**OQP Special Study: Quality of VHA Prostate Cancer Care**

**Quality Indicators and Timeliness Measures**

**Introduction**

This project is a nationwide evaluation of quality of care provided to veterans with prostate cancer. This document provides detailed information about the prostate cancer quality indicators and timeliness measures for a special study by the Veterans Health Administration (VHA) Office of Quality and Performance (OQP) to identify opportunities for improvement and inform quality improvement (QI) activities within the VHA Healthcare System.

The quality indicators were developed by the Office of Quality and Performance and collaborators from the Atlanta and Greater Los Angeles VHA Medical Centers, with input from numerous VHA clinical and measurement experts.[[1]](#footnote-1) In most cases, they are adapted from existing quality indicators developed by professional societies and are based on published sources or existing evidence-based clinical guideline recommendations. Some measures were used in the Program Evaluation of Oncology Programs in the Veterans Health Administration, conducted under the auspices of the Office of Policy and Planning (OPP) in compliance with the Government Performance and Results Act of 1993 (GPRA) by contract with Abt Associates and subcontract with Harvard School of Public Health. Feasibility of reliable chart abstraction was also a major factor in measure selection. A brief discussion of the evidence base and rationale is included in the description of each measure, with selected references listed at the end of the document

In addition to the quality indicators, several measures of the timeliness of prostate cancer care are included. There is broad agreement that patients should receive appropriate care in a “timely” fashion. However, evidence linking specific timeframes to outcomes is sparse, and widely-accepted benchmarks are not available. Consequently, each timeliness measure will be reported descriptively (e.g., median time, interquartile range) rather than as the proportion of patients meeting a pre-determined timeliness criterion.

Also included is a set of “descriptive data” presenting information useful for characterizing VHA cancer care but lacking the evidence base or expert opinion consensus required for quality indicators.

There are many important aspects of prostate cancer care that cannot be measured for this study because there are no established guidelines nor consensus standards and/or reliable data cannot be abstracted from the medical record. The measures used for this special study, as with quality measures in general, cannot take into consideration all the nuances of care and thus the results will rarely be 100%. Despite these limitations, we anticipate that the data will be helpful in identifying improvement opportunities. Reporting of results will be accompanied by an improvement toolkit to facilitate addressing these opportunities.

**Measurement Population**

Data will be collected for all (approximately 12,000) pathologically-confirmed incident cases of adenocarcinoma of the prostate from calendar year 2008 reported to the VHA Clinical Cancer Registry (VACCR). Results will be reported at the medical center, VISN, and national level. Since there will be too few cases with metastatic prostate cancer (M>0) at initial diagnosis to assess facility-level results, all metastatic cases (M1) will be included in the sample and only national rates will be reported for measures applicable to M1 disease.

Cases with any of the following will be excluded from all measures:

* prostate cancer other than adenocarcinoma
* recurrence of prior prostate cancer

 enrollment in a cancer clinical trial[[2]](#footnote-2)

 pre-existing or concurrent diagnosis of metastatic cancer other than prostate cancer

* diagnosis and/or treatment for cancer other than prostate cancer (excluding non-melanoma skin cancer) during the 12 months following initial diagnosis of prostate cancer
* enrollment in hospice prior to diagnosis of prostate cancer or < 30 days after cancer diagnosis

 documentation of “comfort measures only” in a hospital discharge summary or nursinghome note <30 days after cancer diagnosis

 diagnosis at autopsy or death < 30 days after cancer diagnosis

 life expectancy less than 6 months documented in the Medical Record or on the PROBLEM LIST at time of diagnosis

**Data Collection and Analysis**

Data used to calculate these indicators will be collected by trained medical abstractors from the West Virginia Medical Institute (OQP’s contractor for abstraction of External Peer Review Program (EPRP) measures), using 2008 VHA Central Cancer Registry (VACCR) case information, Fee Basis files[[3]](#footnote-3), and patients’ VHA electronic medical records. Cancer stage will be determined by VACCR data using clinical or pathologic stage as appropriate. If no VACCR stage is available, the abstracted stage will be used. Data will be reported at three levels: medical center (MC), VISN and national. For calculation of MC-level rates, cases will be attributed to medical centers per VACCR attribution. Only analytic cases (VACCR case codes 0-2) will be selected. If a veteran has more than one VACCR prostate cancer report for 2008, the earliest analytic case will be selected. Medical centers will have the opportunity to review and correct measure results before publication using the same mechanism employed for EPRP measure abstraction[[4]](#footnote-4).

**Staging**

The highest documented clinical stage at time of original diagnosis, whether abstracted from the medical record or recorded in the VACCR, will be used to determine eligibility for measures related to all primary therapy.

**Use of Fee Basis Data**

Fee basis data are used to identify VA-purchased care, the quality of which should be equivalent to that provided at a VAMC. The fee basis care is attributed to the VAMC that paid for the care. More detailed information regarding how fee basis codes and data were used in the study may be found in Appendix II.

**List of Measures for Prostate Cancer Study**

Detailed specifications for each measure are described in subsequent sections. Analytic algorithms linked to the data collection instrument will be provided in the final report.

**Diagnosis and Treatment Quality Indicators**

DTP1: At least 10 cores samples taken at prostate needle biopsy.

DTP2: No bone scan or PET scan prior to primary therapy for prostate cancer at low risk of recurrence and treated with surgery, radiation therapy or cryotherapy

DTP3: Three-dimensional radiation therapy

DTP4: Central axis doses of at least 75 Gy for three-dimensional conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT) external beam radiation therapy (EBRT), with or without image guidance (IGRT)

DTP5: Docetaxel-based regimen for castration-resistant metastatic prostate cancer (reported at national

level only)

DTP6: Neoadjuvant and/or adjuvant hormonal therapy for high-risk patients receiving external beam radiation therapy

**Timeliness Measures**

TP1: Time from pathologic diagnosis of early stage prostate cancer to primary therapy

**Descriptive Data**

DD1: Type of primary therapy for clinically localized prostate cancer

DD2: Negative margins for radical prostatectomy specimens

DD3a: PSA monitoring following primary therapy or Active Surveillance decision for early stage prostate cancer

DD3b: Time to first PSA monitoring after primary therapy for early stage prostate cancer

DD4a: Digital rectal exam monitoring in Active Surveillance for early stage prostate cancer

DD4b: Time to first digital rectal exam following Active Surveillance decision for early stage prostate cancer

##### DD5a: Repeat biopsy following Active Surveillance decision for early stage prostate cancer

DD5b: Time to repeat biopsy following Active Surveillance decision for early stage prostate cancer

DD6: Pre-Treatment Documentation *in a single note* of PSA, Tumor Stage, and Gleason Score

**Diagnosis and Treatment Quality Indicators for Prostate Cancer (DTPs)**

DTP1: At least 10 core camples taken at prostate needle biopsy

At least 10 core samples obtained if needle biopsy of prostate performed for initial pathologic diagnosis of prostate cancer (or documented reason why not)

**Denominator**: Cases with initial pathologic diagnosis obtained by needle biopsy of prostate at a VAMC or Fee Basis provider

**Exclude:** Cases:

* + - meeting study exclusion criteria (see page 2)
    - with no pathology report in medical record
    - not undergoing needle biopsy at a VAMC or Fee Basis provider
    - with stage > M0
    - with stage > N0

**Numerator**: Cases with:

* + - 10 or more core samples taken during prostate needle biopsy;

OR

* + - documentation by physician, nurse practitioner, or physician assistant that obtaining 10 or more core samples was not possible (e.g., surgical complications)

**Note**: In addition to overall results, the following will also be reported:

* + - stratified results: initial diagnostic biopsy at VAMC vs Fee Basis provider

**Rationale:** Many studies have shown the superiority of extended core biopsy techniques for detecting prostate cancer, including prospective and computer simulation analyses in which cancer etection is improved from 73-82% seen with routine sextant biopsy schemes to upwards of 96% when systematic sampling of at least 10 cores occurs (Chen et al. 1997, Chang et al. 1998, Presti et al. 2000). Thus, although not derived from guideline recommendations, this measure was adopted given the strong evidence base in the literature during the timeframe of this study. Subsequent literature (Thura et al 2011) has raised questions about the need for 10 cores, and this measure will need to be reconsidered before using this quality indicator formore recent cases.

**DTP2: No bone scan or PET scan prior to primary therapy for prostate cancer at low risk of recurrence and treated with surgery, radiation therapy or cryotherapy**

No bone scan or PET scan performed between diagnosis and primary therapy for cases at low risk of recurrence receiving interstitial prostate brachytherapy OR external beam radiation therapy to the prostate OR radical prostatectomy OR cryotherapy; or documentation why bone scan or PET scan performed.

**Denominator**: Cases:

* at low risk of recurrence, defined as [[5]](#footnote-5):

Stage T1c or T2a AND PSA 10 ng/mL AND Gleason score 6.

* receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy at a VAMC or Fee Basis provider.

**Include:** Cases with:

Gleason score < 6 **AND** PSA <10 ng/mL**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* with documented clinical T2b, T2c, or T3-4 tumor stage; or disease extending beyond the prostate (i.e.,extraprostatic or non-organ-confined disease); or metastatic (i.e.,M1) disease
* with clinical stage not documented in VACCR and not able to be abstracted from clinical record
* not receiving surgery, radiation therapy, or cryotherapy as primary therapy at a VAMC or Fee Basis provider

**Numerator**: Cases with:

* ***no*** bone scan or PET scan performed at a VAMC or Fee Basis provider between pathologic diagnosis and initiation of the earliest of one the following primary therapies: interstitial prostate brachytherapy, external beam radiation therapy to the prostate, radical prostatectomy, cryotherapy; OR
  + documentation by physician, nurse practitioner, or physician assistant of reason for a bone scan or PET scan (e.g., presence of bone pain, suspicious or abnormal result in another imaging study suggesting metastatic disease, other documented reason).

**Note**: In addition to overall results, stratified results (primary therapy at VAMC vs Fee Basis care provider) will also be reported.

**Rationale:** A bone scan or PET scan is generally not required for staging disease in asymptomatic men with a low risk of recurrence who receive primary therapy or those with a low risk of metastatic disease. This indicator (limited to bone scan) is recommended by the Physician Consortium for Performance Improvement ® (American Medical Association 2007) based on clinical evidence supporting American Urological Association guidelines (2007) and National Comprehensive Cancer Network guidelines (2008). The measure including bone scans only is also currently endorsed by the National Quality Forum (National Quality Measures Clearinghouse 2007).

**DTP3: Three-dimensional radiation therapy**

Use of three-dimensional conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT)[[6]](#footnote-6) with or without image guidance (IGRT)[[7]](#footnote-7) for cases with clinically localized prostate cancer receiving external beam radiation therapy (EBRT) as primary[[8]](#footnote-8) therapy[[9]](#footnote-9)

**Denominator**: Cases with clinically-localized prostate cancer (Stages T1-T2 AND N0 AND M0)  
receiving external beam radiation therapy (EBRT) as primary therapy at a VAMC or Fee Basis provider

**Include:** Cases with:

* Clinical stage:
  + - * T1 or T2 and
      * N0 and
      * M0

AND

* EBRT as primary therapy at a VAMC or Fee Basis provider

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* with clinical staging not documented by VACCR and not able to be abstracted from clinical record
* not receiving primary treatment with EBRT at a VAMC or Fee Basis provider [[10]](#footnote-10)

**Numerator**: Cases with 3D -CRT or IMRT as primary therapy

**Note**: In addition to overall results, stratified results (EBRT at VAMC vs Fee Basis provider) will also be reported.

**Rationale:** Current, computer-aided radiation therapy techniques improve the precision of the irradiation of cancerous tissue and should be employed for all patients receiving external beam radiation therapy as primary therapy to the prostate. (Physician Consortium for Performance Improvement (PCPI) ® (American Medical Association 2007, National Comprehensive Cancer Center Guidelines, 2008). Advanced technologies in EBRT have allowed for delivery of higher cumulative treatment doses to target tissues with lower risk of morbidity and late radiation effects. Since guideline-suggested doses upwards of 75 Gy generally are not achievable using conventional EBRT without significant toxicity, 3D-CRT and IMRT, are the recommended EBRT modalities (Zelefsky et al. 2002, Dolezel et al. 2009, Al-Mamgani et al. 2010).

**DTP4: Central axis doses of at least 75 Gy for three-dimensional conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT) external beam radiation therapy (EBRT), with or without image guidance (IGRT)**

Central axis doses of > 75 Gy for patients at intermediate- or high-risk of recurrence who receive three-dimensional conformal radiation therapy (3D-CRT) or intensity-modulated radiation therapy (IMRT) orimage-guided radiation therapy (IGRT) to the prostate as primary therapy[[11]](#footnote-11) (or documented reason why not)

**Denominator**: Cases at intermediate- or high-risk of recurrence receiving 3D-CRT or IMRT or IGRT types of EBRT to the prostate as primary therapy at a VAMC or Fee-Basis provider

**Include:** Cases who:

* received EBRT as primary therapy for prostate cancer

AND

* are at intermediate or high-risk for recurrence defined as:
  + - Clinically staged
  + T2 or T2c or T3a; and
  + N0; and
  + M0;

OR

* Gleason score >7;

OR

* PSA > 10 ng/mL

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* with neither staging nor PSA nor Gleason score documented by VACCR or able to be abstracted from clinical record
* not receiving primary treatment with EBRT at a VAMC or Fee Basis provider

**Numerator:** Cases with:

* + 3D-CRT or IMRT dose > 75 Gy, with or without IGRT; OR
  + documentation by physician, nurse practitioner, or physician assistant of reason for receiving a different dose (e.g., prior radiation therapy to prostate, concurrent brachytherapy, positive margins for prostate biopsy, toxicity from radiation therapy, other documented reason).

**Note**: In addition to overall results, the following will also be reported:

* + - stratified results: 3D-CRT or IMRT or IGRT received at VAMC vs Fee Basis provider
    - number of cases for which neither stage nor Gleason score nor PSA documented.

**Rationale:** Advanced technologies in EBRT have allowed for delivery of higher cumulative treatment doses to target tissues with lower risk of morbidity and late radiation effects. Results of randomized trials suggest that dose escalation using newer EBRT modalities for prostate cancer treatment is safe and is associated with improved biochemical outcomes (Pollack et al. 2002, Zietman et al. 2005, Peeters et al. 2006). In patients with stage T1b-T3 disease, Kuban et al (2008) demonstrated superior freedom from biochemical or clinical failure in the group randomized to 78 Gy compared to 70 Gy (78% vs 59%, *p*=.004). Based on such findings, conventional doses of 70 Gy are no longer considered adequate, and doses of at least 75 Gy are recommended by current National Comprehensive Cancer Network guidelines (NCCN 2008).

**DTP5: Docetaxel-based regimen for castration-resistant metastatic prostate cancer (reported at national level only)**

Docetaxel-containing chemotherapy regimen for prostate cancer patients with progressive metastatic disease following treatment with androgen deprivation therapy (ADT) [[12]](#footnote-12) (or documented reason why not)

**Denominator**: Cases who received androgen deprivation therapy (ADT) as primary treatment and were subsequently diagnosed with progressive metastatic disease

**Include:** Cases with:

* Androgen deprivation therapy (ADT) received as primary treatment at a VAMC or a Fee Basis provider prior to diagnosis of progressive disease

AND

* Progressive metastatic disease documented in a VAMC or Fee-Basis clinician note [[13]](#footnote-13)

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* not receiving ADT as primary treatment at a VAMC or Fee Basis provider

**Numerator**: Cases who within 6 months of diagnosis of progressive disease:

* Received a docetaxel-based regimen;

OR

* Have documentation by physician, nurse practitioner or physician assistant why  
   docetaxel-based regimen was not received

**Note**: This measure will be reported only at national level because of the low number of eligible cases.

In addition to national results, stratified results (primary ADT at VAMC vs Fee Basis provider)

will also be reported.

**Rationale:** This indicator was derived from data from randomized clinical trials and National Comprehensive Cancer Center Network guidelines (NCCN, 2007). Patients who relapse following androgen deprivation therapy may be considered for systemic therapy. In two phase II studies (SWOG 9916 and TAX 327)[[14]](#footnote-14),[[15]](#footnote-15), docetaxel-based regimens were shown to provide a survival benefit among such patients[[16]](#footnote-16). Based on these data, a regimen of docetaxel with steroids given every three weeks is the recommended first-line treatment for metastatic castration-resistant prostate cancer.

**DTP6**: **Neoadjuvant and/or adjuvant hormonal therapy for high-risk patients receiving external beam radiation therapy as primary therapy**

Neoadjuvant and/or adjuvant hormonal therapy[[17]](#footnote-17) prescribed for cases at high risk of recurrence and receiving external beam radiation therapy (EBRT) to the prostate as primary therapy[[18]](#footnote-18) (or documented reason why not)[[19]](#footnote-19)

**Denominator:** Cases at high risk of recurrence receiving external beam radiation therapy to the prostate as primary therapy at a VAMC or Fee Basis provider

**Include:** Cases with:

* PSA > 20 mg/dL:

OR

* Gleason score 8-10;

OR

* Clinical stage T2c or T3a or T3b or T4

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* with clinical stage N >0 or M >0
* neither clinical staging nor PSA nor Gleason score documented by VACCR or able to be abstracted from clinical record
* not receiving primary treatment with EBRT at a VAMC or Fee Basis provider

**Numerator:** Cases who:

* were prescribed hormonal therapy six months before and/or six months after EBRT;

OR

* have documentation by physician, nurse practitioner or physician assistant why neoadjuvant and/or adjuvant hormonal therapy was not received

**Note**: In addition to overall results, the following will also be reported:

* + - stratified results: EBRT received at VAMC vs Fee Basis provider
    - number of cases with neither stage nor Gleason score nor PSA documented

**Rationale**: In patients receiving external beam radiation therapy (EBRT) as primary therapy who are also at high risk of recurrence, multiple studies alone and in meta-analysis have demonstrated a survival benefit with neoadjuvant or adjuvant hormonal therapy compared to expectant management at relapse (Kumar 2006, D'Amico 2008). Results from the prospective, randomized Phase III trial of the European Organisation for Research and Treatment of Cancer reported five-year disease-free survival rates of 74% (95% CI 67-81%) for the combined treatment group versus 40% (95% CI 32-48%) for radiation alone in a cohort with locally advanced disease, with 5-year disease-specific survival of 94% (95%CI 90-98%) versus 79% (95% CI 72-86%), respectively (Bolla 2002). In a cohort with clinically localized disease, the randomized trial performed by the Radiation Therapy Oncology Group revealed significantly improved actuarial 10-year survival (49% vs. 39%, p=0.002) and 10-year local failure rates (23% vs. 38%, p<0.001) for those receiving neoadjuvant or adjuvant hormonal therapy with EBRT vs. EBRT alone (Pilepich 2005). Such studies have prompted the American Urological Association and the National Comprehensive Cancer Network to include this standard in guidelines with their highest levels of recommendation ("Standard" and "Category 1", respectively), and it is a measure of the American Medical Association Physician Consortium for Performance Improvement®. The National Cancer Institute assessment of the level of evidence supporting this therapeutic strategy is 1iiA (randomized, controlled, non-blinded clinical trial with total mortality as an endpoint).

**Timeliness Measures**

**Rationale for Timeliness Measures**: Timeliness of care is one of six important dimensions of health care quality recognized by the Institute of Medicine. Although data regarding the effect of timely care on patient outcomes is sparse and conflicting, particularly given the generally lengthy disease course of prostate cancer, timeliness is an important aspect of high-quality, patient-centered care. This is a descriptive measure only.

**TP1:** **Time from pathologic diagnosis of early stage prostate cancer to primary therapy**[[20]](#footnote-20)

Median number of days from pathologic diagnosis of early stage prostate cancer and primary therapy or decision to defer or forego treatment during first 12 months post-diagnosis

**Include:** Cases with:

* Clinical stage:
  + - T1 or T2; and
    - N0; and;
    - M0

AND

* One of the following::
* radical prostatectomy, cryotherapy, brachytherapy, external beam radiation therapy, hormonal therapy as primary therapy at a VAMC or Fee Basis provider (with the earliest being used in calculation); or
* documented decision to pursue active surveillance as primary therapy or not to treat

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* without documentation of dates to calculate this measure
* not initially diagnosed at a VAMC
* with clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Note**: In addition to median number of days, the following results will also be reported:

* stratification by type of primary treatment
* for each type of primary treatment (excluding active surveillance and decision not to treat), stratification by VACCR VAMC vs other VAMC vs Fee Basis provider[[21]](#footnote-21)

Descriptive Data (DD)

The following information will also be reported. These measures address processes of care where valid and feasible quality indicators are difficult to construct given the current level of evidence, yet whose value to the health care provider may be of interest, import, or utility in understanding and improving VHA cancer care.

**DD1: Type of primary therapy for clinically localized prostate cancer**

Proportion of cases of early stage prostate cancer receiving each type of primary therapy[[22]](#footnote-22) during the first 12 months following definitive diagnosis of early stage prostate cancer:

**Denominator:** Cases with:

* Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
  + T1 or T2; and
  + N0; and
  + M0;

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* with clinical staging not documented by VACCR and not able to be abstracted from clinical record
* with documentation of primary therapy at a non-VAMC and non-Fee Basis provider, except for active surveillance or decision not to treat, which will be included for all VAMC and non-VA providers.

**Numerator(s):** Number of cases receiving each of the following as primary therapy at a VAMC or Fee Basis provider during the first 12 months following definitive diagnosis of prostate cancer at the above-referenced stages:

* + - * surgery; or
      * brachytherapy; or
      * external beam radiation therapy; or
      * cryotherapy; or
      * hormonal therapy[[23]](#footnote-23); or
      * active surveillance; or
      * decision not to treat

**Note**: In addition to overall results, the following results will also be reported:

* for each type of primary therapy (other than active surveillance or decision not to treat), stratification by site of primary therapy (VACCR VAMC vs other VAMC vs Fee Basis provider)[[24]](#footnote-24)
* cases where type of primary therapy and/or whether therapy received at VAMC or Fee Basis provider cannot be determined

**Rationale:** It is unclear whether long-term outcomes differ significantly among early stage prostate cancer patients who receive treatments with curative intent versus active surveillance, and the improvement in early detection afforded by the PSA test has raised concern regarding overtreatment of the growing numbers of patients with early disease (Draisma et al. 2003, Parker 2004, Dall’Era et al. 2008, Miller 2009, Shao 2009). The proportion of VHA patients selecting each of these primary treatment options has not yet been well-described. *This measure is descriptive only and will provide information on patterns of care for patients with prostate cancer in the VHA.*

**DD2: Negative margins for radical prostatectomy specimens**

Proportion of cases with radical prostatectomy surgical specimen(s) with margins free of tumor reported by recurrence risk level

**Denominator**: Cases with prostate pathologic specimen obtained from a radical prostatectomy procedure:

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* undergoing cystoprostatectomy
* with salvage prostatectomy for radiation therapy failures
* not undergoing radical prostatectomy at a VAMC or Fee Basis provider
* with no pathology report in medical record
* with neither staging nor PSA nor Gleason score documented by VACCR or able to be abstracted from clinical record

**Numerator**: Cases with negative surgical margins documented in the pathology report for the radical prostatectomy specimen

**Note**: In addition to overall results, the following will also be reported:

* results stratified by by risk recurrence level[[25]](#footnote-25)

LOW recurrence risk:

* + Stage T2a or less AND
  + PSA ≤10 ng/mL AND
  + Gleason score ≤6

INTERMEDIATE recurrence risk:

* Stage T2b; OR
* PSA >10 and ≤20 ng/mL; OR
* Gleason score=7

HIGH recurrence risk:

* Stage T2c or greater; OR
* PSA >20 ng/mL; OR
* Gleason score ≥8
* results for each recurrence risk level stratified by whether prostatectomy was performed by VAMC vs Fee Basis provider.

**Rationale**: Numerous studies have demonstrated that positive surgical margins following radical prostatectomy as definitive local treatment for prostate cancer are associated with biochemical and clinical recurrence and thus predictive of need for secondary treatment (Zietman et al. 1993, Grossfeld et al. 2000). However, several questions limit the ability to use this measure as a quality indicator. The ideal positive margin rate has never been defined and even at high volume centers of excellence, the reported positive margin rate is not zero (range: 11% to 38% , Tan et al, 2010). In addition, Evans at al reported in 2008 that interobserver variability between expert genitourinary pathologists is 10% when examining radical prostatectomy specimens for the presence of margin status. *Although the conflicting evidence makes this measure inappropriate as a quality indicator, is should provide a useful description of prostate surgical specimen margin status within VHA.*

**DD3a: PSA monitoring following primary therapy decision for early stage prostate cancer**

Proportion of cases with PSA monitoring within 18 months following initiation of primary therapy[[26]](#footnote-26) for early stage prostate cancer

**Denominator:** Cases with:

* + - * Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
        + T1 or T2; and
        + N0; and
        + M0;

AND

* + - * Surgery, brachytherapy, external beam radiation therapy, cryotherapy, or hormonal therapy as primary therapy at a VAMC or Fee Basis provider;

**Exclude**: Cases:

* + meeting study exclusion criteria (see page 2)
  + who died < 540 days (18 months) after initiation of primary therapy not receiving primary therapy at a VAMC or Fee Basis provider
  + with clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Numerator:** Cases with serum PSA test < 540 days (18 months) after initiation of

primary therapy

**DD3b:** **Time to first PSA monitoring after primary therapy for early stage prostate cancer**

Median number of days to first PSA following initiation of primary therapy for early stage prostate cancer (among cases with monitoring within 18 months)

**Include:** Cases with:

* + Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
    - T1 or T2; and
    - N0; and
    - M0;

AND

* + Surgery, brachytherapy, external beam radiation therapy, cryotherapy, or hormonal therapy as primary therapy at a VAMC or Fee Basis provider;

AND

* + Serum PSA test drawn at a VAMC < 540 days (18 months) following primary therapy

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* who died < 540 days (18 months) after initiation of primary therapy not receiving primary therapy at a VAMC or Fee Basis provider
* with clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Note**: In addition to reporting the median number of days, the following will also be reported:

* + - results stratified by type of primary therapy;
    - results stratified by site of primary therapy (VACCR VAMC vs other VAMC vs Fee Basis provider)[[27]](#footnote-27)

**Rationale:** Guidelines for timing and frequency of post-therapy PSA monitoring are few and differ substantially. National Comprehensive Cancer Network clinical guidelines suggest PSA testing every 6-12 months for the first five years following therapy with curative intent, then annually thereafter; for locally advanced or metastatic disease treated with ADT or radiation therapy, PSA testing every 6-12 months is suggested. American Society for Therapeutic Radiology and Oncology guidelines suggest PSA testing every 3 months for the first two years following treatment, then every 6 months thereafter (1997). In view of the lower level of evidence regarding optimal follow-up for patients on AS, *these measures are descriptive only and will provide information on patterns of care for patients with prostate cancer receiving a variety of treatment options, including AS, in the VHA*.

**DD4a:** **Digital rectal exam monitoring in Active Surveillance for early stage prostate cancer**

Proportion of cases with digital rectal examination (DRE)[[28]](#footnote-28) within 18 months following Active Surveillance decision for early stage prostate cancer

**Denominator**:Cases with:

* prostate cancer clinically staged (per VACCR or medical record abstraction) as:
  + T1 or T2; and
  + N0; and
  + M0;

AND

* active surveillance as primary therapy at a VAMC[[29]](#footnote-29)

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* who died < 540 days (18 months) after initiation of primary therapy or Active Surveillance decision
* with Active Surveillance as primary therapy at a non-VHA facility, including Fee Basis providers;
* clinical staging not documented by VACCR and not able to be abstracted from clinical record
* **Numerator:** Cases with: DRE performed at a VAMC[[30]](#footnote-30)

AND

* DRE performed < 540 days (18 months) after decision to pursue Active Surveillance

**DD4b:** **Time to first digital rectal exam following Active Surveillance decision for early stage prostate cancer**

Median number of days to first digital rectal exam following Active Surveillance decision for early stage prostate cancer (among cases with DRE within18 months)

**Include** Cases with:

* Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
  + T1 or T2; and
  + N0; and
  + M0;

AND

* Active surveillance as primary therapy at a VAMC;

AND

* Digital rectal exam performed at a VAMC < 540 days (18 months) following the decision for active surveillance following a diagnosis of early stage prostate cancer

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* who died < 540 days (18 months) after Active Surveillance decision
* with Active Surveillance as primary therapy at a non-VHA facility, including Fee Basis providers
* clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Rationale**: There is limited evidence addressing follow-up of patients electing Active Surveillance for early stage prostate cancer. The National Collaborating Centre for Cancer’s guidelines (2008) recommend that patients who choose AS should be followed in accordance with the ProSTART (Phase III randomized study of active surveillance versus radical treatment in patients with favorable-risk prostate cancer) protocol, including at least one re-biopsy. The National Comprehensive Cancer Network (NCCN) guidelines descriptive only and will provide information on patterns of care for patients with prostate cancer on AS in the VHA. (v.2008, call for regular follow-up for men who are monitored through AS, including PSA (every 3-6 months), DRE (every 6-12 months), repeat needle biopsy within 6 months (if initial biopsy was <10 cores or assessment discordant) or within 18 months (if initial biopsy > 10 cores). *In view of conflicting recommendations for follow-up for patients on AS, this measure is descriptive only to provide information on patterns of Active Surveillance follow-up in VHA.*

##### DD5a: Repeat biopsy following Active Surveillance decision for early stage prostate cancer

##### Proportion of cases with repeat biopsy within 18 months following Active Surveillance decision for early stage prostate cancer

##### Denominator: Cases with:

* + - Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
      * T1 or T2; and
      * N0; and
      * M0;

AND

* + - Active surveillance as primary therapy at a VAMC[[31]](#footnote-31)

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* who died < 540 days (18 months) after initiation of primary therapy or Active Surveillance decision
* with Active Surveillance monitoring as primary therapy at a non-VHA facility, including Fee Basis providers
* clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Numerator:** Number of cases with documented dates and findings for first repeat prostate biopsy < 540 days (18 months) following decision for active surveillance

##### DD5b: Time to repeat biopsy following Active Surveillance decision for early stage prostate cancer

##### Median number of days to first repeat biopsy following Active Surveillance decision for early stage prostate cancer (among cases with DRE within 18 months)

##### 

**Include:** Cases with:

* + - Prostate cancer clinically staged (per VACCR or medical record abstraction) as:
      * T1 or T2; AND
      * N0; AND
      * M0; AND
    - Active surveillance as primary therapy at a VAMC; AND
    - Documented dates and findings for first repeat prostate biopsy < 540 days (18 months) following decision for Active Surveillance

**Exclude**: Cases:

* meeting study exclusion criteria (see page 2)
* with Active Surveillance monitoring as primary therapy at a non-VHA facility, including Fee Basis providers
* clinical staging not documented by VACCR and not able to be abstracted from clinical record

**Rationale**: The evidence for best practices for active surveillance (AS) decision for early stage prostate cancer is limited. The National Collaborating Centre for Cancer guidelines (2008) recommend that patients who choose AS should be followed in accordance with the ProSTART (Phase III randomized study of active surveillance versus radical treatment in patients with favorable-risk prostate cancer) protocol, including at least one re-biopsy. The National Comprehensive Cancer Network (NCCN) guidelines (v.2008,) call for regular follow-up for men who are monitored through AS, including PSA (every 3-6 months), DRE[[32]](#footnote-32) (every 6-12 months), repeat needle biopsy within 6 months (if initial biopsy was <10 cores or assessment discordant) or within 18 months (if initial biopsy > 10 cores). *In view of the conflicting recommendations regarding optimal follow-up for patients on AS, this indicator is descriptive only, but may be useful in understanding patterns of care provided to prostate cancer cancer on AS in the VHA.*

**DD6: Pre-Treatment Documentation *in a single note* of PSA, Tumor Stage, and Gleason Score**

Documentation of PSA, clinical tumor (T) stage and/or digital rectal exam (DRE) findings, and Gleason score for newly-diagnosed cases of non-metastatic (i.e., M0) prostate cancer in one note in medical record or reference in note to evaluation of these three elements prior to treatment decision-making (or documented reason why not)

**Denominator**: Cases who:

* receive primary therapy (i.e., interstitial prostate brachytherapy OR external beam radiation therapy to the prostate OR radical prostatectomy OR cryotherapy OR hormonal therapy OR active surveillance) at a VAMC; OR
* have documentation of a decision not to treat.

**Exclude:** Cases:

* meeting study exclusion criteria (see page 2)
* with metastatic (i.e., N1 or M1) disease at initial clinical staging
* not receiving primary therapy at a VAMC

**Numerator**: Cases with:

* + documentation within 12 months of diagnosis but prior to initiation of earliest treatment or decision not to treat of all the following in a single note:
    - PSA; AND
    - Gleason score; AND
    - clinical T stage or DRE[[33]](#footnote-33) findings

**Rationale:** This indicator is included in the Physician Consortium for Performance Improvement (PCPI)®measurement set (American Medical Association, 2007), an Institute of Medicine report on quality indicators in cancer care (Institute of Medicine, 2005), and the National Comprehensive Cancer Network (NCCN) guidelines (NCCN 2008). Stratification of recurrence risk by PSA, tumor stage, and Gleason score has been correlated significantly with biochemical failure and cancer-specific mortality following treatment (American Urological Association, 2007); the three factors are thus used routinely to aid in prognosis and guide treatment decision-making. For this measure documentation of DRE is considered equivalent to documentation of T stage because clinical T staging is a reflection of DRE findings. The intent of the measure is to ensure that all three elements were considered prior to treatment decision-making. Thus, documentation of findings for all three items (PSA, stage/DRE, and Gleason score) should be included in a single note in the medical record, or a reference to all three items specifically as part of evaluation prior to treatment decision-making should be documented in one note.

##### Selected References

###### DTP1

Babaian RJ, Toi A, Kamoi K, et al: A comparative analysis of sextant and an extended 11-core multisite directed biopsy strategy. *J Urol* 2000;163:152-157.

Chang JJ, Shinohara K, Chang JJ, Shinohara K, Bhargava V, et al. Prospective evaluation of lateral biopsies of the peripheral zone for prostate cancer detection. *J Urol* 1998;160:2111-2114.

Chen ME, Troncoso P, Johnston DA, et al. Optimization of prostate biopsy strategy using computer based analysis. *J Urol*. 1997;158:2168-2175.

Eskew LA, Bare RL, McCullough DL, Systematic 5 region prostate biopsy is superior to sextant method for diagnosing carcinoma of the prostate. *J Urol* 1997; 157:199-203

Naughton CK, Miller DC, Mager DE, et al: A prospective randomized trial comparing 6 versus 12 prostate biopsy cores: Impact on cancer detection. *J Urol*. 2000;164:388-392

Presti JC, Chang JJ, Bhargava V, Shinohara K. The optimal systematic prostate biopsy scheme should include 8 rather than 6 biopsies: Results of a prospective clinical trial. *J Urol* 2000;163:163-167.

Thura T. Abd, Michael Goodman, John Hall, Chad W. M. Ritenour, John A. Petros, Fray F. Marshall, and Muta M. Issa. Comparison of 12-Core Versus 8-Core Prostate Biopsy: Multivariate Analysis of Large Series of US Veterans. *Urology* 2011; 77: 541–547.

Thura T. Abd, Michael Goodman, John Hall, Chad W. M. Ritenour, John A. Petros,

Fray F. Marshall, and Muta M. Issa. Comparison of 12-Core Versus 8-Core Prostate Biopsy: Multivariate

Analysis of Large Series of US Veterans. *Urol* 77: 541–547, 2011.

**DTP2**

American Medical Association. American Urological Association/Physician Consortium for Performance Improvement ®. Prostate Cancer Physician Performance Measurement Set. <http://www.ama-assn.org/ama1/pub/upload/mm/370/prostate-cancer-ms.pdf> [last update October 2009]

American Urological Association (AUA). Guidelines for the management of clinically localized prostate cancer: 2006 Update. American Urological Association Education and Research, Inc., 2006. DRAFT copy.

D’Amico AV, Whittington R, Malkowicz SB, et al**.** Biochemical Outcome After Radical Prostatectomy, External Beam Radiation Therapy, or Interstitial Radiation Therapy for Clinically Localized Prostate Cancer. *JAMA* 1998;280:969-974.

National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2005. [www.nccn.org/professionals/physician\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

National Quality Measures Clearinghouse. <http://www.qualitymeasures.ahrq.gov/browse/nqf-endorsed.aspx?term=prostate%20cancer%20bone%20scan> [accessed August 25, 2010]

**DTP3**

Al-Mamgani A, Heemsbergen WD, Peeters STH, Lebesque JV. Role of Intensity-Modulated Radiotherapy in Reducing Toxicity in Dose Escalation for Localized Prostate Cancer. *Int J Radiat Oncol Biol Phys* 2009, 73(3): 685-691.

American Medical Association. American Urological Association/Physician Consortium for Performance Improvement ®. Prostate Cancer Physician Performance Measurement Set. <http://www.ama-assn.org/ama1/pub/upload/mm/370/prostate-cancer-ms.pdf> [last update October 2009]

De Meerleer GO, Fonteyne VH, Vakaet L, et al. Intensity-modulated radiation therapy for prostate cancer: late morbidity and results on biochemical control. *Radiother Oncol* 2007, 82(2): 160-166.

Dolezel M, Odrazka K, Vaculikova M, et al. Dose Escalation in Prostate Radiotherapy up to 82 Gy Using Simultaneous Integrated Boost: Direct Comparison of Acute and Late Toxicity with 3D-CRT 74 Gy and IMRT 78 Gy. *Strahlenther Onkol*  2010, 816(4): 197-202.

Guckenberger M, Flentje M. Intensity-Modulated Radiation Therapy (IMRT) of Localized Prostate Cancer: A Review and Future Perspectives. *Strahlenther Onkol* 2007, 183: 57-62.

Kupelian PA, Thakkar VV, Khuntia D, et al. Hypofractionated intensity-modulated radiotherapy (70 Gy at 2.5 Gy per fraction) for localized prostate cancer: long-term outcomes. *Int J Radiat Oncol Biol Phys* 2005, 63: 1463-1468.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2009. [www.nccn.org/professionals/physician\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

Zelefsky MJ, Chan H, Hunt M, et al. Long-Term Outcome of High Dose Intensity Modulated Radiation Therapy for Patients with Clinically Localized Prostate Cancer. *J Urol* 2006, 176(4): 1415-1419.

Zelefsky MJ, Fuks Z, Hunt M, et al. High-dose intensity modulated radiation therapy for prostate cancer: early toxicity and biochemical outcome in 772 patients. *Int J Radiat Oncol Biol Phys* 2002, 53(5): 1111-1116.

Zelefsky MJ, Fuks Z, Hunt M, et al. High dose radiation delivered by intensity modulated conformal radiotherapy improves the outcome of localized prostate cancer. *J Urol*  2001, 166: 876-881.

**DTP4**

Kuban DA, Tucker SL, Dong L, et al. Long-term results of the MD Anderson randomized dose-escalation trial for prostate cancer. *Int J Radiat Oncol Biol Phys* 2008; 70(1):67-74.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2009. [www.nccn.org/professionals/physician\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

Peeters, ST, Heemsbergen WD, Koper PC, et al. Dose-response in radiotherapy for localized prostate cancer: results of the Dutch multicenter randomized phase III trial comparing 68 Gy of radiotherapy with 76 Gy. *J Clin Oncol* 2006; 24: 19901996.

Pollack A, Zagars GK, Stakschall G, et al. Prostate cancer radiation dose response: results of the MD Anderson phase III randomized trial. *Int J Radiat Oncol Biol Phys* 2002; 53: 1097-1105.

Zietman AL, DeSilvio ML, Slater D, et al. Comparison of conventional-dose vs high-dose conformal radiation therapy in clinically localized adenocarcinoma of the prostate: a randomized controlled trial. J*AMA* 2005; 294:1233-1239.

**DTP5**

Berthold DR, Pond GR, Soban F, de Wit R, Eisenberger M, Tannock IF. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer: updated survival in TAX 327 study. *J Clin Oncol* 2008; 26:242-245.

Machiels JP, Mazzeo F, Clausse M, et al. Prospective randomized study comparing docetaxel, estramustine, and prednisone with docetaxel and prednisone in metastatic hormone-refractory prostate cancer. *J Clin Oncol* 2008; 26: 5261-5268.

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2009. [www.nccn.org/professionals/physician\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

Petrylak DP, Tangen CM, Hussain MH, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer. *N Engl J Med* 2004; 351:1513-1520.

Tannock IF, de Wit R, Berrry WR, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. *N Engl J Med* 2004; 351: 1502-1512.

**DTP6**

American Medical Association. American Urological Association/Physician Consortium for Performance Improvement ®. Prostate Cancer Physician Performance Measurement Set. <http://www.ama-assn.org/ama1/pub/upload/mm/370/prostate-cancer-ms.pdf> [last update October 2008]

American Urological Association (AUA). Guidelines for the management of clinically localized prostate cancer: 2006 update. 2006. American Urological Association Education and Research, Inc. DRAFT copy.

Bolla M, Collette L, Blank L, et al. Long- term results with immediate androgen suppression and external irradiation in patients with locally advanced prostate cancer (an EORTC study): a phase III randomised trial. *Lancet* 2002, 360(9327): 103-108.

D'Amico AV, Chen MH, Renshaw AA, et al.: Androgen suppression and radiation vs radiation alone for prostate cancer: a randomized trial. *JAMA* 2008, 299 (3): 289-295.

Kumar S, Shelley M, Harrison C, et al.: Neo-adjuvant and adjuvant hormone therapy for localised and locally advanced prostate cancer. *Cochrane Database Syst Rev* 2006, 4: CD006019.

National Cancer Institute.

<http://www.cancer.gov/cancertopics/pdq/treatment/prostate/HealthProfessional/page7> [Accessed 23 October 2010]

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 2.2005. Available at: [www.nccn.org/professionals/physician\_gls/default.asp](http://www.nccn.org/professionals/physician_gls/default.asp).

Pilepich MV, Winter K, Lawton CA, et al.: Androgen suppression adjuvant to definitive radiotherapy in prostate carcinoma--long-term results of phase III RTOG 85-31. *Int J Radiat Oncol Biol Phys* 2005, 61(5): 1285-1290.

**DD1**

Dall’Era MA, Cooperberg MR, Chan JM, et al. Active surveillance for early-stage prostate cancer: review of the current literature. *Cancer* 2008; 112(8):1650–1659.

Draisma G, Boer R, Otto SJ, et al. Lead times and overdetection due to prostate-specific antigen screening: estimates from the European Randomized Study of Screening for Prostate Cancer. *J Natl Cancer Inst* 2003; 95(12): 868–878.

Miller DC, Gruber SB, Hollenbeck BK, et al. Incidence of initial local therapy among men with lower-risk prostate cancer in the United States. *J Natl Cancer Inst* 2006; 98(16):1134–1141.

Parker C. Active surveillance: towards a new paradigm in the management of early prostate cancer. *Lancet Oncol* 2004; 5(2):101–106.

Shao YH, Demissie K, Shih W, et al. Contemporary risk profile of prostate cancer in the United States. J Natl Cancer Inst 2009; 101(18):1280–1283.

DD2

Bolla M, van Poppel H, Collette L, et al. Postoperative radiotherapy after radical prostatectomy: a randomised controlled trial (EORTC trial 22911). *Lancet* 2005; 366: 572–578.

Grossfeld GD, Chang JJ, Broering JM, et al. Impact of positive surgical margins on prostate cancer recurrence and the use of secondary cancer treatment: data from the CaPSURE database*. J Urol* 2000; 163(4):1171-1177.

Evans AJ, Henry PC, Van der Kwast TH, Tkachuk DC, et al. [Interobserver variability between expert urologic pathologists for extraprostatic extension and surgical margin status in radical prostatectomy specimens.](http://www.ncbi.nlm.nih.gov/pubmed/18708939) Am J Surg Pathol. 2008 Oct;32(10):1503-12.

Tan PH, Cheng L, Srigley JR, Griffiths D, Humphrey PA, van der Kwast TH, Montironi R, Wheeler TM, Delahunt B, Egevad L, Epstein JI. International Society of Urological Pathology (ISUP) Consensus Conference on Handling and Staging of Radical Prostatectomy Specimens. Working group 5: surgical margins. Mod Pathol. 2010 Aug 20. [Epub ahead of print]

Thompson Jr., IM, Tangen CM, Paradelo J et al. Adjuvant radiotherapy for pathologically advanced prostate cancer: a randomized clinical trial. *JAMA* 2006; 296: 2329–2335.

Thompson IM, Tangen CM, Paradelo J, et al. Adjuvant radiotherapy for pathological T3N0M0 prostate cancer significantly reduces risk of metastases and improves survival: long-term followup of a randomized clinical trial. *J Urol* 2009; 181**:**956–962.

Wiegel T, Bottke D, Steiner U, et al. Phase III postoperative adjuvant radiotherapy after radical prostatectomy compared with radical prostatectomy alone in pT3 prostate cancer with postoperative undetectable prostate-specific antigen: ARO 96-02/AUO AP 09/95, *J Clin Oncol* 2009; 27: 2924–2930.

Zietman AL, Shipley WU, Willett CG. Residual disease after radical surgery or radiation therapy for prostate cancer: clinical significance and therapeutic implications. *Cancer* 1993; 71: 959–969.

**DD3**

American Society for Therapeutic Radiology and Oncology Consensus Panel. Consensus statement: Guidelines for PSA following radiation therapy. *Int J Radiat Oncol Biol Phys* 1997; 37(5): 1035-1041.

National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Prostate Cancer. v1.2010. <http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf>

**DD4**

National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 146 p. (NICE clinical guideline; no. 58).

ProSTART (Phase III randomized study of active surveillance versus radical treatment in patients with favorable-risk prostate cancer. [<http://www.cancer.gov/clinicaltrials/CAN-NCIC-CTG-PR11>]

National Comprehensive Cancer Network. V.2009. Practice Guidelines in Oncology. Prostate Cancer.

[www.nccn.org](http://www.nccn.org)

**DD5**

National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 146 p. (NICE clinical guideline; no. 58).

ProSTART (Phase III randomized study of active surveillance versus radical treatment in patients with favorable-risk prostate cancer. [<http://www.cancer.gov/clinicaltrials/CAN-NCIC-CTG-PR11>]

National Comprehensive Cancer Network. V.2009. Practice Guidelines in Oncology. Prostate Cancer.

[www.nccn.org](http://www.nccn.org)

**DD6**

American Medical Association. American Urological Association/Physician Consortium for Performance Improvement ®. Prostate Cancer Physician Performance Measurement Set. <http://www.ama-assn.org/ama1/pub/upload/mm/370/prostate-cancer-ms.pdf> [last update October 2009]

American Urological Association. Guidelines for the Management of Clinically Localized Prostate Cancer: 2007 Update. <http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines.cfm> [last update 2009]

Institute of Medicine. Assessing the Quality of Cancer Care: An Approach to Measurement in Georgia. National Academies Press, 2005.

National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology: Prostate Cancer. v1.2010.? <http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf>

**Appendix I**

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**Appendix II**

**FEE BASIS CODES AND DATA USAGE**

**The following describes how fee basis activities were identified and used for this project:**

Use of Fee Basis Data in Analyses:

**Initial diagnostic biopsy**: Date and distinguishing VA vs fee-based vs non-VA

* + If abstracted as VAMC but there is fee-basis claim for bx 1 week before or after VACCR diagnosis date, use the earlier date
    - Bx codes: 55700, 55705, 55812, 0417T, 76942
  + If abstracted as non-VA (fee basis or non fee basis), considered to be fee-basis if there is fee-basis claim for bx 1 week before or after VACCR diagnosis date
  + If abstracted date of fee-basis biopsy is different from the fee-basis claim, use date from fee-basis claim.

**Initial treatment: Total prostatectomy**

* If abstracted as VAMC but there is fee basis claim for total prostatectomy before VAMC date but after date of dx, use earliest date and treatment site.
  + Codes for total prostatectomy : 55810 – 55815, 55840 – 55845, 55831, 55821, 55801, 55866, 60.5
* If abstracted as non-VA (fee basis or non fee basis), considered to be fee-basis if there is a fee basis claim. Fee basis service delivery date to be used.
* If abstracted date of fee-basis prostatectomy is different from the fee-basis claim, use date from fee-basis claim.

**Initial treatment: RT**

* If abstracted as VAMC but there is fee basis claim for delivery of RT to prostate before VAMC RT date but after date of dx, use earliest date and treatment site.
  + Codes for RT to prostate: 77216 – 77499, 77750 – 77799, 77427, 92.2 – 92.29, V58.0, V67.1, V66.1, 77520, 77523, G0256, G0261, 0073T, 0197T, 77014, 76950
* If abstracted as non-VA (fee basis or non fee basis), considered to be fee-basis if there is a fee basis claim. Fee basis service delivery date to be used.
* If abstracted date of fee-basis RT is different from the fee-basis claim, use date from fee-basis claim.

**Initial treatment: Hormonal therapy**

* If abstracted as VAMC but there is fee basis claim for delivery of hormonal therapy before VAMC date but after date of dx, use earliest date and treatment site.
  + Codes for hormonal therapy: 90772, J1950, J9202, J9217 – J9219, 54520, 54530, 54690, 62.3, 62.4, 62.41, 62.42, J8999, J9999, J9155 (orchiectomy and oral ADT agents were also included here)
* If abstracted as non-VA (fee basis or non fee basis), considered to be fee-basis if there is a fee basis claim. Fee basis service delivery date to be used.
* If abstracted date of hormonal therapy is different from the fee-basis claim, use date from fee-basis claim.

**Receipt of RT AND brachytherapy**

* **Retrieve and record both EBRT and brachytherapy codes.**
* **If got both, primary therapy determined by initial date of therapy by type**
* **Date, fee-basis non fee-basis attribution as above.**

**Bone/CT/PET scans:**

* If more than one imaging test performed: Could be VA, fee-basis, non-VA.
* The following codes were not mentioned above but added to the data pull in case they are needed:
  + Codes for Bone Scan: 78300, 78306, 78315, 78320
  + Codes for PET Scan: 78205, 78206, 78320, 78807, 78811, 78812, 78813
  + Codes for PSA: 84152 – 84154, G0103
  + Codes for Docetaxal: J9170
  + Codes for Cryotherapy: 55873, 60.62
  + Codes for Brachytherapy: 77326 – 77328, 77761 – 77763, 77785 – 77787, 77789, 77790, 77799, 0182T, 55860, 55862, 55865, 55875, 55876, 76873, 76965, 77776 – 77778, 92.27, C1715, C1717, C2638, C2639, C2640, C2641, Q3001

**Data retrieval and programming to identify fee basis data were as follows:**

The fee basis data was queried based on the codes listed below. In addition to the name, date of birth and social security number for each case, the query returned the following variables:

* Was there a code for a fee basis prostate biopsy performed during CY2008 (procedure/treatment date, NOT billing date) – yes, no. The biopsy codes: 55700, 55705, 55812, 0417T, 76942
  + If yes: for each prostate biopsy during CY2008, what was procedure/treatment date?
* Was there a code in fee basis files for a radical prostatectomy performed during CY2008-9 (procedure/treatment date, NOT billing date) – yes, no. Codes for total prostatectomy : 55810 – 55815, 55840 – 55845, 55831, 55821, 55801, 55866, 60.5
  + If yes: what was procedure/treatment date?
* Was there a code in fee basis files for radiation therapy to the prostate performed during CY2008-9 (procedure/treatment date, NOT billing date) – yes, no. Codes for RT to prostate: 77216 – 77499, 77750 – 77799, 77427, 92.2 – 92.29, V58.0, V67.1, V66.1, 77520, 77523, G0256, G0261, 0073T, 0197T, 77014, 76950
  + If yes: what was procedure/treatment date for the first treatment in this time period?
  + If yes: what was the procedure code associated with the radiation therapy?
* Was there a code in the fee basis files for brachytherapy to the prostate performed during CY2008-9 (procedure/treatment date, NOT billing date) – yes, no. Codes for Brachytherapy: 77326 – 77328, 77761 – 77763, 77785 – 77787, 77789, 77790, 77799, 0182T, 55860, 55862, 55865, 55875, 55876, 76873, 76965, 77776 – 77778, 92.27, C1715, C1717, C2638, C2639, C2640, C2641, Q3001
  + If yes: what was procedure/treatment date for the first treatment in this time period?
* Was there a code in the fee basis files for cryotherapy to the prostate performed during CY2008-9 (procedure/treatment date, NOT billing date) – yes, no. Codes for Cryotherapy: 55873, 60.62
  + If yes: what was procedure/treatment date for the first treatment in this time period?
* Was there a code in the fee basis files suggesting that that patient received androgen deprivation therapy during CY2008-9 (procedure/treatment date, NOT billing date) – yes, no. Codes for hormonal therapy and oral ADT agents: 90772, J1950, J9202, J9217 – J9219, 54520, 54530, 54690, 62.3, 62.4, 62.41, 62.42, J8999, J9999, J9155
  + If yes: what was procedure/treatment/pharmacy date for the first treatment in this time period?
* Was there a code in the fee basis files suggesting that the patient received the drug docetaxal during CY2008-10? (note – this time period is different from the others) (procedure/treatment date, NOT billing date) – yes, no. Codes for Docetaxal: J9170
  + If yes: what was procedure/treatment/prescription date for the first treatment in this time period?
* Some other codes that were used for the fee basis query are listed below:
  + Codes for Bone Scan: 78300, 78306, 78315, 78320
  + Codes for PET Scan: 78205, 78206, 78320, 78807, 78811, 78812, 78813
  + Codes for PSA: 84152 – 84154, G0103

There were a total of 3,221 patients with fee basis data. There were 9 patients with the same SSN. These 18 records were excluded from the study.

1. Expert panel members and their affiliated institutions are listed in Appendix I [↑](#footnote-ref-1)
2. These cases are excluded because documentation in CPRS may not be complete. [↑](#footnote-ref-2)
3. The Department of Veterans Affairs (VA) can make payments to non-VA health care providers under many arrangements. The most common are sharing agreements with affiliate medical schools and contracts with medical specialists. Non-VA care may also be authorized under the Fee Basis program, under which a VA facility refers the veteran for care paid for by the VA when VA cannot offer needed care, when a non-VA provider would be economical to the VA or more convenient for the veteran,, or on an emergency basis when travel to a VA facility is medically infeasible. Each VA station tracks Fee Basis invoices and submits reports to the national office. These reports are merged to form a system-wide database, which is being used for this study. [↑](#footnote-ref-3)
4. Information on the review process may be obtained from each medical center’s Quality Manager and/or EPRP liaison. [↑](#footnote-ref-4)
5. The criteria for identification of patients at very low risk and at low risk of recurrence are based on the original definition of low-risk disease by D’Amico et al. (1998). [↑](#footnote-ref-5)
6. Intensity-modulated radiation therapy (IMRT) is an advanced form of [three-dimensional conformal radiotherapy](http://www.pamf.org/radonc/tech/3d.html) (3D-CRT). It uses sophisticated software and hardware to vary the shape and intensity of radiation delivered to different parts of the treatment area. It is one of the most precise forms of external beam radiation therapy (EBRT) available. Both 3D-CRT and IMRT link CT scans to treatment planning software that allows the cancerous area to be visualized in three dimensions. Regular 3D-CRT and IMRT differ in how the pattern and volume of radiation delivered to the tumor is determined. Both approaches allow higher doses of radiation to be delivered more precisely to the tumor targets. [↑](#footnote-ref-6)
7. Image-guided radiation therapy (IGRT) uses imaging technology that incorporates movement of the tumor to ensure that the target is in the same position for every treatment session. [↑](#footnote-ref-7)
8. The initial therapy received within one year after diagnosis (including active surveillance) is considered the “primary therapy” EXCEPT for (a) radiation therapy with neoadjuvant androgen deprivation therapy, where radiation therapy is considered the primary therapy; and (b) brachytherapy within three months (before or after) EBRT, where brachytherapy is considered the primary therapy. [↑](#footnote-ref-8)
9. This measure is similar, although not identical, to a measure recommended by the Physician Consortium for Performance Improvement (PCPI) ® (American Medical Association 2007). This indicator modifies the PCPI measure by including cases in both numerator and denominator for which explicit reasons are recorded for not using 3D-CRT or IMRT (e.g., patient refusal, medical comorbidities, etc.). Since results from these measures are designed to be used for quality improvement, clear documentation of why a process was NOT performed or a treatment NOT given is felt to meet current standards of care; thus provision of such care is reflected in the measure construction. [↑](#footnote-ref-9)
10. These cases are excluded from evaluation due to potential problems with locating documentation related to radiation treatment received by patients delivered at a site that is neither a VAMC nor a fee-basis care provider. [↑](#footnote-ref-10)
11. See footnote 8. [↑](#footnote-ref-11)
12. Androgen deprivation therapy (ADT) includes include: androgen ablation, androgen suppression; androgen blockade; anti-androgen therapy; hormone/hormonal therapy; bilateral orchiectomy; medical orchiectomy; surgical castration (bilateral orchiectomy) and medical castration. An oral medication will be considered “received” if a prescription is documented in the medical record. [↑](#footnote-ref-12)
13. Progressive disease is defined as: (a) progression of a bidimensionally measurable lesion; (b) progression that could be evaluated but not measured (e.g., evaluated by bone scan). For purposes of this measure, any description consistent with “progressive metastatic disease” in a clinician note will be acceptable, so long as it is not based solely on an increased PSA. Information contained only in a radiology report will NOT be used. See data collection instrument for abstraction rules. [↑](#footnote-ref-13)
14. Petrylak DP, Tangen CM, Hussain MH, et al. Docetaxel and estramustine compared with mitoxantrone and prednisone for advanced refractory prostate cancer *N Engl J Med 351*: 1513-1520, 2004. [↑](#footnote-ref-14)
15. Tannock IF, de Wit R, Berry WR, et al. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer *N Engl J Med 351*: 1502-1512, 2004. [↑](#footnote-ref-15)
16. # [Berthold DR](http://www.ncbi.nlm.nih.gov/pubmed?term=%22Berthold%20DR%22%5BAuthor%5D), [Pond GR](http://www.ncbi.nlm.nih.gov/pubmed?term=%22Pond%20GR%22%5BAuthor%5D), [de Wit R](http://www.ncbi.nlm.nih.gov/pubmed?term=%22de%20Wit%20R%22%5BAuthor%5D), [Eisenberger M](http://www.ncbi.nlm.nih.gov/pubmed?term=%22Eisenberger%20M%22%5BAuthor%5D), [Tannock IF](http://www.ncbi.nlm.nih.gov/pubmed?term=%22Tannock%20IF%22%5BAuthor%5D); [TAX 327 Investigators](http://www.ncbi.nlm.nih.gov/pubmed?term=%22TAX%20327%20Investigators%22%5BCorporate%20Author%5D). Survival and PSA response of patients in the TAX 327 study who crossed over to receive docetaxel after mitoxantrone or vice versa. [*Ann Oncol.*](javascript:AL_get(this,%20'jour',%20'Ann%20Oncol.');) *19*:1749-53, 2008.

    [↑](#footnote-ref-16)
17. See footnote 12. [↑](#footnote-ref-17)
18. See footnote 8. [↑](#footnote-ref-18)
19. This measure is similar, although not identifical to, a measure recommended by the Physician Consortium for Performance Improvement (PCPI) ® (American Medical Association 2007). This indicator modifies the PCPI measure by including cases in both numerator and denominator for which explicit reasons are recorded for not prescribing adjuvant hormonal therapy (e.g., patient refusal, medical comorbidities, etc.). Since results from these measures are designed to be used for quality improvement, clear documentation of why a process was NOT performed is felt to meet current standards of care; thus provision of such care is reflected in the measure construction. [↑](#footnote-ref-19)
20. See footnote 8. [↑](#footnote-ref-20)
21. VACCR VAMC vs other VAMC are stratified separately for this measure since other studies have documented increased time to treatment for intra-VA referrals. [↑](#footnote-ref-21)
22. 22See footnote 8 [↑](#footnote-ref-22)
23. 23 See footnote 12 [↑](#footnote-ref-23)
24. 24 VACCR VAMC vs other VAMC are stratified separately for this measure to better elucidate intra-VA referral patterns. [↑](#footnote-ref-24)
25. 25 The criteria for identification of patients at low, intermediate, and high risk of recurrence are based on the original definition by D’Amico et al. (1998). Risk recurrence level will be categorized based on last available staging/PSA/Gleason score prior to prostatectomy. [↑](#footnote-ref-25)
26. 26 PSA testing after Active Surveilllance decision is addressed in measure DD5. [↑](#footnote-ref-26)
27. 28VACCR VAMC vs other VAMC are stratified separately for this measure to better elucidate intra-VA referral patterns. [↑](#footnote-ref-27)
28. 29DRE may also be referred to as (clinical) prostate exam, rectal exam,or physical examination of the prostate. [↑](#footnote-ref-28)
29. 30 Because of the challenges finding documentation related to Active Surveillance, this measure only includes cases where the primary Active Surveillance decision occurs at a VAMC. [↑](#footnote-ref-29)
30. 32 Some patients may have their first post-treatment DRE test outside the VHA. This descriptive measure is limited to DREs at VAMCs because of the abstraction time required to find non-VHA DREs in the VA medical record. [↑](#footnote-ref-30)
31. 33Because of the challenges finding documentation related to Active Surveillance, this measure only includes cases where initial Active Surveillance decision occurs at a VAMC. [↑](#footnote-ref-31)
32. 34DRE may also be referred to as digital rectal exam, (clinical) prostate exam, rectal exam, or physical examination of the prostate. [↑](#footnote-ref-32)
33. 35DRE may also be referred to as digital rectal exam, (clinical) prostate exam, rectal exam,or physical examination of the prostate. [↑](#footnote-ref-33)