This guideline is a statement of consensus of the GU Disease Site Team regarding their views of currently accepted approaches to treatment. It is not intended to replace the independent medical judgment of the physician in the context of individual clinical circumstances to determine any patient’s care or treatment.
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Team Structure
The GU Team is a Multidisciplinary Team whose agenda is the treatment of genitourinary malignancies. This team is composed of medical, radiation and surgical oncologists (Urologists) with close association with urologists at LHSC, St. Joseph’s Health Centre and in our Region. Our team at the London Regional Cancer Centre also includes social workers, dietitians, nurses, clinical research associates and translational scientists, palliative care professionals and home-care team.

Referral Mechanism
The oncologists see patients diagnosed with cancer on a referral basis only. The role of the oncologist is to provide a comprehensive treatment plan including review of information given by the referring physician and further investigations as indicated. An appropriate treatment plan will be implemented in conjunction with the GU team and supervised by the individual oncologist.

Referrals to the London Regional Cancer Centre are triaged in order of importance. GU cancer emergencies are treated either by the GU team, if possible; otherwise it will be by the on-call physician. Potential emergencies include spinal cord compression, severe bleeds and superior vena cava obstruction, as well as symptomatic bronchial obstruction, brain metastases with seizures or mass effect. Potential emergency or urgent referrals include patients with brain metastases, patients with poorly controlled symptomatic metastatic disease, and patients with germ cell tumors or Wilm’s tumors. Referring physicians are directed to one of the disease site team members or on call physicians if they feel their patient should be treated urgently or emergently.

After completing cancer treatment, the patient may continue to be followed by their oncologist who will keep in touch with the referring physician and family physician. Prior to the completion of therapy, the patient will be assessed jointly by the physician and team nurse with regard to the need for dietary, social services, or home care referrals, as well as any other physician/specialist which may be requested in dealing with the patients specific oncologic needs.

During and following treatment, patient concerns are addressed during follow-up visits with their oncologists or through their referring physicians. Primary nurse contact phone numbers are provided and a telephone triaging system is in place to direct patient or physician inquiries appropriately.

Nursing
Nursing provides symptom assessment and intervention, patient and family education and supportive care. Collaborative practice across disciplines within the GU DST is intended to provide comprehensive coordinated care. Referrals to other team members (Social Work, Dietitian, CCAC, Spiritual Care Provider and Pain and Symptom Management Nursing etc) toward reducing patient symptom burden are integral. The nursing practice model is currently under review toward optimizing on patient and family care centered care delivery in a timely and effective manner. An Advanced Practice Nurse may provide disease specific (e.g. Germ Cell tumours) follow up such as and advanced symptom management through close collaboration with the attending oncologist.
Dietary/Nutrition
The role of the dietitian is to address the specific needs of a given cancer patient with regard to the special diets that might be required while on radiation therapy, or to counsel with regard to caloric supplements for those patients who are having difficulty consuming enough calories. Also, our dietitians offer a comprehensive assessment and are able to assess the dietary needs of all patients, including those not related to the malignancy process i.e.: diabetic diet, low fat diet. Dieticians provide information and to patients who have specific needs related to their treatment and assess patients for special forms of dietary support as appropriate.

Social Services
Our social service department offers a wide range of supportive therapies including counseling i.e. stress or family distress due to the diagnosis of cancer, assessing the patients needs for financial health, and furthermore exploring the services that are available to help the financially distressed patient in regards to general finances or in order to meet the expenses of drugs and dressings. Our social services department also aids patients in finding placement or housing depending on their individual circumstances.

Pharmacy
Clinical pharmacists and pharmacy assistants are responsible for the safe dispensing of hormonal and non-hormonal drug therapies for the treatment of patients requiring systemic therapy. The pharmacy team works closely with the oncology and nursing professionals to ensure that medications are being selected, prescribed and delivered in the optimal fashion.

Regional Clinics
Cancer units at hospitals throughout the Region supported by the LRCP are engaged in the delivery of systemic therapy closer to home as well as supporting visiting oncologists engaged in patient follow-up. In all cases, services delivered through the regional clinics are coordinated with the treatment conventions/policies/procedures of the LRCP.

Prostate Cancer Centre
A community based outreach clinic, the Prostate Cancer Centre is a partnership between the London Hospitals, and hosts cancer prevention trials, patient education sessions and well follow-up clinics. www.lpcc.ca

Clinical Research Unit
Our Clinical Research Unit has clinical research associates whose primary role is to inform the patients about clinical research trials and to gather data and organize diagnostic tests required as part of the trial protocol. In general, patients are encouraged to participate on clinical trials whenever possible and the Disease Site Team endeavors to ensure a comprehensive trial portfolio is available to permit patients with all stages of disease to participate if so desired. Lists of clinical trials are available through the LRCP and OICR websites: http://www.lhsc.on.ca/Research_Training/LRCP/Clinical_Trials/trials.htm http://ontariocancertrials.ca

Clinical Guidelines
Clinical guidelines are based on those of the National Comprehensive Cancer Networks. Algorithms are derived from these guidelines and where specific LRCP conventions apply these are outlined below the relevant Algorithm. The complete NCCN source document is available at: http://www.nccn.org/professionals/physician_gls/PDF/prostate.pdf
Treatment Nomograms
Nomograms to assist clinical decision making for a variety of clinical scenarios are available at:

Program in Evidence Based Care
Genitourinary clinical practice guidelines are available through the Cancer Care Ontario PEBC guidelines initiative:
http://www.cancercare.on.ca/index_genitourinaryCancerguidelines.htm

Monthly Telemedicine Rounds
Providers (i.e. regional urologists, oncologists) are encouraged to participate in the monthly GU telemedicine rounds where case based discussion and education occurs. Telemedicine contact administrator is Erin Baker (erin.baker@lhsc.on.ca)
LRCP Conventions

Staging/Workup

- Biopsy typically performed by TRUS guidance; minimum 8 biopsies (apex, base, mid and transition zones bilaterally) and any suspicious (DRE or U/S) lesions
- Staging is as per AJCC 2002 guidelines (see Appendix 1)
- Biopsy results should be reported in synoptic fashion (see Appendix 1)

Risk Assessment

- For consideration of prostatectomy Partin Tables to probability of organ confined disease
- For consideration of radiotherapy, Canadian Consensus Guidelines for risk assessment
- Percentage of positive cores involved by cancer emerging as an independent risk factor in addition to PSA, palpation stage and grade. Generally speaking, >50% sampled cores positive for cancer will move patient into the next highest risk category; <33% sampled cores positive can move patients into the next lower risk category

References

LRCP conventions (see also Appendix 2)

- Low risk patients may be managed with Active Surveillance, Radical Prostatectomy, External Beam Radiotherapy or Permanent Implant Brachytherapy
- Intermediate risk patients may be managed with high dose external beam radiation alone, hormone ablation (4-9 months) plus external beam radiation, external beam radiotherapy plus HDR (high dose-rate brachytherapy) or radical prostatectomy
- Ideally low and selected intermediate risk patients should have a multidisciplinary assessment (radiation oncology and urology) prior to treatment
- Patients should be encouraged to participate in clinical trials where available

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**NCCN® Practice Guidelines in Oncology – v.2.2007**

**Prostate Cancer**

<table>
<thead>
<tr>
<th>RECURRENCE RISK</th>
<th>EXPECTED INITIAL THERAPY</th>
<th>ADJUVANT THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically Localized:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low: T1a-T2a and Gleason score 2-6 and PSA &lt; 10 ng/mL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 10 y</td>
<td>Expectant management* or RT (3D-CRT or brachytherapy)</td>
<td>If radical prostatectomy and positive margins, observe or RT</td>
</tr>
<tr>
<td>≥ 10 y</td>
<td>Expectant management* or RT (3D-CRT or brachytherapy) or Radical prostatectomy ± pelvic lymph node dissection if predicted probability of lymph node metastasis is ≥ 7%</td>
<td>If radical prostatectomy and lymph node metastasis, observe or androgen deprivation therapy*</td>
</tr>
</tbody>
</table>

*Patients with multiple adverse factors may be shifted into the next higher risk group

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**Note:** All recommendations are category 2A unless otherwise indicated.

**Clinical Trials:** NCCN believes that the best management of every cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

**Source:** NCCN 2007; American Society for Radiation Oncology (ASTRO) 2007; American Society of Clinical Oncology (ASCO) 2007; American Urological Association (AUA) 2007; International Society for Therapeutic Radiology and Oncology (ISTR) 2007; European Organization for Research and Treatment of Cancer (EORTC) 2007; Society for Surgery of the Alimentary Tract (SSAT) 2007; Society of Urologic Oncology (SUO) 2007; Society of Urologists in Canada (SUC) 2007

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**LRCP conventions (see also Appendix 2)**

- Low risk patients may be managed with Active Surveillance, Radical Prostatectomy, External Beam Radiotherapy or Permanent Implant Brachytherapy
- Intermediate risk patients may be managed with high dose external beam radiation alone, hormone ablation (4-9 months) plus external beam radiation, external beam radiotherapy plus HDR (high dose-rate brachytherapy) or radical prostatectomy
- Ideally low and selected intermediate risk patients should have a multidisciplinary assessment (radiation oncology and urology) prior to treatment
- Patients should be encouraged to participate in clinical trials where available
LRCP Conventions (see also Appendix 2)

• High-risk patients may be managed with hormone therapy alone or external beam radiotherapy plus adjuvant hormone therapy (minimum of 2 years of adjuvant therapy with an LHRH agonist; optional neoadjuvant and combined androgen blockade).

• Patients with high risk features post-prostatectomy should be considered for adjuvant hormone therapy (if node +ve) or adjuvant radiation (if positive surgical margins or pT3)

• Androgen blockage with monotherapy (LHRH agonist or orchidectomy) is generally recommended as first line therapy for M1 disease. Anti-androgen monotherapy is not recommended. Steroidal anti-androgens are not recommended either as monotherapy or in combination therapy. Anti-androgen for suppression of flare when initiating LHRH is recommended. Combined androgen blockade (anti-androgen + LHRH agonist) may be considered for patients with suspicion of more biologically aggressive disease (i.e. short PSADT). Observation may be an option for asymptomatic patients with suspicion of biologically indolent disease (i.e. long PSA doubling time). Intermittent hormone therapy is not recommended outside of a clinical trial.

• Patients should be encouraged to participate in clinical trials where available

References

LRCP Conventions

Regular follow-up is intended to monitor for early disease recurrence or treatment toxicity

Patients on clinical trials will be followed as per specified trial protocol

Patient information (i.e. PSA, notes) should be shared between providers providing follow-up

**Patients opting for active surveillance or surgery**
- Follow-up with referring Urologist
- PSA every 6-12 months for first 5 years then annually

**Patients completing adjuvant or salvage radiotherapy post-prostatectomy**
- Follow-up visit with Rad Onc within 6 months of completing XRT
- Subsequent follow-up will be with referring Urologist

**Patients completing primary radiation treatment (+/- short term hormonal therapy)**
- First follow-up with Rad Onc within first 6 months of completing XRT
- Subsequent visits are every 6 months alternating between Rad Onc and Urologist
- Follow-ups should include clinical assessment and PSA

**Patients completing primary radiation and continuing on long term hormone therapy**
- First follow-up with Rad Onc within first 6 months of completing XRT
- Subsequent visits are every 6 months alternating between Rad Onc and Urologist
- Follow-ups should include clinical assessment and PSA
- BMD monitoring and management by GP

**Criteria for discharge from follow-up by Radiation Oncology or Urology**
- >5 years from active treatment with no evidence of biochemical failure (impending or existing)
• Appropriate community provider who can continue annual assessment (PSA + DRE)
**LRCP Conventions**

- Rising PSA > 0.2 indicative of biochemical failure post radical prostatectomy
- Salvage XRT most effective when the PSA at time of treatment is ≤ 0.5
- Salvage XRT considered for patients with salvage rate of ≥50% according to algorithm
- Observation if not a candidate for salvage radiation and slow (>10 months) PSADT
- Enrollment on clinical trials of adjuvant and salvage therapy encouraged (i.e. RADICALS)

**Reference**

LRCP Conventions

Treatment of Biochemical Failure Post Primary Radiation (see also Appendix 2)

- Biochemical failure is suspected if there is a sustained rise in the PSA to a level of 2+current nadir (i.e. generally a rising PSA >3.0 ng/ml). This should be verified with at least 2 PSA at least 3 months apart. Calculation of the PSA doubling time is helpful to guide treatment.
- Consider referral back to LRCP if not currently being followed by Radiation Oncologist
- If PSA at time of BF is > 20 or the PSA doubling time is < 12 months
  - Repeat bone scan
  - Discuss salvage hormonal therapy or available clinical trials
  - If surveillance, follow-up at intervals no longer than 6 months
  - If hormone therapy BMD monitoring by GP
- If PSA < 20 and PSA doubling time ≥ 12 months
  - Surveillance or clinical trial recommended
  - Salvage hormonal therapy if patient preference for treatment
  - If hormone therapy BMD monitoring by GP
- If PSA < 10 at time BF failure diagnosed
  - If initially favorable risk consider for local salvage as available (Cryo, HIFU, PDT, implant) preferably on trial

Monitoring of patients post biochemical failure

- Patients should be assessed at least yearly with a PSA to monitor for development of hormone refractory disease; more frequently (i.e. q4-6 months) if on intermittent hormones
- Patients should have bone mineral density and liver function tests monitored by GP at least annually while on hormone therapy
Hormone refractory disease is defined by disease progression (clinical or rising PSA) in the presence of castrate testosterone level.

It is currently recommended that LHRH agonist therapy be continued in men without prior orchidectomy even once hormone refractory disease develops.

Symptom control should be optimized including use of narcotic analgesics and palliative radiotherapy.

If patient is asymptomatic and only sign of hormone refractory disease is a rising PSA, observation, secondary hormonal manipulations or investigational therapies may be offered. Men with bone metastases may benefit from prophylactic bisphosphonate therapy (CCO PEBC CPG 3-14).

Chemotherapy with docetaxel has been shown to improve symptoms, provide disease control, and provide modest survival benefits (CCO PEBC CPG 3-15).

Patients with disease progression despite docetaxel may be offered chemotherapy, systemic radiopharmaceutical, or participation in clinical trials.
Appendix 1 – Staging and Pathology Reporting Guidelines

**Staging**

<table>
<thead>
<tr>
<th>Table 1</th>
<th>2002 American Joint Committee on Cancer (AJCC) TNM Staging System for Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Tumor (T)</td>
<td>Clinical</td>
</tr>
<tr>
<td>T0</td>
<td>No evidence of primary tumor</td>
</tr>
<tr>
<td>T1</td>
<td>Clinically apparent tumor neither palpable nor visible by imaging</td>
</tr>
<tr>
<td>T1a</td>
<td>Tumor incident histologic finding in 5% or less of tissue resected</td>
</tr>
<tr>
<td>T1b</td>
<td>Tumor incident histologic finding in more than 5% of tissue resected</td>
</tr>
<tr>
<td>T1c</td>
<td>Tumor identified by needle biopsy (e.g., because of elevated PSA)</td>
</tr>
<tr>
<td>T2</td>
<td>Tumor confined within the prostate*</td>
</tr>
<tr>
<td>T2a</td>
<td>Tumor involves one-half of one lobe or less</td>
</tr>
<tr>
<td>T2b</td>
<td>Tumor involves more than one-half of one lobe but not both lobes</td>
</tr>
<tr>
<td>T2c</td>
<td>Tumor involves both lobes</td>
</tr>
<tr>
<td>T3</td>
<td>Tumor extends through the prostatic capsule **</td>
</tr>
<tr>
<td>T3a</td>
<td>Extracapsular extension (unilateral or bilateral)</td>
</tr>
<tr>
<td>T3b</td>
<td>Tumor invades the seminal vesicles</td>
</tr>
<tr>
<td>T4</td>
<td>Tumor is fixed or involves adjacent structures other than seminal vesicles; bladder neck, external sphincter, rectum, levator muscles, and/or pelvic wall</td>
</tr>
<tr>
<td>*Note: Tumor found in one or both lobes by needle biopsy, but not palpable or notably visible by imaging, is classified as T1c.</td>
<td></td>
</tr>
<tr>
<td>**Note: Invasion into the prostatic space or into (but not beyond) the prostatic capsule is not classified as T3, but as T4.</td>
<td></td>
</tr>
</tbody>
</table>

**Pathologic (pT)**

| pT2 | Organ confined |
| pT2a | Unilateral, involving one-half of one lobe or less |
| pT2b | Bilateral, involving more than one-half of one lobe but not both lobes |
| pT2c | Bilateral disease |
| pT3 | Extracapsular extension** |
| pT3a | Extracapsular extension** |
| pT3b | Seminal vesicle invasion |
| pT4 | Invasion of bladder, rectum |

**Regional Lymph Nodes (N)**

| N0 | No regional lymph node metastasis |
| N1 | Metastasis in regional lymph node(s) |

**Pathologic (pN)**

| pN0 | No positive regional nodes |
| pN1 | Metastasis in regional node(s) |

**Distant Metastasis (M)**

| M0 | No distant metastasis |
| M1 | Distant metastasis |
| M1a | Non-regional lymph node(s) |
| M1b | Bone(s) |
| M1c | Other site(s) with or without bone disease |

*Note: When more than one site of metastasis is present, the most advanced category is used. pM0 is most advanced.*

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**Histopathologic Type**

This classification applies to adenocarcinomas and squamous carcinomas, but not to sarcoma or transitional cell carcinomas of the prostate. Adjectives used to describe adenosquamous carcinomas include mucinous, ameloblastic, papillary, ductal, and neuroendocrine. Transitional cell carcinomas of the prostate are classified as a urethral tumor. There should be histologic confirmation of the disease.

**Histopathologic Grade (G)**

Gleason score is considered to be the optimal method of grading, because this method takes into account the inherent heterogeneity of prostate cancer, and because it has been clearly shown that this method is of great prognostic value. A primary and a secondary pattern (the range of each is 1–5) are assigned and then summed to yield a total score. Scores of 2–10 are thus possible. (If a single focus of disease is seen, it should be reported as both scores. For example, if a single focus of Gleason’s 3 disease is seen, it is reported as 3 + 3.)

GX: Grade cannot be assessed

- G1: Well differentiated (slight anaplasia) (Gleason 2–4)
- G2: Moderately differentiated (moderate anaplasia) (Gleason 3–5)
- G3: Poorly differentiated or undifferentiated (marked anaplasia) (Gleason 7–10)
## SYNOPTIC REPORT – PROSTATE BIOPSIES

<table>
<thead>
<tr>
<th>CASE SUMMARY</th>
<th>SURGICAL NUMBER:</th>
</tr>
</thead>
<tbody>
<tr>
<td>negative for prostatic adenocarcinoma</td>
<td></td>
</tr>
<tr>
<td>positive for prostatic adenocarcinoma</td>
<td></td>
</tr>
<tr>
<td>(other, specify)</td>
<td></td>
</tr>
</tbody>
</table>

### Overall Gleason score (predominant pattern + most poorly differentiated pattern)

- \(\text{Gleason score} = \) \(\frac{\text{predominant}}{\text{most poorly differentiated}}\) /10
- not applicable
- cannot be determined due to therapy effects

Notes:
1. Adenosquamous and small cell carcinoma are not graded using the Gleason system (report as not applicable).
2. Gleason grading should not be performed when there is evidence of treatment effect. Radiation and/or hormonal therapy can induce pattern alterations mimicking high grade carcinoma.

### Percentage of Gleason patterns 4 and/or 5 (if present)

- \(\%\) of Gleason patterns 4 and/or 5
- not applicable

### Estimated percentage of adenocarcinoma in all specimens

- \(\%\)
- not applicable

### Number of positive specimens / total number of specimens submitted

- \(\%\) / \(\%\)

### Perineural invasion

- absent
- present, specimen(s) (specify which biopsy or biopsies)

### Invasion of periprostatic adipose tissue

- absent
- present, specimen(s) (specify which biopsy or biopsies)

### Atypical small acinar proliferation (ASAP)

- absent
- present, specimen(s) (specify which biopsy or biopsies)

### High grade prostatic intraepithelial neoplasia (HGPIN)

- absent
- present, specimen(s) (specify which biopsy or biopsies)

### Acute inflammation

- absent
- present

### Significant chronic inflammation

- absent
- present

## DIAGNOSIS

### A: Prostate biopsy, right base PZ

- positive for prostatic adenocarcinoma
- positive for (specify cancer type)
  - Gleason score (predominant + most poorly differentiated pattern): \(\frac{\text{predominant}}{\text{most poorly differentiated}}\) /10
  - number of cores involved / number of cores submitted: \(\%\) / \(\%\)
  - % of tissue involved in this specimen: \(\%\)
- negative for prostatic adenocarcinoma

### B: Prostate biopsy, right mid PZ

- positive for prostatic adenocarcinoma
- positive for (specify cancer type)
  - Gleason score (predominant + most poorly differentiated pattern): \(\frac{\text{predominant}}{\text{most poorly differentiated}}\) /10
  - number of cores involved / number of cores submitted: \(\%\) / \(\%\)
  - % of tissue involved in this specimen: \(\%\)
- negative for prostatic adenocarcinoma

### C: Prostate biopsy, right apex PZ

- positive for prostatic adenocarcinoma
- positive for (specify cancer type)
  - Gleason score (predominant + most poorly differentiated pattern): \(\frac{\text{predominant}}{\text{most poorly differentiated}}\) /10
  - number of cores involved / number of cores submitted: \(\%\) / \(\%\)
  - % of tissue involved in this specimen: \(\%\)
- negative for prostatic adenocarcinoma
<table>
<thead>
<tr>
<th>Section</th>
<th>Biopsy Site</th>
<th>Cancer Status</th>
<th>Cancer Type</th>
<th>Gleason Score</th>
<th>Core Involvement</th>
<th>Tissue Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>Left base PZ</td>
<td>Positive</td>
<td>Prostatic adenocarcinoma</td>
<td>4 + 4 = 8/10</td>
<td>3/3</td>
<td>33%</td>
</tr>
<tr>
<td>E</td>
<td>Left mid PZ</td>
<td>Positive</td>
<td>Prostatic adenocarcinoma</td>
<td>4 + 4 = 8/10</td>
<td>3/3</td>
<td>33%</td>
</tr>
<tr>
<td>F</td>
<td>Left apex PZ</td>
<td>Positive</td>
<td>Prostatic adenocarcinoma</td>
<td>4 + 4 = 8/10</td>
<td>3/3</td>
<td>33%</td>
</tr>
<tr>
<td>G</td>
<td>Right TZ</td>
<td>Positive</td>
<td>Prostatic adenocarcinoma</td>
<td>4 + 4 = 8/10</td>
<td>3/3</td>
<td>33%</td>
</tr>
<tr>
<td>H</td>
<td>Left TZ</td>
<td>Positive</td>
<td>Prostatic adenocarcinoma</td>
<td>4 + 4 = 8/10</td>
<td>3/3</td>
<td>33%</td>
</tr>
</tbody>
</table>

☐ Add Minimal Volume Comment (SDMINVOL)
# Prostate Resection Synoptic Report

<table>
<thead>
<tr>
<th>Patient Name:</th>
<th>Surgical Number:</th>
<th>Specimen ID:</th>
</tr>
</thead>
</table>

## Histological Type
- adenocarcinoma (conventional, not otherwise specified)
- prostatic duct adenocarcinoma
- mucinous (colloid) adenocarcinoma
- signet ring cell carcinoma
- adenosquamous carcinoma
- small cell carcinoma
- sarcomatoid carcinoma
- undifferentiated carcinoma, not otherwise specified
- (other, specify)
- cannot be determined

## Total Gleason Score
- ______ + ____ (primary + secondary pattern) = ___/10
- not applicable
- cannot be determined due to therapy effects

**Notes:**
1. If 3 patterns are present, record the predominant and second most common patterns; the tertiary pattern should be recorded if higher grade than primary and secondary patterns.
2. Adenosquamous and small cell carcinoma are not graded using the Gleason system (report as not applicable).
3. Gleason grading should not be performed when there is evidence of treatment effect. Radiation and/or hormonal therapy can induce pattern alterations mimicking high grade carcinoma.

## % of Pattern 4 and/or 5 (if present)
- ___ %
- not present

## Tumour Location
- apex
- base
- left half (left “lobe”)
- right half (right “lobe”)

## Tumour Quantitation (proportion of prostate involved by tumour)
- ____ %

## Extraprostatic Extension
- absent
- present, right radial unifocal / multifocal (circle one) ______ (specify)
- present, left radial unifocal / multifocal (circle one) ______ (specify)
- present, left basal, unifocal / multifocal (circle one) ______ (specify)
- present, right basal, unifocal / multifocal (circle one) ______ (specify)

Descriptive phrases that may be used when extraprostatic extension present (optional):
- tumour abutting on fat
- tumour admixed with fat
- tumour in perineural space of neurovascular bundle(s)
- tumour extends beyond confines of normal glandular prostate in anterior prostate
- tumour extends beyond confines of normal glandular prostate in bladder neck region
- distinct bulging tumour nodule
- distinct bulging tumour nodule with a desmoplastic stromal reaction

Note: Extraprostatic extension (EPE) is the preferred term for the presence of tumour beyond the confines of the prostate gland. Tumour abutting on or admixed with fat constitutes extraprostatic extension. EPE also may be reported when tumour involves perineural spaces in the neurovascular bundles, even in the absence of prostatic fat involvement. In certain locations, such as the anterior prostate and bladder neck regions, there is a paucity of fat, and in these locations EPE is determined when the tumour extends beyond the confines of the normal glandular prostate. Sometimes there is a distinct bulging tumour nodule, which may be associated with a desmoplastic stromal reaction.
Resection Margins:

<table>
<thead>
<tr>
<th>Area</th>
<th>Condition</th>
<th>Circle (circle one)</th>
<th>Specify (specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apical</td>
<td>uninvolved by invasive carcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>involved by invasive carcinoma, unifocal / multifocal</td>
<td>(circle one) _______</td>
<td>(specify)</td>
</tr>
<tr>
<td>Bladder neck</td>
<td>uninvolved by invasive carcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>involved by invasive carcinoma, unifocal / multifocal</td>
<td>(circle one) _______</td>
<td>(specify)</td>
</tr>
<tr>
<td>Radial</td>
<td>uninvolved by invasive carcinoma</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>involved by invasive carcinoma, unifocal / multifocal</td>
<td>(circle one) _______</td>
<td>(specify)</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Seminal Vesicle Invasion

- absent
- present, right
- present, left
- no seminal vesicle present

Note: Invasion of muscular wall required.

Perineural Invasion

- absent
- present

Lymphovascular Invasion

- absent
- present

Lymph Node Status

- no malignancy in regional lymph nodes
- metastatic carcinoma in regional lymph nodes, ________________________ (specify location)
- no lymph nodes submitted

Results of Ancillary Investigations

- none identified
- atypical adenomatous hyperplasia
- benign prostatic hyperplasia
- high grade prostatic intraepithelial neoplasia (HGPIN)
- inflammation, ________________________ (specify type)
- treatment effect, ________________________ (other, specify)

Pathological Stage

- ________________________ (format pTxCNyMx)

Comment

Diagnosis

Lymph nodes, ________________________ (specify location), resection: negative for malignancy / positive for malignancy (circle one).

Lymph nodes, ________________________ (specify location), resection: negative for malignancy / positive for malignancy (circle one).

For conventional prostatic adenocarcinoma:
Prostate gland, radical prostatectomy: prostatic adenocarcinoma (conventional, not otherwise specified); Gleason score ___/10 (see synoptic report). (SDPROSRES)

For other histological types:
Prostate gland, radical prostatectomy: ________________________ (histological type); Gleason score ___/10 (see synoptic report). (SDSYN)

2.1 Active Surveillance

- Monitoring with PSA and DRE q6-12monthly
- Repeat TRUS guided biopsy q3yrly or at time of suspected progression (recommended)
- Indications for definitive treatment
  - Progression in Gleason Grade from low to intermediate or intermediate to high
  - PSA doubling time less than 1 year
  - Clinical progression
  - Patient preference
- Participation on randomized trials of active surveillance encouraged (i.e. NCIC START trial)

PRINCIPLES OF EXPECTANT MANAGEMENT

- Expectant management involves actively monitoring the course of disease with the expectation to intervene if the cancer progresses.
- Patients with clinically localized cancers who are candidates for definitive treatment and choose expectant management should have regular follow up:
  - DRE and PSA every 6 mo for life expectancy > 10 yrs and every 6-12 mo for life expectancy < 10 yrs
  - Needle biopsy of the prostate may be repeated within 6 mo of diagnosis if initial biopsy was < 10 cores or assessment discordant (eg, palpable tumor contralateral to side of positive biopsy)
  - Needle biopsy may be performed within 18 mo if > 10 cores obtained initially, then periodically.
- Cancer progression may have occurred if:
  - Primary Gleason grade 4 or 5 cancer is found upon repeat prostate biopsy
  - Prostate cancer is found in a greater number of prostate biopsies or occupies a greater extent of prostate biopsies
  - PSA doubling time < 3 yrs or PSA velocity is > 0.75.
- A repeat prostate biopsy is indicated for signs of disease progression by exam or PSA.
- Advantages of expectant management:
  - Avoid possible side effects of definitive therapy that may be unnecessary
  - Quality of life/normal activities retained
  - Risk of unnecessary treatment of small, indolent cancers is reduced.
- Disadvantages of expectant management:
  - Chance of missed opportunity for cure
  - Risk of progression and/or metastases
  - Subsequent treatment may be more intense with increased side effects
  - Nerve sparing may be more difficult, which may reduce chance of potency preservation after surgery
  - Increased anxiety
  - Requires frequent medical exams and periodic biopsies
  - Uncertain long term natural history of prostate cancer.
2.2 Radical Prostatectomy

PRINCIPLES OF SURGERY

Pelvic Lymph Node Dissection (PLND):
- An extended PLND includes removal of all node-bearing tissue from an area bounded by the external iliac vein anteriorly, the pelvic sidewall laterally, the bladder wall medially, the floor of the pelvis posteriorly, Cooper’s ligament distally, and the internal iliac artery proximally.
- A limited PLND includes removal of all node-bearing tissue from an area bounded by the external iliac vein anteriorly, the pelvic sidewall laterally, the bladder wall medially, the obturator nerve posteriorly, Cooper’s ligament distally, and the internal iliac vein proximally.
- An extended PLND will discover metastases approximately twice as often as a limited PLND. Extended PLND provides more complete staging and may cure some men with microscopic metastases.
- Dissection of nodes anterior and lateral to the external iliac vessels is associated with an increased risk of lymphedema and is discouraged. Extended PLND compared to limited PLND increases the risk of lymphedema after external beam radiation therapy. In addition, an extra peritoneal dissection is preferred if EBRT is anticipated.
- A PLND can be excluded in patients with <7% predicated probability of nodal metastases by nomograms, although some patients with lymph node metastases will be missed.
- PLND can be performed using an open, laparoscopic or robotic technique.
- An extra peritoneal dissection is preferred if EBRT is anticipated.

Radical Prostatectomy (RP):
- RP is appropriate therapy for any patient with clinically localized prostate cancer that can be completely excised surgically, who has a life expectancy of 10 years or more and no serious co-morbid conditions that would contraindicate an elective operation.
- High volume surgeons in high volume centers generally provide better outcomes.
- Laparoscopic and robot-assisted radical prostatectomy are used commonly. In experienced hands, the results of these approaches appear comparable to open surgical approaches.
- Blood loss can be substantial with radical prostatectomy but can be reduced by careful control of peri-prostatic vessels.
- Urinary incontinence can be reduced by preservation of urethral length beyond the apex of the prostate and avoiding damage to the distal sphincter mechanism. Bladder neck preservation may decrease the risk of incontinence. Anastomotic strictures increase the risk of long-term incontinence.
- Recovery of erectile function is directly related to the degree of preservation of the cavernous nerves. Replacement of resected nerves with nerve grafts is investigational. Early restoration of erections may improve late recovery.
- Salvage radical prostatectomy is an option for highly selected patients with local recurrence after EBRT, brachytherapy, or cryotherapy in the absence of metastases, but the morbidity (incontinence, loss of erection, anastomotic stricture) is high.
2.3 External Beam Radiation – General Principles

**PEBC: The Use of Conformal Radiotherapy and the Selection of Radiation Dose in T1 or T2 Prostate Cancer**

- All patients should be planned with CT simulation
- IMRT Planning and image guidance as per algorithm
- Bladder (full) and rectum (empty) instruction to patient prior to CT simulation and treatment
- Avoidance of iatrogenic sources of systematic error at CT SIM (urethrogram or rectal tube)
- Contouring of rectum and bladder should be as solid organs over entire anatomic extent
- Ideally image guidance with ultrasound or MVCT for daily image guidance for treatment recommended for doses >74Gy (BED) or fraction sizes ≥2.5Gy; see algor
- Dose Volume Constraints as per RTOG P0126 (PROFIT guidelines included for comparison)

**DVH Recommendations: PROFIT**
- Wall volumes; dosimetric definition
- Rectal and Bladder wall: D50<53Gy and D30<71Gy

**DVH Recommendations: RTOG P0126**
- lumen volumes; anatomic definition

<table>
<thead>
<tr>
<th>Normal organ limit†</th>
<th>No more than 15% volume receives dose that exceeds</th>
<th>No more than 25% volume receives dose that exceeds</th>
<th>No more than 35% volume receives dose that exceeds</th>
<th>No more than 50% volume receives dose that exceeds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder Constraint</td>
<td>80 Gy</td>
<td>75 Gy</td>
<td>70 Gy</td>
<td>65 Gy</td>
</tr>
<tr>
<td>Rectum Constraint</td>
<td>75 Gy</td>
<td>70 Gy</td>
<td>65 Gy</td>
<td>60 Gy</td>
</tr>
<tr>
<td>Pelvic Bulb</td>
<td>Mean dose less than or equal to 52.5 Gy</td>
<td></td>
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</tbody>
</table>

2.4 External Beam Radiation – Low risk patient
- Gross Target Volume = Clinical Target Volume = Prostate
- CTV minimum dose 74Gy (BED2)

2.5 External Beam Radiation – Intermediate risk patient
- CTV1= prostate + proximal seminal vesicles = minimum 50Gy (BED2)
- CTV2=prostate = minimum 74Gy (BED2)

2.6 External Beam Radiation + HDR – Intermediate risk patient
- CTV1= prostate + proximal seminal vesicles = minimum 50Gy (BED2)
- CTV2=prostate = HDR boost of 12-18 Gy in 2 fractions

2.7 External Beam Radiation – High risk patient
- CTV1 = regional pelvic lymph nodes = minimum 44Gy (BED2)
- CTV2= prostate + proximal seminal vesicles = minimum 50Gy (BED2)
- CTV3= prostate = minimum 74 Gy (BED2)
2.8 External Beam Radiation – Post-operative or Salvage

- CTV1 = peri-prostatic tissues = minimum 60Gy (BED2)
- IMRT or 3D CRT depending DVH criteria (same as for intact prostate)
- PEBC: Draft Evidence-Based Series: Adjuvant radiotherapy following radical prostatectomy for pathologic T3 or margin positive prostate cancer (EBS 3-17) High-intensity focused ultrasound (HIFU) for prostate cancer (EBS 3-16)

2.9 Brachytherapy: Low Dose Rate

- Brachytherapy (implantation of the prostate) with permanent seeds is considered a standard treatment option for men with early stage, low risk prostate cancer. There is now published 15-year follow-up data (Seattle Prostate Institute) indicating excellent outcomes comparable to that of surgery and external beam radiation. At the LRCP, this procedure is done with Iodine-125 seeds as an outpatient elective procedure. It is offered to selected men with the following criteria:
  1) Clinical stage T1c, T2a or T2b (AJCC 2002 Staging). (Those with a prior TURP or stages T1a or T1b are NOT suitable)
  2) Gleason score less than or equal to 6.
  3) PSA ≤ 10
  4) Prostate volume less than or equal to 50cc. (Those with a greater volume may be considered if gland is downsized with hormonal therapy)
  5) No evidence of pubic arch interference
- Other factors determine suitability for the procedure including the number of biopsies positive, % core involvement urinary function and overall health
- Guidelines for planning and reporting of permanent implant patients should be followed
- GTV = prostate; MPD 145Gy; I125
- PEBC: The Use of Brachytherapy in T1 or T2 Prostate Cancer 3-10 ES: May 2001 Update PDF: Summary
2.10 Brachytherapy: High Dose Rate

- For patients with intermediate and high-risk disease, escalated doses of radiation appear to improve outcomes when radiation is used on its own. High dose rate (HDR) brachytherapy is an alternative to IMRT that allows for dose escalation. There is published data phase III data demonstrating improved disease control with dose escalated external beam radiotherapy alone and data from several institutions showing excellent outcomes by dose escalation using HDR (+/- external beam radiotherapy) such as the data from William Beaumont Hospital. Multi-institutional studies further investigating this procedure are ongoing like the recently completed RTOG 0321 study. Eligibility criteria:
  - Intermediate or high risk disease (Canadian consensus guidelines) being treated with dose escalated radiation +/- hormones
  - Not suitable for dose escalated radiotherapy with image-guided IMRT external beam radiotherapy due to anatomy or co-morbidities
  - Should have reasonable urinary function (as measured by IPSS score)
  - Prostate volume 50cc or less at time of implant
  - No prior TURP
  - No evidence of distant metastases
  - Motivated and compliant patient

- The potential advantages to HDR include:
  1) The ability to implant disease outside the prostate capsule and base of seminal vesicles (compared to LDR)
  2) Deliver a large radiation fraction size to the prostate (theoretically more effective than smaller fraction sizes in prostate)
  3) Fewer number of treatments compared with external beam alone
  4) Boost the radiation dose within the prostate to known areas of disease
  5) Giving a higher dose to areas within the prostate or beyond the capsule ("intra-prostatic boost") compared with external beam.

- Unlike permanent seeds, this procedure is:
  1) Done as a temporary implant
  2) Combined with a 5 week course of external beam radiation
  3) Requires overnight hospitalization

- As this treatment is an invasive procedure and requires overnight hospitalization with catheters in place, it requires a motivated patient who is able to lie in bed for about 36 hours. The current HDR regimen at the LRCP consists of:

  HDR Brachytherapy
  Two fractions of 9.5Gy given over 24hrs

  2 week break

  External beam radiation
  to prostate ± pelvis
  4500cGy/25
  over 5 weeks
2.11 Radiopharmaceuticals

- Use of radiopharmaceuticals (strontium-89 and samarium-153) may be considered as an option for the palliation of multiple sites of bone pain from metastatic prostate cancer.
- The selection of patients for radiopharmaceutical therapy should consider the patient’s marrow function, performance status, recent use of other marrow suppression agents (chemotherapy or radiotherapy), unsuitability for alternate palliative interventions (wide field or local field radiotherapy, hormone therapy, chemotherapy, bisphosphonates) and anticipated life expectancy.
- Ideally the decision for radiopharmaceutical use should be based on a multidisciplinary (radiation oncology, nuclear medicine, medical oncology, palliative care) patient assessment.
- Patients with a partial response or complete response following radiopharmaceutical therapy may be considered for repeat administration for persistent or recurrent bone pain if the following is ruled out: rapid systemic disease progression, mechanical component to bone pain, underlying other bone pathology, impending or established fracture or spinal cord compression.
- The recommended dose for strontium-89 is 148 mBq (4mCi) by slow intravenous injection (1-2 minutes), accompanied by intravenous or oral hydration (at least 500 mL). The recommended dose for samarium-153 is 37 mBq/kg (1 mCi/kg) by slow intravenous injection (1-2 minutes), accompanied by intravenous or oral hydration (at least 500 mL).

**PEBC:** Radiopharmaceuticals for the Palliation of Painful Bone Metastases 14-1 PG: June 2004 PDF: Summary

**PEBC:** Use of Strontium-89 in Patients with Endocrine-Refractory Carcinoma of the Prostate Metastatic to Bone 3-6 PG: October 2001 Update PDF: Summary

2.12 External Beam Radiation – Palliative

- Uncomplicated focal bone pain: 8Gy/1 fraction or 20Gy/5 fractions
- Complicated bone pain (compromised bone integrity, neuropathic pain, cord compression): 20Gy/5 fractions or 30Gy/10 fractions
- Patients with cord compression with isolated single or contiguous levels of vertebral involvement who are ambulatory and good performance status (KPS ≥ 70) and have an anticipated life expectancy > 3 months should be considered for neurosurgical decompression/stabilization and postoperative radiotherapy

**PEBC:** Radiotherapy Fractionation for The Palliation of Uncomplicated Painful Bone Metastases 13-2 PG: March 2003 PDF: Summary

2.13 Hormone Therapy - Primary

- LHRH Agonist: Eligard, Zoladex, Lupron
- Antagonist: Bicalutamide (casodex)
- Patients on long term hormone therapy should be counseled re: exercises, calcium and vitamin D supplementation and screened with bone mineral density at start of treatment and q yearly thereafter (can be coordinated through family doctor)

2.14 Hormone Therapy - Secondary

- Prednisone
- Ketoconazole
2.15 Chemotherapy – First Line
- Docetaxol
- PEBC: Non-hormonal Systemic Therapy in Men with Metastatic Hormone-refractory Prostate Cancer
  3-15 EBS: November 2005
  PDF: Practice Guideline  Evidence-Based Series

2.16 Chemotherapy – Bisphosphonates
- Zoledronate
- PEBC: The Use of Bisphosphonates in Men with Hormone-Refractory Prostate Cancer
  3-14 PG: January 2005
  PDF: Summary  Summary & Full Report

Authors, Contact Information

Glenn Bauman, MSc, MD, FRCPC (Radiation Oncologist)
Medical Director, GU Disease Site Team
London Regional Cancer Program
London Health Sciences Centre
790 Commissioners Road East
London, Ontario, Canada N6A 4L6

Telephone: 519.685.8600 Ext. 53177

This guideline is a statement of consensus of the GU Disease Site Team regarding their views of currently accepted approaches to treatment. It is not intended to replace the independent medical judgment of the physician in the context of individual clinical circumstances to determine any patient’s care or treatment.