Protocol for the Examination of Biopsy Specimens From Patients With Carcinoma of the Prostate Gland

Version: ProstateBiopsy 4.0.3.1  Protocol Posting Date: February 2019

Accreditation Requirements
The use of this protocol is recommended for clinical care purposes but is not required for accreditation purposes.

This protocol may be used for the following procedures AND tumor types:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopsy</td>
<td>Includes specimens designated needle biopsy, biopsy case summary, and others</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tumor Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinoma</td>
<td>Includes all adenocarcinoma and histologic variants, neuroendocrine carcinomas, and others.</td>
</tr>
</tbody>
</table>

The following should NOT be reported using this protocol:

<table>
<thead>
<tr>
<th>Procedure</th>
</tr>
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<tbody>
<tr>
<td>Transurethral resection of the prostate (TURP) (consider Prostate TURP protocol)</td>
</tr>
<tr>
<td>Radical Prostatectomy (consider Prostate Radical Prostatectomy protocol)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tumor Type</th>
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</thead>
<tbody>
<tr>
<td>Urothelial tumor, including variants (consider the Urethra (prostatic urethra) protocol)</td>
</tr>
<tr>
<td>Lymphoma (consider the Hodgkin or non-Hodgkin Lymphoma protocols)</td>
</tr>
<tr>
<td>Sarcoma (consider the Soft Tissue protocol)</td>
</tr>
</tbody>
</table>

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With guidance from the CAP Cancer and CAP Pathology Electronic Reporting Committees.

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CAP Prostate Protocol Summary of Changes
Version 4.0.3.1
Separate needle biopsy case summary document

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Surgical Pathology Cancer Case Summary

Protocol posting date: February 2019

PROSTATE GLAND: Needle Biopsy (Specimen-Level Summary) (Note A)

Note: This specimen-level summary is recommended for reporting biopsy specimens but is NOT REQUIRED for accreditation purposes. Core data elements are bolded to help identify routinely reported elements.

Select a single response unless otherwise indicated.

Specimen Location (specify): __________________________

Histologic Type (select all that apply) (Note B)
- Acinar adenocarcinoma
- Ductal adenocarcinoma
- Small-cell neuroendocrine carcinoma
- Isolated intraductal carcinoma
- Other histologic type not listed (specify): __________________________

Histologic Grade (Note C)

<table>
<thead>
<tr>
<th>Grade Group and Gleason Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not applicable</td>
</tr>
<tr>
<td>Cannot be assessed</td>
</tr>
<tr>
<td>Grade group 1 (Gleason Score 3+3=6)</td>
</tr>
<tr>
<td>Grade group 2 (Gleason Score 3+4=7)</td>
</tr>
<tr>
<td>Grade group 3 (Gleason Score 4+3=7)</td>
</tr>
<tr>
<td>Grade group 4 (Gleason Score 4+4=8)</td>
</tr>
<tr>
<td>Grade group 4 (Gleason Score 3+5=8)</td>
</tr>
<tr>
<td>Grade group 4 (Gleason Score 5+3=8)</td>
</tr>
<tr>
<td>Grade group 5 (Gleason Score 4+5=9)</td>
</tr>
<tr>
<td>Grade group 5 (Gleason Score 5+4=9)</td>
</tr>
<tr>
<td>Grade group 5 (Gleason Score 5+5=10)</td>
</tr>
</tbody>
</table>

Percentage of Pattern 4 in Gleason Score 7(3+4, 4+3) Cancer (only if applicable): ____%

Percentage of Gleason Patterns 4 and 5 (applicable to Gleason score greater than 7):
- Percentage of pattern 4: ____%
- Percentage of pattern 5: ____%

Intraductal Carcinoma (IDC) (Note D)
- Not identified
- Present
- Cannot be determined
Tumor Quantitation (Note E)

Cores
Number of positive cores: ____
Total number of cores: ____
Cannot be determined
and
Estimated percentage of prostatic tissue involved by tumor for core with the greatest amount of tumor: ____%
Percentage of tumor in each core: ____%

OR

Cores
Number of positive cores: ____
Total number of cores: ____
Cannot be determined
Percentage of tumor in each core: ____%

Continuous Measurement
Estimated percentage of prostatic tissue involved by continuous tumor: ____%
and/or
Total linear millimeters of carcinoma: ____ mm
Total linear millimeters of needle core tissue: ____ mm

AND/OR

Discontinuous Measurement
Estimated percentage of prostatic tissue involved by discontinuous tumor: ____%
and/or
Total linear millimeters of carcinoma: ____ mm
Total linear millimeters of needle core tissue: ____ mm

Periprostatic Fat Invasion (report if identified in specimen) (Note F)
Not identified
Present

Seminal Vesicle/Ejaculatory Duct Invasion (report if identified in specimen) (Note F)
Not identified
Present

Lymphovascular Invasion
Not identified
Present
Cannot be determined

Perineural Invasion (Note G)
Not identified
Present

Additional Pathologic Findings (select all that apply)
None identified
High-grade prostatic intraepithelial neoplasia (PIN) (Note H)
Atypical small acinar proliferation (ASAP)
Inflammation (specify type): _____________________________
Other (specify): _____________________________
Atypical Small Acinar Proliferation (ASAP) in Absence of Carcinoma in Case (Note I)
Specimen Location(s) (specify): ___________________________

Additional Pathologic Findings with ASAP (select all that apply)
   ___ None identified
   ___ High-grade prostatic intraepithelial neoplasia (PIN) (Note H)
   ___ Inflammation (specify type): ___________________________
   ___ Other (specify): ___________________________

High-grade Prostate Intraepithelial Carcinoma (PIN) in Absence of Carcinoma in Case
Specimen Location(s) (specify): ___________________________

High-grade PIN Focality (report only if tumor is multifocal)
   ___ Focal (present in 1 or 2 cores)
   ___ Multifocal (present in more than 2 cores)

Tumor Microfocus (Note C)
Tumor Microfocus Location(s) (specify): ___________________________

Histologic Type of Tumor Microfocus (select all that apply) (Note B)
   ___ Acinar adenocarcinoma
   ___ Other histologic type not listed (specify): ___________________________

Greatest Percentage of Tumor Involvement (specify): ____%

Negative Specimen(s) or Zone(s)
Specimen Location(s) (specify): ___________________________

Additional Pathologic Findings (select all that apply)
   ___ None identified
   ___ Inflammation (specify type): ___________________________
   ___ Other (specify): ___________________________

Treatment Effect (select all that apply)
   ___ No known presurgical therapy
   ___ Not identified
   ___ Radiation therapy effect present
   ___ Hormonal therapy effect present
   ___ Other therapy effect(s) present (specify): _______________________
   ___ Cannot be determined

Comment(s)
Surgical Pathology Cancer Case Summary

Protocol posting date: February 2019

PROSTATE GLAND: Needle Biopsy (Case-Level Summary) (Note A)

Note: This case-level summary is recommended for reporting aggregate biopsy findings, but NOT REQUIRED for accreditation purposes. Core data elements are bolded to help identify routinely reported elements.

Select a single response unless otherwise indicated.

In situations where a case level summary is used and specimen level summaries are not used, the Gleason patterns, score, grade group and tumor extent should be documented for each positive specimen (container) in the line diagnosis. The essential information could be conveyed with a simple diagnostic line such as, “Adenocarcinoma, Gleason grade 3 + 4 = score of 7 (Grade group 2), in 1 of 2 cores, involving 20% of needle core tissue, and measuring 4 mm in length.” (Note A.)

Histologic Type (select all that apply) (Note B)

___ Acinar adenocarcinoma
___ Ductal adenocarcinoma
___ Small-cell neuroendocrine carcinoma
___ Isolated intraductal carcinoma
___ Other histologic type not listed (specify): ________________________

Histologic Grade (Note C)

Note: This applies in cases where there are 2 or more cores involved by cancer with different Gleason scores or 2 or more sites (containers) contain cancer with different Gleason scores.

Grade Group Based on Highest Gleason Score

___ Not applicable
___ Cannot be assessed
___ Grade group 1 (Gleason Score 3+3=6)
___ Grade group 2 (Gleason Score 3+4=7)
___ Grade group 3 (Gleason Score 4+3=7)
___ Grade group 4 (Gleason Score 4+4=8)
___ Grade group 4 (Gleason Score 3+5=8)
___ Grade group 4 (Gleason Score 5+3=8)
___ Grade group 5 (Gleason Score 4+5=9)
___ Grade group 5 (Gleason Score 5+4=9)
___ Grade group 5 (Gleason Score 5+5=10)

Percentage of Pattern 4 in Highest Gleason Score 7(3+4, 4+3) Cancer (report if applicable): ____%

Percentage of Gleason Patterns 4 and 5 (applicable to Highest Gleason score greater than 7):
Percentage pattern 4: ____%
Percentage pattern 5: ____%

Site(s) with Highest Gleason Score (specify): ________________________

The routinely reported core data elements are bolded.
Composite Gleason Score

*Note: The composite Gleason score takes into account the topographic distribution of tumor and the relative percentage of the different Gleason patterns in all positive cores.*

**Composite Grade Group and Gleason Score**

- Not applicable
- Cannot be assessed
- Grade group 1 (Gleason Score 3+3=6)
- Grade group 2 (Gleason Score 3+4=7)
- Grade group 3 (Gleason Score 4+3=7)
- Grade group 4 (Gleason Score 4+4=8)
- Grade group 4 (Gleason Score 3+5=8)
- Grade group 4 (Gleason Score 5+3=8)
- Grade group 5 (Gleason Score 4+5=9)
- Grade group 5 (Gleason Score 5+4=9)
- Grade group 5 (Gleason Score 5+5=10)

**Percentage of Pattern 4 in Composite Gleason Score 7(3+4, 4+3) Cancer (report if applicable):**

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**Percentage of Gleason Patterns 4 and 5 (applicable to Composite Gleason score greater than 7):**

- Percentage of pattern 4: ____%
- Percentage of pattern 5: ____%

**Intraductal Carcinoma (IDC) (Note D)**

- Not identified
- Present
- Cannot be determined

**Tumor Quantitation (Note E)**

**Cores**

- Number of positive cores: ____
- Total number of cores: ____
- Cannot be determined

**Measurement Technique**

- Continuous
- Discontinuous

- Greatest length of core involvement by cancer in any core (millimeters): ____ mm
  - Specify site(s): ________________________

- Greatest percentage of core involvement by cancer in any core: ____%
  - Specify site(s): ________________________

- Percentage of total prostatic tissue involved by tumor: ____% and/or

- Total linear millimeters of carcinoma: ____ mm
- Total linear millimeters of needle core tissue: ____ mm

**Periprostatic Fat Invasion (Note F) (report if applicable)**

- Not identified
- Present
Seminal Vesicle/Ejaculatory Duct Invasion (Note F) (report if applicable)
___ Not identified
___ Present
___ Present in targeted seminal vesicle biopsy

Lymphovascular Invasion
___ Not identified
___ Present
___ Cannot be determined

Perineural Invasion (Note G)
___ Not identified
___ Present

Additional Pathologic Findings (select all that apply)
___ None identified
___ High-grade prostatic intraepithelial neoplasia (PIN) (Note H)
___ Inflammation (specify type): ___________________________
___ Other (specify): ___________________________

Treatment Effect (select all that apply)
___ No known presurgical therapy
___ Not identified
___ Radiation therapy effect present
___ Hormonal therapy effect present
___ Other therapy effect(s) present (specify): ____________________
___ Cannot be determined

Comment(s)
Explanatory Notes

A. Level of Biopsy Reporting (Core, Specimen, Case)
In a prostate biopsy case, 10 to 14 cores are generally received; however, in some protocols, 15 or more cores are provided. In the situation, for example, where 12 cores are submitted, they may be received in 12 separate site-specific labeled containers, 6 containers each with 2 cores with typical sextant designations, or 6 cores in each of 2 containers labeled left and right. In addition to systematic biopsies, MRI-guided biopsies of focal abnormalities are increasingly used, especially in patients being considered for active surveillance. With respect to technical quality, single-core site-specific labeled submission is ideal but 2 core submission is acceptable.1 When more than 2 cores are submitted in a single container, there is an increased likelihood of fragmentation.

The reporting of prostate biopsies may be done at core, specimen, and case level. The International Society of Urological Pathology (ISUP) recommended in 2005 that Gleason grading be done at the core level, if the cores are separately identified.2 This approach has been endorsed in the 2016 World Health Organization (WHO) classification.3 For single cores in individual containers, this recommendation is not a problem. When there is more than 1 core in a container, individual core reporting is recommended if the cores are separately labeled as to their specific location with colored inks. In the situation where there are multiple unidentified intact cores submitted in 1 specimen container and each shows cancer, individual reporting may be done; however, some pathologists may choose to report aggregated measurements for each specimen. For the purpose of this protocol, the minimum required reporting is at the specimen level, and more granular reporting would be considered optional. This approach is important as it takes into account workload considerations. In workload measurement systems (at least those based on the CPT system), the units of work are the specimens and not the individual pieces or fragments that constitute a single specimen.

For the purpose of this protocol, two biopsy case summaries are provided. One is a specimen-level summary, which would be used for each positive specimen. In a case where 6 of 12 specimens show prostate cancer, 6 specimen summaries would be used. An optional case-level summary is also provided, which can be used in conjunction with the specimen level summaries or on its own. In the latter situation, a simple diagnosis documenting the Gleason grades, score, extent measurements, and other relevant observations should be provided for each positive specimen. When 2 or more sites (containers) contain cancer of the same Gleason score, the case-level protocol may be used for the summary of tumor quantification.

References

B. Histologic Type
This protocol applies only to invasive adenocarcinomas of the prostate gland, as shown below. Carcinomas other than adenocarcinoma are exceptionally uncommon, accounting for less than 0.5% of prostatic tumors. The protocol does not apply to pure squamous cell carcinoma, basal cell carcinoma, urothelial carcinoma, small cell neuroendocrine carcinoma, and large cell neuroendocrine carcinoma. If these rare subtypes of carcinoma, however, are mixed with acinar type adenocarcinoma, the protocol may be used.

Classification of Invasive Adenocarcinoma of Prostate (2016 WHO classification1)
Acinar adenocarcinoma
- Atrophic
- Pseudohyperplastic
- Microcystic
Foamy gland
Mucinous (colloid)
Signet ring-like cell
Pleomorphic giant cell
Sarcomatoid
Ductal adenocarcinoma
Cribriform
Papillary
Solid
Neuroendocrine tumors
Adenocarcinoma with neuroendocrine differentiation
Well-differentiated neuroendocrine tumor
Small-cell neuroendocrine carcinoma
Large cell neuroendocrine carcinoma

References

C. Histologic Grade
Gleason Score
The Gleason grading system is recommended for use in all prostatic specimens containing adenocarcinoma, with the exception of those showing treatment effects, usually in the setting of androgen withdrawal and radiation therapy.1,2 The Gleason score is an important parameter used in nomograms, such as the Kattan nomograms,3,4 and the Partin tables,5 which guide individual treatment decisions. Readers are referred to the recommendations of 2 ISUP consensus conferences dealing with the contemporary usage of the Gleason system (also see Figure 1).6,7 The Gleason score is the sum of the primary (most predominant in terms of surface area of involvement) Gleason grade and the secondary (second most predominant) Gleason grade. Where no secondary Gleason grade exists, the primary Gleason grade is doubled to arrive at a Gleason score. The primary and secondary grades should be reported in addition to the Gleason score, that is, Gleason score 7(3+4) or 7(3+4). In needle biopsy specimens, Gleason score is the sum of the primary (most predominant) Gleason grade and highest Gleason grade.

Figure 1. 2015 modified ISUP Gleason schematic diagram.7
In needle biopsy specimens, it is recommended that Gleason scores be assigned for each separately identified core (see Note A). If multiple cores in a specimen container are not separately identified, a Gleason score can be assigned to each positive core, provided they are intact; however, some pathologists may choose to report an overall Gleason score for that specimen. The highest Gleason score should be provided in the summary. It is optional to provide a composite Gleason score that takes into account the topographic distribution of tumor and the relative percentage of the different Gleason patterns in all positive cores using the method illustrated in a recent study by Arias-Stella et al.\textsuperscript{8}

In needle biopsy specimens where there is a minor secondary component (<5% of tumor) and where the secondary component is of higher grade, the latter should be reported. For instance, a case showing more than 95% Gleason pattern 3 and less than 5% Gleason pattern 4 should be reported as Gleason score 7(3+4). Conversely, if a minor secondary pattern is of lower grade, it need not be reported. For instance, where there is greater than 95% Gleason pattern 4 and less than 5% Gleason pattern 3, the score should be reported as Gleason score 8(4+4).

In needle biopsy specimens where more than 2 patterns are present, and the worst grade is neither the predominant nor the secondary grade, the predominant and highest grade should be chosen to arrive at a score (eg, 75% pattern 3, 20-25% pattern 4, <5% pattern 5 is scored as 3+5=8). This approach has been validated in a large clinical series.\textsuperscript{9} The above rules apply to both specimen-level and case-level reporting.

Uncommonly in needle biopsy specimens, there will be limited carcinoma focus that is too small to confidently render a grade. This focus may occur in isolation or concomitant to a more discrete gradable carcinoma focus. Rather than providing a potentially inaccurate grade that can influence the management, it is recommended that grade should not be rendered to this small focus and a “tumor microfocus” label be reported. The above apply only to specimen-level reporting.

For transurethral resection and enucleation (simple prostatectomy) specimens, the above grading principles also apply.

**Grade Group**

The 9 Gleason scores (2-10) have been variably lumped into different groups for prognosis and patient management purposes. Epstein and associates proposed grouping scores into 5 prognostic categories, grade groups 1-5.\textsuperscript{10} This grade grouping, shown below in the table, strongly correlate with biochemical recurrence and have been incorporated into the new Partin tables.\textsuperscript{10-12} At the 2014 ISUP Consensus Conference, details of this prognostic system were clarified and it was recommended for usage together with the Gleason system.\textsuperscript{7} This grade grouping has also been subsequently validated by other independent studies in surgical and radiation cohorts show significant correlation with survival.\textsuperscript{13-15} The new grade grouping has been endorsed in the 2016 WHO classification.\textsuperscript{1}

The grade grouping has also been endorsed by ISUP and is referred to as ISUP grade in some publications. Like Gleason scoring in needle biopsies, the grade group can be applied at core, specimen, or case levels.

**Table: Grade Groups**

<table>
<thead>
<tr>
<th>Grade Group</th>
<th>Gleason Score</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>≤6</td>
<td>Only individual discrete well-formed glands</td>
</tr>
<tr>
<td>2</td>
<td>3+4=7</td>
<td>Predominantly well-formed glands with lesser component of poorly formed/fused/cribriform glands</td>
</tr>
<tr>
<td>3</td>
<td>4+3=7</td>
<td>Predominantly poorly formed/fused/cribriform glands with lesser component ((\ast)) of well-formed glands</td>
</tr>
</tbody>
</table>
### Percentage Gleason Patterns 4 and 5 (applicable to Gleason Scores ≥7)

Another recommendation from the 2014 ISUP consensus conference endorsed in the 2016 WHO classification is that the percentage of pattern 4 should be recorded in all Gleason score 7(3+4, 4+3) cases.¹ This measurement further stratifies Gleason score 7 and allows identification of cases with limited pattern 4 (e.g., <10%) or extensive pattern 4 (e.g., >75%).¹⁶,¹⁷ This has practical importance since selected patients with Gleason score 7(3+4) but small amounts of pattern 4 (≤10%) may be eligible for active surveillance.¹⁶-¹⁹

In tumors with Gleason scores >7, the percentage of patterns 4 and 5 has been shown to be of prognostic significance¹⁶ and may be included in the report. Currently there is no consensus on how the percentage of pattern 4+5 should be recorded although it may be captured in 10% intervals or other stratifications such as <5%, 5-10%, 10-25%, 25-50%, 50-75%, >75%.

### References


D. Intraductal Carcinoma (IDC)

The presence of intraductal carcinoma (IDC) is important to record since it has independent prognostic significance. Intraductal carcinoma is uncommon in needle biopsies and when present is usually found within invasive tumor.1-3 Pure intraductal carcinoma is rare in needle biopsies. It is important to distinguish IDC from high-grade prostatic intraepithelial neoplasia. The differential diagnosis of IDC is beyond the scope of this protocol.

IDC is strongly associated with high Gleason score and high volume tumor in radical prostatectomies and with metastatic disease.3-5 At the 2014 ISUP consensus conference, it was agreed that Gleason scores or grade groups (ISUP grades) should not be assigned to IDC.6

References

E. Quantitation of Tumor

Studies have shown prostate cancer volume is a prognostic factor, although the data are conflicting as to its independent prognostic significance. There are many methods of estimating the amount of tumor in prostatic specimens.1-3 For needle core biopsy specimens, the number of positive cores out of the total number of cores
should always be reported, except in situations where fragmentation precludes accurate counting. The estimated percentage of prostatic tissue involved by tumor and/or the linear millimeters of the tumor should also be reported. Reporting of the positive core with the greatest percentage of tumor is an option since in some active surveillance (AS) protocols, the presence of any cores with >50% involvement is an exclusion criterion. It is not uncommon that a core is discontinuously involved by cancer foci. One practical consideration is how to record discontinuous areas of tumor involvement. For instance, in a 20-mm core with 5% involvement at each end, the amount may be recorded as 5% + 5% = 10% involvement or 100% involvement in a discontinuous fashion even though there is only 2 mm of actual tumor length. The pattern of reporting may actually exclude a patient from an AS protocol. In such situations, it may be worthwhile reporting discontinuous involvement by both including and subtracting the intervening tissue; for example, in the 20-mm core, there are discontinuous foci of adenocarcinoma spanning a distance of 20 mm (100% linear extent) and measuring 1+1=2 mm (10% linear extent). Most studies have also shown that recording the cancer length from one end to the other correlates better with radical prostatectomy findings and prognostic outcomes than subtracting the intervening benign prostate tissue. These findings are supported by recent studies that showed that 75% to 80% of discontinuous cancer foci in prostate biopsy cores may represent the same tumor focus.

References


**F. Local Invasion in Needle Biopsies**

Occasionally in needle biopsies, periprostatic fat is involved by tumor. This observation should be noted since it indicates that the tumor is at least pT3a in the TNM system. Furthermore, if seminal vesicle tissue is present (either unintentionally or intentionally, as in a directed biopsy) and involved by tumor, this should be reported since it suggests that the tumor may be pT3b (if the involved seminal vesicle is extraprostatic). Seminal vesicle invasion is defined by involvement of the muscular wall. At times, especially in needle biopsy specimens, it is difficult to distinguish between seminal vesicle and ejaculatory duct tissue. It is important not to overinterpret the ejaculatory duct as seminal vesicle since involvement of the former by tumor does not constitute locally advanced disease.

References


G. Perineural Invasion

Perineural invasion in core needle biopsies has been associated with extraprostatic extension in some correlative radical prostatectomy studies, although its exact prognostic significance remains unclear.\(^1\)\(^{-4}\) Perineural invasion has been found to be an independent risk factor, in some studies, for predicting an adverse outcome in patients treated with external beam radiation,\(^5\) but not for patients treated with brachytherapy or radical prostatectomy.\(^6\) The value of perineural invasion as an independent prognostic factor has been questioned in a multivariate analysis.\(^4\)

References


H. Prostatic Intraepithelial Neoplasia

The diagnostic term *prostatic intraepithelial neoplasia* (PIN), unless qualified, refers to high-grade PIN. Low-grade PIN is not reported. The presence of an isolated PIN (PIN in the absence of carcinoma) should be reported in biopsy specimens, especially if more than 1 site is involved.\(^1\) The reporting of PIN in biopsies with carcinoma is considered optional. High-grade PIN in a biopsy without evidence of carcinoma has in the past been a risk factor for the presence of carcinoma on subsequent biopsies, but the magnitude of the risk has diminished, and, in some studies, high-grade PIN was not a risk factor at all.\(^2\)\(^{-3}\) More recent data suggests that if high-grade PIN is present in 2 or more sites, there is an increased risk of detecting carcinoma in subsequent biopsies.\(^4\)\(^{-5}\)

References