

MEDICAL RECORD ABSTRACTION PROTOCOL

General Instructions

The medical record abstraction form should be used to record information included in the medical record provided by the diagnosing urologist.

- Several visits may have been necessary to establish the definitive diagnosis of prostate cancer. Follow the instructions for each section to determine the visit or visits that are relevant to that section.
- Information from visits to other physicians and/or from diagnostic evaluations performed by others (e.g., pathology or radiology reports) may be included in the material provided for the patient. Follow instructions provided for each section to determine if or when this information should be recorded.
- Information from examinations done by another urologist in the same practice (or hospital if the diagnosing urologist is not affiliated with a private practice) should be treated as though it was provided or determined by the diagnosing urologist.

General Information

PCaP ID#	
Diagnosing Physician	
Treating Physician	
Clinic/Hospital	
Date abstracted	
Abstractor	
Location	Field office____ Clinic____ Hospital____
Referring MD (general practice)	
Earliest record date	
Diagnosis date (first positive biopsy)*	
New vs. regular patient	New____ Regular____ Unknown____

*Notify the Project Manager if the diagnosis date in the medical record differs from the diagnosis date on file for the participant.

Instructions: General Information

Diagnosing Physician: MD who performed the diagnostic biopsy (including TURP) (ok if something other than a urologist)

Treating Physician: MD providing treatment for prostate cancer, if applicable (may be same as Diagnosing Physician)

Clinic/Hospital: Name of the urologist's private practice, or hospital if not affiliated with a private practice. Record 'NA' if information is not available.

Date abstracted: Date abstraction completed.

Abstractor: Abstractor's code #

Location: Check the site where the abstraction was performed.

Referring MD (general practice): Record the patient's general practice or regular MD, or 'NA' if this information is not available. If multiple referring MDs are noted, list the one most closely associated with the referral leading to the diagnosis.

Earliest record date: Note the first date for which medical record information has been provided, including information from other doctors or facilities, regardless of whether the date preceded visits associated with the diagnostic evaluation.

Diagnosis date: The date the first positive prostate biopsy was performed. May be taken from medical record or pathology report. Be sure to record the date of the surgery, not the date the report was filed. If the date of the first positive biopsy differs from the diagnosis date already recorded for the patient, notify the project manager.

New or regular patient

- New patient: Check if the patient was not seen by the diagnosing urologist prior to visits associated with the diagnosis of CaP (e.g., if the patient was seen for the first time by the urologist after being referred for evaluation of an abnormal screening exam).
- Regular patient: Check if the patient was a client of the diagnosing urologist prior to visits associated with the diagnosis of CaP (e.g., if the patient was first seen by the urologist for a problem that was not directly related to CaP).
- Unknown: Check if you are unable to determine if the patient was a new patient.

Medical History (at or before diagnosis)

Not noted_____

System or condition	Record date	Status			Comments (specific condition/disease, etc.)
		Normal/ none	Abnormal/ present	Not noted	
Cardiovascular					
Pulmonary					
GU/Renal					
GI					
Endocrine					
Musculoskeletal					
Neurologic					
Immune					
BPH					

Prostatitis					
Family history of CaP					
Other (specify)					
Other (specify)					

Instructions: Medical History (at or before diagnosis)

For current or chronic diseases, conditions or problems present on or before the CaP diagnosis was confirmed. Note all that apply.

- Include medical history information recorded during visits that occurred after the diagnosis as long as conditions were present or had occurred at or before diagnosis.
- **If the available medical record did not include any medical history information, check the ‘Not noted___’ box at the beginning of the Medical History section and skip to ‘Reasons for presentation’.**
 - ‘Not noted’ boxes at the beginning of a section are used in this manner throughout the medical records abstraction form.
- If information is available for some (but not all) of the medical history categories check the ‘Not noted’ box for the category or categories with missing data.

System or condition

Check the appropriate box for current or chronic diseases, conditions or problems that occurred or were present at or before diagnosis. Include medical history information recorded during post-diagnostic visits regarding medical history at or before diagnosis.

- Conditions or diseases to be recorded under each heading are shown below.
 - Acute or minor conditions (for example, an upper respiratory tract infection) should be counted only if clearly associated with the visit(s) leading to CaP diagnosis.
 - If a condition is listed under more than one heading it may be appropriate to check each. For example, a man with SLE (lupus) would have a check in the abnormal/present boxes for both “Musculoskeletal” (for arthritis) and “Immune” (for autoimmune disease) if he had arthritis in association with SLE.
 - If a condition is listed under only one heading categorize it under that heading, even if you believe another heading may have been appropriate. For example, sexually transmitted diseases could be considered “Immune” conditions since they are infectious, but count them only under the heading “GU”, as indicated.
 - If a chronic or significant condition (i.e., one that is being actively treated or monitored) is not listed below check “Other” and specify the condition under “Comments”.

Partial list of symptoms, conditions and diseases to be counted under each ‘System and conditions’ category

Cardiovascular	Chronic hypertension , high blood pressure, elevated systolic blood pressure (SBP), elevated diastolic blood pressure (DBP). Arteriosclerosis , atherosclerosis, coronary artery disease, bypass surgery, angioplasty, myocardial infarction (MI or heart attack), angina (chest pain). Cerebrovascular diseases , stroke, TIA (transient ischemic attack), intracranial arteriosclerosis, CVA (cerebral vascular accident), brain infarction. Other vascular diseases , Raynaud syndrome, vasculitis, phlebitis. Dyslipidemia , hyperlipidemia, hypercholesterolemia, high cholesterol, high triglycerides.
Pulmonary	Upper respiratory tract diseases or conditions, chronic rhinitis, chronic sinusitis, nasal cancer, laryngeal cancer, tracheal cancer. Lung diseases, asthma, emphysema, chronic obstructive pulmonary disease (COPD), chronic cough, chronic bronchitis, chronic or recurrent lower respiratory tract infections (pneumonia, bronchitis, tuberculosis (TB)), lung cancer. Pleural diseases , pleurisy, mesothelioma. Chronic respiration (breathing) disorders , apnea, sleep apnea.

GU/Renal	Renal (kidney) diseases, chronic renal disease (CRD), chronic renal failure (CRF), dialysis, polycystic kidney disease (PKD), kidney stones (nephrolithiasis), nephritis, glomerulonephritis, proteinuria, kidney infection, upper urinary tract infection, kidney cancer (renal pelvis cancer, renal cell cancer). Lower urinary tract or bladder diseases, cystitis, bladder infection(s), lower urinary tract infection (UTI), urinary incontinence, urinary obstruction (may be in conjunction with BPH), lower urinary tract symptoms (LUTS), bladder cancer. Genital diseases, penile neoplasms. Testicular diseases, epididymitis, cryptorchidism (undescended testicle), orchitis (testicular inflammation), male infertility, male sterility, oligospermia, testicular cancer. Sexually transmitted diseases, STDs, gonorrhea, syphilis, Chlamydia trachomatis, genital herpes. NOTE: prostatic diseases should be noted under 'BPH' or 'Prostatitis', as appropriate. Sexual disorders , including sexual dysfunction, erectile dysfunction (ED), impotence.
GI	Esophageal diseases, esophagitis, Barrett's esophagus, gastroesophageal reflux disease (GERD), esophageal cancer. Gastric disease, gastritis, peptic ulcer, gastric ulcer, Helicobacter pylori, gastric cancer, stomach cancer. Intestinal diseases, duodenal ulcer, inflammatory bowel disease (IBD), Crohn's syndrome, Crohn's disease, ulcerative colitis, colitis, colon cancer, rectal cancer, colon adenoma(s), polyps, chronic constipation or diarrhea that requires treatment. Gall bladder disease, cholecystitis, cholelithiasis, gall stones. Liver diseases, liver failure, cirrhosis, hepatitis, viral hepatitis, HCV, HBV, HAV, liver cancer. Pancreas diseases, pancreatic cancer, pancreatitis.
Endocrine	Diabetes mellitus (DM), Type I Diabetes, Insulin-dependent diabetes, Type II Diabetes, adult-onset diabetes, non-insulin-dependent diabetes. Thyroid diseases, hyperthyroidism, hypothyroidism, goiter. Parathyroid diseases. Adrenal gland diseases, Cushing syndrome, Addison's disease. " Andropause ", "male menopause", testosterone deficiency, testosterone replacement therapy, hypogonadism.
Musculoskeletal	Joint diseases , arthritis, osteoarthritis, rheumatoid arthritis (RA), other immune-mediated arthritis (e.g., systemic lupus erythematosus (SLE or lupus), Sjogren's syndrome), gout, infectious arthritis (e.g., due to Lyme disease), bursitis. Bone or cartilage diseases, bone cancer, osteoporosis, spinal diseases, disc disease, spinal stenosis, spondylitis. Muscle diseases, myositis, myopathy, fibromyalgia.
Neurologic	Neurologic diseases, nervous system diseases, Parkinson's disease, multiple sclerosis (MS), neurodegenerative diseases, epilepsy, seizures, Alzheimer's disease, dementia, cognitive impairment, neurologic deficits secondary to stroke or TIA, encephalitis, migraine headaches. Peripheral neuropathy , diabetic neuropathy, paralysis, paresis, sciatica, paraesthesia, lower limb weakness (neurologic). Clinical or chronic psychological disorders or conditions, depression, psychosis.
Immune	Immune deficiencies , AIDS. Autoimmune or immune-mediated diseases, rheumatoid arthritis, systemic lupus erythematosus (SLE or lupus), Sjogren's syndrome. Psoriasis.
BPH	Benign prostatic hyperplasia , prostatic hyperplasia, prostatic adenoma
Prostatitis	Chronic or acute prostatitis
Family history of CaP	
Other (specify)	
Other (specify)	

Record Date

Note the date the medical history information was recorded in the medical record. If information was recorded on multiple dates, record the date and information collected closest to the date of diagnosis.

Status

- **Normal/none:** Medical record specifically indicates that this system was normal at presentation and that there were no significant conditions in this category prior to presentation.
- **Abnormal/present:** One or more conditions or diseases in this category were noted at presentation (either currently present, or noted because of a prior history).

- **Not noted:** Check if no mention was made in the medical record with regard to current or past conditions related to this specific system or category, or if information is not available for this system or category (i.e., the medical record is incomplete). *If information is not available for any of the categories in the box below, check the 'Not noted_' box at the beginning of the section and skip to "Reasons for presentation".*

Comments

Briefly note the specific condition(s) noted for each system or condition in the "comments" box for that category, using the terminology (name of the disease or condition) recorded in the medical record. Do not include additional details, as these may be ascertained in the future if needed.

Indications for Urology Consultation(s)

Not noted _____

Date	√	Symptom	Comments
		Urinary dysfunction	
		Sexual dysfunction	
		Abnormal PSA	
		Abnormal DRE	
		Axial bone pain	
		Other (specify)	

Instructions: Indications for Urology Consultation(s)

Check the appropriate boxes for problems, conditions, or symptoms that resulted in a visit or visit(s) to the diagnosing urologist, including conditions that may have been unrelated to the patient's prostate cancer, and conditions first noted by another physician if they prompted a referral to the urologist (e.g., an abnormal DRE noted by a general practitioner during a routine physical exam). Check all that apply.

- If the available medical record did not indicate the reason(s) for the urology consult, check the 'Not noted_____' box.

Date

Note the date of the urologist visit associated with the condition(s) noted. If a single condition led to multiple visits for the condition, record the date of the first visit. If new episodes or occurrences of a condition led to multiple visits or referrals, record the date of the first visit associated with each new episode of the condition.

- If a man was referred for an elevated PSA and the diagnostic work-up required 2 visits, record the date of the first visit.
- If the same man was referred a second time for evaluation of an elevated follow-up PSA test (e.g., a test done a year after the diagnostic work-up for the first elevated PSA was negative for prostate cancer), record the date of the first visit associated with the second referral on a separate line (below where the date of the visit for the first referral was recorded).

Symptom

- **Urinary dysfunction:** Check if the medical record indicates that the patient was seen by the diagnosing urologist for lower urinary tract symptoms, conditions or diseases (acute or chronic) including cystitis, urethritis, dysuria, painful or difficult urination, urinary retention, urinary hesitancy, obstruction, incontinence, urgency incontinence, stress incontinence, nocturia, and hematuria. Briefly note the specific condition(s) under “comments”.
- **Sexual dysfunction:** Check if the medical record indicates that the patient was evaluated by the diagnosing urologist because of impotence, erectile dysfunction, loss of libido, or other conditions associated with sexual function were noted in the medical record. Briefly note the specific condition under “comments”.
- **Abnormal PSA:** Check here if the patient was referred to the diagnosing urologist for evaluation because of PSA tests performed elsewhere, or if the urologist performed a follow-up PSA months or years after a negative diagnostic work-up prompted by a previous abnormal PSA.
- **Abnormal DRE:** Check here if the patient was referred to the diagnosing urologist for evaluation because of a DRE performed elsewhere.
- **Axial bone pain:** Bone metastases most often occur in the axial bones (pelvis, lumbar spine, and/or proximal femur), resulting in pain. Check if pain in the axial bones was noted as an indication for a urologist visit. (Note that bone metastases may occur in other bones such as the ribs, sternum, and skull. Indicate pain in bones that are not part of the axial skeleton, under “Other”.)
- **Other (specify):** Note other primary indications for urologist consultations. If pain in bones outside of the axial skeleton was noted, it should be indicated here.

Comments

Briefly note the specific symptom(s) or condition(s) for each ‘Symptom’ category checked.

Physical Examination (at or near diagnosis)

Not noted _____

					Status				
Date			Date		Norm.	Abn.	?	Not noted	Comments
	Temp			Inguinal nodes					
	Pulse			Clavicular nodes					
	SBP			Other (specify)					
	DBP			Other (specify)					
	Wt			Other (specify)					
				Other (specify)					
				Other (specify)					

Instructions: Physical Examination (at or near diagnosis)

Record data from the physical examination closest to the date of diagnosis.

- For many patients these data would be from the initial visit with the urologist. However, data from a subsequent visit should be recorded if it was the examination closest to the date of diagnosis, as long as that visit did not occur after treatment (surgery, radiation therapy, hormonal therapy, chemotherapy) for the diagnosed cancer was begun.
- If there is no physical exam information available (because it was not recorded in the medical record for the initial visit or other visit prior to treatment, or because the record provided is

incomplete), check the 'Not noted ____' box at the beginning of the section and skip to 'Imaging Examinations'.

Date: Record the date of the physical examination where each item was noted. If data were collected on multiple dates (exams) record the date closest to the date of diagnosis.

Temp: Record the patient's body temperature (specify units as F for Fahrenheit, C for Celsius). Record NA if not available.

Pulse: Heart rate in beats per minute. Record NA if not available.

SBP: Systolic blood pressure (the first value recorded for blood pressure if written as, for example, BP 140/62). Record NA if not available.

DBP: Diastolic blood pressure (the second value recorded for blood pressure if written as, for example, BP 120/60). Record NA if not available.

Wt: Body weight (specify units as lb for pounds, kg for kilograms). Record NA if not available.

Status

- **Normal:** Medical record specifically indicates that the examination was normal.
- **Abnormal:** Medical record specifically indicates that the examination was abnormal.
- **?:** Check if it is unclear from the medical record whether the examination was normal or abnormal.
- **Not noted:** Check if no mention was made in the medical record or no data were available with regard to a specific aspect of the physical examination (e.g., if no mention is made concerning the status of the clavicular lymph nodes).

Inguinal lymph nodes: Status of the inguinal (superficial and/or deep inguinal, groin, pelvic) lymph nodes. Note specific information on size, tenderness, consistency, etc. under 'Comments'.

Clavicular lymph nodes: Status of the clavicular (supraclavicular, subclavicular, neck) lymph nodes. Note specific information on size, number, location (right, left or both), tenderness/pain, consistency, etc. under 'Comments'.

Other (specify): Note any other significant finding(s) recorded at the initial physical exam unless already noted under 'Medical History' or 'Indications for the diagnostic biopsy'. In particular, note any previously undiagnosed conditions that might influence treatment decisions (i.e., that prompt additional diagnostic tests prior to initiating treatment).

Note: Results of prostate or DRE exams should be recorded under 'Digital Rectal Examinations'.

Imaging Examinations

Not noted _____

Date	Type of Exam	Status			Comments
		Normal	Metastases	Abnormal-other	

Instructions: Imaging Examinations

Record results of radiographic and other imaging examinations noted in the medical record, including post-diagnostic tests to help determine stage prior to treatment. Use results recorded by the urologist as the primary source of information, but refer to information included in radiology reports provided with the medical record if it is not noted elsewhere.

- If there is no information available (because exams were not performed, because results were not recorded in the medical record, or because the record provided is incomplete), check the 'Not noted ____' box at the beginning of the section and skip to 'Digital Rectal Examinations'.
- Note that radiographic and other imaging exams are not always performed.

Date of each imaging examination. If the specific date is not available (for example, if the exam was done elsewhere and was noted in the medical record without a radiology report) give the approximate date.

Type of Exam

Indicate the type of radiographic examination performed, using the abbreviations in parentheses below.

- Bone Scan (BS): Used to identify bone metastases. Also referred to as ‘whole body scans’, ‘total body bone scans’, ‘TBBS’.
- Prostate Ultrasound (US): Transrectal ultrasound (TRUS) or other ultrasound examinations to evaluate the prostate and regional extent of disease. Also used to guide needle biopsy. Record information on the size of the prostate etc. under “comments”
- Chest X-ray (CXR): For pulmonary (lung) metastases and/or bone metastases. Record chest (thoracic) x-rays separately from other x-rays.
- X-rays (XR): X-rays taken of sites other than the chest, for bone metastases. If multiple sites (other than the chest) were evaluated on the same day (e.g., lumbar spine and cervical spine) combine on the same line and note each area evaluated under comments, even if each location has a separate report. If one area was abnormal and others were normal, record abnormal.
- CT (CT): Computerized tomography. Typically used to evaluate the prostate, regional lymph nodes and regional extent of disease.
- MRI (MRI): Magnetic resonance imaging. Axial MRI is used for cross-sectional imaging of the pelvis to evaluate the prostate, regional lymph nodes and regional extent of disease. Endorectal MRI may also be used for clinical staging (if endorectal MRI is specified, note it under comments).
- Include other radiographic or imaging exams, e.g., 3D MRS (3 dimensional magnetic resonance spectroscopy), radioscinigraphy (e.g., Prostate scan for soft tissue metastases), cystoscopy (examination of the bladder).
- Also note exams that were repeated more than once.

Status

- **Normal:** Medical record specifically indicates that the examination was normal.
- **Metastases:** Medical record specifically indicates evidence of distant metastatic lesions. Look for text indicating lytic lesions or areas of abnormal bone density (e.g., on conventional x-rays) or abnormal uptake of contrast (e.g., on bone scans) that are noted to be consistent with (or evidence of) metastases.
- **Abnormal – other:** Check here if abnormalities other than lesions consistent with metastatic prostate cancer are noted. For example, check if abnormal prostate on TRUS exam here. Do not include degenerative arthritis or other changes consistent with aging.

Comments

Briefly summarize specific information concerning abnormal results, as noted in the medical record. Include any imaging-based information concerning the following prognostic factors when available:

- estimated prostate volume (typically cm³) or weight (g)
- lymph nodes (normal or abnormal, lymphadenopathy or enlarged nodes)
- extracapsular extension (ECE) or other regional spread
- seminal vesicle invasion
- bone lesions, bone metastases

Digital Rectal Examinations

Not noted_____

Date	Type of Exam				Status			Comments
	Screen	Diagnostic	Post-diagnostic	?	Norm.	Abn.	?	

Instructions: Digital Rectal Examinations

Note all digital rectal exams (DREs) for which information is available in the medical record, including routine screening DREs and exams performed in conjunction with CaP diagnosis and treatment. Include information on DREs performed by someone other than the diagnosing urologist if noted in the medical record.

- If there are no DRE results available (because results were not recorded in the medical record, or because the record provided is incomplete), check the 'Not noted____' box at the beginning of the section and skip to 'PSA Tests'.

Date

Note the date of each examination (MM/DD/YYYY, or approximate date as available). If the specific date is not available (for example, if the DRE was done elsewhere and was noted in the medical record) give the approximate date.

Type of Exam

- **Screening:** DRE performed on a healthy individual as part of a routine physical examination, or in individuals with symptoms or conditions unrelated to prostate cancer, including sexual disorders and renal disease.
- **Diagnostic:** Any DRE prompted by patient symptoms, complaints or other abnormalities, including worsening or acute lower urinary symptoms (see 'urinary dysfunction', above), a prior abnormal DRE or PSA, rising or fluctuating PSA levels, unexplained weight loss, loss of appetite, axial or other bone pain.
- **Post-Diagnostic:** DREs after the CaP diagnosis was confirmed.
- **?:** Check here if the distinction between diagnostic and screening DRE cannot be made.

Status

Normal: Medical record specifically indicates that the DRE was normal.

Abnormal: Medical record specifically indicates that the DRE was abnormal.

?: Check here if there is insufficient information to determine whether the examination was normal or abnormal.

Comments

Note any other information concerning abnormal DREs as noted in the medical record, such as the size (with units, e.g., cm or cm³), location, and/or laterality (right, left or both lobes abnormal), consistency.

PSA Tests

Not noted _____

Date	Type of exam				Total PSA (ng/ml)	% Free PSA	Assay (or Lab)
	Routine	Diagnostic	Post- diag.	?			

Instructions: PSA tests

Note all PSA results available in the medical record, including routine screening tests, tests performed in conjunction with CaP diagnosis, and tests performed after diagnosis. Include PSA tests ordered by someone other than the diagnosing urologist if results are noted in the medical record.

- If there are no PSA results available (because results were not recorded in the medical record, or because the record provided is incomplete), check the 'Not noted _____' box at the beginning of the section and skip to 'Other laboratory (at or near diagnosis)'.

Date

Note the date of each PSA (MM/DD/YYYY, or approximate date as available). If the specific date is not available (for example, if the test was done elsewhere and was noted in the medical record without a lab report) give the approximate date.

Type of Exam

- Screening:** A PSA test performed on a healthy individual as part of a routine physical examination, or in individuals with symptoms or conditions unrelated to prostate cancer, including sexual disorders and renal disease. PSA tests performed in men with stable benign prostatic hyperplasia (in the absence of acute or worsening urinary symptoms) should also be classified as screening examinations.
- Diagnostic:** Any PSA test prompted by patient symptoms, complaints or other abnormalities, including worsening lower urinary symptoms, a prior abnormal DRE or PSA, rising or fluctuating PSA levels, unexplained weight loss, loss of appetite, axial or other bone pain.
 - For more on screening vs. diagnostic tests, see Godley et al. Retrospective classification of prostate-specific antigen tests: differentiating screening from diagnostic clinical encounters. *J Clin Epidemiol*, 54: 884-8, 2001.
- Post-Diagnostic:** PSAs after the CaP diagnosis was confirmed.
- ?: Check here if the distinction between diagnostic and screening PSA cannot be made.

Total (ng/ml)

Record total PSA in ng/ml.

- If numeric results are not available, write 'normal' or 'abn' in the box instead.

% Free PSA

Record % free PSA, if available. Use the following conversion formulas as needed.

- If free and total PSA are reported

$$\% \text{ free PSA} = (\text{free PSA} / \text{total PSA}) * 100$$
- If free:total PSA ratio is reported

$$\% \text{ free PSA} = (\text{free PSA} / \text{total PSA}) * 100$$
- If complexed PSA is reported (cPSA, in ng/ml)

$$\% \text{ free PSA} = ((\text{total PSA} - \text{cPSA}) / \text{total PSA}) * 100$$

- If free PSA is not available, record 'NA'.

Assay (or Lab): Note the name of the assay performed (e.g., Immuno 1 PSA (Bayer Diagnostics), Abbott IMX PSA, Hybritech Tandem R). Check the laboratory report for this information, if available.

- If the name of the assay or test is not available, note the name of the laboratory or hospital that performed the test (see laboratory report, if available)
- If this information is not available (either in the medical record or on laboratory reports included with the medical record) record 'NA'.
- Note that this information is important to control for variability in results associated with different PSA assays.

Other Laboratory (at or near diagnosis)

Not noted _____

Date	Exam	Value	Status			Comments
			Normal	Abnormal	Unknown	
	Hb					
	Hct					
	Creatinine					
	ALT					
	AST					
	LDH					
	AlkP					
	Other					
	Other					

Instructions: Other Laboratory (at or near diagnosis)

Record results of tests below if performed in conjunction with the diagnosis, initial clinical staging and/or evaluation of comorbid conditions that might influence treatment or prognosis.

- If tests were repeated, record results closest to the date of definitive diagnosis (i.e., the date of the first positive biopsy), including tests performed at or shortly after diagnosis to assist with initial staging and/or treatment decisions.
- Do not include tests after treatment has begun or tests used to monitor disease progression in men who elect watchful waiting.

Note: Direct data entry version should accommodate multiple test results.

Date

Date of test (not the date that test results were reported).

Exam

Note: Normal ranges vary among laboratories and assays; ranges listed below are for reference only and are not to be used to determine whether test values are normal or abnormal.

- **Hb:** Hemoglobin, Hgb (g/dL).
 - UNC adult male reference range: 13.5-17.5 g/dL
- **Hct:** Hematocrit (% , RBC vol /total blood volume).
 - UNC adult male reference range: 41-53%
- **Creatinine:** Serum creatinine (mg/dL or μmol/L (SI units)).
 - UNC adult male reference range: 0.8-1.4 mg/dL or 70.7-123.8 μmol/L.

- Do not report urine creatinine test results here, including creatinine clearance tests (creatinine excretion, 24hr. urine creatinine) or urine protein:creatinine ratios.
- Do not confuse with creatinine kinase (CPK) or creatine tests.
- **ALT:** Alanine aminotransferase (u/L).
 - Also known as SGPT, GPT.
 - UNC adult male reference range: 19-72 u/L.
- **AST:** Aspartate aminotransferase (u/L).
 - Also known as SGOT.
 - UNC adult male reference range: 19-55 u/L.
- **LDH:** Lactate dehydrogenase, LD (u/L).
 - UNC adult male reference range: 338-610 u/L.
- **AlkP:** Serum alkaline phosphatase, ALP (u/L).
 - UNC adult reference range (male and female): 38-126 u/L.
- **Other:** Any previously unreported test result that might influence treatment decisions (i.e., that prompted additional diagnostic tests prior to initiating treatment).

Note: Do not record results as negative unless the record states that the specific test result was negative. For example, do not check negative for ALT, AST etc. based on a comment in the medical record text that “all blood chemistries were normal” unless a lab report listing the specific results is available.

Status

- Normal: Medical record or laboratory specifically indicates that the exam was normal (within normal reference range for the lab). *Do not determine this based on UNC reference ranges listed above.*
- Abnormal: Medical record or laboratory specifically indicates that the exam was outside of the normal reference range for the lab. *Do not determine this based on UNC reference ranges listed above.*

Comments

Additional comments recorded by the urologist in the medical record concerning these laboratory results, as appropriate (use your judgment). Include problems noted with specimen collection or handling/processing that may have influenced the validity of the test.

Prostate Biopsies prior to Diagnosis

Not noted _____

Date	Indication				Results
	Elevated PSA	Rising PSA	Abnormal DRE	Other or Unknown	

Instructions: Prostate Biopsies prior to Diagnosis

Record indications and results for all prostate biopsies performed prior to the biopsy that was positive for CaP. Record any abnormalities noted in the results (e.g., PIN, hyperplasia, inflammation, atypia, suspicious, etc.)

Use results recorded by the urologist as the primary source of information, but refer to information included in pathology or other physicians’ reports provided with the medical record if it is not noted elsewhere.

Diagnostic Pathology Data

Enter pathology data from the diagnostic biopsy [either a positive needle biopsy or an incidental positive TURP sample (transurethral resection of the prostate surgery to relieve symptoms of BPH)].

Confirm Date of Procedure (MM/DD/YYYY):

Note: Contact the Project Manager if the procedure date differs from the diagnosis date on file for the patient.

Clinical Grade: NA__

1° Gleason Grade: _____

2° Gleason Grade: _____

Gleason Sum: _____

Recorded Clinical Stage:

American (Whitmore-Jewett): A1 __A2__ B1 __B2__ C1 __C2__C3__ D1 __D2__ NA__

TNM: T _____ N _____ M _____ NA__

Derived Clinical Stage:

TNM: T _____ N _____ M _____ NA__

Instructions: Diagnostic Pathology Data

Enter pathology data from the diagnostic biopsy [either a positive needle biopsy or an incidental positive TURP sample (transurethral resection of the prostate surgery to relieve symptoms of BPH)]. Use results included on the pathology report as the primary source of information, but refer to information recorded by the urologist or other physicians' reports provided with the medical record if it is not noted elsewhere.

Date (MM/DD/YYYY)

Record the date the diagnostic biopsy procedure (needle biopsy or TURP) was performed. Contact the Project Manager if the procedure date differs from the diagnosis date on file for the patient.

Clinical Grade

- Clinical grade is assigned based on histologic evaluation of needle biopsy or TURP samples only. If the medical record lists tumor grade based on a prostatectomy sample, record where indicated under Pathologic Grade. If information is not available, record 'NA'.
- Tumor grade will almost always be assigned according to the Gleason system. Components include the 1° Gleason grade or pattern (assigned to the most predominant histologic pattern in the sample and listed first), the 2° Gleason grade or pattern (assigned to the second most predominant histologic pattern in the sample and listed second) and the Gleason sum or score (the sum of the 1° and 2° Gleason grades, which may be sometimes be the only value listed).
- If grades and scores are listed for each positive core or site, enter the values that apply to the highest grade (sum).

Recorded Clinical Stage

- Enter any staging information as noted in the medical record by the urologist or other staff member.
- Clinical stage is typically based only on PSA values, physical examination, diagnostic imaging. Occasionally, clinical grade (based on needle biopsy or TURP) and percutaneous fine needle aspiration of inguinal lymph nodes may contribute to clinical staging.
- Stage may be recorded as TNM or American, or sometimes both.

- Most often, stage will be recorded according to the TNM system. Record three values, one for each of the three (T, N, M) components.
 - These will sometimes be listed as cT, cN, cM to distinguish them from pathologic TNM stage classifications.
 - Record 'NA' if no Clinical TNM stage information is given.
 - Record 'NA' for individual components for which information is not available. (T stage is often the only component of clinical stage that is recorded.)
- The less common Jewett (American or Whitmore-Jewett) system will have one component only (A1, A2, B1, B2, C1, C2, C3, D1 or D2). Check 'NA' if this information is not available.

Derived Clinical Stage

Use test results and other information provided in the medical record to derive the Clinical Stage (TNM) as follows:

➤ Determining T (tumor)

- Was a TURP performed?

1. Yes

- a. If the TURP pathology report indicates $\leq 5\%$ prostate cancer \rightarrow T1a
- b. If the TURP pathology report indicates $> 5\%$ prostate cancer \rightarrow T1b

2. No

- a. DRE/Ultrasound

- i. Normal or asymmetric \rightarrow T1c
- ii. Abnormal

1. Enlarged \rightarrow T1c

2. Induration/firm/nodule (DRE)

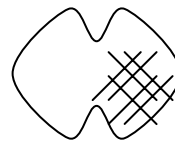
- a. One lobe (right or left) only, $\leq 50\%$ \rightarrow T2a
- b. One lobe (right or left) only, $> 50\%$ \rightarrow T2b
- c. One lobe only, % undeterminable \rightarrow "T2 a or b"
- d. Both lobes \rightarrow T2c



Nodule



Induration:
Possible CaP



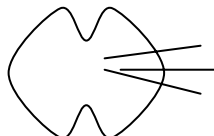
Induration:
Probable CaP

3. Hypoechoic region (US)

- a. One lobe (right or left) only, $\leq 50\%$ \rightarrow T2a
- b. One lobe (right or left) only, $> 50\%$ \rightarrow T2b
- c. One lobe only, % undeterminable \rightarrow "T2 a or b"
- d. Both lobes \rightarrow T2c

- Is there cancer beyond the prostate (i.e., "invasion")?

1. Outside the prostate but not into the seminal vesicles \rightarrow T3a



2. Into the seminal vesicles \rightarrow T3b



3. Fixed or invaded into the pelvic side wall/rectum → T4

➤ Determining N (node)

- Most cases → NX (lymph nodes not assessed)
 - Lymph nodes are assessed primarily through lymphadenectomy, in conjunction with prostatectomy; however, this is Clinical, not Pathologic, Grade.
- If regional lymph node(s) involved (i.e., by CT/MRI and positive biopsy) → N1

➤ Determining M (metastasis)

- no bone scan performed → MX (distant metastases not assessed)
- negative bone scan → M0 (no distant metastases)
 - or suspicious bone scan followed by negative CT/MRI → M0
- positive bone scan → M1b (bone involvement)
- lung or liver metastasis → M1c (other sites involved)
- [Note: M1a (non-regional lymph node involvement) is not used.]

Note: If the information provided in the medical record is insufficient for determining the Derived Clinical Stage, use the Medical Records Request for Missing Information form. Check the boxes for the required additional information and fax it to the urologist/hospital with a copy of the signed Medical Records Release.

- If the additional information has not been received after 3 weeks, call the clinic/hospital; if necessary, re-fax the request and release forms.
- If the additional information has not been received after 3 more weeks (total 6 weeks and 2 additional requests), close out the record (transfer to database with clinical staging unavailable).
- Dr. Mohler will review exported cases that are missing aggressiveness.

TREATMENT

Information on treatment provided? Yes _____ No _____

Check to determine whether any information was provided regarding treatment, including a decision to elect “watchful waiting”.

- If any information regarding treatment (or active or passive watchful waiting) is provided check ‘Yes___’ and continue with the abstraction.
- If no information regarding treatment (or active or passive watchful waiting) is provided check ‘No___’. Medical record abstraction is complete for this patient.

Surgery (after diagnosis)

Not noted _____

Date	Procedure		Details / Comments	
	√		√	
		Prostatectomy		Prostatectomy Approach:
				Radical retropubic
				Radical perineal

				Robotic
				Laparoscopic
				Not specified
			Prostatectomy Type:	
				Left nerve spared
				Right nerve spared
				Both nerves spared
				Neither nerve spared
				Not specified
		Lymphadenectomy	Lymphadenectomy Approach:	
				Open
				Laparoscopic
				Robotic
				Not specified
		Orchiectomy		
		TURP (after diagnosis)		
		Follow-up needle biopsy		

Instructions: Surgery (after diagnosis)

- If no information regarding surgery is provided check ‘No ___’ and proceed to ‘Medical Therapy’.

Date

Record the date that each procedure was performed. If the listed procedure was not performed or noted in the available medical record, or if the specific date is not available, leave blank. Do not record planned surgeries: record surgeries that were performed only.

Procedure

Check the box to the left of the procedure if it was performed. If the listed procedure was not performed or noted in the available medical record, leave the check box blank.

Details / Comments

- Prostatectomies and lymphadenectomies: Check the box to the left of the appropriate description (approach, type) for the procedure. See below for details.
- Orchiectomies, TURPs, Follow-up needle biopsies: Include brief comments about the procedure, if needed.

Prostatectomy

Check the procedure checkbox to the left of ‘Prostatectomy’ if a prostatectomy was performed. Otherwise, leave the checkbox blank.

Prostatectomy Type

If a prostatectomy was performed, check the box to the left of the appropriate ‘Prostatectomy Type’ (one box only). Leave checkboxes blank if prostatectomy was not performed.

- Left nerve spared: neurovascular bundle on the left side of the prostate left intact to limit post-operative loss of erectile function and urinary continence.
- Right nerve spared: neurovascular bundle on the right side of the prostate left intact
- Both nerves spared: neurovascular bundles on both sides of the prostate left intact
- Neither nerve spared: both neurovascular bundles surgically removed, typically because of evidence of extracapsular extension
- Not specified: No indication whether a nerve-sparing procedure was used.

Prostatectomy Approach

If a prostatectomy was performed, check the box to the left of the appropriate 'Prostatectomy Approach' (one box only). Leave checkboxes blank if prostatectomy was not performed.

- Radical retropubic: Open prostatectomy via an abdominal incision (lower midline)
- Radical perineal: Open prostatectomy via a perineal incision.
- Robotic: Robotically assisted prostatectomy via laparoscopic incision(s) using an endoscopic camera for visualization (e.g., 'da Vinci').
- Laparoscopic: Prostatectomy via laparoscopic incision(s) using an endoscopic camera for visualization.
- Not specified: Prostatectomy performed, but approach not specified in the medical record.

Lymphadenectomy

Check the procedure checkbox to the left of 'Lymphadenectomy' if pelvic or other lymph nodes were surgically removed in conjunction with a prostatectomy, or during a separate procedure. Otherwise, leave the checkbox blank.

- Be sure to indicate the date of the lymphadenectomy, even if it was performed in conjunction with a prostatectomy.

Lymphadenectomy Approach

If a lymphadenectomy was performed, check the box to the left of the appropriate 'Lymphadenectomy Approach' (one box only). Leave checkboxes blank if lymphadenectomy was not performed.

- Open: Lymph nodes removed through an open incision, typically through the same incision used for a radical retropubic prostatectomy.
- Laparoscopic: Lymph nodes removed laparoscopically, e.g., through a separate incision in conjunction with a radical perineal prostatectomy, or during laparoscopic prostatectomy.
- Robotic: Robotically assisted, probably in conjunction with robotic prostatectomy.
- Not specified: Lymphadenectomy performed but approach not specified in the medical record.

Orchiectomy

- Surgical castration.

TURP (after diagnosis)

- Transurethral resection of the prostate after CaP diagnosis, e.g., palliative therapy to treat urethral obstruction.

Follow-up needle biopsy

- Post-diagnosis needle biopsies to monitor disease progression, e.g., in patients treated with radiation.
- Note whether the biopsy was positive or negative for CaP under 'Comments'

Medical therapy (hormonal therapy, chemotherapy, investigational drugs)

Not noted _____

Start Date	End Date	Medication	Dose	Comments / Complications

Instructions: Medical therapy

Record information on all medications used to treat CaP, including medications used to relieve symptoms associated with CaP. Do not record planned treatments: record medications that were actually given only.

- If no information regarding medical therapy is provided check 'No ___' and proceed to Other Therapy.

Start Date

Date medication was started (MM/DD/YYYY or approximate date).

End Date

Date medication was ended (MM/DD/YYYY or approximate date, or leave blank if ongoing/unknown).

Medication

Indicate the complete name of the medication, as noted in the medical record.

If the patient is using an unnamed investigational drug, indicate 'investigational' and note study/trial name under comments. See list below for partial list of drugs used to treat CaP.

Dose

Indicate the dose and frequency and route with which the medication is given.

Comments / Complications

Note if medication was used in conjunction with other treatment(s), for example if used as neoadjuvant therapy prior to surgery or radiation, or as adjuvant therapy after surgery or radiation. Note any significant complications recorded in the medical record.

The following list includes common medications used to treat CaP. Record all medications prescribed for CaP treatment, regardless of whether they appear on this list.

Hormonal Therapy

LHRH Analogues

- Goserelin (Zolodex)
- Leuprolide (Lupron)

Non-steroidal Antiandrogens

- Flutamide (Eulexin)
- Nilutamide (Anandron)
- Bicalutamide (Casodex)

Steroidal Antiandrogens (glucocorticoids)

- Cyproterone acetate (Androcur)
- Megesterol acetate (Megace)

Adrenal Suppressants

- Ketoconazole (Nizoral)
- Aminoglutethimide (Cytadren)

Estrogens

- DES (diethylstilbesterol)

5 α -reductase Inhibitors

- Finasteride (Proscar)
- Dutasteride (Avodart)

Chemotherapy (typically for hormone-refractory CaP)

Mitoxantrone (Novantrone)
Estramustine (Emcyt)
Paclitaxel (Taxol)
Docetaxel (Taxotere)

Palliative therapy (for bone metastases)

Bisphosphonates

- Etidronate disodium (Didronel IV or oral)
- Pamidronate disodium (Aredia)
- Zoledronic acid (Zometa)

Radiopharmaceuticals

- Strontium-89 chloride (Metastron)
- Samarium-153 ETDMP (Quadramet)

Other Therapy

Not noted _____

	√	Start Date	End Date	Type	Dose	Comments / Complications
External Beam Radiation						
Brachytherapy						
Cryotherapy						
Watchful Waiting						

Instructions: Other Therapy

Check the appropriate box if any of the therapies listed were elected and instigated, and complete additional boxes as appropriate. If therapy was not used, leave all boxes in that row blank. Do not record planned treatments: record treatments that were given or performed only.

- If no information regarding other therapy is provided check 'No ___' and proceed to Surgical Pathology Data.

External Beam Radiation

May be abbreviated as EBRT, XRT

- Start Date: Date that therapy began (MM/DD/YYYY or approximate date)
- End Date: Date that therapy ended ((MM/DD/YYYY or approximate date, leave blank if ongoing).
- Type: conventional (2D), 3D conformational (3D-CRT), intensity-modulated (IMRT), or other (specify). If not specified, indicate 'NOS'.
- Dose: Units usually in Gy. May be reported as total dose (typically 60-80 Gy) or per treatment dose and frequency (e.g., 1.8-2 Gy delivered 5 times/week). Be sure to indicate units appropriately.
- Comments/Complications: Note significant complications indicated in the medical record (e.g., fecal incontinence)

Brachytherapy

Radiation therapy delivered via radioactive 'seeds' implanted permanently or temporarily in the prostate. CT or TRUS may be used to determine placement and dose.

- Start Date: Date that seeds were implanted (MM/DD/YYYY or approximate date).

- **End Date:** Date that seeds were removed (MM/DD/YYYY or approximate date, leave blank if ongoing).
- **Type:** Note type of radioactive compound (¹²⁵I, ¹⁰³Pd , other (specify) or NOS) and whether implants are permanent or temporary.
- **Dose:** Units usually in Gy or RADs. May be given as 'D90' dose (approximate range 100-250 Gy or 6,000-8,000 RADs). Be sure to indicate units.
- **Comments/Complications:** Note if performed in conjunction with external beam radiation. Note significant complications indicated in the medical record.

Cryotherapy

Tumor ablation by freezing.

- **Start Date:** Note the date the procedure was performed (MM/DD/YYYY or approximate date).
- **Comments/Complications:** Note significant complications indicated in the medical record (e.g., urethral stricture).

Watchful Waiting

Check if medical record notes that patient actively elected to forgo medical or surgical CaP treatment.

- **Start Date:** Date that watchful waiting was decided on, if indicated in the medical record. If it is clear that the patient chose watchful waiting but it is not possible to identify a specific start date, leave blank (but be sure to check the box for 'watchful waiting').
- **End Date:** Date that watchful waiting ended (i.e., that active treatment was started) if indicated in the medical record. If watchful waiting is ongoing, leave blank.

Surgical Pathology Data

Not noted_____

Date of Procedure (MM/DD/YYYY):

Pathologic Stage:

TNM: T _____ N _____ M _____ NA _____

Walsh:

	Yes	No	Not examined	Unknown /not specified
Organ confined				
Capsule penetrated (extracapsular extension, ECE)				
Seminal vesicle(s) invaded				
Lymph nodes positive				
Surgical margin(s) positive				

Pathologic Grade: _____ **NA**_____

1° Gleason Grade: _____

2° Gleason Grade: _____

Gleason Sum: _____

Instructions: Surgical Pathology Data

- If no information regarding other therapy is provided check 'No_____'.
Date of Procedure (MM/DD/YYYY)

Date of Procedure (MM/DD/YYYY)

Indicate date surgical procedure was performed.

Pathologic Stage

- Pathologic stage is based on prostatectomy samples only. If stage is determined based on results of a needle biopsy or TURP sample, record as Clinical Stage.
- Use results recorded by the urologist as the primary source of information, but refer to information included in pathology or other physicians' reports provided with the medical record if it is not noted elsewhere. Enter stage data *as recorded*.
- TNM and Walsh pathologic stage (or elements of Walsh stage) may both be recorded in the medical record.

TNM Stage

- Stage usually will be recorded according to the TNM system. Record three values, one for each of the three (T, N, M) components. If no pathologic stage data are noted in the medical record, check 'NA'. If data are available for some but not all of the pathologic stage components, indicate 'NA' for each individual component with missing data.

These will sometimes be listed as pT, pN, pM to distinguish them from clinical TNM stage classifications.

Walsh Stage

In addition to recording TNM stage (when available), check any components of Walsh stage noted in the medical record (including urologist notes and pathology reports), even if they are not formally labeled "Walsh stage".

- Organ confined: tumor does not extend beyond the prostatic capsule.
 - Check 'Yes' if the record states that the tumor is organ-confined.
 - Check 'No' if the record indicates extracapsular extension (ECE), extraprostatic extension, seminal vesicle invasion or other regional spread (i.e., to the bladder, rectum or other local structures), positive regional lymph nodes, or distant metastases to lymph nodes, bone(s) or other organs.
 - Check 'Unknown/not specified' if medical record information is inadequate to determine status or if status is uncertain.
- Capsule penetrated: tumor invades the prostatic capsule.
 - Check 'Yes' if the record indicates extracapsular extension (ECE), seminal vesicle invasion, or other regional spread (direct extension to other regional organs or structures).
 - Check 'No' if the record indicates that there is no ECE (capsule not involved or penetrated), or that the tumor is organ confined.
 - Check 'Unknown/not specified' if medical record information is inadequate to determine status or if status is uncertain.
- Seminal vesicle invaded: tumor invades seminal vesicle(s).
 - Check 'Yes' if indicated.
 - Check 'No' if the record indicates that the seminal vesicles are not involved, that the tumor is organ confined, or that there is no ECE.
 - Check 'Not examined' if seminal vesicles were not examined.
 - Check 'Unknown/not specified' if medical record information is inadequate to determine status or if status is uncertain.
- Lymph nodes positive
 - Check 'Yes' if lymph node involvement or positive lymph nodes are indicated.
 - Check 'No' if the record indicates that the lymph nodes are not involved.
 - Check 'Not examined' if lymph nodes were not removed for examination.
 - Check 'Unknown/not specified' if medical record information is inadequate to determine status, or if status is uncertain.
- Surgical margins positive:
 - Check 'Yes' if positive surgical margin(s) indicated.
 - Check 'No' if the record indicates that surgical margins were negative.

- Check 'Unknown/not specified' if medical record information is inadequate to determine status, or if status is uncertain.

Pathologic Grade

- Pathologic grade is assigned based on prostatectomy samples only. If the medical record lists tumor grade based on a needle biopsy or TURP sample, record where indicated under Clinical Grade. If data are not available, record 'NA'.
- Use results recorded by the urologist as the primary source of information, but refer to information included in pathology or other physicians' reports provided with the medical record if it is not noted elsewhere.
- Tumor grade will almost always be assigned according to the Gleason system. Components include the 1° Gleason Score (assigned to the most predominant histologic pattern in the sample), the 2° Gleason Score (assigned to the second most predominant histologic pattern in the sample) and the Gleason sum (the sum of the 1° and 2° Gleason Scores, which may be sometimes be the only value listed).

If multiple grades are listed (i.e., for each positive core or site) enter the values for the most prominent only.

Appendix

Table 1. Clinical staging

The table below is provided for clarification, but should not be used to independently determine TNM stage.

TNM		Jewett
Tumor		
T1 (NOS)	Nonpalpable tumor, NOS	
T1a	Incidental finding in TURP specimen, tumor <=5% of specimen	A1 Incidental finding in TURP specimen, tumor <=5% of specimen, Gleason sum <=4
T1b	Incidental finding in TURP specimen, tumor >5% of specimen	A2 Incidental finding in TURP specimen, tumor >5% of specimen, Gleason sum >4
T1c	Non-palpable, not visible by TRUS, identified via biopsy after elevated PSA screen	
T2 (NOS)	Palpable tumor, NOS	
T2a	Palpable or visible by TRUS, one lobe	B1 Palpable, one lobe, <=1.5cm
T2b	Palpable or visible by TRUS, both lobes	B2 Palpable, both lobes, >1.5cm
T3a	Extracapsular extension	C1 Extracapsular extension, negative surgical margins (prostatectomy only)
T3b	Seminal vesicle involvement	C2 Extracapsular extension, positive surgical margins (prostatectomy only)
T4	Bladder neck, external sphincter, rectal, levator muscles, or pelvic side wall involvement	C3 Seminal vesicle involvement
T3/4 (NOS)	Tumor extends beyond prostate, NOS	
Node		
NX	Lymph nodes not assessed	
N0	No regional lymph node involvement	
N1	Metastases, regional lymph node(s)	D1 Pelvic lymph node involvement
Metastasis		
MX	Distant metastases not assessed	
M0	No distant metastases	
M1a	Non-regional lymph node involvement	D2 Bone and/or distant organ involvement
M1b	Bone involvement	
M1c	Other sites involved	

Adapted from DeVita 2001

Correspondence between TNM and Jewett stages is approximate only.

Table 2. Pathologic TNM Staging

The table below is provided for clarification, but should not be used to independently determine pTNM stage.

Pathologic TNM Staging*

Tumor

T2 (NOS**)	Organ confined, NOS
T2a	Unilateral, <=50% of one lobe
T2b	Unilateral, >50% of one lobe only
T2c	Bilateral
T3 (NOS)	Extraprostatic extension, NOS
T3a	Extraprostatic extension
T3b	Seminal vesicle invasion
T4	Bladder neck, external sphincter, rectal, levator muscles, or pelvic side wall involvement
T3/4 (NOS)	Tumor extends beyond prostate, NOS

Node

NX	Lymph nodes not assessed
N0	No regional lymph node involvement
N1	Metastases, regional lymph node(s)

Metastasis

MX	Distant metastases not assessed
M0	No distant metastases
M1a	Non-regional lymph node involvement
M1b	Bone involvement
M1c	Other sites involved

*AJCC/UICC 2004

**NOS: not otherwise specified.