9 percent) who had chronic urinary symptoms that ultimately led to the performance of cystoscopy at which time a urethral stricture was identified. Of these nine patients, one had undergone a second "touch-up implant" at the Seattle VAMC and this patient's urethral stricture was diagnosed approximately one year after this second procedure. Thus, overall we found eight patients (7 percent) that developed urethral strictures after one implant only, and one patient (0.9 percent of total patients [1/114] or 10 percent of patients who had two implants [1/10]) who developed a stricture after a second implant.

We also found that with cystoscopic intervention, patients' urinary symptoms improved.

Urethral Strictures – Conclusions

The incidence of urethral strictures of 7.9% of the 114-patient PVAMC prostate brachytherapy patient cohort was within the American College of Radiology's *Appropriateness Criteria® [for] permanent source brachytherapy for prostate cancer* published rate of 1 – 12 percent.[23]

OHI Chart Review Findings: Radiation Proctitis/Proctopathy

We identified 24 cases in which PVAMC prostate brachytherapy patients developed symptoms or signs that their clinicians felt were consistent with radiation proctitis and/or rectal ulceration. Often, these patients' clinicians made a presumptive diagnosis of mild radiation proctitis and simply treated the patient symptomatically, for example, with corticosteroid enemas. Of these 24 cases, however, 16 were specifically identified as having radiation proctitis or rectal ulcer by a PVAMC or other VISN 4 gastroenterologist on endoscopy and/or biopsy. These 16 patients who had a clearly declared radiation proctitis diagnosis in their medical records displayed wide-ranging symptoms from mild to very serious. In an attempt to further quantify our analysis, we found from chart review that four patients met the NIH adverse events grading system criteria for Grade 3 or higher toxicity, namely "severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL," (Grade 3) or "life-threatening consequences; urgent intervention indicated" (Grade 4).

These cases were as follows:

Case AA: Almost 5 years after his implant, a patient with increasing rectal bleeding and anal pain underwent colonoscopy at PVAMC. A region of friable rectal mucosa, with shallow ulceration that was felt to be consistent with proctitis and a large anal ulcer with associated skin tags were identified. A CT scan showed a thickening of the rectal vault. The diagnosis of anal stricture was made, and plans were made for an anal dilatation under anesthesia. This diagnosis (anal stricture) was confirmed operatively, at which time the patient was demonstrated to have an anal ulcer and stricture and radiation proctitis.

Case BB: This patient's current attending radiation oncologist expressed great concern about the patient's radiation proctitis/proctopathy. A progress notes from July 2009, almost 3 years after the patient's brachytherapy, indicated that the patient was experiencing daily rectal bleeding. Colonoscopy revealed "changes consistent with radiation proctitis." The case was complicated by the patient being prescribed two anticoagulant drugs, Plavix® (clopidogrel) and Coumadin® (warfarin), for a coronary artery stent and a left ventricle thrombus respectively. However, the patient's

[23] http://www.guideline.gov/summary/summary.aspx?doc_id=9616&nbr=005136&string=brachytherapy [accessed 1/2010 and 4/2010]

anticoagulant therapy notwithstanding, based on daily rectal bleeding, we classified this case a demonstrating a Grade 3 AE.

Case CC: Eleven months after his brachytherapy at PVAMC, the patient was admitted to a private hospital with "a massive bleed, and the findings on colonoscopy were those of radiation proctitis and rectal polyps." Approximately 6 months later he was again hospitalized emergently for rectal bleeding that was "attributed to proctitis." The patient ultimately underwent a colectomy. Although the patient's VA care was limited, we concluded that there was sufficient information from the medical record and our discussions with patient's attending radiation oncologist to classify the case as demonstrating a Grade 4 AE.

Case DD: This PVAMC brachytherapy patient had extensive care both within the VA system and at non-VA hospitals. A progress note written 11 months after prostate brachytherapy at PVAMC noted that the patient was having constant rectal pain ("'24-7'") and bleeding with his bowel movements. A colonoscopy revealed "whitish plaques and friable tissue," although the patient had not had "major [rectal] bleeding." A rectal biopsy showed, "'suppurative necrotic tissue [that], may suggest [an] adjacent ulcer.'" The patient's clinicians were suspicious for rectal ulcer, which was subsequently confirmed after an examination under anesthesia. This failed medical treatment, remaining non-healing, the patient consulted a colorectal surgeon at a non-VA hospital, and was scheduled for surgery there. The precise procedure is not noted in VA records, although the patient later returned to the VA and stated that he had surgery for his rectal ulcer with "good results," and that he no longer needed pain medication. We classified this case a demonstrating a Grade 3 AE.

Radiation Proctitis/Proctopathy — Conclusions

Gastrointestinal symptoms after prostate brachytherapy were common and this is neither an unexpected nor unusual finding. Of the 114 PVAMC patients, 16 had endoscopy and/or biopsy documented radiation proctitis/proctopathy or rectal ulceration, although, also not unexpectedly, far more had symptoms consistent with radiation proctitis/proctopathy. Of the 16 patients with documented radiation proctitis/proctopathy or rectal ulceration, we determined that four met the NIH adverse events classification criteria for Grade 3 or Grade 4 toxicity. Since Grade 3 and above toxicity allows for "medically significant" toxicity, and patients often received care outside the VA system, it is possible that additional cases exist.

The incidence (3.5% percent) of Grade 3 or above AEs is consistent with other data cited in the literature.

C. Alleged Substandard Implants

Overview

While this review is able to examine the clinical outcomes and complications across a cohort of 114 PVAMC patients treated with prostate brachytherapy, it is beyond the scope of this report to perform a retrospective peer review of the quality of each prostate brachytherapy implant performed at PVAMC.

As noted, we have concluded that the use of D90 to define and report medical events from a regulatory perspective in the setting of Postoperative Day 1 CT scans was problematic. Likewise, we do not believe the D90 alone can be used to assess clinical quality of implants. Thus, we do not believe that the 92 — and later 97 — total cases reported to the NRC as "medical events" constitute poor implants.

VHA's Advisory Panel for Prostate Brachytherapy which concluded its work in December 2009, developed criteria to assess prostate brachytherapy implants employing seed activity and location criteria.

Based upon this work, on January 28, 2010, VHA wrote to NRC:

> VHA developed ME [medical event] criteria based on recommendations by a blue ribbon panel [VHA's Advisory Panel for Prostate Brachytherapy] of external experts. A copy of the ME criteria that were approved by the National Radiation Safety Committee is provided separately. Use of the new ME criteria identify that from the 105 evaluable patient implants that 17 of the implants should be considered as MEs.
>
> > a. Of these 17 [medical events], *11 are considered to be MEs on the basis of 20% or more seeds having been placed outside of the treatment site.* [OHI emphasis]

This approach suggests that there were 11 implants that had substantial placement of seeds outside of the treatment area.

No matter what criteria are used to assess quality of an implant, two factors should be recognized:

1) A "medical event" is a regulatory, not clinical occurrence.

2) The presence and reporting of a medical event does not reveal information about patient outcome.

Etiology

Without a peer being present in the OR to observe intraoperative technique, initial guide needle placement by the urologist, and other facets of the actual prostate brachytherapy implant, OHI cannot ascertain how substandard implants occurred. We have indicated

that there were at least two "red flags" that something was amiss, notably the 2003 and 2005 cases in which large numbers of seeds were extruded into the patients' bladders. However, with the exception of these two cases, we saw no evidence in CAPRI that PVAMC practitioners were aware of substandard implants occurring as a matter of course.

In the interview process, the medical physicist who worked frequently with one of the radiation oncologists indicated in testimony both to the ABI and to OHI that he had concerns about postoperative dosimetry revealing low values. He told OHI that he brought his concerns to the attention of the radiation oncologist with whom he performed these implants, as well as his physicist supervisor. As noted, we were unable to interview all PVAMC radiation oncologists and, thus, were unable to fully follow up on this assertion. The physicist's supervisor denied that the physicist brought concerns of this nature to him. The physicist also told us that a non-VA radiation oncologist with whom he worked (in a non-VA facility) offered to let the VA radiation oncologist observe him (the non-VA radiation oncologist) perform an implant. We found no evidence that such observation ever occurred.

The radiation oncologist that performed the majority of implants at PVAMC appeared to assess the quality of his implants primarily by examining the postoperative CT scan. We concluded that the radiation oncologist could not have regarded postoperative dosimetry as an indispensable element in performance of prostate brachytherapy, in that multiple implants were performed when postoperative dosimetry was not obtainable due to computer inoperability in 2006 and 2007.

We found no evidence that senior officials at PVAMC or the University of Pennsylvania were aware of an excessive number of substandard implants.

D. Review of a May 5, 2008 Wrong Seed Strength Case

In its simplest exposition, the etiology of the May 5, 2008, incident in which a patient received I-125 seeds of 0.38 mCi strength, when the implanting radiation oncologist intended seeds of 0.509 mCi strength is straightforward. A *pre-printed computer generated* template called for 0.38 mCi seeds favored by Radiation Oncologist 1, the radiation oncologist who performed most of PVAMC's brachytherapy procedures, when it was Radiation Oncologist 2, who preferred 0.509 mCi seed strength, that performed the May 5 implant; and no one revised the pre-printed template accordingly.

This was an isolated occurrence. No other PVAMC prostate brachytherapy patient had a similar mishap.

PVAMC's May 5 prostate brachytherapy patient received only 47% of the prescribed dose of 160 Gray. Nine months later, on February 11, 2009, he had a second or "touch-up" implant at the Seattle VAMC. At this time, 21 seeds were placed (strength/seed not noted in the electronic medical record) in "the upper portion of the prostate and sparingly

in the lower anterior and posterior regions." As of December 31, 2009, there was no evidence of cancer recurrence and/or biochemical relapse.

We found that the patient's prostate cancer had been diagnosed in 2006. He was first seen by a PVAMC radiation oncologist on April 17, 2006. At that time, the patient opted for radical retropubic prostatectomy. The patient later decided not to go through with that operation, and was seen again by the same PVAMC radiation oncologist on January 25, 2008. On April 18, 2008, a treatment planning ultrasound for prostate brachytherapy was performed.

The radiation oncologist and a medical physicist completed a pre-plan. The medical physicist requested that the written directive be done by another physicist, because the initial medical physicist was going to be unavailable to complete it. This second medical physicist agreed to complete the written directive. A computer-generated template was obtained. This template *used 0.38 mCi seed strength as the default seed strength*, as preferred by Radiation Oncologist 1. The consulting radiation oncologist, who was also the radiation oncologist who ultimately performed the procedure had a correct pre-plan seed dose of 0.509 mCi/seed noted. This radiation oncologist, however, received the computer template written directive and signed it, apparently not noting that the other radiation oncologist's preferred dose of 0.38 mCi/seed was in that written directive. The RSO placed an order with the vendor for the seeds based on the signed written directive and apparently also did not compare the pre-plan with the computer-generated written directive. Thus, the error went uncaught.

Seeds are shipped preloaded with sterilized needles and delivered to the warehouse staff that securely stores the package and notifies the RSO. The RSO staff picks up the package, performs a receipt survey, and then stores the seeds until the time of the brachytherapy procedure. When the seeds in this case were delivered, a medical physicist performed a verification that the seeds were of the activity ordered. The vendor's documentation was compared with *the written directive, not the pre-plan documentation*, and thus, again the discrepancy went unnoted.

In May 2008, a medical physicist took the delivered seeds to the OR for implantation and the 0.38 mCi/seed strength seeds were implanted.

Conclusions

Medication errors are the most common type of medical errors. Although this particular case involved radioactive seeds for implantation, in many ways it mirrors wrong dose medication errors that are abundantly described in the medical literature. As noted, in its simplest terms, one strength seed was printed on a default computer template, but the prescribing physician had intended another strength seed. This discrepancy was not identified until after the implant had been performed. There were multiple opportunities to the identify the seed strength discrepancy and prevent the error.

This case was an isolated incident.

Issue 3: PVAMC Medical Records Documentation Surrounding Clinical Care

A. Alleged Medical Records Alteration

The allegation of medical records alteration is not substantiated.

In our review of PVAMC medical records we saw no evidence of medical record falsification in either electronic or paper medical records.

Although not specifically stated, the question of medical document falsification appears to be most suggested in relation to the 2003 and 2005 cases in which two PVAMC patients had 40 and 45 seeds respectively recovered from the bladder. In both cases the attending radiation oncologist was aware intra-operatively of this seed extrusion and modified the operative plan to reflect this difference between the pre-plan and the actual number of seeds implanted. All such records modifications were completed prior to the patient leaving the OR. This is not considered a document alteration. In fact, VHA's National Director of Radiation Oncology Programs stated that it was a requirement to change the medical record to properly reflect the number of seeds that the implanting radiation oncologist believes to have been implanted. We note that the issue was clarified by NRC in NUREG 1556 vol 9 Appendix S:

> D. After implantation but before completion of the procedure: record in the WD [written directive] the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose) as required by 10 CFR 35.40(b)(6). For example, after insertion of permanent implant brachytherapy sources, an AU [authorized user] should *promptly record the actual number of radioactive sources implanted* [OHI emphasis] *and the total source strength*. The WD may be maintained in the patient's chart.

B. Assessment of Clinical Care Documentation

OHI inspectors reviewed several thousand progress notes encompassing all 114 PVAMC prostate brachytherapy patients. Virtually all post-implant PVAMC Radiation Oncology and Urology Service notes were reviewed. Additionally, notes by patients' primary care providers and nursing staff were reviewed as these often provided excellent insight into patients' day-to-day status while at home and patients' longitudinal care, often long after the brachytherapy procedure.

We found that in selecting brachytherapy as the modality to treat patients' prostate cancer, individual medical, psychological, and geographic circumstances were taken into account, as were expressions of patient preference for the procedure. Overall, notes by PVAMC's two brachytherapists, as well as other PVAMC clinicians, were clear, and appropriate subjective, objective, and laboratory data were routinely recorded. The records reflected concern for patients' well-being. Records also demonstrated continued

interest in patients' longitudinal follow-up, and the involvement of other specialists as necessary.

Issue 4: Quality Assurance in 114 Patients Undergoing Brachytherapy at PVAMC, 2002 – 2008

A. Overview

Quality Management (QM) is a critical health care system activity that helps to optimize processes and outcomes. When conducted systematically and credibly, QM can result in both immediate and long term improvements in patient care by revealing areas for improvement in both institutional and individual providers' practice.[24] Committee minutes of QM activities create a historical record of how a medical center chooses to address problems and issues. Accordingly, we examined PVAMC QM practices as they pertained to its Radiation Oncology Service, in general, and prostate brachytherapy in particular. Specifically, OHI reviewed PVAMC's Radiation Oncology Service's QM activities pertaining to prostate brachytherapy with regard to peer reviews, credentialing and privileging, follow-up of adverse events, and PVAMC's Radiation Safety Committee (RSC).

It should be noted that at PVAMC, prostate brachytherapy services were provided under a contract with its affiliate, the University of Pennsylvania. Nevertheless, VHA policy maintains the responsibility of monitoring the quality of services provided within VHA by academic affiliates under contract to VHA within VHA. QM remains inherent to the VA health care system.[25]

B. Peer Review

In 2002, established providers from the University of Pennsylvania were contracted to provide prostate brachytherapy services to PVAMC. However, this contract did not delineate responsibilities for peer review or other QM processes.

From 2002 to 2006, no peer review or quality assessments took place at PVAMC for prostate brachytherapy. We also did not find any prostate brachytherapy cases that were referred for case conferences or morbidity and mortality conferences in this time period.

C. Credentialing and Privileging

VHA licensed independent practitioners must be fully credentialed and privileged to provide direct patient care, including providers utilized on a full-time, part-time, intermittent, consultant, attending, without compensation, on-station fee-basis, on-station contract, or on-station sharing agreement basis. "Credentialing" refers to the systematic process of screening and evaluating qualifications and other credentials of medical center

[24] VHA Directive 2008-004, *Peer Review for Quality Management,* January 28, 2008.
[25] VHA Directive 2009-040, *Quality of Medical Services Performed Within VA Facilities by Academic Affiliates Under Contract*, August 31, 2009.

caregivers and "clinical privileging" is the process by which a practitioner is permitted by the facility to practice independently and to provide specified medical or other patient care services based on credentials and demonstrated clinical proficiencies. Privileges granted may be determined by peer references, documented professional experience, health status, education, training, and licensure. Clinical privileges must be both facility and provider-specific.

OHI reviewed the credentialing and privileging folders for both PVAMC radiation oncologists who performed prostate brachytherapy, as well as the credentials of the physicists involved in the prostate brachytherapy program.

We found that PVAMC's radiation oncologists had been appropriately credentialed. However, they were not privileged appropriately. We found no evidence of prostate brachytherapy training or experience in one of the radiation oncologist's folders (this was corrected while we were on site).

While both PVAMC radiation oncologists that performed prostate brachytherapy were board certified in radiation oncology, only minimal training in brachytherapy is required to achieve American Board of Radiation Oncology board eligibility and board certification in radiation oncology. Thus, a radiation oncologist could be board certified in radiation oncology and privileged to perform the procedure with only nominal prior experience. This aspect of preparation in radiation oncology, which relates to privileging, did not appear to have been recognized or addressed within the privileging process.[26]

In the reprivileging folders we reviewed, there were general attestations of practitioners' competence. However we found no specific data — quality assurance or otherwise — that actually demonstrated observation, critique, comments, statistics, etc. that could be evidence of ongoing proficiency in performing brachytherapy. For example, in the folders provided to OHI, we found no indication that the 2003 and 2005 incidents in which large numbers of seeds were extruded into patients' bladders were discussed or considered in the reprivileging process.

We found that PVAMC complied with VHA policy in the credentialing of the physicists.

[26] The American Board of Radiation Oncology "requires that each program director verify the professional qualifications of each candidate including attestation of completion of the essential elements of training in radiation oncology." Attestation includes, "I have reviewed the logs of the applicant and verify that they have completed the essential training requirements defined by the RRC [Residency Review Committee] in Radiation Oncology in:
(Please initial each line and/or submit the indicated log)
External beam irradiation (at least 450 simulations) ____
*Interstitial radiation (at least 5 cases)*____ [OHI emphasis]
Intracavitary radiation (at least 15 insertions)_____
Unsealed sources (3 oral I131 and 3 Parenteral) Submit Log."

D. Failure to Follow Up Patient Safety Issues When Identified

The Radiation Safety Committee (RSC) reviews safety issues arising from procedures using radiation including prostate brachytherapy. We reviewed PVAMC's RSC Minutes from 2002 to present.

We identified two examples of problems identified for the RSC, which the RSC failed to track to resolution. The first involved recommended actions resulting from an RCA and the second involved a lack of follow-up on a backlog of post-dose calculations that were not performed during a 12-month time period due to a network and connectivity problem.

As noted earlier in this report, the ninth prostate brachytherapy procedure performed at PVAMC in February 2003 resulted in an extensive extrusion of seeds into the patient's bladder. The procedure had to be redone approximately two months later and an NRC and NHPP investigation of the incident was completed. Additionally, PVAMC performed an RCA of the incident. The RCA made pertinent recommendations but the RSC minutes do not document appropriate corrective actions.

A second example RSC failure to follow up on recommended actions involved the VariSeed™ computer, the technical details of which are discussed at length in the next section of this report. However, from a QM perspective, we found that although a PVAMC audit discussed the inability to transfer CT images and identified a significant backlog of post-implant dose calculations that needed to be completed, the RSC repeatedly failed to follow up to document and ensure that the problem was corrected.

Conclusions

There were substantial deficiencies in PVAMC's quality oversight of its prostate brachytherapy program. There was no evidence that appropriate peer review was conducted in PVAMC's Radiation Oncology Service and no evidence of PVAMC prostate brachytherapy case review by the University of Pennsylvania. Privileging problems were identified and PVAMC RSC minutes do not document appropriate corrective actions of problems identified by audits and an RCA. We concluded that these deficiencies in combination deprived PVAMC of the opportunity to identify possible problems with its implants prior to May 5, 2008. For example, although the NRC did not rule the 2003 and 2005 cases in which excessive numbers of seeds were extruded into patients' bladders as medical events, clearly, these cases militated for serious peer review of individual practitioner performance and overall implant quality at PVAMC.

Issue 5: Review of Information Technology Systems Malfunction for 17 Patients Undergoing Brachytherapy at PVAMC, 2006 – 2007

A. Overview

Prostate brachytherapy treatment relies in part on information systems to assist a multidisciplinary team in using dosimetry to calculate radiation dosages.[27] Prior to seed implantation a "pre-planning" process takes place. This includes obtaining ultrasound images of the prostate. At PVAMC, these images were analyzed by the radiation oncologist using VariSeed™ treatment planning system (TPS) software approved by the U.S. Food and Drug Administration (FDA). Using this software, the radiation oncologist is able to delineate the prostate borders, determine its volume, and calculate the number of seeds required for maximum treatment effectiveness. After seed implantation, a "post-planning process" occurs. Computed tomography (CT) scan images of the pelvic region are taken. These images are then reviewed by the radiation oncologist to determine the next appropriate steps in treatment and monitoring.

VariSeed™ TPS software enables the radiation oncologist to focus prostate brachytherapy treatment on the disease "hot spots." Since prostate cancer is a multifocal disease that will be present in some areas of the gland and absent in others, it is desirable to direct radiation to the cancerous areas within the prostate, and within the cancer itself, the areas that are most aggressive.

Prior to February 2006, University of Pennsylvania staff assumed responsibility for IT, medical equipment maintenance, and support to PVAMC's Radiation Oncology Service as it pertained to PVAMC's prostate brachytherapy program. After February 2006, PVAMC assumed these responsibilities.

From November 2006 to November 2007, there was an IT systems failure that resulted in a 12-month time period during which PVAMC brachytherapists were unable to obtain postoperative dosimetry data. This section further discusses the etiology and circumstances surrounding this problem as well as related IT issues.

B. VariSeed™ Not Operational for Twelve Months

For a period of twelve months, the VariSeed™ TPS for use in prostate brachytherapy could not receive CT images because of a network connectivity issue. The root cause of this was the result of the installation of a new information system in PVAMC's Radiation Oncology Service, this installation not addressing ancillary issues that often arise during IT changeovers.

[27] In Radiation Oncology, dosimetry is the formal science that measures and calculates doses and format of radiation to be administered to a patient with a disease requiring radiation therapy, in particular cancer.

Sometime in November 2006, the Automated Data Processing Application Coordinator (ADPAC) for PVAMC's Radiation Oncology Service was told by a contract University of Pennsylvania medical physicist to submit a telephone service request (TSR) to install a new network drive or jack for a new Radiation Oncology Service computer system. Before this TSR was submitted, the system vendor and an IT representative worked together to install the new system. However, since there were not enough jacks available, *the system vendor and the IT representative unplugged the VariSeed™ TPS and plugged in the new system's workstation*.

In early December 2006, the ADPAC submitted a paper copy TSR for a new jack and approximately ten days later an outside contractor came and installed a new jack. On January 24, 2007, the ADPAC then submitted a local work ticket or National On-Line Information System (NOIS) request requesting the VariSeed™ TPS be connected to the network. In the NOIS ticket, the ADPAC expressed, "it's effecting patient care."

One week later, a January 31, 2007, audit, conducted by a health physicist in PVAMC's Radiation Safety Department indicated, "VariSeed™ workstation communication/network problem. No post planning being performed as of this date. This should be resolved as soon as possible." The health physicist then took the initiative to perform quarterly audits of PVAMC's Radiation Oncology Service. These audit summaries were distributed and reviewed by the RSC including its chairman, the RSO, and the Chief, Radiation Oncology Service.

On February 8, 2007, a network administrator stated Information Resources Management (IRM) wanted to know if patient records were being stored on the VariSeed™ TPS. This was an important question because if patient information was stored within the VariSeed™ TPS, then its workstation was required to be in a Virtual Local Area Network (VLAN) and Biomed needed to coordinate with another software group known as IMPAC in order to proceed.[28]

On March 21, 2007, the RSC discussed the medical physicist's audit findings. We were unable to find documentation of actions addressing these findings, but we did learn that on April 19, 2007, the network administrator requested an update on the situation from the ADPAC. The next day, April 20, 2007, the ADPAC wrote, "The connection to the jack has been resolved. However the problem now is that the PC is not on the domain ... I am planning on placing a NOIS [request] to have the CT IP address reconnected to the PC." The original NOIS ticket (i.e., request) was then closed. However, the ADPAC did not submit another NOIS request.

On June 12, 2007, the health physicist, documented in another audit that was reviewed by the RSC, that the "Varian VariSeed treatment planning system continues to have network/communication problems. Images cannot be transferred. As a result there is an approximate three month backlog of prostate implant post plans."

[28] A VLAN is a network of computers that behave as if they are connected to the same wire even though they may actually be physically located on different segments of a LAN; a VLAN is a method of separating network devices into different logical segments without regard to their physical location.

On August 21, 2007, the health physicist's audit stated, "There continues to be a problem causing a now six month backlog."

On September 25, 2007, these audits were reviewed and discussed by the RSC members. No action was mentioned and the minutes were signed off by PVAMC's Director.

The problem was ultimately solved in November 2007. In that PVAMC did not cease performing prostate brachytherapy implants during this 12-month interval when the VariSeed™ TPS was inoperable, a total of 17 patients had implants without post-implant dosimetry.

In January 24, 2008, the health physicist's audit stated "the computer deficiency is corrected."

From our interviews, review of e-mails and other documentation, and review of RSC minutes, this computer connectivity problem was widely known within PVAMC's Radiation Oncology Service. However, despite exhaustive examination, we did not find any indication that the problem was elevated to PVAMC management above the level of the Radiation Oncology Service, nor was it elevated to University of Pennsylvania senior officials.

C. Failure to Properly Isolate a Medical Device and Inappropriate Transfers of Personally Identifiable Information

FDA defines a medical device as any device that is used in health care for diagnosis, treatment, monitoring of physiological measurements, or for health analytical purposes. As such, the VariSeed™ TPS described above meets the definition of a medical device. The *Health Information Portability and Accountability Act (HIPAA)* mandates that, "Any Personally Identifiable Information (PII) and electronic Patient Health Information (ePHI) that is collected, stored, or transmitted across medical device systems should be protected with the best possible security tools for the deployed systems."

On April 26, 2004, VHA's Deputy Under Secretary for Health for Operations and Management distributed a memo to all VISN directors mandating strengthening "the security posture of medical devices connected to facility information networks requiring a strategy using isolation architecture to be fully implemented by September 30, 2004." On April 30, 2004, VA's Center for Engineering & Occupational Safety and Health (CEOSH) in conjunction with VHA published the *Department of Veterans Affairs Medical Device Isolation Architecture Guide*. This guide provides step-by-step instructions for securing medical devices within a VLAN structure, the VLAN structure becoming a means of isolating a system containing medical information from other operating systems.

In examining the 12-month inoperability of the VariSeed™ TPS at PVAMC, we identified a failure at PVAMC to isolate the VariSeed™ computer from other operating systems, as well as inappropriate transfers of information using unsecured media. According to the ADPAC, PVAMC's VariSeed™ TPS was also being used as a personal

computer by staff in the Radiation Oncology Service. We were told that this was, in fact, the primary reason the VariSeed™ TPS was not placed on a VLAN in 2004. This was also apparently the reason for the delay in reconnecting the VariSeed™ TPS. It was believed that the VariSeed™ TPS did not need to be placed in a medical VLAN because that would prevent it from being used as a computer to view email and access the internet.

We also were told that inappropriate transferring of HIPAA protected materials occurred at PVAMC. CT scan images at PVAMC were transmitted to the VariSeed™ TPS from a CT scanner directly or through an image storage workstation and backed up on tapes. In order for the VariSeed™ computer system to analyze these tapes, they had to be first converted to compact disc (CD) format. However, during our inspections, we did not find any evidence that PVAMC's Radiation Oncology Service had the capability to convert tapes to CDs. It appeared that during 2002-2003 tapes were taken to the University of Pennsylvania to be converted to CD by staff within the prostate brachytherapy program. Ultimately, this practice was halted due to HIPPA concerns.

D. Failure to Maintain Appropriate Contract Oversight

We found that PVAMC failed to appropriately oversee expenditures and services provided under the contract with the University of Pennsylvania.

Although the University of Pennsylvania had responsibility for IT support systems for prostate brachytherapy under the 2002 contract, contracting invoices for the Radiation Oncology Service include charges for engineering services from 2002. The engineering services ceased after February 2006. It was unclear what services had actually been provided because there are no requirements in the contract, including the statement of work, for engineering services.

In a contract awarded in April 2005 to purchase Radiation Therapy Services for PVAMC from the University of Pennsylvania, IT responsibility shifted to PVAMC. The contract stated, in section A.8 Accountability, paragraph c, "The VA shall furnish all medical and office supplies required to maintain and operate the Radiation Therapy Service. The VA shall maintain all medical equipment utilized in the provision of radiation therapy services."

We found that no hand off or coordination with the University of Pennsylvania in transferring responsibility for IT systems took place. Although there is email correspondence in early February 2006 regarding the need for Biomed staff to receive training on the Radiation Therapy equipment, PVAMC's Chief, Biomedical Engineering, states nearly eight months later in an email dated October 20, 2006, "Unfortunately Biomed staff knows very little about the equipment in this department, as devices have been maintained mostly by HUP [the University of Pennsylvania], vendors, and IMS in the past."

Conclusions

We concluded that relatively simple, although bureaucratically complex, computer hardware and software problems prevented PVAMC patients during a 12-month time period from having post prostate brachytherapy dosimetry studies. We believe the performance of these studies is a generally accepted practice. We concluded that the problem should have been fixed expeditiously. As long as it remained unresolved, prostate brachytherapy implants should have been halted.

We concluded that this problem was not shared with PVAMC management beyond the Radiation Oncology Service nor with senior leaders at the University of Pennsylvania. It took IT and Biomed almost one year to fix the computer network problem, and there was a lack of documentation of the work performed by Biomed to solve the VariSeed™ TPS network connection problems. We concluded that there were communication problems between Biomed and IT.

We concluded that there were failures in the isolation of a medical device and patient personally identifiable information. However, despite identifying this vulnerability, we found no evidence that actual patient personal information was compromised, exposed, or misused.

We concluded that there was inadequate PVAMC coordination with the University of Pennsylvania in transferring IT and medical equipment responsibility.

We concluded that there was poor contract administration, resulting in clinical support responsibility gaps to PVAMC's Radiation Oncology Service.

Issue 6: Brachytherapy Issues at Jackson, Mississippi VA Medical Center

A. Overview

Jackson VAMC (JVAMC) is a tertiary care facility located in Jackson, MS, that provides a broad range of inpatient and outpatient health care services. The medical center is part of VISN 16 and serves a veteran population of approximately 132,000 throughout 19 counties in Mississippi and Arkansas.

The Radiation Oncology Service at JVAMC provided brachytherapy in the treatment of prostate cancer from February 2005, to September 18, 2008, when the medical center voluntarily suspended the program. The program was subsequently cancelled on May 4, 2009.

In the course of VHA's CRAAB's review of prostate brachytherapy at PVAMC, the CRAAB expanded its review beyond PVAMC. It requested a sample of 10 brachytherapy cases from each VAMC that performed the procedure. These cases were to be reviewed by an expert not affiliated with the submitting facility. This review process identified additional VAMCs where D90 values were below the 80% threshold,

ultimately triggering further reviews. Concerns were greatest at Jackson VAMC. As well as having dosimetric data raising concerns about the possibility of substandard prostate brachytherapy, the CRAAB also identified that JVAMC had information systems problems that appeared similar to PVAMC's.

On November 3-5, 2009, OHI performed an inspection of Jackson VAMC's brachytherapy program.

B. Findings

JVAMC Did Not Conduct Appropriate Quality Oversight of Its Prostate Brachytherapy Program

We found that JVAMC did not ensure that quality care was being provided in its prostate brachytherapy program. VHA policy requires medical centers to conduct peer review routinely. In the course of our site visit, we could find no evidence of peer review activities or tracking of individual provider performance data within JVAMC's Radiation Oncology Service.

Treatment Planning System Issues

The JVAMC Radiation Oncology Service, like PVAMC, utilized the VariSeed™ TPS to perform dosimetry for planning and evaluating brachytherapy procedures. We identified several problems with both pre-operative and post-operative dosimetry as follows:

- JVAMC's Radiation Oncology Service had not isolated the VariSeed™ from other IT operations as mandated in 2005 by the VA Deputy Under Secretary for Health Operations and Management.
- JVAMC's two radiation oncologists that performed brachytherapy reportedly could not agree on prostate volumes, and due to disagreements, had not conducted post-treatment planning evaluations since February, 2005.
- A medical physicist was permitted to maintain inappropriate computer access.
- A dosimetrist was unable to review CT images from the network server from May 2007 – February 2008 because this individual did not know the location of the folders on the network server. From May 2007 – February 2008, the dosimetrist attempted to retrieve CT scan data as the medical physicist had done, but was unable to obtain images because this individual did not have an "administrative password." The dosimetrist was also unable to review the CT images from the network server from May 2007 to February 2008 because the dosimetrist did not know the location of the folders on the network server.

Conclusions

We concluded that brachytherapy as practiced at the JVAMC had some common issues with PVAMC. Somewhat similar to PVAMC, in the final analysis the computer issues were not of a highly technical nature such as systems compatibility or programming, but rather of the failure of various parties with an interest in computers taking the steps necessary in an expeditious manner to make systems function.

There was a poor professional continuity on the Radiation Oncology Service in the face of the departure of a medical physicist. This resulted in an inability to locate or retrieve CT images.

Since February 2005, there was no post-planning by the radiation oncologists.

Issue 7: Initiatives in Radiation Oncology Service

A. PVAMC

In 2006, major improvements were made to PVAMC's QM processes. A new QM manager was hired and contract employees were informed that there was mandatory attendance of PVAMC orientation and annual training classes. In late 2008, the QM staff established an internal peer review process for PVAMC's Radiation Oncology Service. This review process will include the prostate brachytherapy program if it is reinstated.

Each provider in the Radiation Oncology Service is now required to peer review three radiation oncology cases. In addition, treatment documentation is reviewed weekly. All results are reported to the Medical Executive Committee on a quarterly basis. When cases do not meet standards of care they are referred to the institutional peer review, morbidity and mortality, or tumor board conferences for further discussion. According to contracting staff, new radiation therapy contracts, currently under development, will include clearly defined institutional and individual QM responsibilities for both PVAMC and University of Pennsylvania.

A summary of QM activities currently occurring regularly on PVAMC's Radiation Oncology Service as provided to OHI by PVAMC's Radiation Oncology Service is bulleted below. Many of these activities predated the concerns regarding brachytherapy.

- Weekly Radiation Oncology Service "on-treatment" patient conference in which review of all active patients and discussion of patient issues occurs.
- Weekly "Patient Consultation" conference in which all patients seen in consultation by the Radiation Oncology Service and/or at an initial visit are discussed.
- Quarterly Morbidity and Mortality conference in which patients who exhibit Grade IV acute radiation side effects or Grade III/IV late radiation side effects are discussed.

- Monthly Radiation Oncology Service meeting. Agenda items are according to ACR guidelines, and are "including but not limited to: chart review; physics QI [quality improvement] report; treatment variations > 10%; new treatment modality or technique report; incidents; treatment interruptions; review of outcome studies; physician peer review; patient outcomes/follow up process; facility patient related outcome data; patient satisfaction."
- Quarterly physician peer review of charts.
- Weekly QA activities at the University of Pennsylvania Health System, including review of all new CT/simulations utilizing ACR guidelines.
- Monthly Patient Chart Audit.
- Quarterly discussion of patient satisfaction results.

B. VHA National Director of Radiation Oncology Programs

With the recruitment of a full time VHA National Director of Radiation Oncology Programs, there has been a substantial increase in QM and oversight activities affecting both brachytherapy and the larger specialty of radiation oncology. Some of the initiatives recently concluded or ongoing include:

- Requirement for mandatory ACR–American Society for Therapeutic Radiology and Oncology (ASTRO) accreditation.
- Establishment of a VHA Field Advisory Committee for Radiation Oncology.
- Ongoing development of a VHA Handbook for Radiation Oncology.
- VHA Advisory Panel for Prostate Brachytherapy (January – December 2009).
- VAMC Radiation Oncology Service review by the Radiological Physics Center, "to provide quality auditing of dosimetry practices at institutions participating in NCI cooperative clinical trials."[29]

[29] "The Radiological Physics Center (RPC) has been funded by the National Cancer Institute (NCI) continuously since 1968 to provide quality auditing of dosimetry practices at institutions participating in NCI cooperative clinical trials… The primary responsibility of the RPC is to assure the NCI and the cooperative clinical trial groups that all participating institutions have the equipment, personnel, and procedures necessary to administer radiation doses that are clinically comparable and consistent. http://rpc.mdanderson.org/rpc/About_RPC/History.htm [accessed 4/5/2010.]

Section II

National Assessment of VHA Prostate Brachytherapy Programs

Scope and Methodology

This evaluation includes all VHA prostate brachytherapy programs that were active during any period of FY 2005-2009. We reviewed applicable regulations, policies, procedures, and guidelines.

Study Population

The study population consists of prostate cancer patients who underwent brachytherapy at VHA for therapeutic disease management during FY2005-2009. In addition, the study population includes patients who received prostate brachytherapy at PVAMC FY2002-2004, to permit analysis of every prostate brachytherapy patient ever treated at PVAMC. PVAMC performed its first prostate brachytherapy procedure on February 25, 2002, and the last one on June 2, 2008. Prostate brachytherapy patients who received their implantation through non-VA services (for example, fee basis) are excluded from this evaluation.

To identify the study population, we first ascertained all VHA facilities that performed any prostate brachytherapy procedures during FY2005-2009. We then contacted each of the prostate brachytherapy facilities for their prostate brachytherapy patient list.

Sample Design

All patients in the study population were included except for those from Cincinnati VAMC. Cincinnati VAMC performed a relatively large volume of prostate brachytherapy and did not compile its post-implantation evaluation data in a spreadsheet file. Using stratified unequal probability-based scheme and the FY2005-FY2009 prostate brachytherapy patient list acquired from the VAMC, we randomly sampled 30 patients within each FY. Fewer than 30 prostate brachytherapy patients were implanted at Cincinnati VAMC in FY2009, thus all of them were included.

Study Outcomes and Data Collection

Clinical outcomes include clinical failure (recurrence), biochemical failure (PSA relapse), and complications (toxicity) after prostate brachytherapy. PSA relapse is not equivalent

to clinical failure although an appropriate early end point for clinical trials. Thus, it is not justification per se to initiate additional treatment.[30]

Clinical failure and toxicity were determined by treating physicians. Information on clinical failure and toxicity were abstracted by retrospective chart review.

Varying criteria have been used in defining biochemical failure in the literature. The Phoenix definition[31] and the American Society of Radiation Oncology (ASTRO) definition are the two most commonly used, both of which were derived from the experience with external radiotherapy. In this evaluation, biochemical failure was defined according to the current (Phoenix) consensus recommendation of the ASTRO as a rise in PSA level by 2 ng/mL or more over the absolute nadir value (i.e., lowest PSA level). Absolute nadir was defined as the lowest PSA measurement during the entire follow-up period of the patient after the prostate brachytherapy, as assessed retrospectively (in contrast to the current nadir defined as the lowest PSA measurement before the current measurement).

Information on biochemical failure was abstracted from the lab section of patient medical records in CAPRI. For PVAMC patients, in addition to the PSA values abstracted from CAPRI, we also abstracted pretreatment PSA values from treating physicians consult notes and progress notes. One PVAMC patient, XRT004, received little post-brachytherapy clinical care at VHA facilities; we extracted his post-implantation PSA data from his progress notes in CAPRI.

Post-implantation CT-based dosimetry is considered an essential component of prostate brachytherapy. Although most implants use I-125 or Pd-103 sources, clinical use of Cs-131 sources has also recently been introduced.[32] These sources produce different dose distributions and irradiate the tumors at different dose rates. Post-implantation dosimetry is the only method of assessing the actual dose delivered to the prostate and normal surrounding structures.

[30] Consensus Statement: Guidelines For PSA Following Radiation Therapy, American Society For Therapeutic Radiology And Oncology Consensus Panel. Int. J. Radiation Oncology Biol. Phys. 1997; 37(5):1035-1041.
[31] Roach M III, Hanks G, Thames H Jr., et al. Defining biochemical failure following radiotherapy with or without hormonal therapy in men with clinically localized prostate cancer: Recommendations of the RTOG-ASTRO Phoenix Consensus Conference. Int J Radiat Oncol Biol Phys. 2006; 65: 965–974.
[32] Prestidge B.R., et al. Cesium-131 permanent prostate brachytherapy: An initial report. Int. J. Radiat. Oncol., Biol., Phys. 2005; 63:S336–S337.

Prescription dose is the intended nominal dose to the 100% isodose. The dose prescribed to individual patients is primarily a clinical decision. When using brachytherapy as the monotherapy for prostate cancer, the American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee recommended the use of 145 Gy prescription dose for I-125[33] and 125 Gy for Pd-103.[34] However, higher doses have also been suggested and used in practice.[35] Although the prescription dose for Cs-131 remains investigational, 115 Gy has been recommended for Cs-131 monotherapy implantation.[36]

In practice, the delivered (absorbed) dose was defined as D90 based on post-implantation dosimetric evaluation. D90 is the minimum absorbed dose covering 90% of the post-implantation computed tomography prostate volume. This was chosen over the D100 (100% of the volume) to take into account difficulties in defining prostate volume on CT images.

Post-implantation dosimetric data were acquired electronically from VAMCs in Seattle, WA and Richmond, VA because these two performed large volumes and kept the dosimetric data in spreadsheets. Data for 81 (out of the 92) patients treated at Jackson VAMC (JVAMC) was compiled by an external expert contracted by VHA and was acquired electronically from the National Director for Radiation Oncology on March 19, 2010. Paper copies of summary reports of post-implantation dosimetric analyses from their treatment planning system (TPS) were acquired from the other 12 VAMCs. The relevant data were abstracted and entered independently by two Health Care Inspectors.

To assess the radiation dose delivered to the normal surrounding structures for patients treated at PVAMC, we analyzed the highest doses to 1 cubic centimeter (cc) of the rectum, 1 cc of bladder wall, and 2 cc of peri-prostatic soft tissues. This data was extracted directly from PVAMC data reported to NRC by NHPP on January 28, 2010.

Various patient and cancer related characteristics were abstracted from medical record review. Medical record reviews, data abstracts and data entry were conducted independently by at least two health care inspectors, except for the JVAMC patient date of birth that was abstracted and entered twice by the same inspector. All data elements collected by the two inspectors were compared electronically for consistency, elements by elements. Any discrepancies detected from data comparisons were resolved or adjudicated. A Senior Physician reviewed all clinical outcomes.

[33] Williamson J.F., et al. Guidance to users of Nycomed Amersham and North American Scientific, Inc., I-125 interstitial sources: Dosimetry and calibration changes: Recommendations of the American Association of Physicists in Medicine Radiation Therapy Committee Ad Hoc Subcommittee on low-energy seed dosimetry. Med. Phys. 1999. 26:570–573.

[34] Williamson, J. F., et al. Recommendations of the American Association of Physicists in Medicine on Pd-103 interstitial source calibration and dosimetry: Implications for dose specification and prescription. Med. Phys. 2000; 27: 634–642.

[35] Kao J., Ston N. N., Lavaf A., Dumane V., Cesaretti J. A., and Stock R. G. I-125 Monotherapy Using D90 Implant Doses Of 180 Gy or Greater .Int. J. Radiation Oncology Biol. Phys. 2008; 70(1): 96–101.

[36] Bice W.S., et al. Recommendations for permanent prostate brachytherapy with Cs-131: a consensus report from the Cesium Advisory Group. Brachytherapy 2008; 7: 290–296.

Statistical Methods

Pretreatment PSA was defined as the maximum value of all preimplantation PSA values abstracted from the CAPRI lab section and, if applicable, from treating physicians' consults and progress notes.

Patients were classified into one of the following three prognostic risk groups according to the National Comprehensive Cancer Network (www.nccn.org):

- Low risk disease: stage T1-T2a, and pretreatment PSA level of <10 ng/mL, and Gleason score of <=6 ,
- Intermediate risk disease: stage T2b or T2c, or pretreatment PSA level of 10-20 ng/mL, or Gleason score of 7,
- High risk disease: stage >=T3a, or a pretreatment PSA level of >20 ng/mL, or Gleason score >=8.

Because the effects of edema caused by postsurgical trauma can vary from one patient to another and resolve at different rates, CT at different timing can yield different doses reported (to have been delivered) for the same implant. The timing of imaging for dosimetry evaluation can alter or have a profound effect on the dose reported.[37,38,39,40] The AAPM recommends that the post-implantation dosimetry should be performed at the following optimum time:

- At 1 month (± 1 week) after the procedure for I-125 implants.
- At 16 (± 4) days after the procedure for Pd-103 implants.
- At 10 (± 2) days after the procedure for Cs-131 implants.[41]

Post-implantation CT-based dosimetry, the method for determining the actual dose delivered to the prostate and normal surrounding structures, was assessed. In accordance

[37] Badiozamani K.R., et al. Anticipating prostatic volume changes due to prostate brachytherapy. Radiat. Oncol. Invest. 1999; 7: 360–36.
[38] Taussky D., et al. Sequential evaluation of prostate edema after permanent seed prostate brachytherapy using CT-MRI fusion. Int. J. Radiat. Oncol., Biol., Phys. 2005; 62: 974–980.
[39] Waterman F.M., et al. Edema associated with I-125 or Pd-103 prostate brachytherapy and its impact on post-implant dosimetry: An analysis based on serial CT acquisition. Int. J. Radiat. Oncol., Biol., Phys. 1998; 41: 1069–1077.
[40] Yamada Y., et al. Impact of intraoperative edema during transperineal permanent prostate brachytherapy on computer-optimized and preimplant planning techniques. Am. J. Clin. Oncol. 2003; 26: 130–135.
[41] Nath R., et al. AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137. Med. Phys. 2009; 36(11): 5310–5322.

with the recommendation of the American Brachytherapy Society,[42] we analyzed the minimum absorbed dose covering 90% of the post-implantation prostate volume (D90) and/or the prostate volume receiving 100% of the prescribed dose (V100) as indicators of implant quality. The D90 and V100 provide a consistent way to compare the quality of the implants. VHA adopted D90 as reporting criteria reporting medical events (ME) in January 2009.

The method for determining the prostate D90 and V100 varied according to treatment center. There is currently no single post-implantation dosimetry evaluation time that is followed consistently by every VA Prostate Brachytherapy program or even within the same VA program by different practitioners. The post-implantation dosimetry time adopted by different programs varied significantly, from immediately after the procedure to several hours or weeks after the procedure. Even within the same VAMC, dosimetry times varied for a variety of reasons to include the avoidance of unnecessary patient travel from remote distances and/or to improve patient's compliance. When more than one dosimetry was evaluated at different times, we chose the one that was closest to the AAPM recommended optimum time. Dosimetry based on CT images obtained more than six months after the implant (non-contemporaneous) were excluded from analyses.

PVAMC used the CT taken the day after prostate brachytherapy (Day-1) for post-implantation evaluation. After PVAMC's index case on May 5, 2008, some PVAMC patient implants were reevaluated on the basis of non-contemporaneous CT-imaging taken in late 2008 and might have reported some medical events (MEs) based on these reevaluations. We used the data abstracted from paper copies of the Day-1 TPS dosimetric analyses summary reports. A patient may have up to 3 Day-1 reports. Report 1 is the original evaluation (original treating physicians delineated prostate on the CT). Report 2 and Report 3 are re-evaluation using independent consultants' re-contouring. Report 3 checked for redundant seed identification[43] so that dose calculation was based on the correct locations of seeds. Report 2 did not check for redundant seeds. It is possible that PVAMC reported some MEs incorrectly based on Report 2 data. When

[42] Nag S., et al. The American Brachytherapy Society Recommendations For Permanent Prostate Brachytherapy Postimplant Dosimetric Analysis. Int. J. Radiation Oncology Biol. Phys.2000; 46(1):221–230.

[43] Redundant seeds refer to false or duplicate seeds. If the thickness of the CT image slices is smaller than the axial dimension of a seed, a portion of that seed may appear in 2 consecutive images. Seed identification is performed slice by slice. It may not be apparent to the physicist (user) that a bright spot on one slice represents the same seed on an adjacent slice. If the user identifies this seed as 2 individual seeds, the TPS system (VariSeed) algorithm will capture it as a "redundant seed." However, VariSeed does not prevent the physicist from presenting the falsely calculated dose. The user must open the "Redundant Seed" tab to check if such an error has been made. If so, the user has the opportunity to correct it. If the correction is not made, one would think that the correct number of implanted seeds were found, and the resultant doses were accurate. In fact, if one or more seeds were counted as 2 seeds then there will be actual seeds unidentified and not calculated as having contributed dose. Furthermore, the system does not warn the treating physician (reviewer) that the user inadvertently placed 2 seeds in the same location (a physical impossibility). The magnitude of the error cannot be realized until the correction is made. Redundant seeds are detected by checking each seed with every other seed. VariSeed's redundant seed detecting algorithm attempts to detect redundant (i.e., false or duplicate) seeds in post–operative CT evaluations. VariSeed generates lists of possibly redundant seeds which the user can selectively correct.

there were no redundant seeds identified, Report 2 results were correct, and no Report 3 was generated. We composited dosimetric data from all available reports in the order of Report 3, Report 2, and Report 1.

Patients XRT 018 and XRT 062 at PVAMC, patient BR59 at Brooklyn VAMC, and patient SF62 at San Francisco VAMC had two implants within 4 months. Their dosimetry data from the second implantation were used in our analyses.

In addition to being administrated as a definitive monotherapy, prostate brachytherapy may also be applied as a boost in combination with external radiotherapy. The post-dosimetric data rarely indicate boost from monotherapy. In addition to the prostate brachytherapy that was indicated as boost by VAMCs, we classified a prostate brachytherapy as a boost procedure if its prescription dose is less than:

- 140 Gy for I-125.
- 120 Gy for Pd-103.
- 100 Gy for Cs-131.

Using the failure criteria of recurrence and Phoenix definition, we defined disease failure as either recurrence or meeting Phoenix criteria (nadir + 2); thus, disease–free are free from both recurrence and PSA relapse.

The date of brachytherapy was considered day 0 for calculation of follow-up duration. For PVAMC, the follow-up cutoff date for clinical outcomes was December 31, 2009. Patients without recurrence were censored for recurrence at death, last follow-up, or December 31, 2009, whichever occurred first. Similarly, disease-free patients were censored for disease relapse. For the eight PVAMC patients who underwent reimplantation at Seattle VAMC in late 2008 and early 2009 because of low delivered doses from their original implant at PVAMC, the follow-up time for biochemical failures were censored at their reimplantation dates. For JVAMC patients, the follow-up time for biochemical failures were censored at their last PSA dates.

Survival curves of PSA relapse-free, recurrence-free, and disease-free were calculated using the Kaplan–Meier method.[44] Log rank tests were used to test differences in survival curves. Cox regression analysis was used to evaluate the associations of disease characteristics and post-implantation dosimetry quantifiers with clinical outcomes.[45] Dosimetric comparisons and relationships between dosimetric values and implant sequence numbers were evaluated using regression analysis. Logistic regression was used to analyze the associations of post-implantation dosimetry quantifiers with

[44]Kaplan E.L., Meier P. Nonparametric estimation from incomplete observations. J Cancer Res Clin Oncol. 1958; 53: 457–9.
[45] Cox D.R., Regression models and life tables. J Roy Statist Soc. 1972; 34: 187–220.

complication outcomes. All statistical tests were two sided, with $p < 0.05$ indicative of statistical significance. Statistical analyses were performed using the SAS Version 9.2 (SAS Inc., Cary, NC). Maps were produced using ArcGIS software, version 9.2 (Environmental Systems Research Institute, Redlands, CA).

Findings

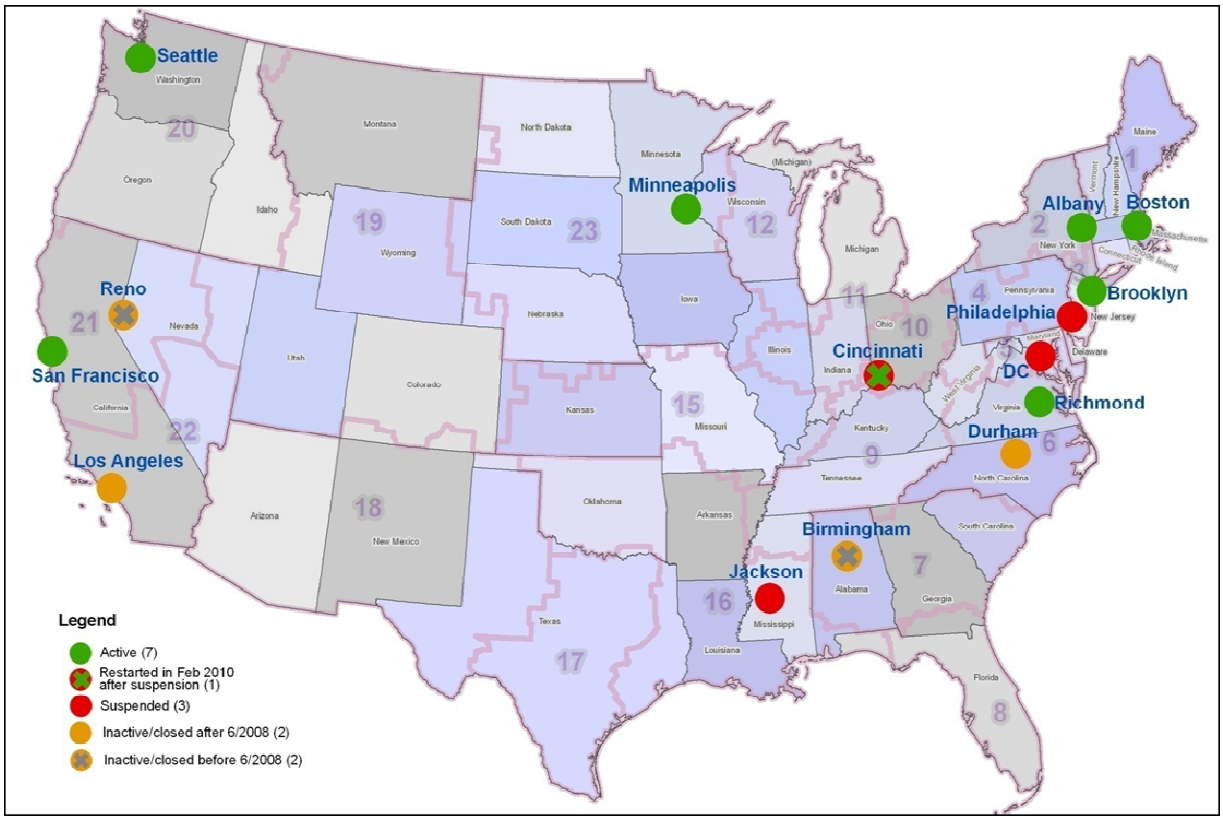
A. VHA Prostate Brachytherapy Programs

Fifteen VA medical facilities performed prostate brachytherapy procedures during FY2005-2009 (Table A). Birmingham VAMC closed its prostate brachytherapy program in 2006. Reno and Durham VAMCs voluntarily suspended their programs in 2008 and 2009, respectively. Los Angeles VAMC closed its program voluntarily in 2009. PVAMC and JVAMC closed their prostate brachytherapy programs in 2009 after suspension by VHA. Cincinnati VAMC was approved for restart effective February 2010 after its suspension in 2008 by VHA. It performed prostate brachytherapy procedures in March 2010 after the restart. Washington DC VAMC was suspended by VHA in September 2008 with possible restart in the future. As of March 12, 2010, eight VA medical facilities continue their prostate brachytherapy program. Figure A geographically depicts the 15 VA medical facilities that performed prostate brachytherapy during FY2005-2009.

Table A. Status (as of March 12, 2010) of the 15 active VHA brachytherapy programs during any period of FY2005-2009

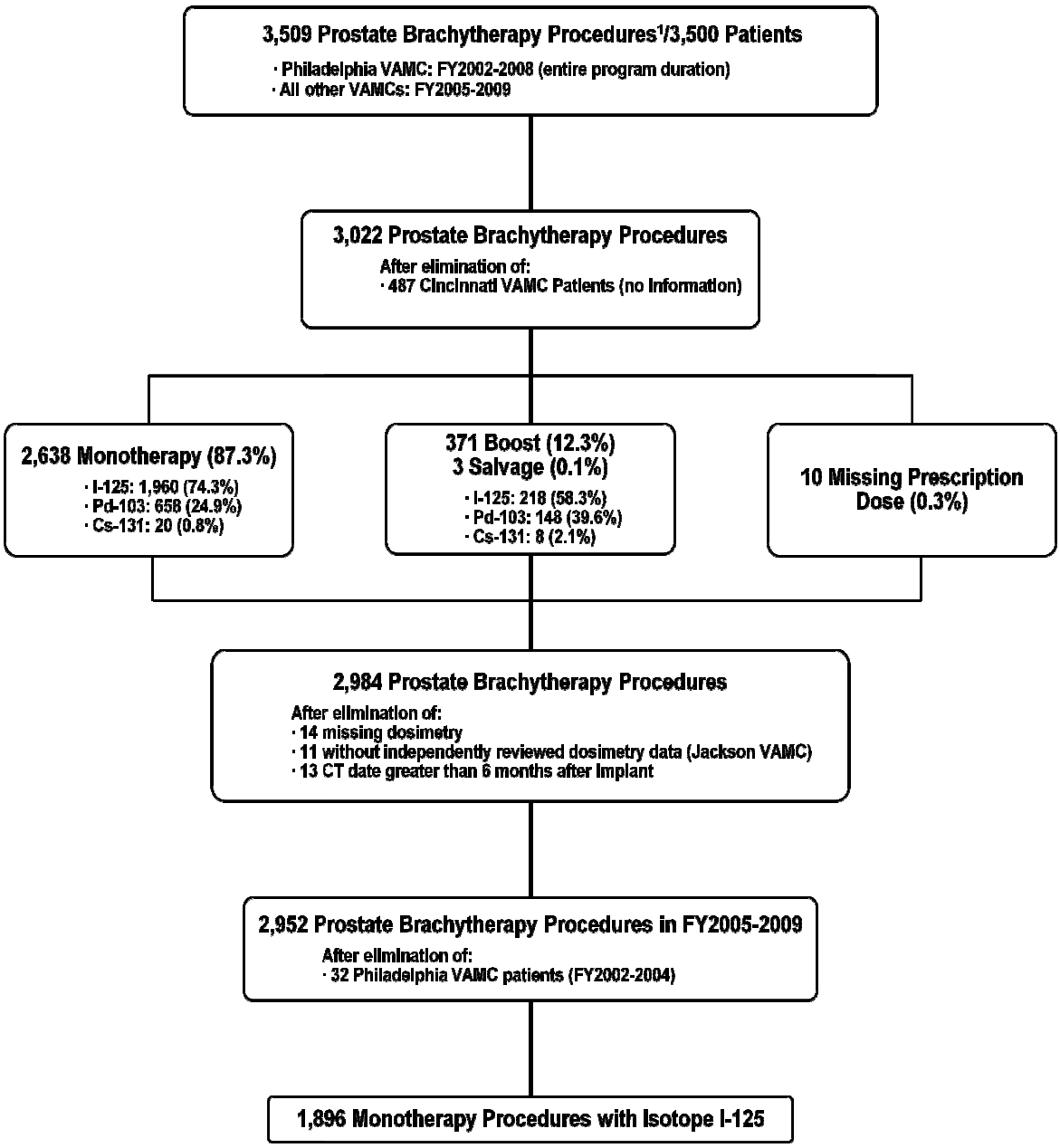
Program Location	Status	Comments
Albany	Active	NHPP inspection in August 2009 with no violations cited
Boston	Active	NHPP inspection in August 2009 with two minor violations cited that did not impact quality of implants
Brooklyn	Active	NHPP inspection in December 2009 with no violations cited
Cincinnati	Active	Suspended effective October 2008; approved for restart effective February 2010
Minneapolis	Active	NHPP inspection in January 2010 with one minor violation cited that did not impact quality of implants
Richmond	Active	NHPP inspection in November 2009 with no violations cited
San Francisco	Active	NHPP inspection in August 2009 with no violations cited
Seattle	Active	NHPP inspection in November 2009 with no violations cited
Birmingham	Inactive	Inactive since 2007
Durham	Inactive	NHPP inspection January 2009 with no violations cited; inactive since February 2009
Los Angeles	Inactive	Inactive since September 2009
Reno	Inactive	Inactive since March 2008
Jackson	Suspended	Suspended effective September 2008
Philadelphia	Suspended	Suspended effective June 2008
Washington DC	Suspended	Suspended effective September 2008; possible restart in the future

Figure A. Status of VHA prostate brachytherapy programs (as of March 12, 2010)



There were 3,509 prostate brachytherapies performed on 3,500 patients at either PVAMC from February 2002 to June 2008 or at one of the other 14 VHA facilities during FY2005 – 2009, after combining the two implant procedures performed within 4 months for Patients XRT 018 and XRT 062 at PVAMC, BR59 at Brooklyn VAMC and SF62 at San Francisco VAMC (Figure B). Eight PVAMC patients went to Seattle VAMC for reimplantation in late 2008 and early 2009 because of the low delivered doses of their original implantation at PVAMC. One Richmond patient underwent a salvage prostate brachytherapy after the original one. Four hundred eighty-seven Cincinnati prostate brachytherapy patients were excluded because of a lack of information on them. About 87 percent of the 3,022 procedures were monotherapy. I-125 was the most commonly used treatment isotope. For the dosimetry, we excluded the 13 procedures whose post-implantation CT was taken more than 6 months after prostate brachytherapy.

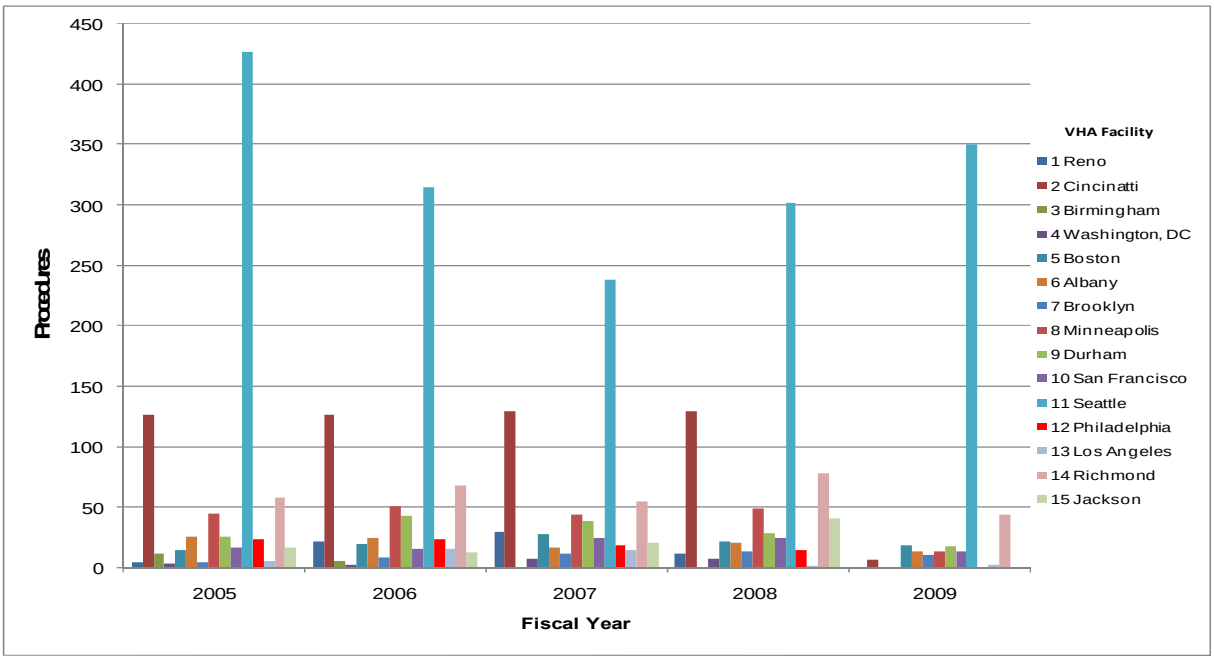
Figure B. Study population for VHA prostate brachytherapy program evaluation



[1] After combining the two implant procedures performed within 4 months for patients XRT 018 and XRT 062 at Philadelphia VAMC, BR59 at Brooklyn VAMC and SF62 at San Francisco VAMC.

Figure C shows that Seattle VAMC performed the most procedures, with a range of 238 to 427 procedures from FY 2005 to 2009; followed by Cincinnati and Richmond VAMCs. Collectively, these 3 VAMCs performed 70 percent of VHA prostate brachytherapy procedures.

Figure C. Prostate brachytherapy procedures performed by VHA facility



During its entire program from February 2005 to August 2008, JVAMC performed prostate brachytherapy on 92 patients. The two radiation oncologists disagreed with each other's prostate contouring on post-implantation CT from the beginning of the program. They stopped contouring for post-implantation dosimetric evaluation after the first several cases. Post-implantation evaluation was retrospectively conducted when VHA requested 10 cases from each prostate brachytherapy program for independent review in August 2008, after PVAMC's index case of May 5, 2008. As evidenced by the results shown in Table B, the retrospectively contouring tended towards "circling seeds." Postimplant dosimetry is highly dependent upon the volume of the prostate contoured. Interobserver differences in the volume of the prostate may lead to large difference in prostate D90. There is an underlying tendency and bias to define the prostate on post treatment CT images by encompassing the distribution of the implanted seeds. This bias is further complicated by the fact that the implanted seeds, which are very dense, create an artifact in the CT images which obscure the anatomy and boundaries of the prostate.

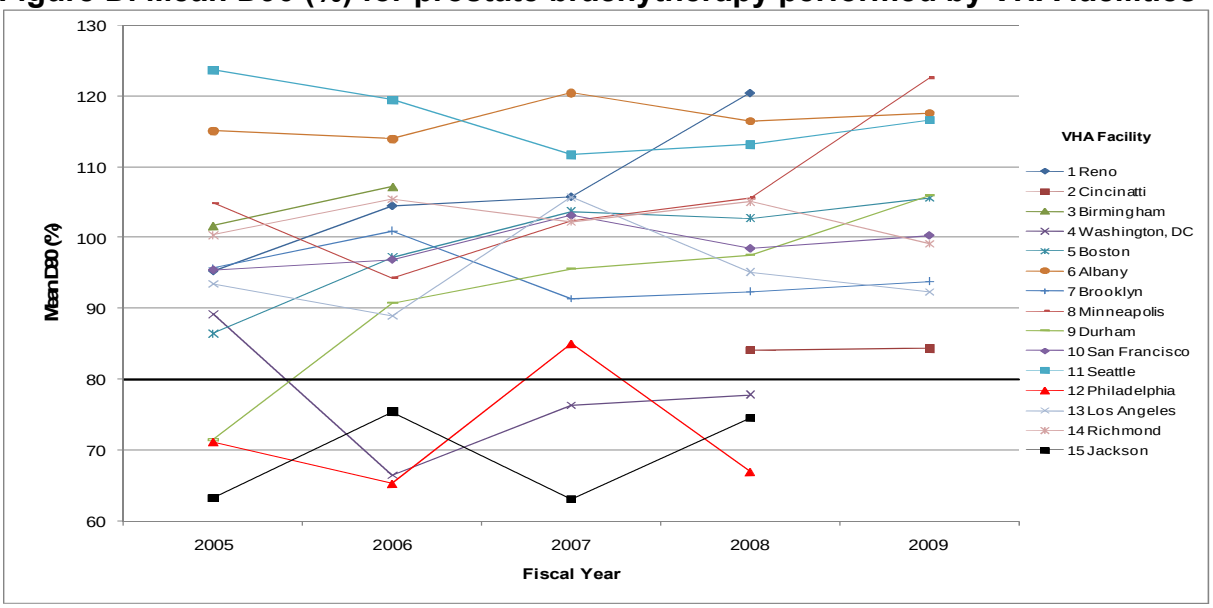
JVAMC has reported 10 MEs to NRC so far. Table B lists only the six cases that we have the D90 values from both JVAMC and VHA evaluations. Because of the apparent bias from "circling seeds", our data analyses used the dosimetric data for the 81 patients from the expert (contracted by VHA from outside of VA), rather than the ones conducted by JVAMC. Hereafter, all JVAMC dosimetric data results presented in this report are based on the expert data available on the 81 patients.

Table B. D90 (%) values evaluated originally by Jackson VAMC and independently by VHA for the 6 Medical Events reported to Nuclear Regulatory Commission

Patient Number	JVAMC D90 (%)	VHA Review D90 (%)
1	106	70
2	102	62
3	93	50
4	99	63
5	85	46
6	97	67

Because patients may be treated with different radionuclides to different prescription doses and may be treated in combination with external radiotherapy, D90 (%) indices provide a consistent way to compare the quality of the implants. Figure D gives the averages of post-dosimetry D90(%) for each of the 15 VAMCs by FY from 2005 to 2009. For all 14 VAMCs other than Cincinnati, the average D90s were based on all available and valid (post-CT was taken within 6 months from the prostate brachytherapy date) post-dosimetric data, including those for boost and salvage procedures. Although we sampled 30 prostate brachytherapy patients within each FY 2005-2008 and included all six prostate brachytherapy patients in FY 2009, Cincinnati VAMC was unable to provide post-dosimetry analysis reports for the patients who underwent prostate brachytherapy prior to 2008. Seven of the 30 sampled FY2008 patients whose prostate brachytherapy date fell into calendar year 2007, thus, the FY2008 average D90(%) was calculated based on the 23 sampled prostate brachytherapy patients whose post-dosimetry report were available to us. The FY2009 average D90(%) was based on all six prostate brachytherapy patients.

Figure D. Mean D90 (%) for prostate brachytherapy performed by VHA facilities



The American Brachytherapy Society (ABS) recommended in 2000 that postimplant dosimetry should be performed on all patients undergoing permanent prostate brachytherapy.[46] It specified that a dose-volume histogram (DVH) of the prostate should be performed and the D90 (%) reported by all prostate brachytherapy programs, while additional dosimetric quantifiers should be reported and ultimately correlated with clinical outcome in the research environment. We found that JVAMC and Cincinnati VAMC prostate brachytherapy program did not follow the ABS (their own professional association) recommendation.

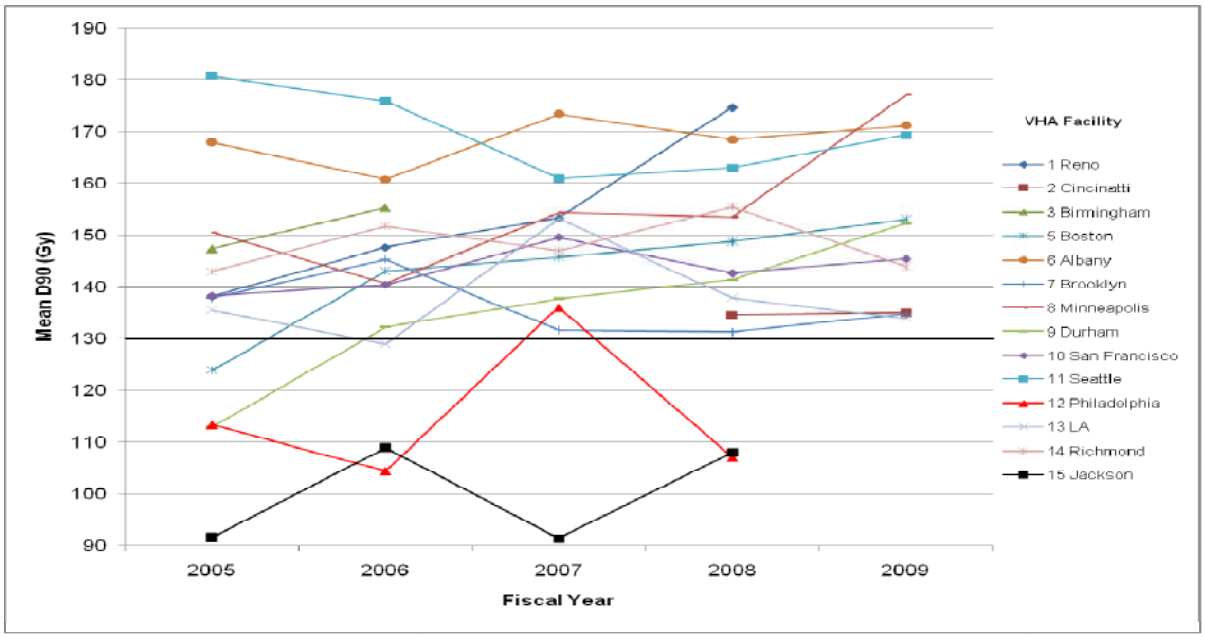
To provide consistent and reproducible dosimetric information, in November 2009 the AAPM Task Group 137 updated the original AAPM Task Group 64 report and issued new recommendations and guidelines on the timing, imaging techniques, dose planning criteria, and dose evaluation parameters that should be followed in documenting each brachytherapy treatment.[47] According to the guideline, radiation dose delivered to the prostate and nearby organs in every brachytherapy procedure should be carefully analyzed using post-implant CT or MRI and uniformly documented in every patient report. Based on recent brachytherapy literature, the AAPM TG-137 continues to follow the current recommendations on using D90 and V100 as the primary dosimetric coverage metrics, with the planning criteria of a good preimplantation dosimetry as V100 > 95% of the clinical target volume or D90 > 100% of prescription dose. The prostate brachytherapy community regards implants with a D90 > 90% and a V100 > 80% as adequate,[48] and high-quality implants typically will result in a D90 of 112–125%.[49] For most VAMCs, average D90 (%)s were in the range of 90 -110%, indicating good quality implants. Two (Seattle and Albany) VAMCs consistently had D90(%) over 110%. However, the average D90(%)s were under 80% of the prescription doses for one VAMC (Durham) in FY2005, PVAMC in FY 2005-2006 and in FY2008, Washington DC VAMC in FY 2006-2008, and Jackson VAMC in all FY 2005-2008.

The exact tumoricidal dose in prostate brachytherapy remains unknown and may potentially vary with the bulk of the disease.[50] It is expected that prostate cancer, like other tumors, exhibits a dose response relationship to radiation. This was demonstrated by Stock et al (1998), Potters et al. (2001), and Zelefsky et al. (2007). As a result, there is good reason to believe that the probability of achieving cure is related to the likelihood of covering the tumor with an adequate dose. Figure E gives the average D90 (Gy) dose levels for each VAMC by FY from 2005 to 2009. Because recommended monotherapy

[46] Nag S., et al. The American Brachytherapy Society Recommendations For Permanent Prostate Brachytherapy Postimplant Dosimetric Analysis. Int. J. Radiation Oncology Biol. Phys. 2000; 46(1):221–230.
[47] Nath R., et al. AAPM recommendations on dose prescription and reporting methods for permanent interstitial brachytherapy for prostate cancer: Report of Task Group 137. Med. Phys. 2009; 36(11): 5310–5322.
[48] Merrick G.S., et al. Initial analysis of Pro-Qura: A multi-institutional database of prostate brachytherapy dosimetry. Brachytherapy 2007:9-15.
[49] Kao J., Ston N. N., Lavaf A., Dumane V., Cesaretti J. A., and Stock R. G. I-125 Monotherapy Using D90 Implant Doses Of 180 Gy or Greater. Int. J. Radiation Oncology Biol. Phys. 2008; 70(1): 96–101.
[50] Roy J.N., Anderson L.L., Wallner K.E., et al. Tumor control probability for permanent implants in prostate. Radiother Oncol. 1993; 28: 72–75.

prescription doses vary by radionuclides and the dose of the same radionuclide prescribed to individual patients is primarily a clinical decision, we show the average dose levels only for I-125 monotherapy.

Figure E. Mean D90 (Gy) for prostate brachytherapy performed by VHA facilities



The D90 is roughly 130 Gy for D90 at the 90 percent of the recommended 145 Gy prescription dose for I-125 monotherapy. Potters et al. (2001) and Zelefsky et al. (2007) associated D90 less than 130 Gy with higher PSA relapse rate. The average D90 dose levels were all above 130 Gy with the exceptions for JVAMC in its entire program (FY 2005-2008), for PVAMC in FY 2005-2006 and 2008, for 2 VAMCs (Boston and Durham) in FY2005, and one in FY2006 (Los Angeles). Washington DC VAMC used Pd-103 and was thus excluded from Figure E.

B. PVAMC Prostate Brachytherapy Program

PVAMC Patient Characteristics

Demographic and clinical characteristics of PVAMC patients are summarized in Table C. Patients' average and median age at prostate brachytherapy were 63.8 and 63 years, respectively, ranging from 50 to 86 years. Thirty-three of the 114 patients (29%) received neo-adjuvant hormonal therapy. Hormonal therapy was mainly used for patients with large prostates, which was confirmed by similar distributions of neo-adjuvant hormonal therapy across patient risk groups (p=0.66).

Table C. PVAMC prostate brachytherapy patients characteristics

Characteristic		Number (%[1])
Age at Procedure		
Range	50 - 86	
Mean	63.8	
Median	63	
Neoadjuvant Hormone Therapy		
Yes		33 (28.9)
No		81 (71.1)
Biopsy Gleason Score		
Range	3 - 7	
2 to 4		4 (3.5)
5 to 6		105 (92.1)
7 (3+4 for all)		5 (4.4)
Tumor stage		
T1c		79 (69.3)
T2a		33 (28.9)
T2b		1 (0.9)
T2c		1 (0.9)
Pre-Treatment PSA, ng/mL		
Range	0.86 - 35.8	
Mean	7.3	
Median	6.2	
Less than 4		13 (11.4)
4 to less than 10		85 (74.6)
10 to 20		14 (12.3)
Over 20		2 (1.8)
Level of Risk[2]		
Low		91 (79.8)
Intermediate		21 (18.4)
High		2 (1.8)

[1] Percentages may not add to 100 exactly due to rounding
[2] Low: Tumor Stage T1c or T2a, Pretreatment PSA < 10 ng/mL, and Gleason score <=6
Intermediate: Tumor Stage T2b or T2c, Pretreatment PSA of 10-20 ng/mL, or Gleason score = 7
High: Pre-PSA level > 20 ng/mL or Gleason Score >= 8

The majority of patients were diagnosed with a Gleason score of 5-6 (92%) with a range of 3-7, at a tumor stage of T1c-T2a (98%) with a range of T1c-T2c, and a PSA level of 4-10 (75%) with a range of 0.86 - 35.8 ng/mL. According to the National Comprehensive Cancer Network prognostic classification, 91 men (80%) had low-risk disease and 23 (20%) had intermediate- to high-risk disease (21 (18%) had intermediate-risk disease and 2 (2%) had high-risk disease). These patient characteristics do not appear to deviate from those in the published literature.

All 114 PVAMC patients were implanted with I-125 as monotherapy, with a prescription dose of 160 Gy for 111 patients and 145 Gy for the other 3 (Patients XRT 026, 038, and 049). One PVAMC radiation oncologist was the prescribing physician for 108 patients. The other PVAMC radiation oncologist was the prescribing physician for the other 6 patients: XRT 019, 062 (two treatments), 069, 070, 077, and 109.

As of December 31, 2009, four of the 114 patients died from causes other than prostate cancer. Ten patients were classified as biochemical failures according to the Phoenix (nadir + 2) definition and 10 were confirmed clinical recurrences by treating physicians. Fifteen patients had disease failure, based on either recurrence or biochemical failure criteria. The median follow-up was 48.5 months for recurrence and 45.5 months for disease failure.

Dosimetric Analysis

Post-implantation dosimetry was calculated using Day-1 CT scans. Dosimetry was available for 107 patients (94 percent) because the archived Day-1 CT images of 7 patients were not able to be retrieved for dosimetric evaluation.

Figures F and G depict D90 (Gy) and D90 (%), respectively, for each of the 107 patients whose dosimetry was available. More than half of the D90s were under 130 Gy and/or under 80%. The mean, median, and range of D90 are as follows: 113.1 Gy, 110.9 Gy, and 39.3 – 203.4 Gy; and 70.9%, 69.3%, and 24.5 – 127.1%.

Figure F. Delivered doses (D90): PVAMC patients

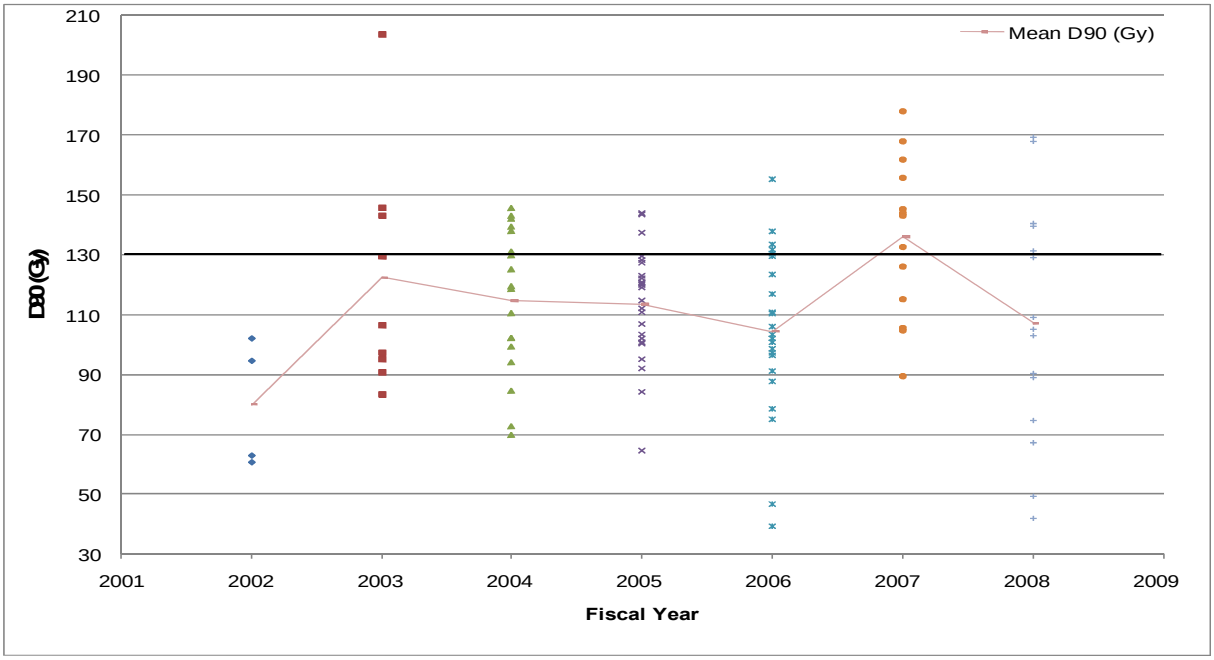
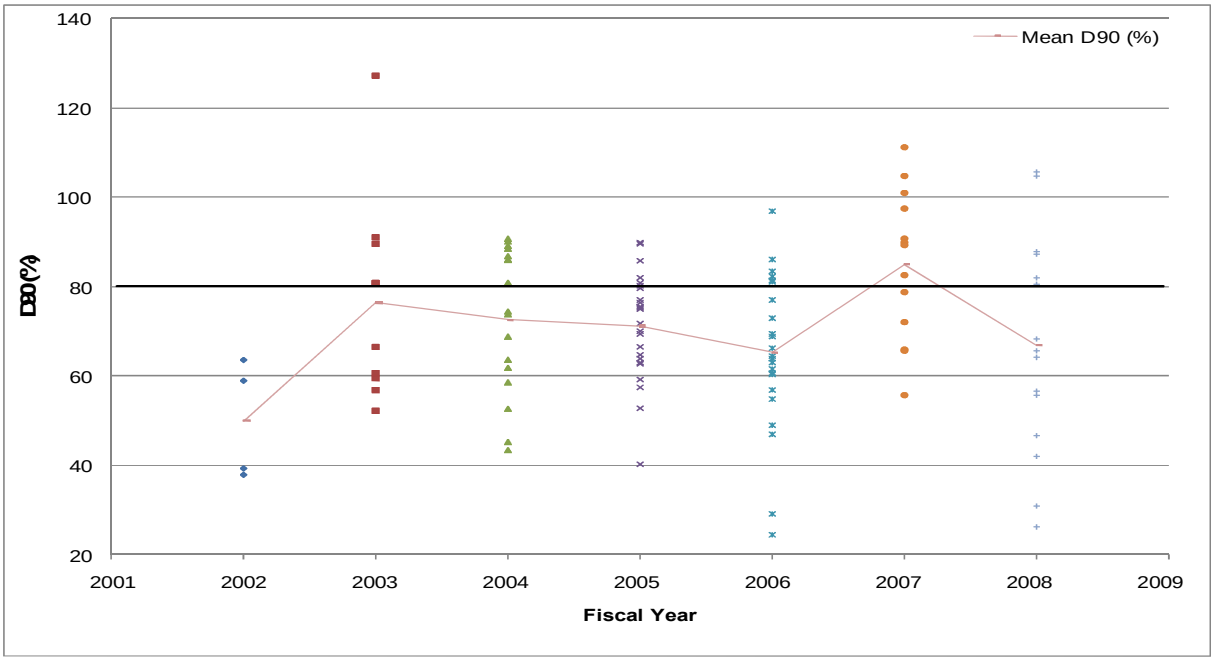


Figure G. D90 (%) (Minimum absorbed doses covering 90% of the post-implantation computed tomography prostate volume): PVAMC patients



For its quality assurance procedure of monitoring the quality of implants, the Prostate Brachytherapy Program at the British Columbia Cancer Agency in Canada defined an implantation[51] as:

- Good implant if V100 > 85%.
- Suboptimal if V100 of 75–85%.
- Poor implant if V100 < 75%.

Based on the criteria, most (90.7%) of 107 PVAMC implants were deemed of either suboptimal (24.3%) or poor (66.4%) quality (Figure H). The mean, median, and range of V100 are 65.4%, 66.6%, and 13.0-97.9%.

[51] Keyes M., et al. 125 I Reimplantation in Patients with Poor Initial Dosimetry After Prostate Brachytherapy. Int. J. Radiation Oncology Biol. Phys. 2004; 60(1): 40–50.

Figure H. V100 (%) (Fraction of prostate volume covered by 100% of prescription dose): PVAMC patients

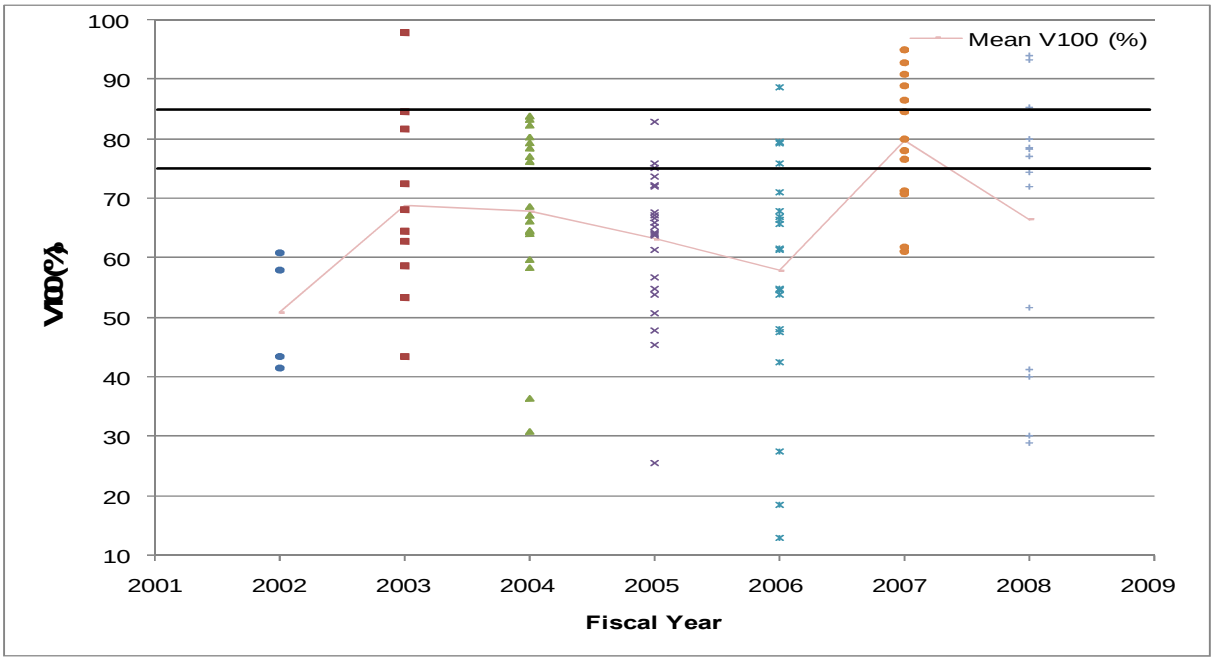
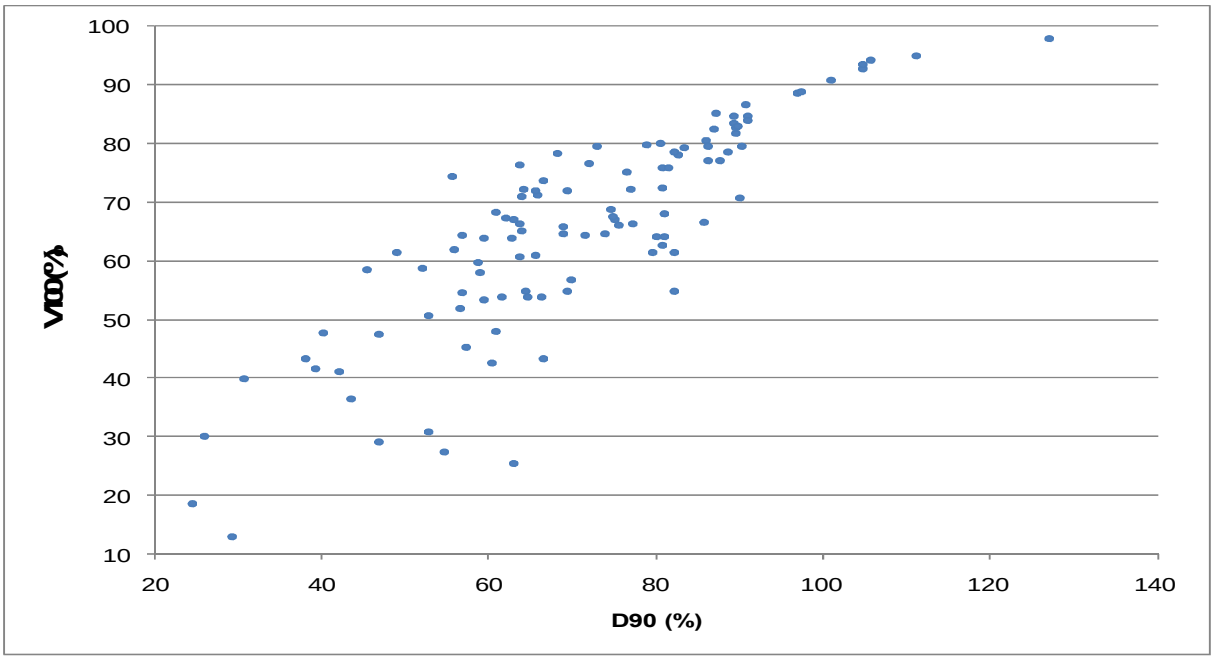


Figure I shows the distribution of V100(%) as a function of D90(%) for all 107 patients. D90 and V100 are highly correlated, with a Pearson correlation coefficient of 0.85 ($p < 0.0001$).

Figure I. Distribution of V100 (%) as a function of D90 (%): PVAMC patients



It has been shown that there is a "learning curve" for prostate brachytherapy in achieving dosimetric coverage and that the adequacy of prostate brachytherapy improves with experience.[52] Dosimetric outcomes were analyzed by implantation sequence number to assess if D90 and V100 were higher in later implantations. Figures J and K display dosimetric values of D90 and V100 by implantation number, respectively. There exists no trend for improvement in achieving dosimetric coverage over time for either D90 or V100, respectively (p-values > 0.32).

Figure J. Post-implantation D90 (%) by implantation number: PVAMC patients

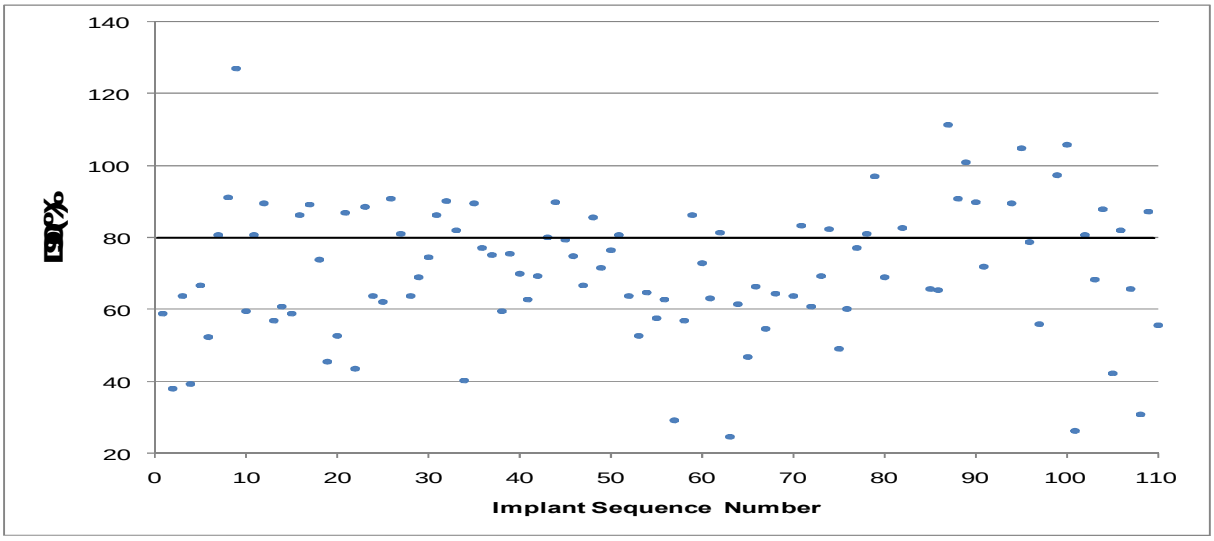
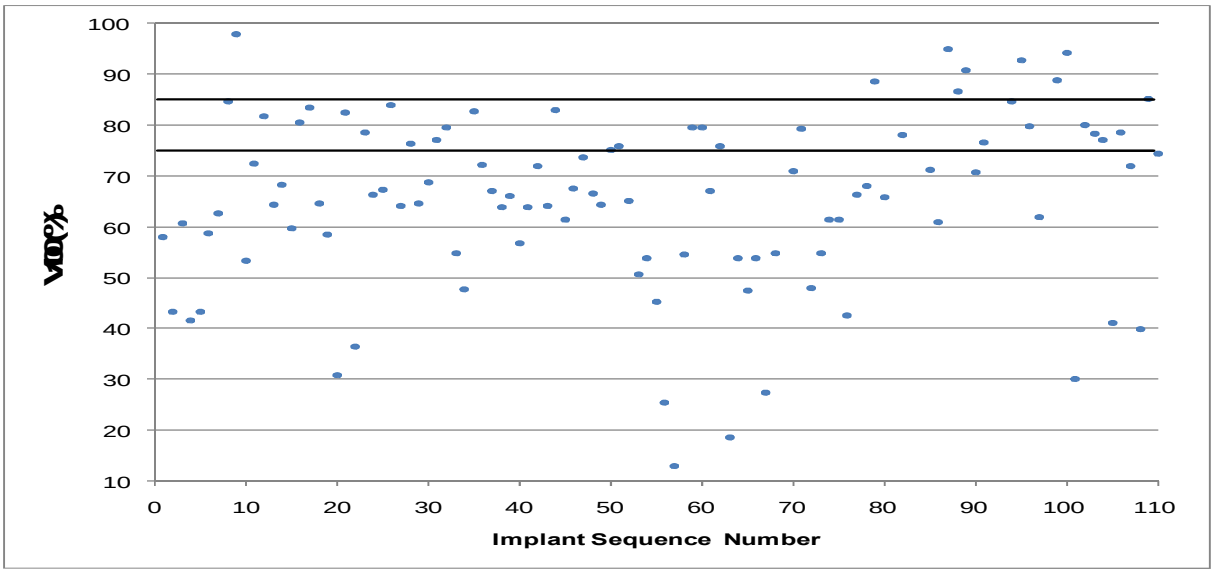


Figure K. Post-implantation V100 (%) by implantation number: PVAMC patients



[52] Lee W.R., et al. Postimplant Analysis of Transperineal Interstitial Permanent Prostate Brachytherapy: Evidence for a Learning Curve in the First Year at a Single Institution. Int. J. Radiation Oncology Biol. Phys. 2000; 46(1): 83–88.

It is arguable that the post-implantation evaluation retrospectively performed by an independent reviewer may deviate from the one by the treating physician because of the difference in determining intended treatment volumes. Figures L and M show the D90 and V100 values performed by both the treating physicians and the independent reviewers.

Figure L. Distribution between D90 (%) evaluated by independent review and that from original evaluation: PVAMC patients

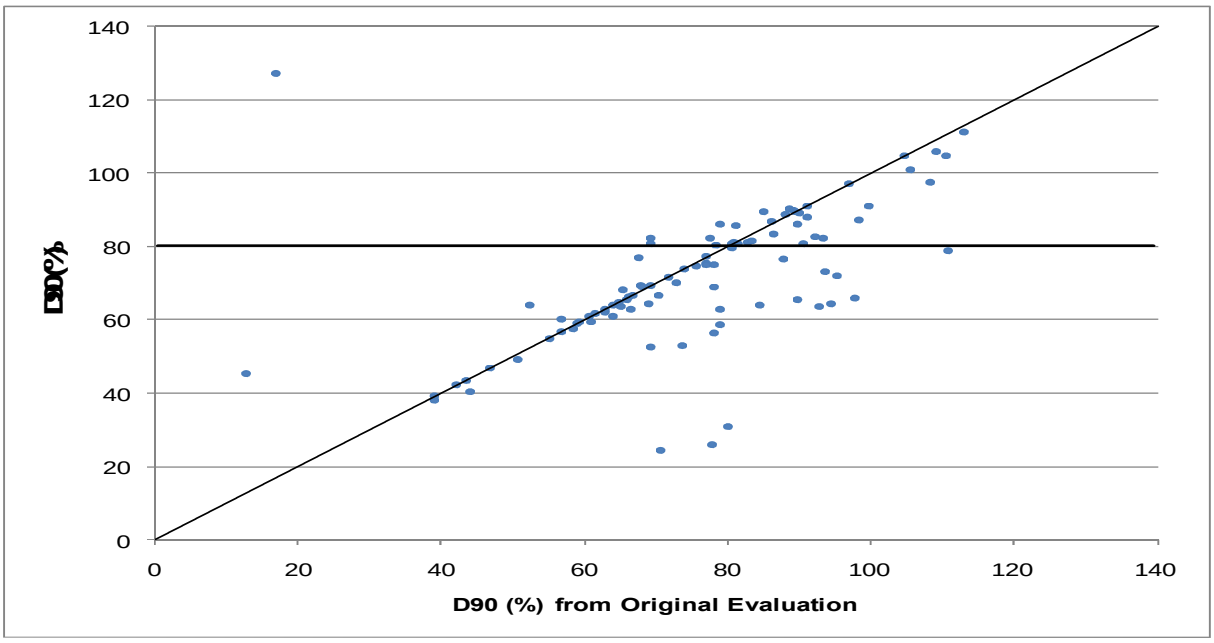
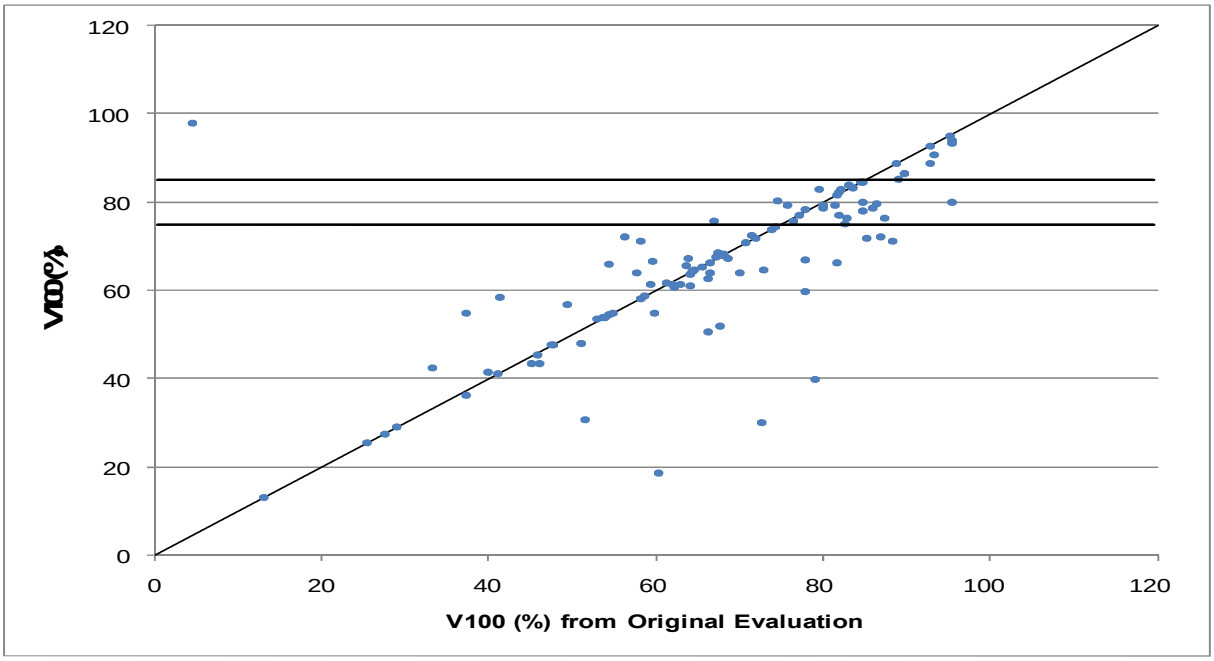


Figure M. Distribution between V100 (%) evaluated by independent review and that from original evaluation: PVAMC patients



The distributions show that the D90 and V100 values from original evaluations are higher than the ones by independent review. The differences between D90 and V100 are statistically significant (both p<0.01). On average, the D90 from independent evaluations is 4.6 points below that from the original ones and the V100 is 2.4 points lower. However, even based on the original evaluation, 59 percent (63 out of 107 patients with available dosimetry) of the D90 were under 80% of the prescription dose and 84 percent (90 out the 107 patients) of prostate brachytherapy procedures were suboptimal or poor based on the criteria of defining implantation of V100 (%) > 85% as of good quality.

Dosimetry and Clinical Outcomes

The Kaplan-Meier overall 5-year recurrence-free rate is 90% and the 7-year is 86% (Figure N). The 6-year recurrence-free rate is 91% for patients diagnosed with low risk diseases, significantly higher (p=0.0001) than 64% for patients diagnosed with intermediate or high risk diseases (Figure O). The D90 were not associated with recurrences, either for per unit of ten D90 percent (Hazard ratio=0.94, with the 95% confidence interval of 0.30-4.57) or using the cutoff of 130 Gy (p=0.81) (Figure P). Patient risk category was statistically significantly associated with recurrence: the hazard of recurrence for patients with intermediate or high risk was 8.5 times that of those with low risk (95% CI: 2.34-31.1). Similar association was shown after adjusting for D90 either as a continuous variable (hazard ratio=9.2 with 95% CI: 2.5 – 33.4) or as a binary variable using the cutoff of 130 Gy (hazard ratio=9.3 with 95% CI: 2.5 – 33.8) in the Cox regression model. Neoadjuvant hormone treatment was not associated with recurrences (p=0.40).

Figure N. Recurrence-free survival (with 95% confidence limits): PVAMC patients

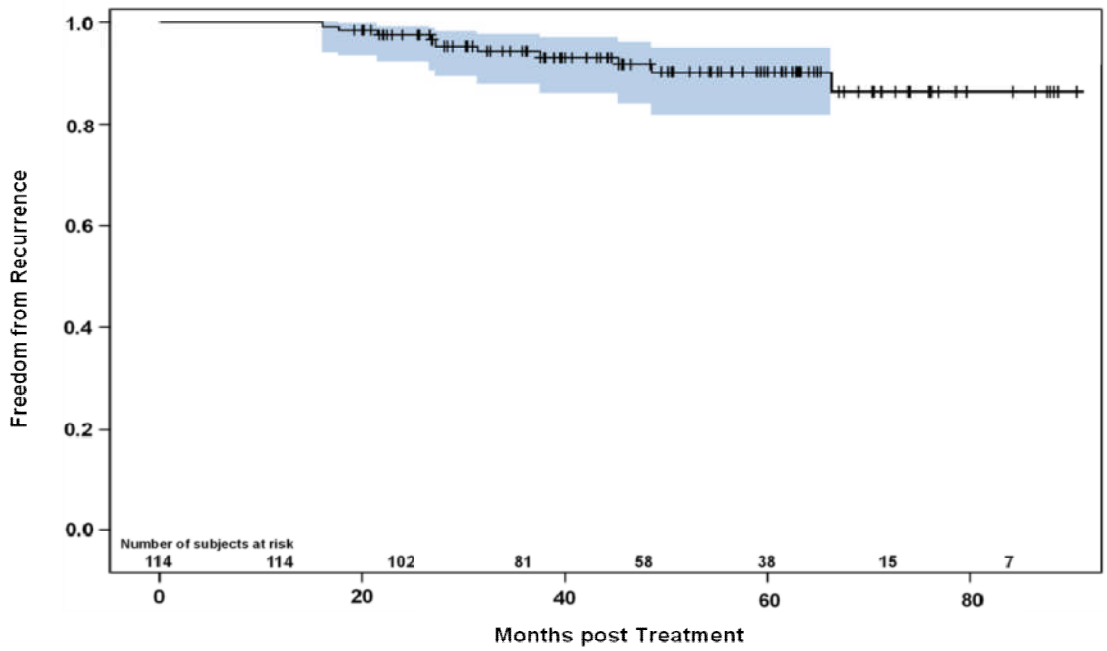


Figure O. Recurrence-free survival (with 95% confidence limits) by risk group status: PVAMC patients

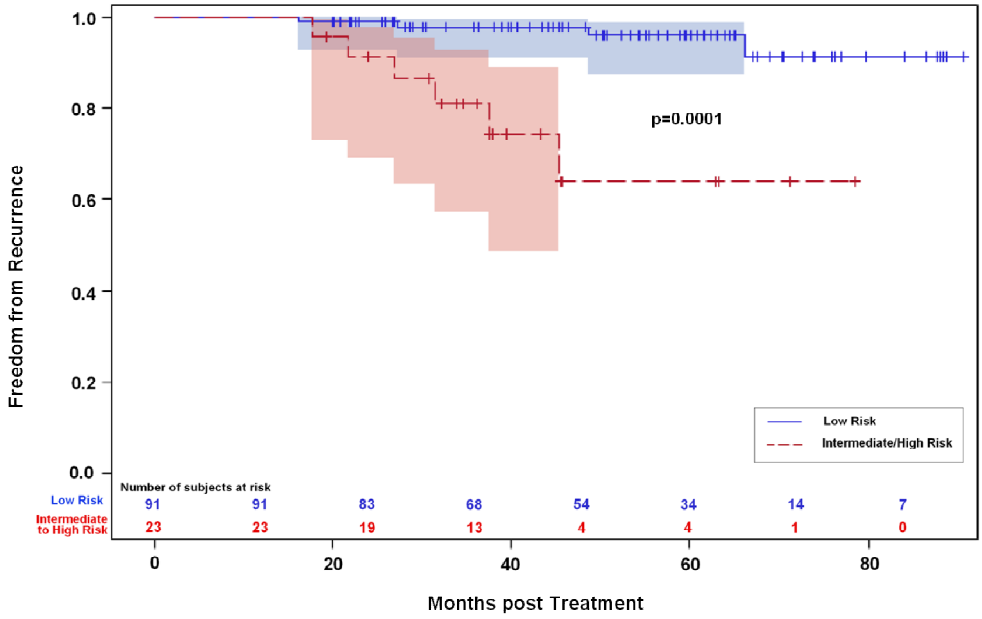
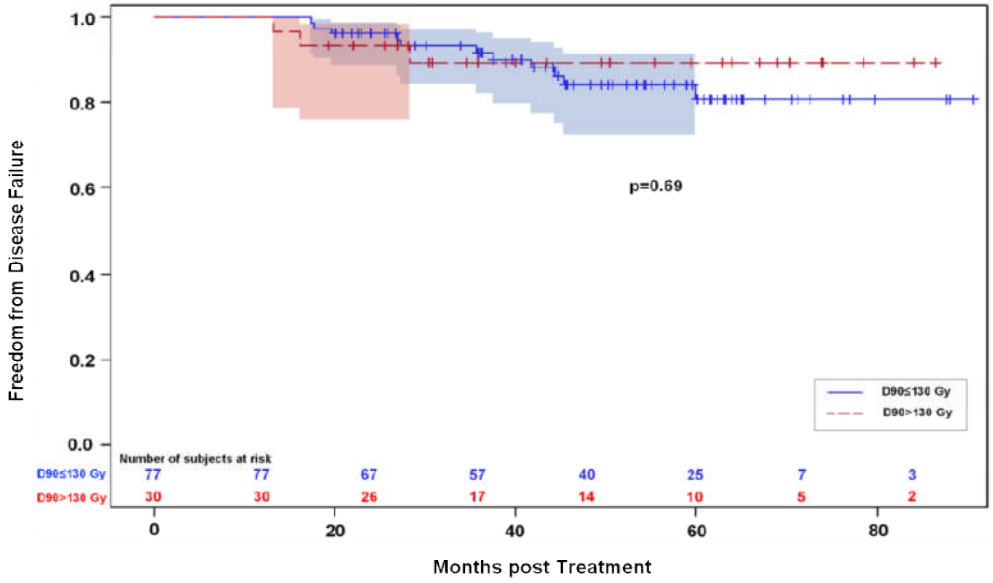


Figure P. Recurrence-free survival (with 95% confidence limits) by dose level: PVAMC patients



There were 15 disease failures in the population, 5 of them were biochemical failures without experiencing recurrence. The Kaplan-Meier overall 7-year freedom from both recurrence and PSA relapse rate is 82% (Figure Q). The 6-year disease-free rate is 88% for patients with low risk diseases (Figure R), compared with 54% for patients with intermediate or high risk diseases (p=0.0016). Similarly to recurrences, patient risk

category was statistically significantly associated with disease failure: the hazard of disease failure for patients with intermediate or high risk was 4.5 times that of those with low risk (95% CI: 1.62-12.5). The D90 cutoff of 130 Gy was not associated (p=0.69) with disease relapse (Figure S), nor was neoadjuvant hormone treatment (p=0.78).

Figure Q. Disease-free survival (with 95% confidence limits): PVAMC patients

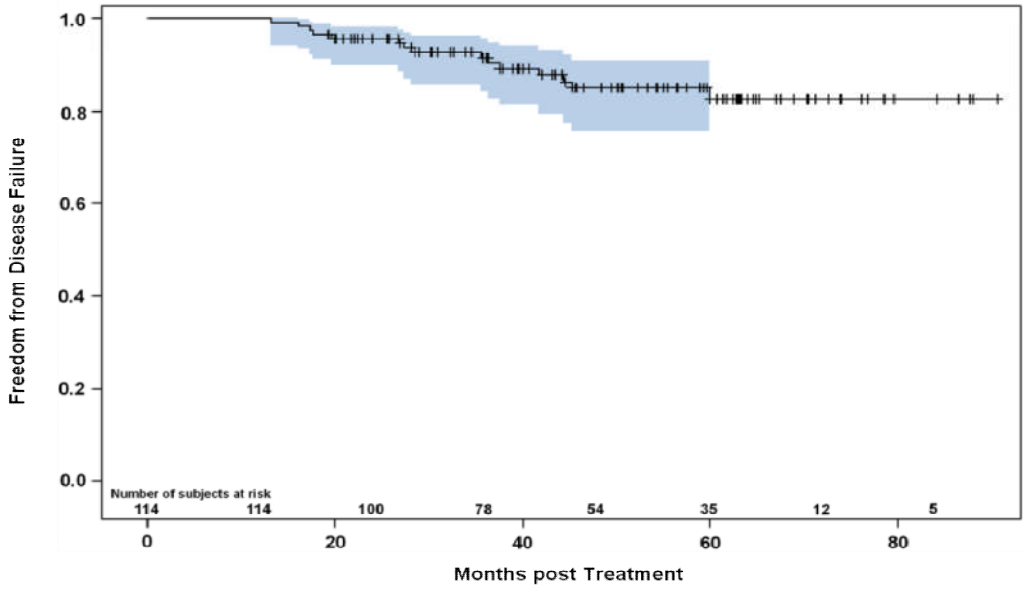


Figure R. Disease-free survival (with 95% confidence limits) by risk group status: PVAMC patients

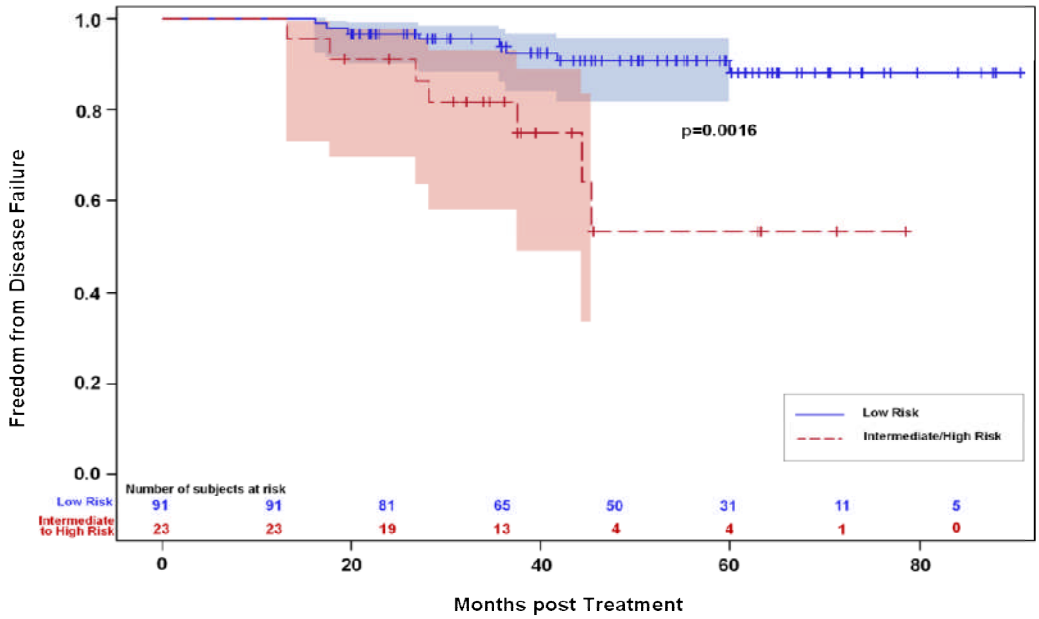
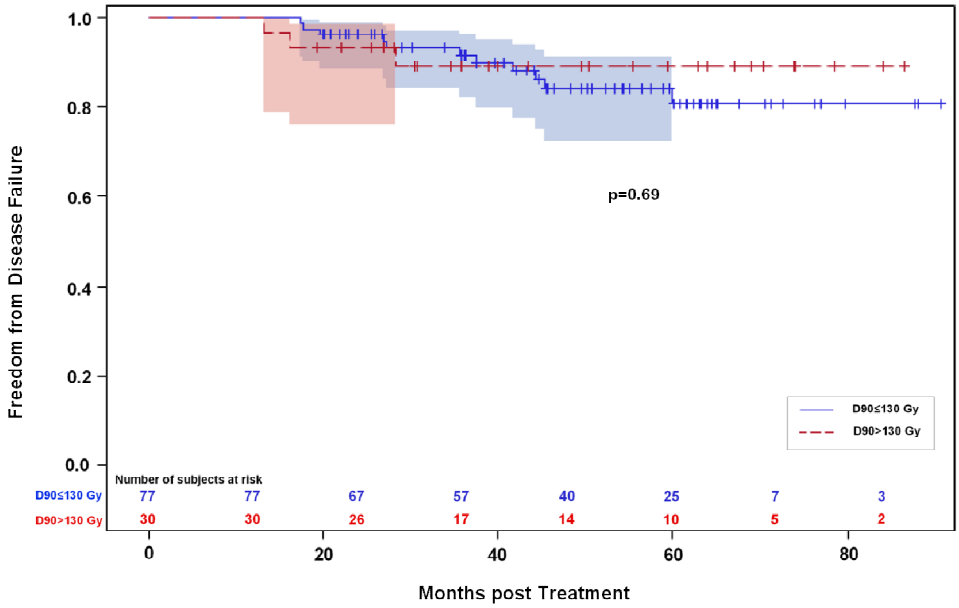


Figure S. Disease-free survival (with 95% confidence limits) by dose level: PVAMC patients



There were 10 recurrences confirmed by the treating physicians in PVAMC's prostate brachytherapy patient population as of December 31, 2009, the cutoff for our evaluation. Thus, one patient (XRT091) confirmed with recurrence on March 2, 2010, was excluded from our analysis. Because this patient met the Phoenix criteria for PSA-relapse and was diagnosed with intermediate risk disease, counting him as a recurrence would not change our analysis results on recurrence-free survival for low-risk patients and for disease-free with or without by risk groups. Counting this recurrence, the Kaplan-Meier overall 5-year recurrence-free rate would reduce from 90% to 89% and the 7-year decrease from 86% to 85%, the 6-year recurrence-free rate reduce from 64% to 58% for patients diagnosed with intermediate or high risk diseases.

The recurrence and disease relapse rates of PVAMC's prostate brachytherapy patient population appear within the norm. For example, Zelefsky et al. (2007) reported multi-institutional analysis of 8-year PSA relapse-free survival as follows:

- 74% for low-risk patients,
- 61% for intermediate-risk patients, and
- 39% for high-risk patients.

Our analysis indicates that the dosimetric outcome D90 does not correlate with either recurrence or disease relapse in the population of PVAMC prostate brachytherapy patients. The data does not permit us to analyze the dose and response association by patient risk group at this time.

Although some studies[53,54,55] showed an association between dose and response, this lack of association has been reported by others.

- In the study of 1,006 consecutive patients who underwent implantation between July 20, 1998, and October 23, 2003, at the British Columbia Cancer Agency (BCCA) Provincial Prostate Brachytherapy Program in Canada, Morris et al.[56] found that dosimetric values were not predictive of biochemical failure. Although their analysis of dosimetric values by implantation sequence number showed statistically significant increases in all dosimetric values with time (D90, V100, V150, and V200; $p < 0.001$), this did not translate into improved freedom from biochemical failure.

- Ash et al.[57] from Cookridge Hospital at Leeds, UK studied the correlation between D90 and PSA relapse from 667 prostate brachytherapy patients treated between 1995 and 2001. The study showed that no significant dose response relationship between D90 and PSA relapse was found in the intermediate and high-risk population of patients, but D90 was found be a good discriminator for those with low risk.

- In the study of dosimetry and cancer control after prostate brachytherapy in the first 63 men treated at Wake Forest University Baptist Medical Center, Lee et al.[58] found that no threshold value of D90 was predictive of the 5-year estimates of biochemical failure-free until the D90 was < 80 Gy ($p = 0.02$).

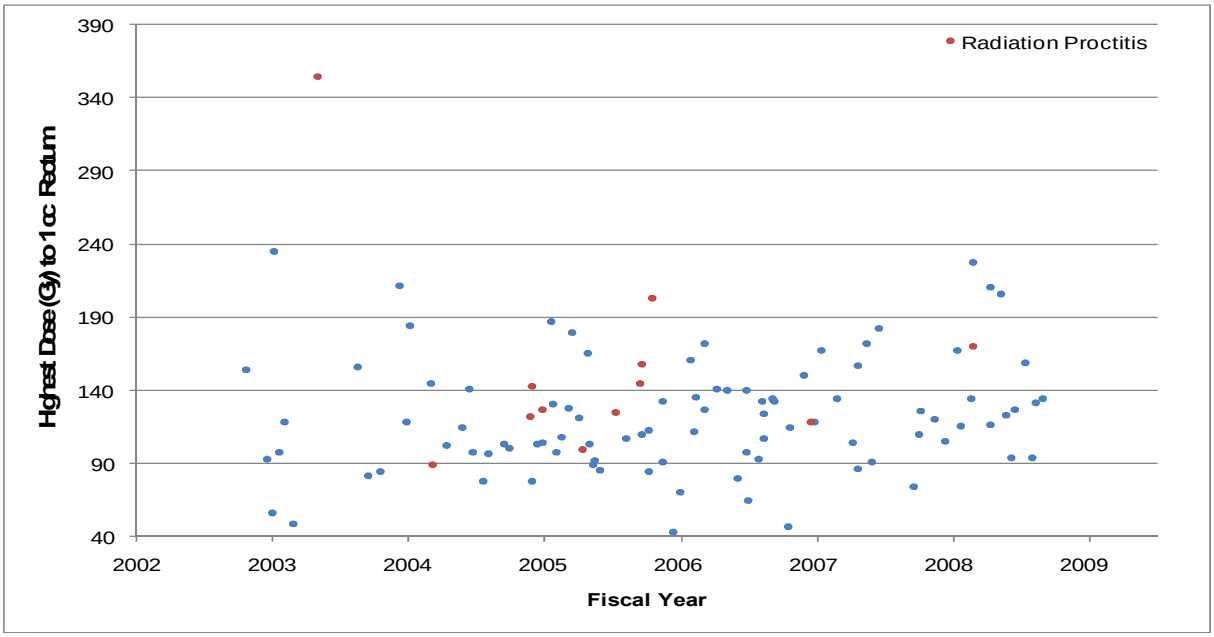
Dosimetry and Complication Outcomes

Radiation proctitis is statistically significantly ($p=0.026$) associated with the highest dose (Gy) to 1 cc (cubic centimeter) rectum (figure T). The odds of being diagnosed with radiation proctitis rises 1.2 times for 1 Gy increase in the highest dose (Gy) to 1 cc rectum. After adjusting for D90 (%), there is no statistically significant association between radiation proctitis and the highest dose to 1 cc rectum ($p=0.09$).

[53] Stock R., et al. A Dose–Response Study for I-125 Prostate Implants. Int. J. Radiation Oncology Biol. Phys. 1998; 41(1): 101–108.
[54] Potters L., et al. A Comprehensive Review of CT-Based Dosimetry Parameters and Biochemical Control in Patients Treated with Permanent Prostate Brachytherapy. Int. J. Radiation Oncology Biol. Phys. 2001; 50(3): 605–614.
[55] Zelefsky M, et al. Multi-Institutional Analysis of Long-Term Outcomes for Stages T1-T2 Prostate Cancer Treated with Permanent Seed Implantation. Int. J. Radiation Oncology Biol. Phys. 2007; 67(2): 327–333.
[56] Morris W.J., et al. Evaluation of Dosimetric Parameters and Disease Response After 125 Iodine Trans perineal Brachytherapy for Low- and Intermediate-Risk Prostate Cancer. Int. J. Radiation Oncology Biol. Phys. 2009; 73(5): 1432–1438.
[57] Ash D., et al. The correlation between D90 and outcome for I-125 seedimplant monotherapy for localised prostate cancer. Radiotherapy and Oncology 79. 2006: 185–189.
[58] Lee W.R., DeGuzman A.F., McMullen K.P., McCullough D.L. Dosimetry and Cancer Control after Low-Dose-Rate Prostate Brachytherapy," Int. J. Radiation Oncology Biol. Phys. 2005; 61(1): 52–59.

Urethral strictures are not associated with any of the following: D90 (%), highest dose (Gy) to 1 cc rectum, 1 cc bladder, and 2 cc periprostatic.

Figure T. Highest dose (Gy) to 1 cc rectum and radiation proctitis



C. JVAMC Prostate Brachytherapy Program

JVAMC Patient Characteristics

JVAMC performed its first prostate brachytherapy on February 16, 2005, and the last one on August 25, 2008. Demographic and clinical characteristics of the 92 JVAMC patients are summarized in Table D. Patients' mean and median age at prostate brachytherapy were 63.4 and 63 years, respectively, ranging from 50 to 76 years. The majority of patients were diagnosed with a Gleason score of 5-6 (91%) with a range of 5-7, at a tumor stage of T1c-T2a (97%) with a range of T1c-T2b, and a PSA level of 4-10 (79%) with a range of 0.4–14.5 ng/mL. According to the National Comprehensive Cancer Network prognostic classification, 76 men (83%) had low-risk disease.

All 92 patients were implanted with I-125, with a prescription dose of 145 Gy for 91 patients and 108 Gy for 1 patient (XRT026) as a boost procedure in combination with external beam radiotherapy. JVAMC used 30 days after prostate brachytherapy as its dosimetric time and took a Day-1 CT for all patients to improve patient compliance.

Table D. JVAMC prostate brachytherapy patients characteristics

Characteristic		Number (%[1])
Age at Procedure		
Range	50-76	
Mean	63.4	
Median	63	
Biopsy Gleason Score		
Range	5 - 7	
5 to 6		84 (91.3)
7 (3+4 for all)		8 (8.7)
Tumor stage		
T1c		67 (72.8)
T2a		22 (23.9)
T2b		3 (3.3)
Pre-Treatment PSA, ng/mL		
Range	0.4 - 14.5	
Mean	5.8	
Median	5.5	
Less than 4		13 (14.1)
4 to less than 10		73 (79.4)
10 to 20		6 (6.5)
Level of Risk[2]		
Low		76 (82.6)
Intermediate		16 (17.4)

[1] Percentages may not add to 100 exactly due to rounding
[2] Low: Tumor Stage T1c or T2a, Pretreatment PSA < 10 ng/mL, and Gleason score < = 6
Intermediate: Tumor Stage T2b or T2c, Pretreatment PSA of 10-20 ng/mL, or Gleason score = 7

Biochemical Failure

One patient did not seek VA care after his implantation and was excluded from our analysis here. The last PSA date in the population is January 4, 2010, and the median follow-up was less than 2 years (21.3 months). Five patients were classified as biochemical failures according to the Phoenix (nadir + 2) definition during the follow-up time period. Their PSA profiles were shown in figure U. The Kaplan-Meier overall 4-year PSA relapse-free is 92% (Figure V). Because of the short follow-up time interval for the JVAMC patient population, no further analyses were conducted.

Figure U. PSA profiles of 5 biochemical failures (Phoenix criteria): Jackson VAMC patients

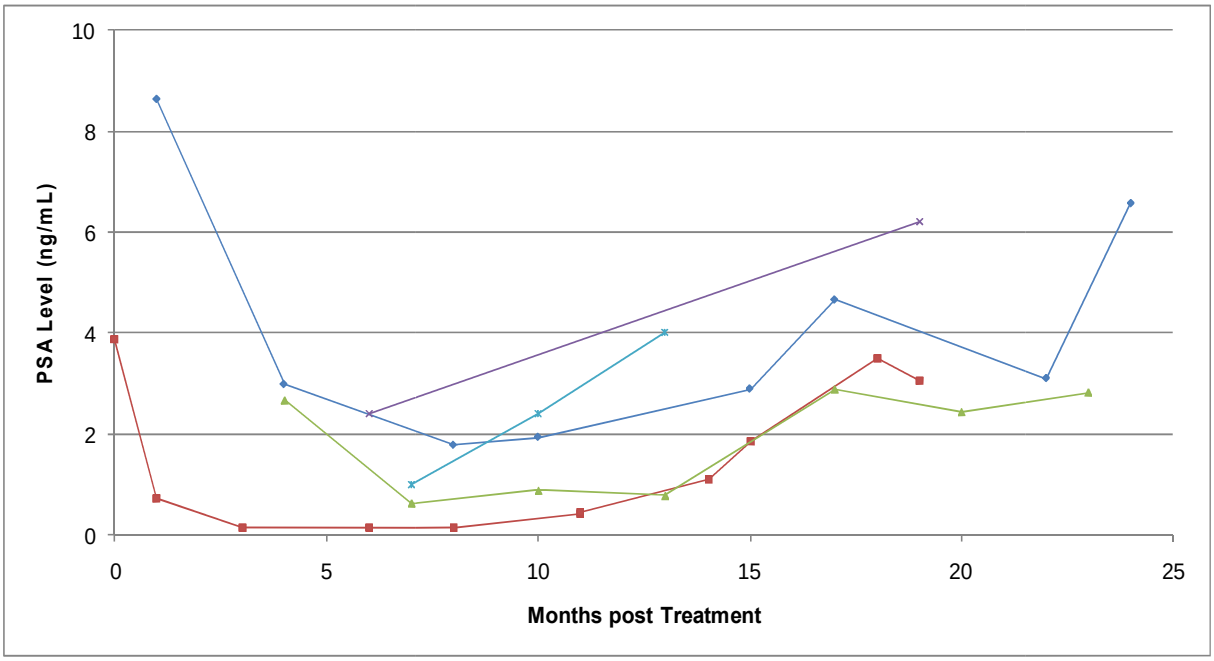
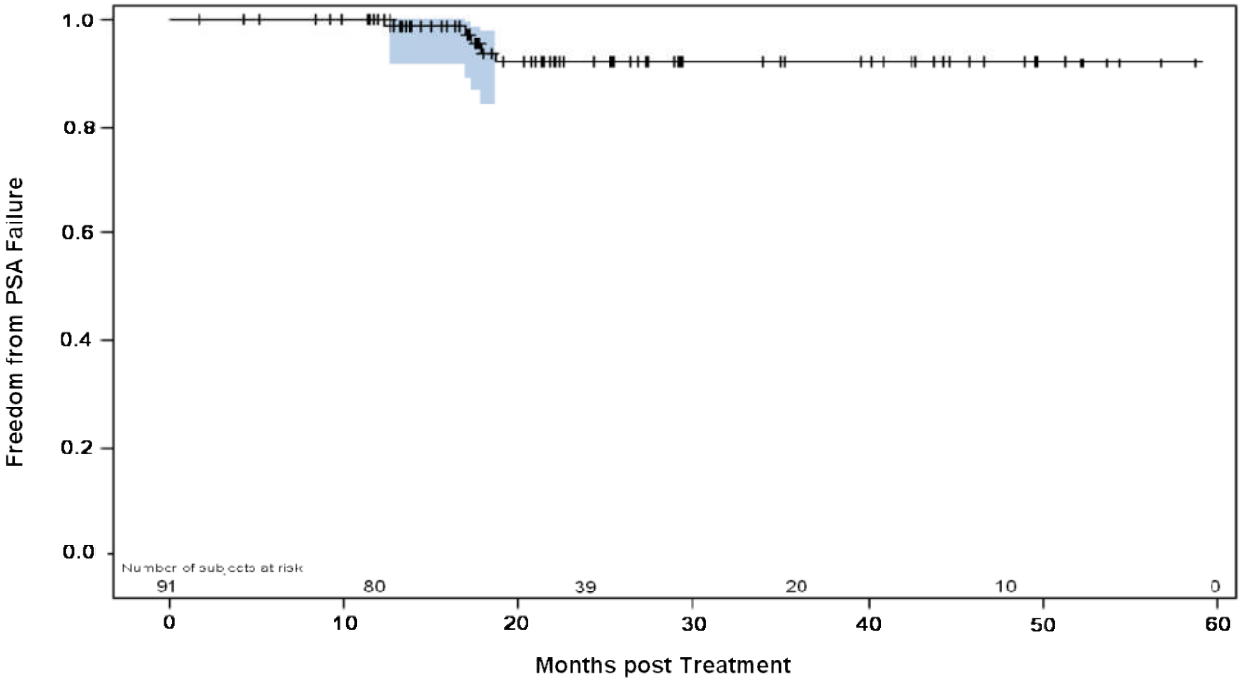


Figure V. PSA relapse-free survival (with 95% confidence limits): Jackson VAMC patients



Conclusions

1. Fifteen VA medical facilities had an active prostate brachytherapy program during some period of FY2005-2009. As of March 12, 2010, eight VA medical facilities continue their prostate brachytherapy program. The American Brachytherapy Society (ABS) recommended that post-implantation dosimetry should be performed on all patients undergoing permanent prostate brachytherapy in 2000 (Nag et al. 2000). In particular, it specified that a dose-volume histogram (DVH) of the prostate should be performed and the D90 (%) reported by all prostate brachytherapy programs. We found that Jackson and Cincinnati VAMC prostate brachytherapy programs did not follow the ABS recommendation to perform post-implant dosimetry as a component of prostate brachytherapy prior to 2008.

2. Over the period of FY 2005-2009, average D90s of most VAMCs were in the range of 90-110%. Two VAMCs consistently had D90s over 110%. However, the average D90s were under 80% of the prescription doses for Durham VAMC in FY2005, Philadelphia VAMC in FY 2005-2006 and FY2008, Washington DC VAMC in FY 2006-2008, and Jackson VAMC for all FY 2005-2008.

3. Our analysis indicates that the dosimetric outcome D90 does not correlate with either recurrence or disease-relapse (recurrence or PSA relapse by nadir +2 criteria) in the population of Philadelphia VAMC prostate brachytherapy patients. The data does not permit us to analyze the dose and response association by patient risk group at this time. Although some studies[59,60,61] showed an association between dose and response, this lack of association has been reported by others.[62,63,64]

4. Recurrence and disease-relapse rates of Philadelphia patients appear within the norm. Zelefsky et al. (2007) reported multi-institutional analysis of 8-year PSA relapse-free survival:

74% for low-risk patients.
61% for intermediate-risk patients.
39% for high-risk patients.

[59] Stock R., et al. A Dose–Response Study for I-125 Prostate Implants. Int. J. Radiation Oncology Biol. Phys. 1998; 41(1): 101–108.
[60] Potters L., et al. A Comprehensive Review of CT-Based Dosimetry Parameters and Biochemical Control in Patients Treated with Permanent Prostate Brachytherapy. Int. J. Radiation Oncology Biol. Phys. 2001; 50(3): 605–614.
[61] Zelefsky M., et al. Multi-Institutional Analysis of Long-Term Outcomes for Stages T1-T2 Prostate Cancer Treated with Permanent Seed Implantation. Int. J. Radiation Oncology Biol. Phys. 2007; 67(2): 327–333.
[62] Morris W.J., et al. Evaluation of Dosimetric Parameters and Disease Response After 125 Iodine Trans perineal Brachytherapy for Low- and Intermediate-Risk Prostate Cancer. Int. J. Radiation Oncology Biol. Phys. 2009; 73(5): 1432–1438.
[63] Ash D., et al. The correlation between D90 and outcome for I-125 seed implant monotherapy for localised prostate cancer. Radiotherapy and Oncology 79. 2006: 185–189.
[64] Lee W.R., DeGuzman A.F., McMullen K.P., McCullough D.L. Dosimetry and Cancer Control after Low-Dose-Rate Prostate Brachytherapy. Int. J. Radiation Oncology Biol. Phys. 2005; 61(1): 52–59.

5. Jackson VAMC did not routinely perform post-implantation dosimetric evaluation as a component of prostate brachytherapy treatment. Independent review shows low delivered dose coverage (D90). Overall 4-year PSA relapse-free is 92%. No further analyses were conducted because of the short follow-up time interval.

Section III

Contract Review And Associated Issues: PVAMC And The University of Pennsylvania

A. Background

Records show that radiation therapy services have been provided to the VA Medical Center by the University of Pennsylvania Health System (UP) since at least 1996. We identified a contract, V642P-2913, awarded in May 1996 for a base year plus two option years under which UP was to provide the services of 1.25 Full Time Equivalent (FTE) physicians, 1.0 FTE physicists, 4.0 FTE radiation therapy technicians, 1.0 FTE dosimetrist, and 1.0 FTE engineer. The Statement of Work delineated requirements for a "full range of Radiation Oncology Services;" but did not identify specific procedures, such as brachytherapy, and did not identify the key personnel who would provide the services. Although the contract included a line item and price for the services of 1.0 FTE for engineering services, there is nothing in the Statement of Work or any other part of the contract that describes the nature or scope of services to be provided. Contract prices were a fixed hourly rate by labor category and were not based on the salary, benefits, and other costs associated with any specific individual. Although documents provided to us did not include modifications exercising either of the two option years, evidence indicates that the option years were exercised and that the contract expired on or around April 1999.

Although records show that the VA continued to pay UP in the same manner for radiation oncology services after the contract expired, no one was able to provide us with a copy of a follow-on contract. From May 1, 1999, through April 25, 2005, VA paid UP for radiation therapy services without a contract or other agreement in place. The invoices submitted by UP and authorized for payment by VA do not include a contract or purchase order number. As such, services were provided without a statement of work defining requirements, agreed upon pricing, and other relevant clauses, such as responsibility in the event of a tort claim, workers' compensation claim, etc. We are not aware of any legal authority to pay for such services absent a valid contract between the parties. Invoices were sent directly to an employee in the Medical Center Director's Office. This employee was not a contracting officer.

Effective April 26, 2005, the VA medical center and UP entered into a 3 month Interim Contract, V642P-5201, under which the University would provide radiation therapy services at VA. The services listed in the contract include 1.5 FTE radiation oncologist, 1.5 FTE radiation physicist, 1.0 FTE dosimetrist, and 5.0 FTE radiation therapists. The contract identified two specific types of procedures, Tele-therapy (External beam), and Brachytherapy, and listed specific processes to be followed for each procedure. The interim contract was extended by modification for successive 3 to 6 month intervals to the present.

B. The Interim Contract Violated VA Policy

VA Manual-1, Part I, Chapter 34, Section III, which was issued in 1993, set forth procedures to be used when awarding an interim contract to obtain health care resource services. Interim contracts were to be used only in emergency situations and were limited in duration to 90 days or less. All requests had to be approved by VHA's Medical Sharing Office. The policy allowed for extension of interim agreements beyond 90 days but required approval by the Associate Chief Medical Director for Operations with justification if the term was to exceed 180 days. The policy also stated: "When negotiating with affiliated institutions, and an agreement cannot be reached within the initial 180 day time period, then the contract shall be competitively bid unless there is compelling justification from the facility and subject to the approval of the VA Central Office Medical Sharing Committee."

In August 2006, VA issued VA Directive 1663 which replaced M-1, Part I, Chapter 34. Under the Directive, all proposed health care resource contracts must be approved by VHA's Prosthetics and Clinical Logistics Office (PCLO) prior to award. The Directive states that "interim contract authority is established to provide required health care resources on an emergency basis for short-term needs, or as an interim measure to complete the contracting cycle for long-term needs," in accordance with the Directive. The Directive strictly limits the terms and renewals of interim contract authority to 180 days but does provide that the authority for an interim contract to be granted on an exception basis, not to exceed 1 year. The Directive gives responsibility to VHA's PCLO "for approving and disapproving all requests for interim contracts required to provide services needed immediately while the long-term contract process is completed."

We found no evidence in the contract file provided by PVAMC of compliance with M-1, Part I, Chapter 34 or VA Directive 1663. Specifically, we found no documentation that the Interim Contract was approved by VHA Medical Sharing Office. Records provided did not show that the contract was needed on an emergency basis. In fact, the services had been provided for many years and without a contract in place. We also found no documentation provided by PVAMC in the records maintained by the PCLO showing approval to extend this interim contract in 3 month intervals for a period exceeding 5 years.

Even if there was justification for the Interim Contract, we found no justification for having the Interim Contract in place for such an extended time per of time. Prior to awarding the Interim Contract, the VA Medical Center had issued a Request for Proposal (RFP) to the University for a long term contract consisting of a base year plus two one-year option periods and, in response, the University had submitted a proposal. On April 12, 2005, consistent with VA policy, the Contracting Officer requested that the OIG Office of Contract Review conduct a pre-award review of the proposal. The pre-award review was delayed by several months because all supporting documentation requested from UP was not received by the Office of Contract Review until mid-September 2005.

The review was completed and the report issued to the Contracting Officer on November 5, 2005. The report made specific recommendations to the Contracting Officer regarding the reasonableness of the offered pricing and changes that needed to be made to the contract before award to ensure that VA's interests were protected for the term of the contract. However, the contract was never awarded and the recommendations were not used by the Contracting Officer to renegotiate the prices on the Interim Contract to ensure they were fair and reasonable. If the parties were unable to negotiate a long term agreement, VA policy required PVAMC to complete the requirement or get approval from VA Central Office's Medical Sharing Committee to continue negotiations if there was compelling justification for doing so. There is no documentation showing that this was done or that there was compelling justification for doing so with or without approval of the Sharing Committee.

We interviewed the Contracting Officer who issued the RFP and to whom the pre-award report was issued. This employee was unable to provide a credible explanation as to why a new contract was not awarded or why the interim contract was extended. The employee told us that the new contract was not awarded because the OIG Office of Contract Review was waiting for additional information from UP. The employee's statement is inconsistent with fact that the pre-award review had been completed, that the employee acknowledged receipt of the report, and that the employee verified in an e-mail that the award could be proceeded upon. We reviewed e-mails from early in 2007 that contain discussions between UP and VA regarding the award of a new contract. The discussions included radiation oncologist B, a contract representative from UP, and the Vice President for Resource Management at VA. The e-mails also refer to discussions with the earlier mentioned employee in the Medical Center Director's Office. No one in the contracting office appears to have been involved in the discussions, which is inconsistent with VA policy.

C. Fair and Reasonable Pricing

In comparison to the prices paid from May 1998 through April 25, 2005, the initial pricing under the Interim Contract increased significantly for each labor category. Records show that prices were increased twice during the term of the Interim Contract through modifications. Although it is understandable that the Interim Contract prices would increase from the 1999 pricing to account for increases in salaries and benefits, we found that VA contracting officials appear to have accepted the prices proposed by UP without conducting an adequate price reasonableness analysis and determination. The documentation shows that UP proposed an hourly rate for the radiation oncologists based on representations regarding the total salary, benefits, and other associated costs for the physicians who held Associate Professor and Assistant Professor faculty appointments at UP. There is nothing in the file showing the basis for the hourly rates awarded for the other labor categories or what VA relied on to make a price reasonableness determination.

The Interim Contract does not identify the key personnel proposed by UP to provide the services. This information is necessary to determine price reasonableness because salary and benefits paid by the contractor usually vary significantly among the individuals performing the same type of work. For example, a more experienced staff member often earns more than new hires.

Although, as previously noted, the Interim Contract was modified twice to increase prices for each labor category, there is nothing in the contract documents provided to justify the increases and there is no documentation indicating that a price reasonableness determination was made before awarding the increases. Table E below shows the changes in prices under the Interim Agreement.

Table E. Changes in Prices Under the Interim Agreement

Service	Pre-Interim Contract (1999-4/25/05)	Interim Contract (4/26/2005)	Interim Contract (5/31/2007)	Interim Contract (12/01/2007)
Radiation Oncologist (Associate Professor)	$81.61/hr	$183.89/hr	$282.03/hr	$230.95/hr
Radiation Oncologist (Assistant Professor)	$60.54/hr	$174.52/hr	$185.14/hr	$219.02/hr
Radiation Physicist	$73.84/hr	$93.27/hr	$116.30/hr	$127.99/hr
Dosimetrist	$32.64/hr	$66.56/hr	$88.26/hr	$101.58/hr
Radiation Therapist	$28.81/hr	$61.53/hr	$81.75/hr	$93.82/hr

The pre-award review of the proposal determined that the prices UP proposed for the physicists, dosimetrists, and radiation therapists for the new contract were fair and reasonable. These prices were comparable to the Interim Contract pricing. However, the review determined that the price of $174.32 for the radiation oncologists at the Assistant Professor level was not fair and reasonable for two of the three physicians identified by UP as the individuals who would provide the services at this rate. The recommended rate for two of the proposed physicians was about $74.00/hr., and was based on the actual salary, benefits, and other administrative costs incurred by UP to provide the services. In addition, one of these two individuals was identified during the pre-award review as an Instructor, not an Assistant Professor. For the third physician whose services were proposed at the Assistant Professor rate, the pre-award found that the proposed rate was fair and reasonable. Based on our review of the invoices, we did not identify any charges for his services.

UP proposed one physician who was to be paid at the Associate Professor rate of $183.89/hr. The pre-award review showed that his faculty appointment was only at the Assistant Professor level. The pre-award review also determined that the fair and reasonable price for this individual was $151.88/hr, which was $32/hr less than proposed and about $23/hr less than the Assistant Professor level. This particular physician

provided the significant portion of the services from 2005 through 2007. He was invoiced at the Assistant Professor and Associate Professor rates.

The differences between the rates proposed by UP for radiation oncologist services on the long-term contract and the rate recommended in the pre-award review are based on representations by UP regarding the salary, benefits, and other administrative costs associated with the individual providers. For the Interim Contract, the University represented that the annual salary and benefits package for an Associate Professor was $363K and $382K for an Assistant Professor. The pre-award review determined that the actual costs incurred by UP differed significantly because only a small portion of each individual's salary and benefits related to their faculty appointment. The larger portion related to the salary paid for clinical services each physician provided for the Clinical Practices of the University of Pennsylvania Medical Center (CPUP). One physician received no CPUP salary and benefits and another had less than $10K.

On June 1, 2007, the Network Contract Manager issued SA#2, which extended the contract and increased pricing to the levels indicated in the table above. The contract file does not contain any justification for the price increases which, as noted in the table below were significant. Based on our pre-award review, we question the reasonableness of the adjustments.

Almost 6 months later on November 26, 2007, the Contracting Officer issued SA#3 which extended the Interim Contract and again modified contract pricing to significantly increase prices for each specialty except the Associate Professor level radiation oncologist, which was lowered. The records provided do not indicate a basis for the increases or how the Contracting Officer determined price reasonableness. When interviewed, the Contracting Officer could not provide an explanation or justification for the increase in prices.

Table F. 2007 Rate Increases

Service	6/01/2007 Increase	12/01/2007 Increase
Radiation Oncologist Associate Professor	53%	(18%)
Radiation Oncologist Assistant Professor	6 %	18%
Radiation Physicist	25%	10%
Dosimetrist	33%	15%
Radiation Therapist	33%	15%

D. Poor Contract Administration

In addition to the price increases for which there is no evidence to support as fair and reasonable, we identified several other deficiencies in the administration of this contract. We found that the COTR authorized payment without personally verifying that the services were provided or that the hours claimed were accurate, or that the services for

which payment was sought were within the scope of the contract. We also identified possible conflict of interest violations in the invoicing/payment process.

Between October 2002 and August 2005, invoices included the nature of the services provided, e.g. physician, therapist, dosimetrist, etc., the number of hours charged for each service, and the total amount due. In mid-2004, the invoices also included a breakdown with the applicable rate for each service and the calculated amount owed for each. Beginning with the invoice for services provided in August 2005, the documents provided to us included sign-in sheets. However, the sheets provided included those for VA radiation oncologists who we concluded were not providing services under the contract because UP did not charge for their services.

Invoices show that the current COTR approved payment for invoices relating to services provided from October 2002 to the present. When interviewed, this employee told us that copies of the applicable contracts were possessed and had been reviewed. However, the employee did not know that there was no contract in place from April 1999 through April 25, 2005.

The employee worked in PVAMC's business office, not the clinical area where the services were provided. When asked what information she relied on to verify the actual hours worked, the employee told us that the Chief, Radiation Oncology Service performed the verification. The COTR stated that the contract employees sign-in on the sheets provided by VA. The Chief, Radiation Oncology Service verifies that they worked the hours listed and the sheets are sent to UP. UP prepares an invoice and a copy goes to her and her supervisor for payment. This is of concern as the Chief, Radiation Oncology Service is a dual VA and UP employee and provided services to VA under the contract from at least August 2005 through January 2008.

We also noted that beginning in January 2003 through at least March 2007, invoices were submitted on behalf of radiation oncologist B, who was, and currently is, a VA employee.

In reviewing the sign-in sheets we noted variations in the manner in which contract employees calculated the hours worked each day. The most consistent finding was that the total for some contract employees included a lunch break, whereas other did not. For example, one contract employee would sign-in at 8:30 a.m. and out at 5:00 p.m. and calculate his total hours for the day at 8.5, which VA was charged. Had he excluded the 30 minutes for lunch, VA would only have paid for 8 hours. Hourly rates are calculated based on a 2,080 hour work year based on an 8 hour workday. When the certifying official was asked about this we were told that VA did not pay for the lunch break. However, these statements were inconsistent with the calculations of hours worked on the sign-in sheets, which were included on the invoices. The only corrections to invoices were the rates charged, not the hours reported as worked. We believe that this resulted in VA overpaying for the services provided.

In reviewing invoices, we noted that beginning in July 2007 and continuing into 2009, services under the Interim Contract were provided by a PVAMC radiation oncologist and

that UP charged at the Assistant Professor level for services. A review of UP's web site lists this radiation oncologist as an Instructor, not an Assistant or Associate Professor. There is no indication that VA was aware of or questioned the status at the UP, or that it might impact the pricing structure of the Interim Contract.

Documentation from the VA Medical Center's Biomedical Engineering Service indicates that until 2006, UP was responsible for the maintenance of the radiation oncology equipment. Although the contract awarded in 1996 included a price for a 1.0 FTE engineer, the Statement of Work did not include any duties or responsibilities for this service. The Interim Contract does not include a requirement or a line item price for an engineer. Nonetheless, the invoices show that VA was consistently charged and paid for these services through February 2006. The services were provided intermittently and did not amount anywhere close to 1.0 FTE. Neither the individual who verified the invoices for payment nor the Contracting Officer could explain why VA was paying for services that were outside the scope of the Interim Contract. Because the services were provided on an intermittent basis, we asked who was responsible for ordering the services and who maintained documentation that the services requested were provided. The COTR, the COTR's supervisor, and the Contracting Officer were unable to answer these questions.

Conclusions

We concluded that from between May 1, 1999 through April 25, 2005, the Medical Center paid UP for Radiation Therapy services without a contract or other agreement authorizing payment for these services. From April 26, 2005, through 2009, VA paid for radiation therapy services under an Interim Agreement that violated VA policy and was unnecessary because VA had issued an RFP, received a proposal from UP, and had a pre-award review conducted on the proposal.

Under the Interim Agreement, VA awarded prices that were not fair and reasonable for the radiation oncologists and increased prices on two occasions without any basis for determining that the prices were fair and reasonable. In addition, VA had little or no control over the hours reported to have been worked. As a result, VA appears to have overpaid for the services provided.

Also, from April 26, 2005 through January 2006, VA improperly paid for engineering services under the Interim Agreement, even though the services were outside the scope of the contract.

Recommendations

Recommendation: VHA's National Director of Radiation Oncology Programs should have sufficient resources, to ensure that VHA provides one high quality standard of care for the prostate brachytherapy population. To achieve this end, VHA should standardize, to a practical extent, the privileging, delivery of care, and quality controls for the procedures required to provide this treatment.

Recommendation: VHA should take the steps required to ensure that patients who received low radiation doses in the course of brachytherapy be evaluated to ensure that their cancer treatment plan is appropriate.

Recommendation: VHA should review the controls that are in place to ensure that VA contracts for healthcare comply with applicable laws and regulations, and where necessary, make the required changes in organization and/or process to bring this contracting effort into compliance.

Recommendation: Senior VA leadership should meet with Senior NRC leadership to determine if there is a way forward that will ensure the goals of both organizations are achieved.

Recommendation: VHA should work with the OIG to develop a list of documents that should routinely be provided to the OIG when an outside agency is notified of a (possible) untoward medical event.

Overview of PVAMC Brachytherapy Patients

ME REPORTING USING BLUE RIBBON PANEL METRIC			SEATTLE CONSULTS/ RE-DO	RISK			HORMONE Tx	RELAPSE			TPS NETWORK ISSUES	COMPLICATIONS		DEATHS
ME reported in Phase I	Proposed Final Status: Declared ME	ME d/t 20% or more seeds outside tx area	Seattle, WA VAMC Puget Sound VAHCS (⊙ = Seattle Consult & Re-do Brachy)	Low	Medium	High	Neoaduvant Hormone Therapy	Clinical Relapse by OHI Review (as of 12/31/09)	Biochemical Relapse by Phoenix Criteria	Disease Relapse	No Post Planning Performed	Urinary Stricture (♦= stricture after 2nd implant)	Radiation Proctitis/ Proctopathy (⊙= Grade III or IV)	Deceased (as of 12/31/09)
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Glossary and Abbreviations

Access Control List (ACP) – This is a filtering mechanism used to allow or disallow network packets. Packets can be filtered by protocol, source, destination, or port number.[65]

ADPAC – Automated Data Processing Application Coordinator

CMS Treatment Planning System – A workstation containing software used to calculate the dosimetry for external beam radiotherapy treatment. CMS Software is a part of the Elekta Group and their mission is to develop leading-edge treatment planning and workflow management IT solutions to radiation therapy providers.[66]

D90 – minimum dose delivered to 90% of prostate volume

Dosimetry – the science that measures and calculates doses and format of radiation to be administered (or that was administered) to a patient with a disease requiring radiation therapy, in particular cancer.

Firewall – A system or systems that enforce a boundary between two or more networks. Most firewalls limit the data allowed between networks by protocol, type, source, destination, port number, or a combination of two or more of these decision factors.[67]

Gy – Gray

IMPAC Software – Is a part of the Elekta Group and their mission is to be the leading provider of oncology IT solutions that streamline clinical and business operations across the spectrum of cancer care.[68]

Internet Protocol (IP) – This is the protocol of the Internet and has become the global standard for communications. IP accepts packets from Transport Control Protocol (TCP), adds its own header and delivers a "datagram" to the data link layer protocol. It may also break the packet into fragments to support the maximum transmission unit (MTU) of the network.

IRM – Information Resources Management (IRM)

Local Area Network (LAN) – A network that interconnects devices over a geographically small area, typically in one building or a part of a building. The most popular LAN type is Ethernet. LANs allow the sharing of resources and the exchange of both video and data.

mCi – millicurie

MML – Master Materials License

[65] Department of Veterans Affairs Medical Device Isolation Architecture Guide dated April 30, 2004
[66] http://www.elekta.com/healthcare_international_cms_software.php
[67] Department of Veterans Affairs Medical Device Isolation Architecture Guide dated April 30, 2004
[68] http://www.elekta.com/healthcare_international_impac_software.php

Network Devices/Standards – A group of stations (computers, telephones, or other devices) connected by communications facilities for exchanging information. Connection can be permanent, via cable, or temporary, through telephone or other communications links. The transmission medium can be physical (i.e., fiberoptic cable) or wireless (i.e., satellite).

NHPP – National Health Physics Program

NRC – United States Nuclear Regulatory Commission

RCA – Root Cause Analysis

Treatment Planning – is the process in which a team consisting of radiation oncologists, medical physicists, and medical dosimetrists plan the appropriate external beam radiotherapy or internal prostate brachytherapy treatment technique for a patient with cancer.

TRUS – trans-rectal ultrasound

VariSeed Treatment Planning System™ – VariSeed™ is a computer based software application approved by the Food and Drug Administration (FDA) for planning and evaluating prostate brachytherapy procedures.[69] The VariSeed™ software interfaced with video sources, printers, network Digital Imaging and Communications in Medicine (DICOM)[70] and other image and data sources with the use of IMPAC software, by IMPAC Medical Systems, Inc., an Elekta company.

Virtual LAN (VLAN) – Short for virtual LAN, a network of computers that behave as if they are connected to the same wire even though they may actually be physically located on different segments of a LAN. A VLAN is a method of separating network devices into different logical segments without regard to their physical location.[71] VLANs are configured through software rather than hardware, which make them extremely flexible. One of the biggest advantages of VLANs is that when a computer is physically moved to another location, it can stay on the same VLAN without any hardware reconfiguration.

Voxel Q – A medical device, workstation that stores images from the PQ 5000 CT Scan.

[69] http://www.varian.com/media/oncology/brachytherapy/pdf/VariSeed_8.0_Brochure.pdf
[70] The standard created by the National Electrical Manufacturers Association (NEMA) to aid the distribution and viewing of medical images, such as CT scans, MRIs, and ultrasound. A single DICOM file contains both a header (which stores information about the patient's name, the type of scan, image dimensions, etc), as well as all of the image data (which can contain information in three dimensions). DICOM image data can be compressed (encapsulated) to reduce the image size. DICOM is the most common standard for receiving scans from a hospital.
[71] Department of Veterans Affairs Medical Device Isolation Architecture Guide dated April 30, 2004

Under Secretary for Health Comments

Department of Veterans Affairs **Memorandum**

Date: April 23, 2010

From: Under Secretary for Health (10)

Subject: **Healthcare Inspection –** Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, PA and Other VA Medical Centers

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the OIG Draft Report, Healthcare Inspection: Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, PA and Other VA Medical Centers. The report is detailed, comprehensive, and informative. It will be of significant value as we consider our options about providing brachytherapy treatment to Veterans.

2. VHA concurs with the report and recommendations. The attached action plan includes details about completed actions as well as future actions that we will take to improve care for Veterans who would benefit from brachytherapy treatment.

3. Thank you for the opportunity to review the report. If you have any questions, please have a member of your staff contact Linda H. Lutes, Director, Management Review Service (10B5) at (202) 461-7245.

Robert A. Petzel, M.D.

Veterans Health Administration (VHA)
Action Plan

Office of Inspector General (OIG) Draft Report Healthcare Inspection: Review of Brachytherapy Treatment of Prostate Cancer, Philadelphia, PA and Other VA Medical Centers

Date of Draft Report: Received April 15, 2010

Recommendations/ Actions	Status	Completion Date

Recommendation 1: VHA's National Director of Radiation Oncology Programs should have sufficient resources, to ensure that VHA provides one high quality standard of care for the prostate brachytherapy population. To achieve this end, VHA should standardize, to a practical extent, the privileging, delivery of care, and quality controls for the procedures required to provide this treatment.

VHA Comments

Concur

Standard procedures for training, written directives and clinical requirements were issued in January 2009, and implemented in May 2009.

Mandatory training of all service chiefs, medical physicists, and RSOs in prostate brachytherapy programs was completed in January 2009.

All radiation oncology programs will be ACR inspected and accredited by December 2012.

NCI RPC medical physics QA coverage to all RO programs will be expanded by December 2010, to include inspection of linear accelerators every year and on site peer review of physics practice every three years.

Adapted ACR radiation oncology guidelines for VHA were completed September 2009.

NHPP completed perform annual inspections at seed implant programs Aug 2009 to Jan 2010. The next cycle of inspections will begin in August 2010.

Recommendation 2: VHA should take the steps required to ensure that patients who received low radiation doses in the course of brachytherapy be evaluated to ensure that their cancer treatment plan is appropriate.

VHA Comments

Concur

All 114 brachytherapy cases were reviewed. Under-dosed Veterans were notified, and re-evaluated for possible additional treatment by Philadelphia VA Medical Center (PVAMC). Eighteen patients were referred to Puget Sound VA Medical Center for the placement of additional seeds. Supplementary seed implants were performed on 8 patients.

Each Veteran is seen every six months for follow-up cancer care. This evaluation is performed by the PVAMC Radiation Oncology (RO) Service. This on-going program in the Radiation Oncology Service continues for five years of cancer-free survival, after which the primary care clinic follows the Veteran at least annually for the lifetime of the Veteran.

Recommendation 3: VHA should review the controls that are in place to ensure that VA contracts for healthcare comply with applicable laws and regulations, and where necessary, make the required changes in organization and/or process to bring this contracting effort into compliance.

VHA Comments

Concur

All facilities are required to ensure contractors comply with applicable regulations and standard procedures. The requirement was established in standard procedures that were implemented May 2009. Reviews during NHPP annual inspections are ongoing.

All contracts for radiation oncology (RO) will be reviewed by the National RO Program Office before start of contract.

Standard language for RO contracts, to include QA programs will be written and posted on the VHA Procurement and Logistics Office (10F) website by December 2010.

VA Directive 1663, Health Care Resources Contracting – Buying, Title 38 U.S.C. 8153, is currently in a re-write status to streamline the process and to clarify some areas of the previous Directive. The goal is to define the requirements so that Contracting Officers will be able to comply in a timely matter. By streamlining the process, it should allow for a reduction of Interims utilized by the Contracting Officers.

Service Area Organization Training Officers will be working with the COTRs to establish a more formal program and to develop specialized COTR Training by types of contracts.

We support the Veterans Affairs Acquisition Academy (VAAA) in implementing the newly developed Medical Sharing (1663) course.

VHA implemented an Ideal Organization that established specific teams to focus on VHA specific requirements. A Medical Sharing Team was established to allow proper/focused training on medical related procurements.

VHA intends to have the above actions completed, unless noted otherwise, by October 2010.

Recommendation 4: Senior VA leadership should meet with Senior NRC leadership to determine if there is a way forward that will ensure the goals of both organizations are achieved.

VHA Comments

Concur

The Under Secretary for Health will coordinate with the Nuclear Regulatory Commission (NRC) leadership for a senior level meeting to discuss implementation of the master materials license and resolving the basis to define a medical event for prostate brachytherapy. The USH will contact NRC no later than April 30th.

Recommendation 5: VHA should work with the OIG to develop a list of documents that should routinely be provided to the OIG when an outside agency is notified of a (possible) untoward medical event.

VHA Comments

Concur

VHA will survey program offices to compile a list of events that are possibly reported to other agencies. The USH will discuss with OIG the events that will require notification. The reporting process to OIG will begin no later than October 2010.

OIG Contact and Staff Acknowledgments

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