

**PROSTATE CANCER
(RADICAL PROSTATECTOMY)
STRUCTURED REPORTING
PROTOCOL
(1st Edition 2010)**

ISBN: 978-1-74187-462-4 (online)

Publications number (SHPN): (CI) 090268

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First published: Feb 2010, 1st Edition (Version 1.0)

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Scope

This protocol contains standards and guidelines for the structured reporting of radical prostatectomy specimens for prostate carcinoma. There are separate protocols for core biopsies and transurethral resection (TUR) specimens.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. This protocol can be used to define and report the minimum data set but the structure is scalable and can equally accommodate a maximum data set or fully comprehensive report.

Abbreviations

AJCC	American Joint Committee on Cancer
CI	capsular incision
EPE	extraprostatic extension
ISUP	International Society of Urological Pathology
LIS	laboratory information system
LVI	lymphovascular invasion
PBS	Pharmaceutical Benefits Scheme
PIN	prostatic intraepithelial neoplasia
PSA	prostate specific antigen
PSM	positive surgical margin
RCPA	Royal College of Pathologists of Australasia
SVI	seminal vesicle involvement
TNM	tumour-node-metastasis
TUR	transurethral resection
TURP	transurethral resection of prostate
UICC	International Union Against Cancer
WHO	World Health Organization

Definitions

The table below provides definitions for general or technical terms used in this protocol. Readers should take particular note of the definitions for 'standard', 'guideline' and 'commentary', because these form the basis of the protocol.

Ancillary study	An ancillary study is any pathology investigation that may form part of a cancer pathology report but is not part of routine histological assessment.
Clinical information	Patient information required to inform pathological assessment, usually provided with the specimen request form. Also referred to as 'pretest information'.
Commentary	<p>Commentary is text, diagrams or photographs that clarify the standards (see below) and guidelines (see below), provide examples and help with interpretation, where necessary (not every standard or guideline has commentary).</p> <p>Commentary is used to:</p> <ul style="list-style-type: none">• define the way an item should be reported, to foster reproducibility• explain why an item is included (eg how does the item assist with clinical management or prognosis of the specific cancer).• cite published evidence in support of the standard or guideline• clearly state any exceptions to a standard or guideline. <p>In this document, commentary is prefixed with 'CS' (for commentary on a standard) or 'CG' (for commentary on a guideline), numbered to be consistent with the relevant standard or guideline, and with sequential alphabetic lettering within each set of commentaries (eg CS1.01a, CG2.05b).</p>
General commentary	<p>General commentary is text that is not associated with a specific standard or guideline. It is used:</p> <ul style="list-style-type: none">• to provide a brief introduction to a chapter, if necessary• for items that are not standards or guidelines but are included in the protocol as items of potential importance, for which there is currently insufficient evidence to recommend their inclusion. (Note: in future reviews of protocols, such items may be reclassified as either standards or guidelines, in line with diagnostic and prognostic advances, following evidentiary review).

Guideline	<p>Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are not essential for clinical management, staging or prognosis of a cancer, but are recommended.</p> <p>Guidelines include key observational and interpretative findings that are fundamental to the diagnosis and conclusion. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail.</p> <p>Guidelines are not used for research items.</p> <p>In this document, guidelines are prefixed with 'G' and numbered consecutively within each chapter (eg G1.10).</p>
Macroscopic findings	Measurements, or assessment of a biopsy specimen made by the unaided eye.
Microscopic findings	In this document, the term 'microscopic findings' refers to histological or morphological assessment.
Standard	<p>Standards are mandatory, as indicated by the use of the term 'must'. Their use is reserved for core items essential for the clinical management, staging or prognosis of the cancer.</p> <p>The summation of all standards represents the minimum dataset for the cancer.</p> <p>In this document, standards are prefixed with 'S' and numbered consecutively within each chapter (eg S1.02).</p>
Structured report	A report format which utilises standard headings, definitions and nomenclature with required information.
Synoptic report	A structured report in condensed form (as a synopsis or precis).
Synthesis	Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new. In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more chapters to derive new information

Introduction

Prostate cancer

Prostate cancer is the most common cancer in men with 16,329 new cases reported in Australia in 2005. It is also the second most common cause of cancer death in males, accounting for almost 3000 in 2005.¹ Both the number of new cases and the number of deaths from prostate cancer are increasing, partly driven by the ageing of the population.² There is a wide variation in the biological behaviour of prostate cancer. Most tumours are relatively slow-growing; however, a significant minority have the propensity for aggressive behaviour, including metastasis, and such tumours can be fatal.³

Benefits of structured reporting

Structured pathology reports with standardised definitions for each component have been shown to significantly enhance the completeness and quality of data provided to clinicians, and have been recommended both in North America and the United Kingdom.⁴⁻⁷

The College of American Pathologists and the Royal College of Pathologists (UK) have recently published useful protocols for the reporting of prostate cancer.⁸⁻⁹ These have been widely used in recent years in Australia and New Zealand, usually in modified formats to suit local requirements and preferences. A protocol endorsed by the Royal College of Pathologists of Australasia and other local organisations involved in the management of prostate cancer is therefore needed. The authors have not attempted to 're-invent the wheel' but have borrowed freely from pre-existing publications. The intention is to provide pathologists with a minimum dataset and guidelines that are comprehensive, easy to use, and in keeping with local capacities and practice.

Importance of histopathological reporting

Information from pathology reports on core biopsy and transurethral resection (TUR) specimens, particularly Gleason grade and pathological stage, has a key role in the rational planning of patient management and is a major component of the most common nomograms used to guide clinical decision making.¹⁰ Likewise, accurate data from the pathological examination of radical prostatectomy specimens is essential in predicting the risk of cancer recurrence after prostatectomy and aids clinical decisions on surveillance, adjuvant therapy etc.¹¹⁻¹²

Design of this protocol

This protocol defines the relevant information to be assessed and recorded in a pathology report for prostate cancer. Mandatory elements (standards) are differentiated from those that are not mandatory but are recommended (guidelines). Also, items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. The structure provided by the following chapters, headings and subheadings describes the elements of information and their groupings, but does not necessarily represent the format of either a pathology report (Chapter 7) or checklist (Chapter 6). These, and the structured pathology request form (Appendix 1), are templates representing information from this protocol, organised and formatted differently to suit their respectively different purposes.

Key documentation

- ISUP Boston 2009 Consensus Conference recommendations^a
- *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols*, Royal College of Pathologists of Australasia, 2009¹³
- *Pathology and Genetics: Tumours of the Urinary System and Male Genital Organs*. World Health Organization Classification of Tumours, Volume 7, 2004¹⁴
- *AJCC Cancer Staging Manual*, 7th edition, American Joint Committee on Cancer, 2010¹⁵

Changes since last edition

Not applicable.

^a ISUP Boston 2009 Consensus meeting recommendations will be published in late 2009.

Authority and development

This section provides details of the committee involved in developing this protocol and the process by which it was developed.

Protocol developers

This protocol was developed by an expert committee, with assistance from relevant stakeholders.

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Acknowledgements

The Prostate expert committee wish to thank all the pathologists and clinicians who contributed to the discussion around this document.

Stakeholders

ACT Health

Anatomical Pathology Advisory Committee (APAC)

Andrology Australia

Australian Association of Pathology Practices Inc (AAPP)

Australian Cancer Network

Australian Commission on Safety and Quality in Health Care

Cancer Australia

Cancer Council ACT

Cancer Council NSW

Cancer Council Queensland

Cancer Council SA

Cancer Council Tasmania

Cancer Council Victoria

Cancer Council Western Australia

Cancer Institute NSW

Cancer Services Advisory Committee (CanSAC)

Cancer specific expert groups – engaged in the development of the protocols

Cancer Voices

Clinical Oncology Society of Australia (COSA)

Colorectal Cancer Research Consortium

Department of Health and Ageing
Faculty of Radiation Oncology Genito-Urinary Group (FROGG)
Grampians Integrated Cancer Services (GICS)
Health Informatics Society of Australia (HISA)
Medical Software Industry Association (MSIA)
National Breast and Ovarian Cancer Centre (NBOCC)
National Coalition of Public Pathology (NCOPP)
National E-Health Transition Authority (NEHTA)
National Pathology Accreditation Advisory Council (NPAAC)
National Round Table Working Party for Structured Pathology Reporting of Cancer.
New Zealand Guidelines Group (NZGG)
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Standards Australia
The Medical Oncology Group of Australia
The Prostate Cancer Foundation of Australia (PCFA)
The Royal Australasian College of Surgeons (RACS)
The Royal Australian and New Zealand College of Radiologists (RANZCR)
The Royal Australian College of General Practitioners (RACGP)
The Royal College of Pathologists of Australasia (RCPA)
The Urological Society Of Australia And New Zealand (USANZ)
Victoria Cancer Council
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Development process

This protocol has been developed following the seven-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols*.¹³

Where no reference is provided, the authority is the consensus of the expert group.

1 Clinical information and surgical handling

This chapter relates to information that should be collected before the pathology test, and to procedures that are required before handover of specimens to the laboratory.

The standards and guidelines in this section specify the particular information and specimens required for prostate cancer. Some of this information can be collected on generic pathology request forms; any additional information required specifically for the reporting of prostate cancer may be recorded on a separate datasheet. Appendix 1 provides a standardised datasheet that may be useful in obtaining all relevant information.

Clinical information relating to presenting symptoms and spread of disease — including pretreatment prostate specific antigen (PSA) — are necessary for staging of the tumour. Details of previous therapy are required because this often impacts upon the grading of the tumour and this needs to be taken into account by the examining pathologist. Similar information is required regardless of whether the specimen is a core biopsy, transurethral resection (TUR) or radical prostatectomy.

Diagnosis of prostate cancer in thin core biopsy, TUR of prostate and prostatectomy specimens cannot be made on clinical grounds alone; rather, the diagnosis relies on histological examination of the specimen (see Chapter 3).

The histopathology report forms part of a patient's permanent medical record and includes information that informs appropriate management. As such, the report provides a method for the recording relevant clinical information that will be permanently available even in the absence of the patient's detailed clinical notes.

S1.01 The Royal College of Pathologists of Australasia (RCPA) *The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers must be adhered to.*¹⁶

CS1.01a This document specifies the minimum information to be provided by the requesting clinician for any pathology test.¹⁶

Items relevant to cancer reporting protocols include:

- patient name
- date of birth and sex
- type of specimen
- date of request
- clinical information relevant to the investigations requested
- identification and contact details of requesting doctor.

CS1.01b Beyond providing identifying information, the age of the patient is necessary for the assessment of the significance of serum PSA levels, as slightly elevated levels in younger patients are of more clinical significance than similar levels in older patients.¹⁷

G1.01 The patient's health identifiers should be recorded where provided.

CG1.01a The patient's health identifiers may include the patient's Medical Record Number as well as a national health number such as a NHI

or UHI.

- G1.02 The pathology accession number of the specimen should be recorded.
- S1.02 The principal clinician involved in the patient's care and responsible for investigating the patient must be identified.**
- CS1.02a The requesting clinician (identified under S1.01) is often the doctor who performs the surgery or biopsy, and may not be the person with overall responsibility for investigating and managing the patient. Identification of the principal clinician is essential, to ensure that clinical information is communicated effectively.
- S1.03 The surgical procedure and nature of the specimen must be clearly stated.**
- CS1.03a For prostatectomy specimens, it is important to state the nature of the surgical procedure — open prostatectomy (for benign disease), or radical prostatectomy (for cancer) and the completeness of excision of the tumour. On those occasions where the surgeon is aware that a surgical incision into the prostate has produced an artificial margin inside the true resection margin, this should be specified in order to ensure that a positive surgical excision margin is not incorrectly reported.
- G1.03 Clinical history should be recorded.
- CG1.03a In many cases the clinical history will influence the ultimate diagnosis and may provide information which will assist in providing prognostic information. Specifically, the Gleason grade and score of prostate cancer in any previously submitted specimen should be provided. This permits assessment of any progression of the tumour towards a more undifferentiated state, which itself is of prognostic significance.
- CG1.03b Symptoms due to prostate cancer are often nonspecific and are often similar to those of benign prostatic hyperplasia. Impotence, priapism or haemospermia may be the presenting feature but such cases are rare. Metastatic tumour is usually associated with bone pain and, in advanced disease, symptoms secondary to organ involvement may be the first clinical evidence of prostate cancer. Most organ-confined prostate cancers are asymptomatic.¹⁸ Approximately 25% of prostate cancers are diagnosed as a result of symptoms and in nearly all of these cases extraprostatic spread of tumour has occurred.¹⁹
- G1.04 Previous therapy should be described.
- CG1.04a Adjuvant radiation and endocrine therapy for prostate cancer has a profound effect on the morphology of both the cancer and the benign prostatic tissue. For this reason, information about any previous therapy is important for the accurate assessment of specimens. This applies to prostate biopsies taken to evaluate local disease or to salvage radical prostatectomy specimens; to transurethral resection of the prostate (TURP) undertaken to relieve obstructive symptoms; and to biopsies of metastatic

tumour.

- CG1.04b Following irradiation, benign, acinar epithelium shows nuclear enlargement and nucleolar prominence²⁰ while basal cells may show cytologic atypia, nuclear enlargement and nuclear smudging.²¹ There may also be increased stromal fibrosis, which may resemble tumour-induced desmoplasia. These changes may persist for a considerable period, have been reported up to 72 months after treatment and are more pronounced in patients who have undergone brachytherapy compared to those who have received external beam radiation therapy.²¹⁻²² It is important to document any previous radiotherapy to help the pathologist to interpret changes accurately. Failure to do so could lead to an incorrect diagnosis of malignancy.
- CG1.04c Radiotherapy has a variable effect on prostate carcinoma. There is debate as to whether or not Gleason grading is appropriate^{20,23} because radiation may be associated with apparent upgrading in prostatectomy specimens.²⁴ It has been suggested that in biopsies undertaken following radiotherapy, tumours that do not show any radiation effect should be graded, while tumours that show a treatment effect should not.²⁵
- CG1.04d Neoadjuvant androgen blockade induces basal cell hyperplasia and cytoplasmic vacuolation in benign prostatic tissue, and this is unlikely to be confused with malignancy.²⁶ The effect of androgen blockage on prostate cancer is variable and an apparent upgrading of the cancer has been reported in a number of studies.^{24,26} The current consensus is that these tumours should not be graded.²⁷
- G1.05 PSA (prebiopsy value) should be recorded.
- CG1.05a Prebiopsy PSA levels are a key factor in stage grouping in the 7th Edition AJCC TNM Staging system¹⁵ (see Chapter 5).
- CG1.05b Despite criticisms about the utility of PSA-based prostate cancer screening, most prostate cancers are detected in asymptomatic men on the basis of PSA testing. Although PSA levels provide some indication of the likelihood of discovering cancer within a biopsy of the prostate, a diagnosis of malignancy should be based on histological findings and should not be influenced by PSA levels. Elevated PSA levels may be due to acute or granulomatous prostatitis and, for this reason, any clinical evidence of prostatitis should be reported to the pathologist as part of the clinical history.¹⁹
- CG1.05c In isolation, PSA levels have a moderately high sensitivity but a low specificity for prostate cancer. Beyond the age of 50 years, PSA levels increase due to an increasing incidence of benign prostatic hyperplasia. There is no cut-off point for PSA levels that is diagnostic for cancer, although the level of 4 ng/mL is widely used as a cutoff point in clinical practice. At higher serum levels the positive predictive value of the test is increased.²⁸ Elevated levels of serum PSA also provide prognostic information; in particular, pretreatment PSA levels have been correlated with

tumour grade and stage.²⁹

- G1.06 Relevant clinical information should be recorded to enable accurate clinicopathological staging (see Chapter 5).
 - CG1.06a Clinical details about the anatomical extent of the tumour should be provided. For radical prostatectomy specimens the details should include a comment about the apparent completeness of resection, the presence or absence of clinically known metastatic disease and the site of any known metastases. Information relating to the presence or absence of extraprostatic tumour, as well as metastases, is rarely evident from examination of the surgical specimen, and details of this should be included in the specimen request form to facilitate accurate staging.
- G1.07 Comments should be included, if appropriate.
 - CG1.07a Space for free text should be included to encourage reporting of ambiguity, or for the addition of other comments.

2 Specimen handling and macroscopic findings

This chapter relates to the procedures required after the information has been handed over from the requesting clinician, and the specimen has been received in the laboratory.

Tissue banking

- G2.01 Pathologists may be asked to provide tissue samples from fresh specimens for tissue banking or research purposes. The decision to provide tissue should only be made if the pathologist is sure that the diagnostic process will not be compromised. As a safeguard, research use of the tissue samples may be put on hold until the diagnostic process is complete.

Specimen handling

- S2.01 The specimen must be handled in a systematic and thorough fashion to ensure completeness and accuracy of pathological data.**

CS2.01a The pathological findings from examination of radical prostatectomy specimens are important in guiding the patient's subsequent clinical management; for example, in predicting a patient's prognosis, or in deciding whether adjuvant therapy such as radiotherapy or chemotherapy is needed. Hence, these specimens must be handled in a systematic and thorough fashion to ensure the completeness and accuracy of the pathological data, such as Gleason score,³⁰ resection margin status, pathological stage etc. The radical prostatectomy specimen may be submitted in its entirety for histological assessment or partially sampled in a standardised manner.

CS2.01b Total and partial sampling methods for examination of radical prostatectomy specimens have been outlined in several articles.³¹⁻³² In summary, the outer surface of the specimen is carefully inked (more than one colour may be used to aid in section orientation) to enable determination of the margin status. The apical segment (distal 10mm) is transversely amputated and sectioned in a perpendicular fashion, generating a series of sagittal slices that are all submitted for histological examination. Likewise, the base of the prostate (bladder neck portion) is transversely amputated and used to generate a series of perpendicular slices that are all submitted. The seminal vesicles can be handled in a variety of ways (eg transverse or longitudinal sections, provided that the junction between each seminal vesicle and the prostate is submitted for histological examination).

Following this, the remaining middle portion of the prostate is serially sectioned transversely at 3–4-mm intervals perpendicular to the rectal surface. These sections are carefully laid out in an orderly manner, and both sides of each slice are macroscopically

examined for the presence of grossly visible tumour. These slices can then be entirely submitted for histological assessment (with the origin of each block recorded on an appropriate diagram, template or macroscopic photograph of the slices). Submitting the entire gland in this fashion facilitates accurate estimation of tumour volume and extent.

Less comprehensive, partial sampling methods have also been described (eg submission of alternate transverse slices or submission of the posterior half of each transverse slice along with a midanterior section from each of the right and left sides.³¹⁻³² However, some studies have found that partial sampling can miss a proportion of cases (15%) with extraprostatic extension and also some with involved resection margins.^{31,33-34}

Macroscopic findings

S2.02 The weight of the prostate gland without the seminal vesicles must be recorded.

CS2.02a Weigh the prostate gland without the seminal vesicles. The seminal vesicles can vary markedly in size; thus, if only a combined weight is recorded, this will introduce error into the measurement of the prostate gland weight and distort comparisons with the radiologically estimated weight. Given this, a working group at the 2009 International Society of Urological Pathology (ISUP) Consensus Conference in Boston recommended that the prostate should be weighed following removal of the seminal vesicles³⁵.

S2.03 Measurements (in millimetres) of prostate gland must be recorded in three dimensions.

CS2.03a Measurements for apex to base, right to left and anterior to posterior enable comparison with data on size of the tumour (eg to estimate the percentage of prostate involved by tumour).

S2.04 The presence or absence of seminal vesicles must be recorded.

CS2.04a If present, measure the greatest dimension in millimetres.

S2.05 The presence or absence of lymph nodes must be recorded.

CS2.05a If present, record site and number. All lymph node tissue should be submitted for histological examination.

G2.02 A descriptive or narrative field should be provided to record any macroscopic information that is not recorded in the above standards and guidelines, and that would normally form part of the macroscopic description.

CG2.02a The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from the cancer dataset. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure

of this protocol.

CG2.02b Much of the information recorded in a traditional macroscopic narrative is covered in the standards and guidelines above and in many cases, no further description is required.

3 Microscopic findings

This section relates to purely histological or morphological assessment. Information derived from multiple investigational modalities, or from two or more chapters, is described in Chapter 5.

S3.01 The tumour type must be recorded as adenocarcinoma (with subclassification) or 'other' (with type).

CS3.01a The classification for 'other' tumours is described in the WHO 2004 classification).¹⁴

G3.01 The tumour location should be recorded.

CG3.01a In what quadrant does the tumour appear? (Specify for the dominant or largest tumour nodule, and also for other nodules >10 mm diameter, if present).

Specify whether right anterior, right posterior, left anterior or left posterior.

CG3.01b Specify location in another plane (eg apex, mid, base of prostate). This information is important for correlation with needle biopsy findings, imaging results, etc.

G3.02 A three-dimensional volume or size estimate should be recorded for the dominant (largest) tumour nodule.

CG3.02a A qualitative descriptor (eg minimal/insignificant, unifocal, multifocal/extensive) should be recorded. This is particularly important for patients with tumours that are minute or histologically difficult to identify, who can be then be appropriately clinically counselled (see CG3.02c below).

CG3.02b It is highly desirable that a three-dimensional volume estimate of the dominant tumour nodule (ie length [cm] × width [cm] × number of involved blocks × block thickness [cm] × 0.4) is given (see CG3.02d below).

(Note that centimetres, a non SI unit, have been deliberately used here to make the calculation much simpler, producing a result in cm³, i.e. mL).

CG3.02c The significance of tumour volume in radical prostatectomy specimens has been somewhat controversial.³² Tumour volume is a prognostic factor in univariate analysis, but in most studies is not an independent prognostic factor in multivariate analysis³⁶⁻³⁸ correlating with Gleason score, pathological stage and margin status.³⁹ Moreover, the irregular distribution and commonly multifocal nature of prostate cancers renders calculations of tumour volume problematic, while partial sampling methods also may have an adverse impact on the accuracy of such estimates. Hence, qualitative descriptors of disease extent (eg minimal/insignificant, unifocal and multifocal/extensive) have often been used, with an insignificant/minimal tumour usually being defined as having a volume of <0.5 cm³⁴⁰ negative margins, Gleason score ≤6, and no EPE (ie are organ confined).⁴¹ Patients with such tumours have a close to 100% biochemical

recurrence free survival.⁴²

Recently, a working group at the 2009 ISUP Consensus Conference in Boston proposed simplifying this definition of clinically insignificant cancer by using an easily measured cut-off point of <10 mm greatest diameter for the dominant nodule instead of tumour volume <0.5 cm³.⁴³

CG3.02d The time and labour-intensive determination of tumour volume using standard methods, such as computerised planimetry or image analysis, is not recommended for routine pathology practice. However, simplified, more readily applicable methods have been developed. Predictions of the risk of disease recurrence based on the volume of the dominant (largest) tumour nodule appear to be comparable to those based on the total tumour volume.⁴⁴⁻⁴⁶ Hence, it is recommended that, as required in the College of American Pathologists protocol,⁸ the dominant tumour nodule is measured in two planes at approximately right angles to each other (on the slide where the tumour has the greatest area). The third dimension is estimated by counting the number of sections involved by the tumour nodule in the third plane, then multiplying by the block thickness, which is usually 0.3 or 0.4 cm (length × width × number of involved blocks × block thickness).

Chen et al⁴⁶ have then demonstrated that multiplying the resulting product by a constant of 0.4, to allow for the irregular shape of most prostate cancers, gives an estimate of tumour volume comparable to that derived from much more time and labour-intensive standard computer-assisted quantitative methods. This method is also relatively accurate in predicting tumour volume in radical prostatectomy specimens assessed by the alternate section partial sampling method.⁴⁶

**S3.02 The Gleason score (ISUP 2005) must be recorded.³⁰
(see Tables S3.02a-d)**

CS3.02a The Gleason grading system has been in use for over 40 years and is now the accepted grading system for prostate cancer throughout the world.⁴⁷ Over time it has undergone a number of modifications, the most recent of which was developed at the 2005 ISUP Consensus Conference on Gleason Grading of Prostatic Carcinoma.³⁰ The Gleason score is an important predictor of tumour behaviour and is a key parameter in the tables and nomograms, such as Partin tables and Kattan nomograms, which are typically used to guide clinical treatment decisions.¹¹⁻¹² A Gleason score must be stated for all prostatic specimens containing adenocarcinomas except for those showing morphological changes consistent with androgen withdrawal.

CS3.02b The method for Gleason scoring is described in the 2005 ISUP Consensus Conference recommendations.³⁰ In line with these recommendations, the Gleason score for radical prostatectomy specimens is assigned from assessment of the dominant nodule (ie the largest nodule). In contrast to needle biopsy specimens, for radical prostatectomy specimens, the entire tumour nodule or nodules is available for examination, and the Gleason score is derived by adding the primary grade (or the primary pattern; ie

that occupying the greatest area) to the secondary grade (ie the pattern occupying the second largest area).

Usually, the dominant nodule has the highest Gleason score; however, in the unusual situation where there is a smaller nodule (nondominant nodule) that is composed of higher Gleason grade patterns, the Gleason score of that nodule is also reported. As pointed out in the 2005 ISUP consensus paper,³⁰ if there is a nodule of Gleason score 4+4=8 in the peripheral zone and a separate, larger nodule of 2+2=4 in the transition zone, it is not logical to expect that the presence of a discrete lower grade tumour could in some way mitigate the poor prognosis associated with the higher grade tumour. In such situations, the Gleason score of both nodules is recorded rather than assigning a misleading score of 2+4=6.

CS3.02c In radical prostatectomy specimens the dominant or highest grade nodule may show more than two Gleason patterns or grades. The grade that is the third most prevalent (ie occupies the third largest area in the tumour nodule) is referred to as the tertiary grade.⁴⁸ In a radical prostatectomy specimen, where the tertiary grade is higher than the primary or secondary grades (usually grade 5 or 4) the tertiary grade is also recorded.⁴⁹ There is an increasing volume of evidence that small volumes of tertiary grade 5 patterns (and to a lesser extent tertiary grade 4) are associated with aggressive pathological features and a higher risk of biochemical recurrence.⁵⁰⁻⁵⁶

Table S3.02a Gleason grading

Gleason grade	Criteria	Comments
1	Closely packed small regular glands forming a circumscribed rounded nodule	Very rarely use in radical prostatectomy specimen reports. Do not use for needle biopsy specimens
2	Glands more loosely arranged; not quite as uniform; fairly circumscribed but may have minimal infiltration at margins	May be used in radical prostatectomy and TURP specimen reports. Do not use for needle biopsies
3	Discrete glandular units/acini with marked variation in size and shape; infiltrates in and amongst benign prostatic tissue Very rarely cribriform (see below)	
4	Fused micro acinar glands; ill-defined glands with poorly formed lumina; large cribriform irregular glands; hypernephroid	
5	Minimal if any glandular differentiation – solid sheets, cords or single cells. Comedocarcinoma	

Table S3.02b Gleason scoring

Number of different grades present	Proportion of grades present	Comments
1	One of 2, 3, 4 or 5 only	Double grade to get score (eg 4+4=8) Record for dominant nodule +/- nondominant (smaller) nodule if of higher grade (if present)
2 – Primary and secondary	Grades mixed	Report both grades, dominant pattern* first (2+3, 3+4, 4+3 ..) Record for dominant nodule +/- nondominant (smaller) nodule if of higher grade (if present)
	Secondary grade is lower and of limited amount (<5%)	Ignore lower grade – 4+3 becomes 4+4 Record for dominant nodule +/- non dominant (smaller) nodule if of higher grade (if present)
	Secondary grade is higher and of limited amount (<5%)	Include higher grade – 3+3 becomes 3+4 Record for dominant nodule +/- non dominant (smaller) nodule if of higher grade (if present)
3 – Primary, secondary and tertiary	Grades 2, 3, 4 or 5	Report dominant grade (largest area) first, then secondary grade (second largest area), then tertiary grade (only if 4 or 5) eg 3+4=7 with tertiary grade 5 eg 2+3=5 with tertiary grade 4 Record for dominant nodule +/- non dominant (smaller) nodule if of higher grade (if present)

Notes:

Dominant (primary) grade is that which occupies the greatest area.

For radical prostatectomy specimens secondary grade is defined as that which occupies the second greatest area.

For radical prostatectomy specimens tertiary grade is defined as that which occupies the third greatest area (provided that it is higher than the primary and secondary grades).

Table S3.02c Gleason scoring of cribriform patterns

Cribriform pattern	Morphology	Comments
Grade 3	Small, well circumscribed, round with smooth regular edges	Rare. Should be used only rarely in scoring
Grade 4	Irregular cribriform and fused gland masses	Should include nearly all cribriform patterns
Grade 5	Any cribriform area with necrosis	Comedonecrosis
PIN		Do not include in score
Intraductal carcinoma	Branched architecture of high grade intraductal proliferation filling lumen	Include as Grade 4 (or 5 if comedonecrosis)

PIN = prostatic intraepithelial neoplasia

Table S3.02d Gleason scoring of unusual patterns

Pattern	Morphology	Comment
Vacuoles	Cytoplasmic change seen in all grades	Grade as if vacuoles were absent, on the underlying architecture
Mucin extravasation		Grade as if were absent
Mucinous fibroplasia	Collagenous micronodules	Grade as if were absent
Glomeruloid structures		Grade as 4
Foamy gland change		Grade as if were absent
Small cell neuroendocrine		Do not assign a grade

S3.03 Extraprostatic extension (EPE) must be recorded.
(see Figure S3.03)

- CS3.03a Extraprostatic extension (EPE) refers to the presence of neoplastic glands outside the prostate in the periprostatic tissue. This became accepted terminology at a 1996 Consensus Conference,⁵⁷ and replaces terms such as extracapsular or extraglandular invasion, penetration, and perforation.
- CS3.03b Specify whether the EPE is negative, focal or extensive (see definitions in CS3.03f).
- CS3.03c Specify the location of the EPE (ie quadrant and base/mid/apex).
- CS3.03d The assessment of EPE can be difficult, as the prostate is not surrounded by a discrete, well defined fibrous capsule. Adding to the difficulty, Chuang and Epstein⁵⁸ note that there is often a fibrotic reaction in the vicinity of EPE, and the neoplastic extraprostatic glands are often seen in fibrous tissue, not fat. Therefore, EPE can be identified in several different situations and can be diagnosed by one of the following:
- The presence of neoplastic glands abutting or within periprostatic fat (most useful at the lateral, posterolateral and posterior aspects of the gland).
 - Neoplastic glands surrounding nerves in the neurovascular bundle (posterolaterally).
 - The presence of a nodular extension of tumour beyond the periphery of the prostate. This latter situation is best identified at low power magnification. In this assessment, the edge of the prostate is defined as the plane between fat and the condensed fibromuscular prostatic stroma which is best initially determined in a region without distortion by tumour. Tracking along the edge of the prostate at low power, EPE is present when there is bulging of the tumour beyond the normal rounded contour of the prostate gland.
- CS3.03e A 'capsule' cannot be readily identified at the base or apex, and in these sites it is more important to comment on the margins and adequacy of excision. It can be particularly challenging for pathologists to identify the boundary of the prostate gland at the apex. At this site, benign glands are frequently admixed with skeletal muscle and the presence of neoplastic glands in skeletal muscle does not necessarily constitute EPE at the apex. The majority of survey respondents at the 2009 ISUP Consensus Conference in Boston believe there is no reliable method to diagnose EPE in sections from the prostatic apex⁵⁹.
- Similarly, the assessment of EPE at the anterior aspect of the prostate may be difficult as the prostatic stroma blends in with extraprostatic fibromuscular tissue, but in this region EPE can be diagnosed when the carcinoma appears to extend beyond the margin of the normal prostatic glandular tissue (see the 3rd bullet point in CS3.03d).
- CS3.03f The degree of extraprostatic extension can be further classified as focal or extensive (also referred to as 'established' or 'nonfocal').

Focal is defined as extraprostatic glands which occupy no more than one high power field on no more than two sections.³⁶ Extensive EPE represents anything more than this.

CS3.03g The identification of any extraprostatic extension is important, as both focal and extensive EPE are associated with a significantly higher risk of recurrence at both 4 and 10 years.³⁷ In one study of prediction of progression following radical prostatectomy,³⁷ the risk of disease progression in node negative patients with negative seminal vesicles at 10 years for organ confined disease was 16%, focal EPE 33% and extensive EPE 42% (all values significant $P = 0.001$).

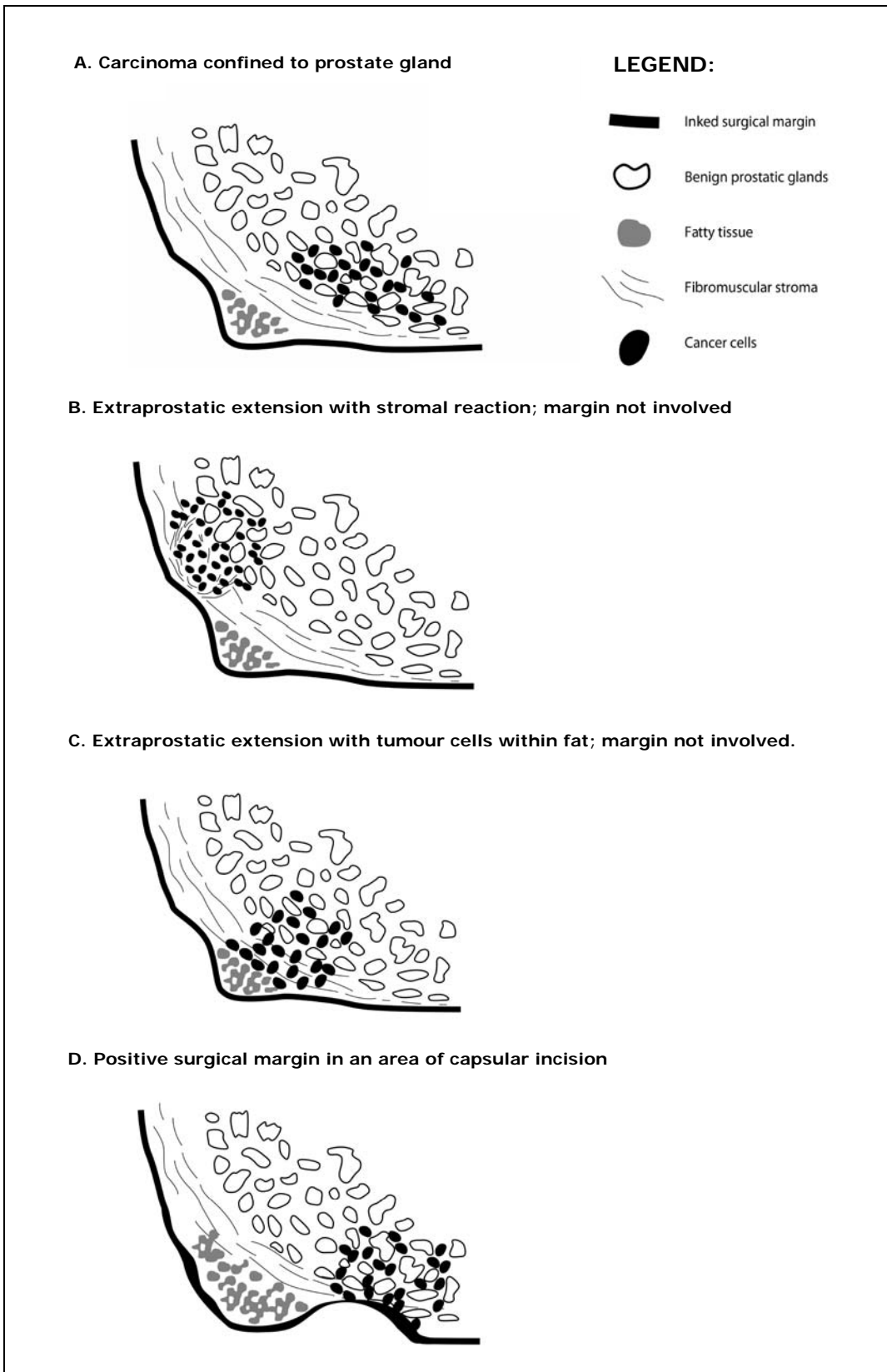


Figure S3.03 Extraprostatic extension.

S3.04 Margin involvement must be recorded.

- CS3.04a Record the following details about any involved resection/surgical margin(s):
- whether it is negative, positive or equivocal for cancer (see definition in CS3.04b and CS3.04c)
 - the length (in millimetres)
 - whether it is extraprostatic or intraprostatic (capsular incision)
 - the location (apex, bladder neck, anterior, lateral, posterolateral, posterior).

CS3.04b A positive surgical margin (PSM) is defined as cancer extending to an inked surface of the specimen, presumably representing a site where the urologist has cut through cancer.^{32,49} A true positive margin must be distinguished from that produced by the pathologist's knife which is relatively sharp and may show contamination by ink carried over by the knife. A positive surgical margin can have a significant adverse impact on progression-free survival, including PSA recurrence-free survival, local recurrence-free survival and development of metastases after radical prostatectomy in multivariate analysis.^{49,60-61}

CS3.04c Carcinoma close to but not involving the margin should not be labelled as a PSM because this feature has been shown to have no prognostic significance.⁶²⁻⁶⁴ Specifically, carcinoma that extends very close to a smooth inked margin (eg carcinoma separated from the ink by a 1 or 2 strands of fibrous tissue or fibroblasts), is not considered a positive margin. This is most commonly seen posterolaterally in cases where neurovascular bundle preservation leaves virtually no extraprostatic tissue. Studies on such cases showed that additional tissue removed from these sites did not contain any carcinoma and the prognosis was not worsened.⁶²⁻⁶³

In very rare cases, it can be impossible to ascertain whether the surgical margin is truly positive.⁶⁵ This can be due to marked crush or thermal artefact causing glandular distortion along the margin so that it cannot be histologically determined whether the crushed glands are malignant or whether the margin is actually positive rather than artificially retracted due to heat coagulation or tissue compression. This can be associated with haemostatic staples, surgical dissection or retraction. On these rare occasions, the margins should be reported as equivocal.

Another cause of difficulty is irregular tracking of ink in areas of tears or lacerations.⁶⁵⁻⁶⁶ This can occur during handling of the specimen in the operating theatre, transportation or processing in the laboratory. It is important not to misdiagnose PSM, as some of these patients receive postoperative radiotherapy with the associated risk of significant complications.⁶⁷

CS3.04d Measurement of the length of PSM is useful to ascertain the extent of margin involvement, which has been shown to be a significant prognostic factor.⁶⁶ The extent of carcinoma at an involved surgical/resection margin correlates with the rate of

postoperative disease recurrence.^{62-64,68}

CS3.04e Intraprostatic margin involvement or capsular incision (CI) occurs when the urologist inadvertently develops the resection margin within the plane of the prostate rather than outside the capsule. CI with a positive surgical margin is diagnosed when malignant glands are cut across adjacent to benign prostatic glands.⁵⁸ In these cases, the edge of the prostate in this region is left in the patient. Data on the prognostic significance of CI vary among studies.⁶⁹⁻⁷¹ According to the largest series published, a significantly higher recurrence rate is found in patients with CI/intraprostatic margin involvement than in patients with organ confined disease with negative margins, or focal EPE with negative margins, although CI has a significantly better outcome than that associated with extensive/nonfocal EPE and positive margins.⁶⁸

Margin involvement associated with EPE is diagnosed when malignant glands in extraprostatic tissue are transected by the resection margin. This can be difficult to distinguish from capsular incision in some cases, particularly posteriorly and posterolaterally if there is a desmoplastic reaction. Cancer extending to a margin which is beyond the normal contour of the prostate gland, or beyond the compressed fibromuscular prostatic stroma at the outer edge of the prostate, can be diagnosed as a positive surgical margin with EPE, similarly to margin involvement when there is cancer in adipose tissue.⁷⁰ At the apex, the histological boundaries of the prostate gland can be difficult to define and again EPE with a positive margin can be difficult to differentiate from CI/intraprostatic margin involvement. Hence, if carcinoma extends to an inked margin at the apex where benign glands are not transected, this is considered a positive margin in an area of EPE by some authors.^{49,70} In contrast, other authors, and the majority of survey participants at the 2009 ISUP Consensus Conference, believe there is no reliable method to diagnose EPE in sections from the prostatic apex (see CS3.03e)⁵⁹.

CS3.04f Stating the location of the PSM is useful information for the urologist who can then modify future operations to avoid iatrogenic margin positivity and increase the likelihood of curative surgery. The site of the PSM and the number of positive margins have been shown to influence biochemical recurrence and risk of progression. For instance, a margin involving the bladder neck or the posterolateral surface of the prostate has a more significant adverse impact on prognosis than an involved apical or anterior margin.⁷²⁻⁷³

S3.05 Presence or absence of seminal vesicle involvement must be recorded.

CS3.05a State if seminal vesicles are involved (positive) or not involved (negative).

Seminal vesicle involvement (SVI) is defined as carcinomatous invasion of the muscular wall of the seminal vesicle exterior to the prostate.⁷⁴⁻⁷⁵

CS3.05b If one or more of the seminal vesicles are involved by cancer,

specify whether left side, right side or both.

- CS3.05c SVI is a well established independent adverse prognostic factor^{49,76-78} and is an integral component of the commonly used nomograms that predict risk of post prostatectomy cancer recurrence.¹¹⁻¹² The finding of SVI at the time of radical prostatectomy is an adverse finding that confers an increased risk of PSA recurrence exceeded only in magnitude by the presence of lymph node metastasis.⁷⁵⁻⁷⁶ The presence of SVI and a positive resection/surgical margin may also influence the response to adjuvant radiotherapy.^{75-76,79}

S3.06 Lymph node status must be recorded.

- CS3.06a State whether lymph nodes are received or not.
- CS3.06b If lymph nodes are received then state whether the lymph nodes are involved (positive) or not (negative). If involved specify:
- number of nodes positive compared with the total number of nodes
 - site of involved lymph nodes.
- CS3.06c Lymph node involvement is a well established independent adverse prognostic factor^{32,49,76} and is an integral component of the commonly used nomograms that predict the risk of post prostatectomy disease recurrence.¹¹⁻¹² There is insufficient evidence at present to support the routine use of immunohistochemistry in the pathological assessment of lymph node involvement.

G3.03 Lymphovascular invasion should be recorded.

- CG3.03a Lymphovascular invasion (LVI) is defined as the unequivocal presence of tumour cells within endothelial-lined spaces with no underlying muscular walls. Retraction and other artefacts should be excluded. LVI is an independent predictor of disease recurrence in multivariate analysis.⁸⁰⁻⁸¹

G3.04 Comments should be included, if appropriate.

- CG3.04a Free text entry to allow any additional, unusual or unexpected findings to be reported.

General commentary

Bladder neck involvement may be reported.

Microscopic bladder neck involvement can be defined as the presence of neoplastic glands within the thick smooth muscle bundles of the bladder neck (in coned sections – see CS2.01b) in the absence of associated benign prostatic glandular tissue. Specifically, neoplastic glands intermixed with benign prostatic glands at the bladder neck is equivalent to capsular incision rather than true bladder neck invasion.⁸²⁻⁸⁴

Microscopic bladder neck involvement is a significant predictor of PSA-recurrence in univariate analysis but not in multivariate modelling in most, but not all, studies.⁸⁴⁻⁸⁶

Microscopic bladder neck involvement by prostatic carcinoma should be considered as stage pT3 disease while the finding of gross involvement by the urologist is necessary for designation as pT4a disease.⁸⁷

The tumour zone may be reported.

Specification of zones (ie peripheral, central, transition) involved by tumour may be included, if desired. Zonal location of prostate cancer is not an independent prognostic indicator on multivariate analysis. The zonal location of the cancer can be difficult to determine with tumours commonly overlapping the peripheral and transition zones.

The Gleason (ISUP 2005) grade of carcinoma at the involved margin may be reported.

The recording of the Gleason grade of the tumour at the positive surgical margin is optional. At present, there is insufficient evidence that this feature is a significant prognostic factor to routinely recommend this.

4 Ancillary studies findings

No ancillary tests are currently used on a routine diagnostic basis for prostate cancer.

5 Synthesis and overview

Information that is synthesised from multiple modalities and therefore cannot reside solely in any one of the preceding chapters is described here.

For example, *tumour stage* is synthesised from multiple classes of information – clinical, macroscopic and microscopic.

By definition, synthetic elements are inferential rather than observational, often representing high-level information that is likely to form part of the 'Summary' or 'Diagnosis' section in the final formatted report.

Overarching case comment is synthesis in narrative format. Although it may not necessarily be required in any given report, the provision of the facility for overarching commentary in a cancer report is essential.

S5.01 The tumour stage must be recorded according to the AJCC/UICC TNM system (7th edition).¹⁵ Used with the permission of the American Joint Committee on Cancer (AJCC), Chicago, Illinois. The original source for this material is the AJCC Cancer Staging Manual, Seventh Edition (2010) published by Springer Science and Business Media LLC, www.springerlink.com.

CS5.01a *Pathologic primary tumor (T)*

pTX Primary tumor cannot be assessed

pT0 No evidence of primary tumor

*

pT2 Organ Confined

pT2a Unilateral, one-half of one side or less

pT2b Unilateral, involving more than one-half of side but not both sides

pT2c Bilateral disease

pT3 Extraprostatic extension

pT3a Extracapsular extension or microscopic invasion of bladder neck**

pT3b Seminal vesicle invasion

pT4 Invasion of rectum, levator muscles and/or pelvic wall.

Notes:

1. Invasion into the prostate apex or into (but not beyond) the prostate capsule is not classified as T3, but as T2.

**Note:* There is no pathologic T1 classification

** *Note:* Positive surgical margin should be indicated by an R1 descriptor (residual microscopic disease)

Pathologic regional lymph nodes (N)

pNX Regional lymph nodes not sampled.

pN0 No positive regional nodes.

pN1 Metastasis in regional node(s).

Clinical and pathologic 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. pM1c is most advanced.

G5.01 The 'Diagnostic summary' section of the final formatted report should include:

- a. specimen type (S1.03)
- b. tumour type (S3.01)
- c. Gleason score (S3.02)
- d. tumour stage (S5.01)
- e. whether or not the specimen margins are involved (S3.04)

S5.02 The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment.

CS5.02a This field may be used, for example, to:

- explain the decision-making pathway, or any elements of clinicopathological ambiguity, or factors affecting diagnostic certainty, thereby allowing communication of diagnostic subtlety or nuance that is beyond synoptic capture
- give recommendations for further action or investigation
- document further consultation or results still pending.

CS5.02b Use of this field is at the discretion of the reporting pathologist.

6 Structured checklist

The following checklist includes the standards and guidelines for this protocol which must be considered when reporting, in the simplest possible form. The summation of all 'standards' is equivalent to the 'minimum data set' for prostate cancer. For emphasis, standards (mandatory elements) are formatted in bold font.

- S6.01 The structured checklist provided may be modified as required but with the following restrictions:**
- a. All standards and their respective naming conventions, definitions and value lists must be adhered to.**
 - b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.**
- G6.01 The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities.
- CG6.01a Where the LIS allows dissociation between data entry and report format, the structured checklist is usually best formatted to follow pathologist workflow. In this situation, the elements of synthesis or conclusions are necessarily at the end. The report format is then optimised independently by the LIS.
- CG6.01b Where the LIS does not allow dissociation between data entry and report format, (for example where only a single text field is provided for the report), pathologists may elect to create a checklist in the format of the final report. In this situation, communication with the clinician takes precedence and the checklist design is according to principles given in Chapter 7.
- G6.02 Where the checklist is used as a report template (see G6.01), the principles in Chapter 7 and Appendix 2 apply.
- CG6.02a All extraneous information, tick boxes and unused values should be deleted.

Clinical information and surgical handling

S1.01	Patient name	_____
	Date of birth	_____
	Sex	_____
	Identification and contact details of requesting doctor	_____
	Type of specimen	_____
	Date of request	_____
	Clinical information relevant to the investigations requested	_____ _____
G1.01	Patient identifiers (eg MRN, UHI, NHI)	_____ _____
G1.02	Pathology accession number	_____
S1.02	Principal clinician	_____
S1.03	Surgical procedure	_____
	Nature of specimen	_____
G1.03	Clinical history (including Gleason grade and score of previous specimens)	_____ _____
G1.04	Previous therapy	_____
G1.05	PSA (prebiopsy) value	_____

G1.06 Relevant clinical information for clinicopathological staging _____

G1.07 Comments _____

Macroscopic findings

S2.02 **Weight of prostate gland without seminal vesicles** _____

S2.03 **Size of prostate gland (in mm):**
Apex–base _____ mm
Right–left _____ mm
Anterior–posterior _____ mm

S2.04 **Seminal vesicles:**
Present _____
Absent _____
Size (greatest dimension) _____ mm

S2.05 **Lymph nodes:**
Present _____
Absent _____
Site _____
Number _____

G2.02 Comments _____

Microscopic findings

S3.01 Tumour type

Adenocarcinoma _____

Subclassification _____

Other _____

Type _____

G3.01 Tumour location (largest nodule):

Right anterior _____

Right posterior _____

Left anterior _____

Left posterior _____

Other _____

Tumour location (other
nodules >10 mm) _____

G3.02 Tumour volume estimate _____ cm³

Qualitative description _____

S3.02 Gleason score:

Primary _____

Secondary _____

Tertiary _____

S3.03 Extraprostatic extension (EPE):

Negative _____

Focal _____

Extensive _____

Location _____

S3.04 Margin involvement:

Negative ___

Positive ___

Equivocal ___

Extraprostatic ___

Intraprostatic ___

Location _____

Length of margin involvement (in mm) ___

S3.05 Seminal vesicles:

Positive ___

Negative ___

If positive:

Left side ___

Right side ___

Both ___

S3.06 Lymph nodes:

Positive ___

Negative ___

If positive:

Left side ___

Right side ___

Both ___

Site ___

G3.03 Lymphovascular invasion:

Present ___

Absent ___

G3.04 Comments

Synthesis and overview

**S5.01 Tumour stage
(AJCC/UICC):**

T ____

N ____

M ____

G5.01 Diagnostic summary

S5.02 Comments

7 Formatting of pathology reports

Good formatting of the pathology report is essential for optimising communication with the clinician, and will be an important contributor to the success of cancer reporting protocols. The report should be formatted to provide information clearly and unambiguously to the treating doctors, and should be organised with their use of the report in mind. In this sense, the report differs from the structured checklist, which is organised with the pathologists' workflow as a priority.

Uniformity in the format as well as in the data items of cancer reports between laboratories makes it easier for treating doctors to understand the reports; it is therefore seen as an important element of the systematic reporting of cancer. For guidance on formatting pathology reports, please refer to Appendix 2. An example of a pathology report is shown in Appendix 3.

Appendix 1 Pathology request form for prostate cancer

S1.01	Patient name	_____
	Date of birth	_____
	Sex	_____
	Identification and contact details of requesting doctor	_____
	Type of specimen	_____
	Date of request	_____
	Clinical information relevant to the investigations requested	_____ _____
G1.01	Patient identifiers (eg MRN, UHI, NHI)	_____ _____
S1.02	Principal clinician	_____
S1.03	Surgical procedure	_____
	Nature of specimen	_____
G1.03	Clinical history (including Gleason grade and score of previous specimens)	_____ _____
G1.04	Previous therapy	_____
G1.05	PSA (prebiopsy) value	_____

G1.06 Relevant clinical information for clinicopathological staging

G1.07 Comments

Appendix 2 Guidelines for formatting of a pathology report

Layout

Headings and spaces should be used to indicate subsections of the report, and heading hierarchies should be used where the LIS allows it. Heading hierarchies may be defined by a combination of case, font size, style and, if necessary, indentation.

Grouping like data elements under headings and using 'white space' assists in rapid transfer of information.⁸⁸

Descriptive titles and headings should be consistent across the protocol, checklist and report.

When reporting on different tumour types, similar layout of headings and blocks of data should be used, and this layout should be maintained over time.

Consistent positioning speeds data transfer and, over time, may reduce the need for field descriptions or headings, thus reducing unnecessary information or 'clutter'.

Within any given subsection, information density should be optimised to assist in data assimilation and recall. The following strategies should be used:

- Configure reports in such a way that data elements are 'chunked' into a single unit to help improve recall for the clinician.⁸⁸
- Reduce 'clutter' to a minimum.⁸⁸ Thus, information that is not part of the protocol (eg billing information or Snomed codes) should not appear on the reports or should be minimised.
- Reduce the use of formatting elements (eg bold, underlining or use of footnotes) because these increase clutter and may distract the reader from the key information.

Where a structured report checklist is used as a template for the actual report, any values provided in the checklist but not applying to the case in question must be deleted from the formatted report.

Reports should be formatted with an understanding of the potential for the information to 'mutate' or be degraded as the report is transferred from the LIS to other health information systems.

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost
- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print
- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting
- supplementary reports may merge into the initial report.

Appendix 3 Example of a pathology report

Citizen, George W. C/O Paradise Close Guantanamo Bay Resort Nar Nar Goon East, 3181 Male DOB 1/7/1951 MRN FMC1096785	Lab Ref: 09/P28460 Referred: 30/2/2009	Copy to: Dr G. Gleason Rainforest Cancer Centre. 46 Smith Road, Woop Woop, 3478	Referred by: Dr V. Smith Suite 3, AJC Medical Centre, Bunyip Crescent Nar Nar Goon West, 3182
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RADICAL PROSTATECTOMY STRUCTURED REPORT Page 1 of 2

Diagnostic Summary

Radical prostatectomy:

Adenocarcinoma, Gleason (ISUP 2005) 4+3 = 7, tertiary grade 5, AJCC Stage T3a, N0, M0; margin involvement (R1).

- Comment:
1. Focal urothelial carcinoma *in situ* (CIS) is noted in the prostatic urethra. The urethral resection margin appears clear.
 2. Equivocal margin involvement (due to crush artefact) by prostatic adenocarcinoma is noted at the apex focally.

Supporting Information

CLINICAL

Specimen type: Radical prostatectomy
PSA: 8.9µg/L
Symptoms: Nil
Clinical stage: No known metastases
Previous biopsy: Gleason 3+3=6
Treatment: Nil

MACROSCOPIC

Weight:
 + Seminal Vesicles: 30g
 - Seminal vesicles: 23g
Dimensions: 40 x 37 x 30mm
Seminal vesicles:
 left: present, 40mm
 right: present, 50mm
Lymph nodes:
 Right pelvic: 1 received
 Left pelvic: 1 received

MICROSCOPIC

Histological type (WHO): Adenocarcinoma
Tumour location:
 Dominant nodule - Right anterior and posterior quadrants in the apex and mid prostate, focally crosses midline posteriorly
 Non-dominant (>10mm): Left posterior quadrant at base
 Smaller nodules: Present
Volume/size - Extensive multifocal
 Dominant nodule - 3.7ml = 2.2cmx2.0cmx7x0.3cmx0.4 (Chen's method)
Gleason score (ISUP2005): Dominant nodule 4+3=7. Tertiary grade 5 present
Extraprostatic extension: Present, focal (Wheeler's definition), right posterior quadrant
Surgical margin: Positive in the right posterior quadrant in an area of EPE, 1.3mm linear extent

MICROSCOPIC (cont.)

Seminal vesicles:	Not involved
Lymph nodes:	2 lymph nodes, not involved
Lymphovascular invasion:	Not identified
Bladder neck:	Not involved
Comment:	N/A

Reported by Dr Bernard Beckstein

Authorised 4/3/2009

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