CARCINOMA OF THE PENIS STRUCTURED REPORTING PROTOCOL

(1st Edition 2018)

Incorporating the:

International Collaboration on Cancer Reporting (ICCR)

Dataset for the reporting of Carcinoma of the Penis and Distal Urethra

www.ICCR-Cancer.org
Core Document versions:

1. ICCR Dataset for the Reporting of Carcinoma of the Penis and Distal Urethra 1st edition
2. AJCC Cancer Staging Manual 8th edition
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   o Numbering of Standards and Guidelines must be retained in the checklist, but can be reduced in size, moved to the end of the checklist item or greyed out or other means to minimise the visual impact.
   o Additional items for local use may be added but must not be numbered as a Standard or Guideline, in order to avoid confusion with the RCPA checklist items.
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The Royal College of Pathologists of Australasia ("College") has developed these protocols as an educational tool to assist pathologists in reporting of relevant information for specific cancers. Each protocol includes "standards" and "guidelines" which are indicators of ‘minimum requirements’ and ‘recommendations’, which reflect the opinion of the relevant expert authoring groups. The use of these standards and guidelines is subject to the clinician’s judgement in each individual case.

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Scope

This protocol contains standards and guidelines for the reporting of specimens from patients with carcinoma of the penis, including resection, biopsy and lymphadenectomy. The protocol applies to primary carcinoma of the penis, as well as distal urethral squamous carcinomas. Proximal urethral tumours of the prostatic and bulbar urethra, which are usually of urothelial origin, are covered in the urethrectomy dataset.

Skin cancer of the penile shaft, appendage tumours, melanomas and proximal/prostatic urethral carcinomas are not included in the scope of the dataset – separate protocols are available and should be used for these carcinomas.

Structured reporting aims to improve the completeness and usability of pathology reports for clinicians, and improve decision support for cancer treatment. The protocol provides the framework for the reporting of specimens of carcinoma of the penis, whether as a minimum data set or fully comprehensive report.
Abbreviations

AJCC  American Joint Committee on Cancer
CG    Commentary for a guideline
CS    Commentary for a standard
FISH  Fluorescent in-situ hybridization
ICCR  International Collaboration on Cancer Reporting
ISUP  International Society of Urological Pathology
LIS   laboratory information system
LVI   lymphovascular invasion
PeIN  Penile intraepithelial neoplasia
PBS   Pharmaceutical Benefits Scheme
RCPA  Royal College of Pathologists of Australasia
SCC   Squamous cell carcinoma
TNM   tumour-node-metastasis
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 “pre-test information”.

Commentary
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).

Commentary is used to:

• define the way an item should be reported, to foster reproducibility
• explain why an item is included (e.g. how does the item assist with clinical management or prognosis of the specific cancer).

• cite published evidence in support of the standard or guideline
• state any exceptions to a standard or guideline.

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 (e.g. CS1.01a, CG2.05b).

General commentary
General commentary is text that is not associated with a specific standard or guideline. It is used:

• 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  Guidelines are recommendations; they are not mandatory, as indicated by the use of the word 'should'. Guidelines cover items that are unanimously agreed should be included in the dataset but are not supported by NHMRC level III-2 evidence. These elements may be clinically important and recommended as good practice but are not yet validated or regularly used in patient management.

Guidelines include key information other than that which is essential for clinical management, staging or prognosis of the cancer such as macroscopic observations and interpretation, which are fundamental to the histological diagnosis and conclusion eg macroscopic tumour details, block identification key, may be included as either required or recommended elements by consensus of the expert committee. Such findings are essential from a clinical governance perspective, because they provide a clear, evidentiary decision-making trail.

Guidelines are not used for research items.

In this document, guidelines are prefixed with ‘G’ and numbered consecutively within each chapter (eg G1.10).

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 histomorphological assessment.

Predictive factor  A predictive factor is a measurement that is associated with response or lack of response to a particular therapy.

Prognostic factor  A prognostic factor is a measurement that is associated with clinical outcome in the absence of therapy or with the application of a standard therapy. It can be thought of as a measure of the natural history of the disease.

Standard  Standards are mandatory, as indicated by the use of the term ‘must’. Standards are essential for the clinical management, staging or prognosis of the cancer. These elements will either have evidentiary support at Level III-2 or above (based on prognostic factors in the NHMRC levels of evidence document). In rare circumstances, where level III-2 evidence is not available an element may be made a Standard where there is unanimous agreement in the expert committee. An appropriate staging system eg Pathological TNM staging would normally be included as a required element. These elements must be recorded and at the discretion of the pathologist included in the pathology report according to the needs of the recipient of the report.

The summation of all standards represents the minimum dataset for the cancer.

In this document, standards are prefixed with ‘S’ and numbered consecutively within each chapter (eg S1.02).
<table>
<thead>
<tr>
<th>Structure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Structured report</strong></td>
<td>A report format which utilises standard headings, definitions and nomenclature with required information.</td>
</tr>
<tr>
<td><strong>Synoptic report</strong></td>
<td>A structured report in condensed form (as a synopsis or precis).</td>
</tr>
<tr>
<td><strong>Synthesis</strong></td>
<td>Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.</td>
</tr>
<tr>
<td></td>
<td>The Oxford dictionary defines synthesis as “the combination of components or elements to form a connected whole”.</td>
</tr>
<tr>
<td></td>
<td>In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.</td>
</tr>
</tbody>
</table>
Introduction

Cancer of the penis is uncommon, with an incidence of 1 in 100,000 men. It typically occurs in older men and, although increasing in frequency, is still uncommon in men less than 40 years of age.

These tumours are usually squamous cell carcinoma (95%), with sarcoma and rarely melanoma, neuroendocrine carcinoma and basal cell carcinoma accounting for the remaining 5% of malignant tumours. Urothelial carcinoma typically occurs in the penile urethra, but can spread onto the glans penis ("extramammary Paget’s disease").

The risk factors for squamous cell carcinoma (SCC) of the penis include lack of circumcision, poor hygiene and phimosis, suggesting that smegma plays a role in carcinogenesis, and this may account for the protective effect of circumcision when performed shortly after birth. A viral aetiology is also important, particularly high risk HPV 16 which is present in approximately 50% of cases. Other factors include lichen sclerosus and smoking. There appear to be two pathways of penile carcinogenesis, with an HPV related pathway in the basaloid and warty penile SCC, and a non-HPV pathway in keratinizing and verrucous forms of the disease.

SCC of the penis usually occurs on the mucosal squamous surfaces of the glans penis, coronal sulcus and the foreskin, and is extremely rare on the cutaneous surface of the foreskin and the shaft. These tumours have three major growth patterns: (1) a superficial spreading growth pattern associated with a widely spreading tumour of long duration and good prognosis; (2) a vertical growth pattern in large, endophytic, deeply infiltrative tumours of poor prognosis; and (3) a verruciform growth pattern of large exophytic, well differentiated tumours with a very good prognosis. The histological types of SCC differ in their risk for nodal metastases: low risk types include verrucous, papillary and warty SCC, the intermediate risk tumours are of usual or mixed types, and the high risk tumours are sarcomatoid, basaloid and adenosquamous carcinomas.

Nodal status is the most important factor in predicting outcome. Pathologically node negative patients have an 85% to 100% five year cancer specific survival. While patients with a single positive superficial inguinal node may have a good outcome, the survival of patients with multiple positive nodes is much less favourable. The prognostic factors which must be assessed in surgical resection specimens include tumour location, histological type (and growth pattern), histological grade, depth of invasion, and the presence of lymphovascular invasion and perineural invasion. The three most important factors predicting nodal status and outcome are tumour grade, depth of invasion, and the presence of lymphovascular invasion. Grade is important, with regional metastasis in 24% of well differentiated carcinomas, 46% in moderately differentiated carcinomas and 82% in poorly differentiated carcinomas. With respect to depth of invasion, a depth of 5mm is an important cut point, with tumours <5 mm in thickness considered to be low risk, and >5 mm at higher risk, especially with invasion into the corpus cavernosum. Because the combination of tumour grade and depth of invasion is better at predicting metastasis and mortality, a prognostic index has been developed which assigns a numerical value to these factors.
Importance of histopathological reporting

The information contained within a pathology report includes prognostic information for the patient and treating clinical team. The content will assist in subsequent management, whether this may be surveillance, further surgery, radiotherapy or chemotherapy, or a combination of these modalities.

Benefits of structured reporting

The pathology report lays the foundation for a patient’s cancer journey and conveys information which:

- Provides the definitive diagnosis
- Includes critical information for Tumour-Node-Metastasis (TNM) staging
- Evaluates the adequacy of the surgical excision
- Provides morphological and biological prognostic markers which determine personalised cancer therapy

However, the rapid growth in ancillary testing such as immunohistochemistry, flow cytometry, cytogenetics, and molecular studies, have made the task of keeping abreast of advances on specific cancer investigations extremely difficult for pathologists. The use of structured reporting checklists by pathologists ensures that all key elements are included in the report specifically those which have clinical management, staging or prognostic implications. Consequently minimum or comprehensive datasets for the reporting of cancer have been developed\(^6,9\) around the world. Both the United Kingdom,\(^10\) and United States\(^11\) have produced standardised cancer reporting protocols or “datasets” for national use for many years.

The use of cancer reporting checklists improves completeness and quality of cancer reporting and thereby ensures an improved outcome for cancer patients. This has long term cost implications for public health by ensuring the most effective and timely treatment based on accurate and complete information.

The use of a structured reporting format also facilitates easy extraction of the necessary information by secondary users of the information ie cancer registries.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), US (CAP) and UK (RCPath) Colleges of Pathology and the Canadian Association of Pathology (CAP-ACP) in association with the Canadian Partnership Against Cancer (CPAC), was established to explore the possibilities of a collaborative approach to the development of common, internationally standardised and evidence-based cancer reporting protocols for surgical pathology specimens.

The ICCR, recognising that standardised cancer datasets have been shown to provide significant benefits for patients and efficiencies for organisations through the ease and completeness of data capture\(^12-15\) undertook to use the best international approaches and the knowledge and experience of expert pathologists, and produce cancer datasets which would ensure that cancer reports
across the world will be of the same high quality – ensuring completeness, consistency, clarity, conciseness and above all, clinical utility.

Representatives from the four countries participating in the initial collaboration undertook a pilot project in 2011 to develop four cancer datasets - Lung, Melanoma, Prostate (Radical Prostatectomy), and Endometrium. Following on from the success of this pilot project, the ICCR was joined by the European Society of Pathology (ESP) in 2013 and in 2014 incorporated a not-for-profit organisation focussed on the development of internationally agreed evidence-based datasets developed by world leading experts. The ICCR Datasets are made freely available from its website www.ICCR-Cancer.org

Design of this protocol

This structured reporting protocol has been developed using the ICCR dataset on carcinoma of the penis and distal urethra as the foundation.

This protocol includes all of the ICCR cancer dataset elements as well as additional information, elements and commentary as agreed by the RCPA expert committee. It provides a comprehensive framework for the assessment and documentation of pathological features of carcinoma of the penis and distal urethra.

ICCR dataset elements for carcinoma of the penis are included verbatim. ICCR required elements are mandatory and therefore represented as standards in this document. ICCR Recommended elements, that is, those which are not mandatory but are recommended, may be included as guidelines or upgraded to a standard based on the consensus opinion of the local expert committee.

The ICCR elements are identified in each chapter with the ICCR logo placed before the Standard or Guideline number or bullet and the ICCR element description and commentary is boarded by a grey box as shown below:

| G3.02 | The intraglandular extent should be recorded as a percentage. |

Additional commentary by the RCPA authorship committee may be added to an ICCR element but is not included in the grey bordered area nor indicated with an ICCR logo eg

| G2.03 | If present, the laterality of the lymph nodes submitted may be recorded as left, right or bilateral. |

| CS2.03a | If present, record site and number. All lymph node tissue should be submitted for histological examination. |

Further information on the ICCR is available at www.iccr-cancer.org
Checklist

Consistency and speed of reporting is improved by the use of discrete data elements recorded from the checklist. Items suited to tick boxes are distinguished from more complex elements requiring free text or narrative. A structured or discrete approach to responses is favoured, however the pathologist is encouraged to include free text or narrative where necessary to document any other relevant issues, to give reasons for coming to a particular opinion and to explain any points of uncertainty.

Report format

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 that represent information from this protocol, organised and formatted differently to suit different purposes.

Key documentation

- Guidelines for Authors of Structured Cancer Pathology Reporting Protocols
- The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers

Updates since last edition

Not applicable.
Authority and development

This section provides information about the process undertaken to develop this protocol.

This 1st edition of the protocol is an amalgam of two separate processes:

1. This protocol is based on the ICCR Dataset for the reporting of carcinoma of the penis and distal urethra 1st edition. All ICCR elements from this dataset, both required (mandatory) and recommended (optional), are included in this protocol, verbatim. (It should be noted that RCPA feedback from all Anatomical Pathology fellows and specifically the local expert committee was sought during the development process of the ICCR dataset.) Details of the ICCR development process and the international expert authoring committee responsible for the ICCR dataset are available on the ICCR website: iccr-cancer.org.

2. Additional elements, values and commentary have been included as deemed necessary by the local expert committee. In addition, the standard inclusions of RCPA protocols eg example reports, request information etc, have also been added.

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Acknowledgements

The Penile cancer authorship committee wish to thank all the pathologists and clinicians who contributed to the discussion around this document.
Stakeholders

ACT Health
ACT Cancer Registry
Australian Cancer Network
Australian Commission on Safety and Quality in Health Care
Australian Digital Health Agency
Australian Institute of Health and Welfare
Cancer Australia
Cancer Council ACT
Cancer Council Queensland
Cancer Council Victoria
Cancer Council Western Australia
Cancer Institute NSW
Cancer Services Advisory Committee (CanSAC)
Cancer Voices NSW
Clinical Oncology Society of Australia (COSA)
Department of Health, Australia
Department of Health, New Zealand
Faculty of Radiation Oncology Genito-Urinary Group (FROGG)
Health Informatics Society of Australia (HISA)
Independent Review Group of Pathologists
Medical Software Industry Association (MSIA)
National Pathology Accreditation Advisory Council (NPAAC)
New Zealand Cancer Registry
Northern Territory Cancer Registry
Pathology Australia
Public Pathology Australia
Queensland Cooperative Oncology Group (QCOG)
RCPA Anatomical Pathology Advisory Committee (APAC)
Representatives from laboratories specialising in anatomical pathology across Australia
Royal Australasian College of Physicians (RACP)
South Australia Cancer Registry
Standards Australia
Tasmanian Cancer Registry
The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
The Medical Oncology Group of Australia
The Prostate Cancer Foundation of Australia (PCFA)
The Prostate Cancer Foundation of New Zealand (PCFNZ)
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)
Western Australia Clinical Oncology Group (WACOG)

Development process

This protocol has been developed following the ten-step process set out in
Guidelines for Authors of Structured Cancer Pathology Reporting Protocols.18

Where no reference is provided, the authority is the consensus of the local expert
group for local inclusions and the ICCR Dataset Authoring Committee for ICCR
components denoted with the ICCR logo.
1 Pre-analytical

This chapter relates to information that should be recorded on receipt of the specimen in the laboratory.

The pathologist is reliant on the quality of information received from the clinicians or requestor. Some of this information may be received in generic pathology request forms, however, the additional information required by the pathologist specifically for the reporting of penile carcinoma is outlined in Appendix 1. Appendix 1 also includes a standardised request information sheet that may be useful in obtaining all relevant information from the requestor.

Surgical handling procedures affect the quality of the specimen and recommendations for appropriate surgical handling are included in Appendix 1.

S1.01 All demographic information provided on the request form and with the specimen must be recorded.

CS1.01a The Royal College of Pathologists of Australasia (RCPA) The Pathology Request-Test-Report Cycle — Guidelines for Requesters and Pathology Providers must be adhered to.\(^{19}\) This document specifies the minimum information to be provided by the requesting clinician for any pathology test.

CS1.01b Whether or not the patient identifies as Aboriginal and/or Torres Strait Islander. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.

CS1.01c The patient’s health identifiers may include the patient’s Medical Record Number as well as a national health number such as a patient’s Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

S1.02 All clinical information as documented on the request form must be recorded verbatim.

CS1.02a The request information may be recorded as a single text (narrative) field or it may be recorded in a structured format.

CS1.02b The copy doctors requested on the request form must be recorded.

S1.03 The pathology accession number of the specimen must be recorded.

S1.04 The principal clinician involved in the patient’s care and responsible for investigating the patient must be recorded.

CS1.04a The principle clinician should provide key information regarding the clinical presentation of the patient. Follow up may be required with the principle clinician for a number of reasons:

- The clinical assessment and staging may be incomplete at
the time of biopsy.

- The pathology request is often authored by the clinician performing the surgical excision/biopsy rather than the clinician who is investigating and managing the patient.

- The identity of this clinician is often not indicated on the pathology request form.

In practice therefore, it is important in such cases that the reporting pathologist should be able to communicate with the managing clinician for clarification.

CS1.04b The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be included, where possible, to identify the principal clinician involved in the patient's care.

G1.01 Any clinical information received in other communications from the requestor or other clinician should be recorded together with the source of that information.
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.

Specimen handling

- Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:
  
  www.rcpa.edu.au/Library/Practising-Pathology/Macroscopic-Cut-Up

Macroscopic findings

S2.01 The labelling of the specimen(s) must be clearly recorded.

S2.02 The operative procedure$^{20-22}$ should be recorded.

<table>
<thead>
<tr>
<th></th>
<th>The specimens may be circumcision only, partial or total penectomy, with or without scrotal skin, testes and lymph nodes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS2.02b</td>
<td>Most penile SCC arise from the distal mucosal surface and may involve the glans, coronal sulcus and / or the foreskin. When only the foreskin is involved, circumcision alone is sufficient. For more extensive disease, a wider excision is taken, with the operative specimen depending on the tumour location. This can include a partial or total penectomy with additional structures including scrotal skin as required.</td>
</tr>
</tbody>
</table>

CS2.03 The anatomical components submitted must be recorded and measured.

<table>
<thead>
<tr>
<th></th>
<th>The specimens may be circumcision only, partial or total penectomy, with or without scrotal skin, testes and lymph nodes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS2.03a</td>
<td>The foreskin should be measured with mucosal and cutaneous margins inked in different colours. After fixation, the foreskin can be sliced vertically and clockwise from 1 to 12 o’clock.</td>
</tr>
</tbody>
</table>
For penectomy specimens, the length and diameter of the specimen should be measured. After fixation, the proximal margin of the specimen should be embedded enface. The specimen should be sliced longitudinally along the urethra from the meatus to the proximal urethral margin and separated into left and right halves. Each half can then be serially sliced.

| S2.04 | The macroscopic tumour site(s)\(^{20,26-29}\) must be described. |
| G2.04a | The site(s) of primary penile and urethral tumours should be noted macroscopically. The prognosis of equivalent tumours of the foreskin may be better than that of the glans. Tumours of the urethra have a worse prognosis than those of the penis or foreskin. The presence or absence of PeIN or urothelial carcinoma \textit{in situ} can be helpful in differentiating primary penile or urethral squamous from urothelial carcinomas. Penile and urethral melanomas and primary skin tumours of the shaft should be handled and reported using melanoma and skin tumour datasets respectively. |

| S2.05 | The maximum macroscopic tumour dimensions\(^7,30,31\) must be recorded. |
| G2.05a | Tumour dimensions have to be determined through a combination of macroscopic and microscopic assessment, particularly if tumours are very large. |

The tumour appearance should be recorded.

| G2.02 | SCC may be exophytic and warty, have a broad spreading growth pattern or have an endophytic, deeply invasive growth pattern. As well as architecture, the colour, borders, and presence of ulceration be recorded |

The macroscopic depth of invasion should be recorded.

| G2.03 | SCC of the foreskin may spread vertically to the lamina propria, dartos and into the outer skin. SCC of the glans can spread into the corpus spongiosum and the corpus cavernosum. |
G2.04 Macroscopic distance of tumour from closest margin should be recorded.

CG2.04a The important margins depend on the anatomical specimen. For circumcision specimens, the coronal sulcus mucosal margin is the most important margin. For penectomy specimens, close attention needs to be made to the proximal urethral margin, as the SCC may spread horizontally along the urethra to this margin. The penile fascial margin is also important. The penile fascia (Buck fascia) lies superficial to the tunica albuginea which surrounds the corpus cavernousum / corpus spongiosum, and the SCC may spread along this fascia to the proximal margin. The skin and corpus cavernosum margins must also be assessed.

G2.05 The appearance of the glans penis should be recorded.

G2.06 If lymph nodes are submitted, the site(s) of the nodes and the number of nodes per site should be recorded.

G2.07 The presence of any nodal metastases or mass seen macroscopically should be recorded and the maximum size recorded (in mm).

CG2.07a If the nodal metastases are forming a confluent mass, then the maximum overall dimension of the mass should be given. This is important in determining “lymph node mass” for accurate nodal staging.

| S2.06 | A block identification key\textsuperscript{20,32-35} listing the nature and origin of all tissue blocks must be recorded. |
|-----------------------------------------------|
| CS2.06a | The origin/designation of all tissue blocks should be recorded and it is preferable to document this information in the final pathology report. This is particularly important should the need for internal or external review arise and in larger more complex specimens and/or those with orientation markings. The reviewer needs to be clear about the origin of each block in order to provide an informed specialist opinion including accurate staging. If this information is not included in the final pathology report, it should be available on the laboratory computer system and relayed to the reviewing pathologist. Specimen photographs and/or annotated diagrams may be of assistance in clarification of block keys. These documents should also be retrievable as part of the pathology record. Recording the origin/designation of tissue blocks also facilitates retrieval of blocks, for example for further immunohistochemical or molecular analysis, research studies or clinical trials. |
The availability of large block technology is strongly recommended for larger specimens, such as glansectomies and penectomies as it facilitates staging with easier identification of deep structures, in particular the urethra, corpus spongiosum and corpora cavernosa. It is recommended that a record is kept of a good representative paraffin block of tumour and if frozen tissue is stored.

CS2.06b A minimum of three blocks of tumour should be taken including the edge of the tumour and the maximum depth of invasion. Also, the entire proximal margin of penectomy specimens needs to be taken (embedded en face), and blocks of glans, foreskin and urethra should be included.

CS2.06c For lymphadenectomy specimens, all lymph nodes need to be submitted for histology. Small nodes up to 3 mm can be submitted whole. Larger nodes should be bivalved or sliced at 3 mm intervals, and at least one slice of every node should be submitted. Ideally, the whole node will be examined histologically.

G2.08 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.

CG2.08a 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.

CG2.08b 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.

CG2.08c A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.

CG2.08d Where the LIS offers an electronic interface for structured data entry the need for narrative can be significantly reduced to describe only information not otherwise captured.
3 Microscopic findings

Microscopic findings relates to purely histological (morphological) assessment. Information derived from multiple investigational modalities, or from two or more chapters, is described in Chapter 5.

<table>
<thead>
<tr>
<th>S3.01</th>
<th>The histological tumour type(^{4,36-41}) must be recorded.</th>
</tr>
</thead>
<tbody>
<tr>
<td>CS3.01a</td>
<td>The most recent World Health Organisation (WHO) book (2016) classifies and codes malignant squamous epithelial tumours of the penis refer Appendix 4. The tumours are further subclassified in the recent WHO publication into non-HPV related and HPV related tumours. However there is some group crossover particularly in Usual type squamous cell carcinomas, a proportion of which are HPV positive. Mixed carcinomas may also show heterogeneity and sometimes include both HPV and non-HPV associated tumour types.</td>
</tr>
</tbody>
</table>

A. Non-HPV-related penile SCCs

1. SCC
   - Usual carcinoma
   - Pseudohyperplastic carcinoma
   - Pseudoglandular carcinoma

2. Verrucous carcinoma
   - Pure verrucous carcinoma
   - Carcinoma cuniculatum

3. Papillary carcinoma, NOS

4. Adenosquamous carcinoma

5. Sarcomatoid squamous carcinoma

6. Mixed carcinoma

B. HPV-related penile SCCs

7. Basaloid carcinoma
   - Papillary–basaloid carcinoma

8. Warty carcinoma
   - Warty–basaloid carcinoma
Different subtypes of penile carcinomas have been defined, which appear to be associated with different outcomes and may also therefore justify the adoption of different treatment strategies.

Over 95% of penile cancers are squamous cell carcinomas, with rare instances of sarcomas, melanomas or neuroendocrine carcinomas (including large cell and small cell neuroendocrine carcinomas). In addition to the most common, usual type of squamous carcinoma, subtypes include papillary, basaloid, warty (condylomatous), verrucous and sarcomatoid subtypes.

Subtyping is required as verruciform carcinomas (papillary, warty or verrucous carcinomas) have better outcomes. Basaloid, pseudoglandular/acantholytic and sarcomatoid carcinomas are always high-grade with a worse prognosis than the usual type of squamous carcinoma and may more readily metastasise via the blood stream to distant sites such as the lung. Mixed patterns are frequently present and in these cases all subtypes identified should be recorded.

Different patterns of growth can also be distinguished. Vertical growth/endophytic carcinomas are associated with a higher risk of metastases than superficial spreading/exophytic carcinomas although it is not clear whether this distinction offers superior prognostic power over tumour stage.

p16 staining or assessment of HPV subtypes may also be of help in subtyping squamous tumours but are not mandatory.

**Tumour subtypes of squamous cell carcinoma**

- Squamous cell carcinoma of usual subtype (NOS).
- Basaloid squamous cell carcinoma.
- Warty (condylomatous) squamous cell carcinoma.
- Verrucous squamous cell carcinoma.
- Papillary squamous cell carcinoma.
- Mixed squamous cell carcinomas (specify subtypes).
### Other rare tumour subtypes

#### Squamous cell carcinoma variants
- Pseudohyperplastic squamous cell carcinoma.\(^{40,47,48}\)
- Verrucous carcinoma variant
- Carcinoma cuniculatum.\(^{47,49}\)
- Sarcomatoid (Spindle cell) squamous cell carcinoma.\(^{50}\)
- Pseudoglandular (Acantholytic adenoid) squamous cell carcinoma.\(^{47,51}\)
- Lymphoepithelioma like squamous cell carcinoma.\(^{52}\)
- Warty carcinoma variants
- Clear cell carcinoma.\(^{47}\)
- Warty basaloid squamous cell carcinoma.\(^{53}\)
- Adenosquamous carcinoma.\(^{54}\)

#### Non squamous tumours – not included in the scope of this protocol
- High grade neuroendocrine carcinomas including large cell neuroendocrine carcinoma and small cell carcinoma.\(^{47,55,56}\)
- Malignant melanoma.\(^{57}\)
- Mesenchymal tumours.\(^{25}\)
- Urothelial carcinoma of urethra.\(^{25}\)
- Extramammary Paget's disease.\(^{25}\)
- Appendage tumours.\(^{25}\)
- Metastatic tumours.\(^{58}\)
- Lymphomas and haematological tumours.\(^{25}\)

### S3.02
The histological grade\(^{16,25,31,50,59,60}\) must be recorded (where appropriate).

### CS3.02a
Accurate staging and grading of tumours are used to determine subsequent clinical management and follow-up. There is no consensus concerning grading, and the most
recent WHO classification (2016) recommends a three step grading system based on degree of pleomorphism and keratinisation with the overall grade determined by the worst area no matter how small the percentage of the tumour. The most recent College of American Pathologists (CAP) guidelines offer some outline global guidance which is applicable to usual type squamous carcinomas.

The “classical” method defines well-, moderately-well and poorly-differentiated carcinomas on the basis of the degree of cytological atypia, keratinisation, intercellular bridges and mitotic activity. These criteria are difficult to apply to some subtypes of penile carcinoma, for example verrucous carcinomas which are well differentiated but often show little or no keratinisation. Sarcomatoid change is a separate category, which is often combined with other tumour types and which conveys a very poor prognosis. All tumours with sarcomatoid areas should be graded as Grade 3 but this finding also needs to be noted separately as tumours with sarcomatoid areas have a worse prognosis than Grade 3 tumours generally.

Tumours are generally graded on their worst component. Although at one time a threshold of 50% of poorly-differentiated cancer was suggested as the cut-off point most predictive of nodal metastases, it has recently been shown that any component of high-grade tumour conveys a worse prognosis so should be included in the final grade. Every effort should be made to assign a final grade as this is an important prognostic factor and this grade must be based on the most poorly-differentiated component, no matter how small.

Refer Tables 1a and b.

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| S3.03 | The maximum microscopic tumour dimensions must be recorded. |
| CS3.03a | Measurement of the depth of invasion, measured in millimetres from the basement membrane of the adjacent epithelium to the deepest point of invasion, or the maximum thickness or size of the tumour may also give prognostic information as seen in squamous tumours of other sites such as skin. Minimal risk for metastasis is reported for tumours measuring less than 5 mm in thickness. Tumours invading deeper into penile anatomical levels are usually associated with a higher risk of nodal involvement. Thickness of penile tumours rather than depth of invasion is more readily assessed, especially in large tumours, because of the anatomical complexity of the organ. |

| S3.04 | The extent of invasion must be recorded. |
| CS3.04a | Tumours invading deeper into penile anatomical levels are |
usually associated with a higher risk of nodal involvement. There is also a correlation between deeper infiltration and higher histological grade, although some exceptions do occur. Tumours invading corpus cavernosum are at higher risk for presenting with nodal metastases than those invading only corpus spongiosum and although these are both staged as T2 in Union for International Cancer Control (UICC) and American Joint Committee on Cancer (AJCC) TNM7, TNM8 now stages corpus cavernosum invasion as T3 irrespective of urethral involvement. The tunica albuginea, which separates corpus spongiosum from corpus cavernosum is considered part of the corpora cavernosa.

The anatomy of the penis is complex and difficulties often arise in distinguishing levels of invasion. The distinction between lamina propria and corpus spongiosum is made on the basis of vascularity. Vessels within erectile tissue are more angular and thin-walled with intervening fibromuscular tissue than those within the lamina propria, which are more variably sized and separated by loose connective tissue.

**S3.05** Evidence of lymphovascular invasion must be recorded.

**CS3.05a** Vascular invasion, lymphatic or venous, adversely affects prognosis of penile cancer. The TNM staging classification in the seventh edition of the AJCC Cancer Staging Manual subdivides T1 tumours into T1a and T1b based on the absence or presence of lymphovascular invasion (LVI) or poorly-differentiated tumours. This is also included in the 8th edition (TNM8) which also includes the additional stratifier of perineural invasion (see PERINEURAL INVASION below).

Embolic involvement of lymphatic vascular spaces occurs usually near the invasive tumour front, but it may also be found at a certain distance from the primary tumour in anatomical areas such as the lamina propria, penile fascia, and especially in the subepithelial connective tissues surrounding the penile urethra. Venous invasion indicates a more advanced stage of the disease and is related to the compromise of the specialized erectile venous structures of corpora spongiosa and cavernosa.

Vascular invasion may be difficult to assess particularly in small biopsies and immunohistochemistry with vascular markers may be of assistance in some cases.

**S3.06** Evidence of perineural invasion must be recorded.

**CS3.06a** Risk groups stratification systems are available to predict the likelihood of inguinal nodal involvement and therapeutic planning and are based on a combination of histological grade and pT stage. Strongest predictive power
is given by the combination of histological grade, deepest anatomical level of infiltration, and presence of perineural invasion. These factors are used for constructing the Prognostic Index. TNM8 now includes perineural invasion as a stratifier between T1a and T1b tumours in addition to LVI.\(^{17}\)

Perineural invasion may be difficult to assess, especially in small and/or superficial biopsies. Immunohistochemistry with neural markers may be helpful in some circumstances.

<table>
<thead>
<tr>
<th>G3.01</th>
<th>Evidence of associated penile intraepithelial neoplasia (PeIN)(^{28,59,66-70}) should be recorded.</th>
</tr>
</thead>
</table>
| CG3.01a | The pathological nomenclature and patterns of different forms of preinvasive lesions of the penis has been radically modified over the last few years with the abandonment of clinical terms such as Erythroplasia of Queyrat and Bowen’s disease and the adoption of the encompassing term Penile Intraepithelial Neoplasia (PeIN) in pathological reports. The new WHO classification of Penile Intraepithelial Neoplasia distinguishes three groups: 1. Non HPV related (differentiated or simplex), 2. HPV related (undifferentiated) PeIN (basaloid, warty and warty-basaloid) and 3. Others (pleomorphic, spindle, clear cell, pagetoid).\(^{58}\) Undifferentiated HPV related PeIN shows full thickness warty and/or basaloid features (previously designated severe dysplasia/carcinoma \textit{in situ}). Differentiated PeIN usually involves only the basal layer and is associated with architectural atypia and aberrant keratinisation with features similar to that seen in precancerous lesions of the vulva. Undifferentiated PeIN is associated with p16 positivity and warty/basaloid invasive tumours but differentiated PeIN is associated with lichen sclerosis (balanitis xerotica obliterans), more commonly seen with verrucous and pseudohyperplastic tumours, and is usually p16 negative. It should also be noted that PeIN of any type is often multifocal.

The presence and subtype of PeIN should be reported together with its margin status independent of associated invasive tumour. The splitting of PeIN into subgrades (for example I-III or low-grade/high-grade) is not recommended by the authors. Written reports should indicate the subtype and extent of PeIN and whether or not there is margin involvement.

Precancerous lesions identical to differentiated and undifferentiated PeIN are seen in the distal penile urethra but there is no guidance on how to report them. Rather than designating these as carcinoma \textit{in situ} or severe dysplasia, it may be advisable to also use the term PeIN in this context.

A potential problem arises when there are cytological
abnormalities not thought to be severe enough to be designated as PeIN of either subtype. Then a category such as ‘atypia falling short of PeIN’ with a recommendation for follow up may be used, to avoid over treatment.

It is not necessary to report PeIN using the full dataset if it is the only abnormality present without invasive carcinoma.

Immunohistochemistry with p16 may be of help in subclassifying PeIN but is not regarded as mandatory. It may also be of use in identifying high-risk HPV in atypical condylomas.

<table>
<thead>
<tr>
<th>S3.07</th>
<th>Margin status(^{71,72}) must be recorded.</th>
</tr>
</thead>
</table>
| CS3.07a | Penile preserving techniques have led to closer surgical tumour resection margins and there is evidence that this does not significantly compromise local recurrence rates if tumour cells are not present at the margin itself. Positive margins must be recorded by site and microscopic distance of tumour from close margins (5 mm or less) recorded in mm. Microscopic margin positivity may be identified unexpectedly in tumours that infiltrate widely without creating a mass effect. The presence of microscopic involvement of surgical margins, however, has implications for audit of pre-operative staging and/or surgical technique. Actual measurement of linear extent of individual involved margins is a non-core item but is valued by surgeons in assessing their techniques.

Staging in the presence of positive margins needs to be undertaken but made clear to clinicians. The term ‘at least’, as in pT2 at least, may be used to indicate a positive margin. It is not helpful to clinicians not to stage if margins are positive.

The deep central soft tissue margin is defined as areas of intervening tissue not identified as periurethral tissue, corpus cavernosum or circumferential shaft margins or may be used if the specific site of the deep margin is indeterminate.

**Margins of resection for penile specimens**

- Urethral
- Periurethral tissues including lamina propria and corpus spongiosum
- Corpus cavernosum
- Circumferential margins of bare penile shaft
- Peripheral skin
- Deep central soft tissue margin (other than periurethral tissue, corpus cavernosum or circumferential shaft)

**Margins of resection of circumcision specimens**
- Coronal sulcus/glans margin
- Peripheral cutaneous margin
- Deep central soft tissue margin

**S3.08**  
**Lymph node status**
21-23,28,29,73-75 must be recorded, recording total number of nodes and the number of positive nodes, the size of the largest metastasis, and the presence or absence of extranodal spread.

**CS3.08a**  
The number of nodes found within an individual specimen should be specified in the report. The size of the largest nodal tumour deposit (not the lymph node size) together with presence of extranodal spread must also be recorded as there is evidence that this may affect prognosis. These parameters must be reported separately for each individual node site. Occasionally individual tumour cells are identified in the peripheral sinus. The significance of these is uncertain but they should be described within reports.

The size of the largest nodal tumour deposit must be recorded as there is evidence that this may affect prognosis in penile cancer. Both TNM7 and TNM8 classify very small amounts of tumour as micrometastases (up to 0.2 mm) and isolated tumour cells as N0 (i+). However there is no evidence for a prognostic cut-off point for lymph node metastasis size in penile cancer so it is recommended that maximum dimension of largest tumour deposit is recorded and tumour deposits over 0.2 mm staged as N1.

**CS3.08b**  
Dynamic sentinel node biopsy, using either the blue dye technique or lymphoscintigraphy, refers to the intraoperative identification of the first node draining the tumour. It relies on the assumption that lymphatic spread is a stepwise process, so that, if the sentinel node is negative, further nodal dissection would yield negative results. This technique may be used in some centres for patients with no clinical signs of nodal involvement.

Immunohistochemistry is essential for the assessment of micrometastases in sentinel lymph nodes as small metastases under 2 mm or single isolated tumour cells may be easily missed.

**CS3.08c**  
Extent of inguinal node involvement and presence of ECS also predicts pelvic node involvement.23,60,70,71 Therefore, the extent of inguinal lymph node involvement including
| CS3.08d | Nodal involvement is a recognised predictor of poor prognosis. In node positive disease, the number of positive nodes, the presence of extracapsular spread (ECS) and the level of nodal involvement (pelvic versus inguinal) have been shown to influence survival by multivariate analysis and this is reflected in both TNM7\(^{23,60}\) and TNM8\(^{11}\) which classify any pelvic lymph node involvement or extracapsular extension of any regional lymph node (inguinal or pelvic) as pN3 in the penile but not in the urethral TNM. However in penile TNM8\(^ {11}\) the number of nodes which stratifies the staging between N1 and N2 is two or more unilateral nodes rather than one or more in TNM7\(^ {23,60}\).

For urethral cancer in TNM7\(^ {23,60}\) the size of metastasis in a single regional node, if greater than 2 cm, stratifies between N1 and N2 nodes or if there are multiple nodes involved, but in TNM8\(^ {11}\) there is no metastasis size specified and the only stratifier is between single and multiple regional nodes.

Although the N categories differ for P(p)enile and U(u)rethral primary tumours it is recommended that data items as specified in this section are recorded for tumours of both these primary sites as tumours of the distal, as opposed to proximal, urethra appear to spread in the same way to local lymph nodes as do those of the penis. |
Table 1: Grading of penile squamous cell carcinoma

1a College of American Pathologists Protocol for the Examination of Specimens From Patients With Carcinoma of the Penis Version: Penis 4.0.1.0 June 2017

Histological grade has been consistently reported as an influential predictive factor of groin metastasis and dissemination of penile cancer. We recommend a method to grade penile SCCs as follows:

<table>
<thead>
<tr>
<th>Grade 1</th>
<th>Extremely well–differentiated carcinoma, with a minimal deviation from the morphology of normal/hyperplastic squamous epithelium.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 2</td>
<td>Tumours show a more disorganized growth as compared to grade 1 lesions, higher nuclear-to-cytoplasmic ratio, evident mitoses, and, although present, less prominent keratinization.</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Tumours showing any proportion of anaplastic cells, identified as solid sheets or irregular small aggregates, cords or nests of cells with little or no keratinization, high nuclear-to-cytoplasmic ratio, thick nuclear membranes, nuclear pleomorphism, clumped chromatin, prominent nucleoli, and numerous mitoses.</td>
</tr>
</tbody>
</table>

A tumour should be graded according to the least differentiated component. Any proportion of grade 3 should be noted in the report.

1b Modified from The Royal College of Pathologists (RCPath) Dataset for penile and distal urethral cancer reports, 2nd Edition 2015

<table>
<thead>
<tr>
<th>Feature</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
<th>Sarcomatoid areas present (Grade 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cytological atypia</td>
<td>Mild</td>
<td>Moderate</td>
<td>Anaplasia</td>
<td>Sarcomatoid</td>
</tr>
<tr>
<td>Keratinisation</td>
<td>Usually abundant</td>
<td>Less prominent</td>
<td>May be present</td>
<td>Absent</td>
</tr>
<tr>
<td>Intercellular bridges</td>
<td>Prominent</td>
<td>Occasional</td>
<td>Few</td>
<td>Absent</td>
</tr>
<tr>
<td>Mitotic activity</td>
<td>Rare</td>
<td>Increased</td>
<td>Abundant</td>
<td>Abundant</td>
</tr>
<tr>
<td>Tumour margin</td>
<td>Pushing/well defined</td>
<td>Infiltrative/ill defined</td>
<td>Infiltrative/ill defined</td>
<td>Infiltrative/ill defined</td>
</tr>
</tbody>
</table>
4 Ancillary studies findings

Ancillary studies may be used to determine lineage, clonality or disease classification or subclassification; as prognostic biomarkers; or to indicate the likelihood of patient response to specific biologic therapies.

Some studies, such as Her-2 testing, are required under the Pharmaceutical Benefits Scheme, to enable certain specific therapies to be prescribed.

G4.01 Whether or not ancillary tests are performed should be recorded and the results incorporated into the pathology report.

CG4.01a Immunohistochemistry can be performed and the results incorporated into the pathology report. For example, p16 may be helpful in the identification of HPV-related carcinomas. Also, cytokeratin stains play a role in the sentinel node assessment of penile carcinoma.
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 report ‘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.

<table>
<thead>
<tr>
<th>S5.01</th>
<th>The tumour stage must be recorded according to the AJCC TNM system (8th edition).(^{11}) (See Appendix 5) Used with the permission of the American College of Surgeons, Chicago, Illinois. The original source for this information is the AJCC Cancer Staging Manual, Eighth Edition (2016) published by Springer Science+Business Media.</th>
</tr>
</thead>
</table>
| CS5.01a | This dataset includes the AJCC TNM 8th edition\(^{11}\) definitions. Refer to Appendix 5. Differences of the AJCC TNM 8th edition from the TNM 7th edition should be noted:

1) Perineural invasion is now included as a stratifier between T1a and T1b tumours of the penis in addition to lymphovascular invasion and high grade in TNM8.

2) The division between T2 and T3 in TNM8 of the penis is entirely dependent on whether there corpus spongiosum or corpus cavernosum invasion irrespective of urethral involvement. This is the most significant change between TNM7 and TNM8.

3) The number of unilateral nodes to indicate N2 rather than N1 of the penis has increased to 3 from 2.

4) The size of metastasis is no longer used as a stratifier between N1 and N2 in unilateral regional nodes in urethral cancer.

5) The use of TX is to be avoided if at all possible and MX is not to be used.

6) Pathological staging should not be reported if the specimen submitted is insufficient for definitive staging. This may occur with biopsies or other specimens where depth of invasion or the required
7) Staging in the presence of positive margins needs to be undertaken but made clear to clinicians. The term ‘at least’, as in pT2 at least, may be used to indicate a positive margin. It is not helpful to clinicians omit the stage if margins are positive.

By convention, the designation T refers to a primary tumour that has not been previously treated. The symbol p refers to the pathologic classification of the TNM, as opposed to the clinical classification, and is based on gross and microscopic examination. pT entails a resection of the primary tumour or a biopsy adequate to evaluate the highest pT category, pN entails removal of nodes adequate to validate lymph node metastasis, and pM implies microscopic examination of distant lesion. Pathologic staging is usually performed after surgical resection of the primary tumour.

Additional Descriptor

The m suffix indicates the presence of multiple primary tumours and is recorded in parentheses, e.g. pTa(m)N0.

S5.02 The year of publication and/or edition of the cancer staging system used in S5.01 must be included in the report.

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

a. Operative procedure (S2.02)
b. Tumour site (S2.03)
c. Tumour type (S3.01)
d. Tumour grade (S3.02)
e. Maximum tumour dimensions ie depth of invasion (S3.03)
f. Margin status (S3.07)
g. Lymph node status (S3.08)
h. Tumour stage (S5.01)

S5.03 The reporting system must provide a field for free text or narrative in which the reporting pathologist can give overarching case comment, if required.

CS5.03a This field may be used, for example, to:

- document any noteworthy adverse gross and/or histological features
– 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

– document further consultation or results still pending.

CS5.03b Use of this field is at the discretion of the reporting pathologist.

G5.02 The edition/version number of the RCPA protocol on which the report is based should be included on the final report.

CG5.02a For example, the pathology report may include the following wording at the end of the report: “the data fields within this formatted report are aligned with the criteria as set out in the RCPA document “ XXXXXXXXXX” XXXX Edition dated XXXXXXXX”.
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 penile resections. 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 and as described in *Functional Requirements for Structured Pathology Reporting of Cancer Protocols*.

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.

G6.03 Additional comment may be added to an individual response where necessary to describe any uncertainty or nuance in the selection of a prescribed response in the checklist. Additional comment is not required where the prescribed response is adequate.
**Item descriptions in italics are conditional on previous responses.**

**Values in all caps are headings with sub values.**

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<th>S/G</th>
<th>Item description</th>
<th>Response type</th>
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<td>S1.01</td>
<td>Demographic information provided</td>
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<td>S1.02</td>
<td>Information provided on request form</td>
<td>Not provided OR Text OR Structured entry as below:</td>
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**Macroscopic findings**

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<td><strong>ANATOMICAL COMPONENTS SUBMITTED</strong></td>
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<td>• Present</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Foreskin</strong></th>
<th>Single selection value list:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Absent</td>
</tr>
<tr>
<td></td>
<td>• Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Coronal sulcus</strong></th>
<th>Single selection value list:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Absent</td>
</tr>
<tr>
<td></td>
<td>• Present</td>
</tr>
</tbody>
</table>

If present, consider recording dimensions.
<table>
<thead>
<tr>
<th><strong>Scrotal skin</strong></th>
<th><strong>Single selection value list:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Absent</td>
</tr>
<tr>
<td></td>
<td>• Present</td>
</tr>
<tr>
<td></td>
<td><strong>If present, consider recording dimensions</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Testis</strong></th>
<th><strong>Absent</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td><strong>Multi select value list:</strong></td>
</tr>
<tr>
<td></td>
<td>• Right present</td>
</tr>
<tr>
<td></td>
<td>• Left present</td>
</tr>
<tr>
<td></td>
<td><strong>If present, consider recording dimensions</strong></td>
</tr>
</tbody>
</table>

| **Dimensions** | **Numeric: __x__x__mm** |

<table>
<thead>
<tr>
<th><strong>Tumour focality</strong></th>
<th><strong>Single selection value list:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Cannot be assessed</td>
</tr>
<tr>
<td></td>
<td>• Indeterminate</td>
</tr>
<tr>
<td></td>
<td>• Unifocal</td>
</tr>
<tr>
<td></td>
<td>• Multifocal, specify number of tumours in specimen</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>G2.01</strong></th>
<th><strong>Tumour focality</strong></th>
</tr>
</thead>
</table>

---

**Notes:**
- If present, consider recording dimensions.
- Specifying dimensions is crucial for accurate measurement.
- Indicate the presence or absence of specific structures.
- For multifocal tumours, specify the number of tumours in the specimen.

---

**Dimensions:**
- Ensure accurate measurement is recorded for each dimension.
- Use the provided format (__x__x__mm) for recording dimensions.

---

**Tumour focality:**
- Assess focality and record accordingly.
- Indicate if focality cannot be assessed or is indeterminate.
- Unifocal tumours require straightforward recording.
- Multifocal tumours require additional detail on specimen contents.

---

**General:**
- Clarity in recording is essential for accurate reporting.
- Use clear and concise language to describe findings.
- Ensure all relevant structures are systematically evaluated.

---

**Tips:**
- Use consistent terminology across documentation.
- Maintain a logical flow in recording findings.
- Cross-reference with medical guidelines for accurate reporting.

---

**Reference:**
- Medical guidelines for comprehensive reporting.
| S2.04 | Macroscopic tumour site | • No macroscopically visible tumour  
• Indeterminate  
OR  
**Multi selection value list (select all that apply):**  
• Glans penis  
• Sulcus  
• Foreskin  
• Distal penile urethra |
| --- | --- | --- |
| S2.05 | Macroscopic maximum tumour dimensions | **Single selection value list:**  
• Cannot be assessed  
• Not applicable  
OR  
Complete the following  
|  | Width | Numeric: __mm |
|  | Thickness | Numeric: __mm |
| G2.02 | Tumour appearance | **Normal**  
OR  
**Multi selection value list (select all that apply):**  
• Nodule |
<table>
<thead>
<tr>
<th>G2.03</th>
<th>Macroscopic depth of invasion</th>
<th><strong>Numeric: __mm</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>G2.04</td>
<td>Macroscopic distance of tumour from closest margin</td>
<td><strong>Numeric: __mm</strong>&lt;br&gt;<strong>AND</strong>&lt;br&gt;<strong>Text</strong> <em>(specify margin)</em></td>
</tr>
<tr>
<td>G2.05</td>
<td>Appearance of the glans penis</td>
<td><strong>Normal</strong>&lt;br&gt;<strong>OR</strong>&lt;br&gt;<strong>Text</strong></td>
</tr>
<tr>
<td>G2.06</td>
<td>Lymph nodes</td>
<td><strong>Single selection value list:</strong>&lt;br&gt;- Submitted&lt;br&gt;- Not submitted&lt;br&gt;<strong>If submitted record, site(s) and number of lymph nodes.</strong>&lt;br&gt;<strong>Site(s) and number of lymph nodes</strong></td>
</tr>
</tbody>
</table>
**Notes:**
Note that the site and number of LN’s for that site will need to be repeated for each site received.

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **G2.07** | Macroscopic nodal metastases or mass | **Single selection value list:**  
  - Absent  
  - Present | **If present, record the maximum size** |
| **Size** | **Numeric: ___mm** |   |

**Block identification key**

**Text**

**G2.08**

**Additional macroscopic comments**

**Text**

---

**Microscopic findings**

**Histological tumour type**

**Multi selection value list (select all that apply):**  
- Squamous cell carcinoma of usual subtype (NOS)  
- Basaloid squamous cell carcinoma  
- Warty (condylomatous) squamous cell carcinoma  
- Verrucous squamous cell carcinoma  
- Papillary squamous cell carcinoma  
- Mixed squamous cell carcinomas, specify subtypes  
- Other, specify*
| S3.02 | **Histological grade** | **Single selection value list:**  
• Not applicable  
• G1: Well differentiated  
• G2: Moderately differentiated  
• G3: Poorly differentiated  
• Sarcomatoid areas present |
| S3.03 | **Microscopic maximum tumour dimensions** | **Single selection value list:**  
• Cannot be assessed  
• Not applicable  
OR  
Complete the following  
| Width | Numeric: ____mm |
| Thickness | Numeric: ____mm |
| S3.04 | **Extent of invasion** | **Multi selection value list (select all that apply):**  
• Subepithelial/lamina propria invasion  
• Invasion of corpus spongiosum of glans  
• Invasion of corpus cavernosum  
• Invasion of the penile urethra  
• Invasion of adjacent structures, specify |
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Single selection value list:</th>
</tr>
</thead>
</table>
| S3.05 | Lymphovascular invasion | • Not identified  
• Present  
• Indeterminate |
| S3.06 | Perineural invasion | • Not identified  
• Present  
• Indeterminate |
| G3.01 | Associated penile intraepithelial neoplasia (PeIN) | Single selection value list:  
• Not identified  
• Indeterminate  
• Present  
  o Undifferentiated (Warty and/or Basaloid)  
  o Differentiated |
| S3.07 | MARGIN STATUS | | |
| | Urethral margin (primary tumours of the penis and foreskin (resections and excision biopsy only)) | Single selection value list:  
• Not applicable  
• Cannot be assessed  
• Involved by PeIN only  
• Involved by invasive carcinoma | If not involved record the distance to invasive tumour |
<table>
<thead>
<tr>
<th>Margin Type</th>
<th>Single selection value list:</th>
<th>If not involved record the distance to invasive tumour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal urethral margin</td>
<td>- Not applicable&lt;br&gt;- Cannot be assessed&lt;br&gt;- Involved by PeIN only&lt;br&gt;- Involved by invasive carcinoma&lt;br&gt;- Not involved</td>
<td></td>
</tr>
<tr>
<td>Peri-urethral tissues</td>
<td>- Not applicable&lt;br&gt;- Cannot be assessed&lt;br&gt;- Involved by invasive carcinoma&lt;br&gt;- Not involved</td>
<td></td>
</tr>
<tr>
<td>Corpus cavernosum</td>
<td>- Not applicable&lt;br&gt;- Cannot be assessed&lt;br&gt;- Involved by invasive carcinoma&lt;br&gt;- Not involved</td>
<td></td>
</tr>
<tr>
<td>Circumferential shaft margin</td>
<td>- Not applicable&lt;br&gt;- Cannot be assessed&lt;br&gt;- Involved by invasive carcinoma&lt;br&gt;- Not involved</td>
<td></td>
</tr>
<tr>
<td>Area</td>
<td>Single selection value list</td>
<td>remarks</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>Peripheral cutaneous margin</td>
<td>• Not applicable • Cannot be assessed • Involved by invasive carcinoma • Not involved</td>
<td>If not involved record the distance to invasive tumour</td>
</tr>
<tr>
<td>Peripheral glans margin</td>
<td>• Not applicable • Cannot be assessed • Involved by PeIN only • Involved by invasive carcinoma • Not involved</td>
<td>If not involved record the distance to invasive tumour</td>
</tr>
<tr>
<td>Deep soft tissue margins (NOS)</td>
<td>• Not applicable • Cannot be assessed</td>
<td>If not involved record the distance to invasive tumour</td>
</tr>
<tr>
<td>Other margin</td>
<td><strong>Text (specify margin)</strong></td>
<td><strong>Complete only if required.</strong> If not involved record the distance to invasive tumour</td>
</tr>
<tr>
<td>--------------</td>
<td>--------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>AND</strong></td>
<td><strong>Single selection value list:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Cannot be assessed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involved by PeIN only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involved by invasive carcinoma</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
</tbody>
</table>

| Distance to invasive tumour | **Numeric: ___mm** | **OR** | >5 mm |

<table>
<thead>
<tr>
<th>S3.08</th>
<th><strong>LYMPH NODE STATUS</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>INGUINAL NODES- SENTINEL</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RIGHT</th>
<th><strong>Not submitted</strong></th>
<th><strong>If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>OR</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Single selection value list:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Isolated tumour cells only</td>
<td></td>
</tr>
<tr>
<td>Field</td>
<td>Value</td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-------------------------------</td>
<td></td>
</tr>
<tr>
<td>Number of lymph nodes examined</td>
<td>Numeric: ____</td>
<td></td>
</tr>
<tr>
<td>Number of positive lymph nodes</td>
<td>Number cannot be determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Numeric: ____</td>
<td></td>
</tr>
<tr>
<td>Maximum dimension of largest deposit</td>
<td>Numeric: ____ mm</td>
<td></td>
</tr>
<tr>
<td>Extracapsular spread</td>
<td>Single selection value list:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not identified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Present</td>
<td></td>
</tr>
<tr>
<td>LEFT</td>
<td>Not submitted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Complete the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single selection value list:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Isolated tumour cells only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involved</td>
<td></td>
</tr>
<tr>
<td>If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of lymph nodes examined</td>
<td>Numeric: ____</td>
<td></td>
</tr>
<tr>
<td>Number of positive lymph nodes</td>
<td>Number cannot be determined</td>
<td></td>
</tr>
<tr>
<td></td>
<td>OR</td>
<td></td>
</tr>
<tr>
<td><strong>INGUINAL NODES – NON SENTINEL</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>RIGHT</strong></td>
<td>Not submitted</td>
<td></td>
</tr>
<tr>
<td>OR</td>
<td>Complete the following:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Single selection value list:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Isolated tumour cells only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involved</td>
<td></td>
</tr>
</tbody>
</table>

*If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.*
<table>
<thead>
<tr>
<th><strong>Extracapsular spread</strong></th>
<th><strong>Single selection value list:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Not identified</td>
</tr>
<tr>
<td></td>
<td>- Present</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>LEFT</strong></th>
<th><strong>Not submitted</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>Complete the following:</td>
</tr>
<tr>
<td></td>
<td><strong>Single selection value list:</strong></td>
</tr>
<tr>
<td></td>
<td>- Not involved</td>
</tr>
<tr>
<td></td>
<td>- Isolated tumour cells only</td>
</tr>
<tr>
<td></td>
<td>- Involved</td>
</tr>
</tbody>
</table>

If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.

<table>
<thead>
<tr>
<th><strong>Number of lymph nodes examined</strong></th>
<th><strong>Numeric:</strong>___</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Number of positive lymph nodes</strong></th>
<th><strong>Number cannot be determined</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td><strong>Numeric:</strong>___</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Maximum dimension of largest deposit</strong></th>
<th><strong>Numeric:</strong>___mm</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>Extracapsular spread</strong></th>
<th><strong>Single selection value list:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Not identified</td>
</tr>
<tr>
<td></td>
<td>- Present</td>
</tr>
</tbody>
</table>

<p>| <strong>PELVIC NODES</strong> |</p>
<table>
<thead>
<tr>
<th><strong>RIGHT</strong></th>
<th><strong>Not submitted</strong></th>
<th><strong>If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complete the following:</strong></td>
<td><strong>Single selection value list:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Isolated tumour cells only</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Involved</td>
<td></td>
</tr>
</tbody>
</table>

| **Number of lymph nodes examined** | **Numeric:** ____ |

| **Number of positive lymph nodes** | **Number cannot be determined** | **OR** |
|  | **Numeric:** ____ |

| **Maximum dimension of largest deposit** | **Numeric:** ____ **mm** |

<table>
<thead>
<tr>
<th><strong>Extracapsular spread</strong></th>
<th><strong>Single selection value list:</strong></th>
<th><strong>If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Not identified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Present</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>LEFT</strong></th>
<th><strong>Not submitted</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Complete the following:</strong></td>
<td><strong>Single selection value list:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Not involved</td>
<td></td>
</tr>
<tr>
<td><strong>Number of lymph nodes examined</strong></td>
<td><strong>Numeric:</strong> ____</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Number of positive lymph nodes</strong></td>
<td>Number cannot be determined OR <strong>Numeric:</strong> ____</td>
<td></td>
</tr>
<tr>
<td><strong>Maximum dimension of largest deposit</strong></td>
<td><strong>Numeric:</strong> ____ mm</td>
<td></td>
</tr>
</tbody>
</table>
| **Extracapsular spread** | **Single selection value list:**  
  - Not identified  
  - Present |
| **OTHER NODES** | **Not submitted** OR Complete the following:  
**Text** *(specify laterality and site)*  
**AND** **Single selection value list:**  
  - Not involved  
  - Isolated tumour cells only  
  - Involved  
Note: report only if required. | **If involved record the number of positive nodes, max. dimension of largest deposit and extracapsular spread.** |
| **Number of lymph nodes examined** | **Numeric:** ____ |
| **Number of positive lymph nodes** | **Number cannot be determined**<br>OR<br>**Numeric:** ____ |
| **Maximum dimension of largest deposit** | **Numeric:** ____ mm |
| **Extracapsular spread** | **Single selection value list:**<br>• Not identified<br>• Present |

G3.02 Additional microscopic comment | **Text** |

**Ancillary findings**

| G4.01 Ancillary studies | **Single selection value list:**<br>• Not performed<br>• Performed, specify tests and results |

**Synthesis and overview**

<p>| S5.01 PATHOLOGICAL STAGING (AJCC 8TH EDITION) |  |
| Primary tumour (T) | <strong>Single selection value list:</strong>&lt;br&gt;PENIS AND FORESKIN&lt;br&gt;Primary tumour (pT) |</p>
<table>
<thead>
<tr>
<th>T0</th>
<th>No evidence of primary tumour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tis</td>
<td>Carcinoma <em>in situ</em> (Penile Intraepithelial Neoplasia [PeIN])</td>
</tr>
<tr>
<td>Ta</td>
<td>Non invasive localised squamous cell carcinoma*</td>
</tr>
<tr>
<td>T1</td>
<td>Tumour invades subepithelial connective tissue, dermis or lamina propria**</td>
</tr>
<tr>
<td>T1a</td>
<td>Tumour is without lymphovascular invasion or perineural invasion and is not high grade</td>
</tr>
<tr>
<td>T1b</td>
<td>Tumour exhibits lymphovascular invasion and/or perineural invasion or is high grade</td>
</tr>
<tr>
<td>T2</td>
<td>Tumour invades into corpus spongiosum with or without urethral invasion</td>
</tr>
<tr>
<td>T3</td>
<td>Tumour invades into corpora cavernosum with or without urethral invasion</td>
</tr>
<tr>
<td>T4</td>
<td>Tumour invades other adjacent structures</td>
</tr>
</tbody>
</table>

* The authors do not recommend the use of the pTa category as it is not evidence based.
| Regional lymph nodes (N) | Single selection value list: PENIS AND FORESKIN  
Regional lymph nodes (pN)  
NX  Lymph node metastasis cannot be established  
N0  No lymph node metastasis  
N1  \( \leq 2 \) unilateral inguinal metastases, no ENE  
N2  \( \geq 3 \) unilateral inguinal metastases or bilateral metastases  
N3  Extranodal extension of lymph node |
|--------------------------|----------------------------------------------------------------------------------------|
| S5.02 Year and/or edition of staging system | Numeric: year  
AND/OR  
Text: Edition eg 1st, 2nd etc |
| G5.01 Diagnostic summary | Text  
Include:  
a. Operative procedure (S2.02)  
b. Tumour site (S2.03)  
c. Tumour type (S3.01)  
d. Tumour grade (S3.02)  
e. Maximum tumour |
<table>
<thead>
<tr>
<th>Overarching comment</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>S5.03</td>
<td></td>
</tr>
<tr>
<td>G5.02</td>
<td></td>
</tr>
</tbody>
</table>

- dimensions (S3.03)
- Margin status (S3.07)
- Lymph node status (S3.08)
- Tumour stage (S5.01)
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.
Appendix 1  Pathology request information and surgical handling procedures

This appendix describes the information that should be collected before the pathology test. Some of this information can be provided on generic pathology request forms; any additional information required specifically for the reporting of renal cancer may be provided by the clinician on a separate request information sheet. An example request information sheet is included below. Elements which are in bold text are those which pathologists consider to be required information. Those in non-bold text are recommended.

Also included in this appendix are the procedures that are recommended before handover of specimens to the laboratory.

Patient information

➢ Adequate demographic and request information should be provided with the specimen.

- Items relevant to cancer reporting protocols include:
  - patient name
  - date of birth
  - sex
  - identification and contact details of requesting doctor
  - date of request
  - Whether or not the patient identifies as Aboriginal and/ or Torres Strait Islander. This is in support of a government initiative to monitor the health of indigenous Australians particularly in relation to cancer.

➢ The patient’s health identifiers should be provided.

- The patient’s health identifiers may include the patient’s Medical Record Number as well as a national health number such as a patient’s Individual Healthcare Identifier (IHI) (Australia) or the National Healthcare Identifier (New Zealand).

➢ The Australian Healthcare identifiers i.e. Healthcare Provider Identifier - Individual (HPI-I) and Healthcare Provider Identifier - Organisation (HPI-O) should be use, where possible, to identify the requesting doctor.
**Clinical Information**

- Any relevant clinical information should be provided.

<table>
<thead>
<tr>
<th>•</th>
<th>History of prior penile tumours and treatments, including topical treatment, radiotherapy and chemotherapy should be given particularly if the patient has been treated elsewhere.</th>
</tr>
</thead>
</table>

It is good clinical practice to transcribe all clinical information from the request form on to the pathology report. This is a recommended rather than a required item as it is the responsibility of the clinician requesting the pathological examination of a specimen to provide information that will have an impact on the diagnostic process or affect its interpretation.

- **The nature of the operation must be recorded.**

- The operative findings should be recorded.

- **Record if this is a new primary cancer or a recurrence of a previous cancer, if known.**

  - The term recurrence defines the return, reappearance or metastasis of cancer (of the same histology) after a disease free period.

    Recurrence should be classified as distant metastases or regional (local) recurrence.

    Regional (local) recurrence refers to the recurrence of cancer cells at the same site as the original (primary) tumour or the regional lymph nodes.

    Distant metastasis refers to the spread of cancer of the same histologic type as the original (primary) tumour to distant organs or distant lymph nodes.

  - This information will provide an opportunity for previous reports to be reviewed during the reporting process, which may provide valuable information to the pathologist. This information also has implications for recording cancer incidence and evidence based research.
Example request information sheet

The above Request Information Sheet is published to the RCPA website.
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. 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.

- Configuring reports in such a way that they ‘chunk’ data elements into a single unit will help to improve recall for the clinician.
- ‘Clutter’ should be reduced to a minimum. Thus, information that is not part of the protocol (e.g. billing information, Snomed codes, etc) should not appear on the reports or should be minimized.
- Injudicious use of formatting elements (e.g. too much bold, underlining or use of footnotes) constitutes 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 for carcinoma of the penis

PENILE CARCINOMA STRUCTURED REPORT

CLINICAL INFORMATION RECEIVED

Clinical information:  SCC penis. Partial penectomy and bilateral radical inguinal lymph node dissection
New primary lesion or recurrence:  New primary

MACROSCOPIC

Specimen labelled as:  Penis.
Operative procedure:  Partial penectomy
ANATOMICAL COMPONENTS SUBMITTED

Glans:  Present - 43 mm (distal to proximal) x 26mm (dorsal to ventral) x 36mm (right to left)
Shaft:  Present - Included above
Foreskin:  Present - 57 mm (distal to proximal) x 46mm (dorsal to ventral) x 43mm (right to left)
Coronal sulcus:  Present – Included above with foreskin
Scrotal skin:  Absent
Testes:  Absent
Tumour focality:  Unifocal
Macrosopic tumour site:  Present over most of the glans penis and reflected onto the foreskin over the coronal sulcus
Macrosopic maximum tumour dimensions:  Width 38mm x 36mm x thickness 13mm
Tumour appearance:  The tumour is raised, soft and friable with soft tan cut surfaces
Macro depth of invasion:  10mm
Macro. dist. of tumour from closest margin:  5mm from the proximal margin of the urethra.
Appearance of the glans penis:  Normal
Lymph nodes:  Submitted
  Right inguinal nodes:  Fat 150x139x59mm with multiple nodes up to 25mm with two nodes replaced by white tumour.
  Left inguinal nodes:  Fat 145x88 x 36mm with multiple nodes up to 31mm with one node replaced by white tumour.
Macrosopic nodal metastases or mass:  Present. Max size 31mm
**MICROSCOPIC**

**Tumour**
- **Histologic tumour type:** Basaloid squamous cell carcinoma
- **Histological grade:** Grade 3 (poorly differentiated)
- **Microscopic maximum tumour dimensions:** Width 50mm x thickness 8mm

**Extent of invasion**
- **Primary tumour of the penis and foreskin:** Subepithelial/ lamina propria invasion
  - Invasion of corpus spongiosum
  - But not corpus cavernosum
- **Lymphovascular invasion:** Present
- **Perineural invasion:** Not identified

**Assoc. penile intraepithelial neoplasia (PeIN):** Present, undifferentiated (warty and basaloid)

**Margin status**
- **Urethral margin:** Not involved, 1mm dist. to invasive tumour
- **Peri-urethral tissues:** Not involved, 1mm from the corpus spongiosum margin
- **Corpus cavernosum:** Not involved, >5mm
- **Circumferential shaft margin:** Not involved, >5mm
- **Peripheral cutaneous margin:** Not involved, >5mm
- **Peripheral glans margin:** Not applicable
- **Deep soft tissue margins (NOS):** Not involved, 1mm dist. to invasive tumour

**Lymph node status**
- **Inguinal nodes- sentinel**
  - **RIGHT:** Not submitted
  - **LEFT:** Not submitted
- **Inguinal nodes- non-sentinel**
  - **RIGHT**
    - No. of lymph nodes examined: 12
    - No. of positive lymph nodes: 3
Max. dimension of largest deposit: 17mm
Extracapsular spread: Not identified

Inguinal nodes- non-sentinel
LEFT
No. of lymph nodes examined: 12
No. of positive lymph nodes: 1
Max. dimension of largest deposit: 21
Extracapsular spread: Not identified

Pelvic nodes
RIGHT
Not submitted

Pelvic nodes
LEFT
Not submitted

Other nodes Not applicable

ANCILLARY TESTS Not performed

Diagnostic Summary

Partial penectomy and bilateral radical inguinal lymph node dissection
Invasive SCC of basaloid type
Grade 3
50mm in largest dimension
8mm in thickness
Involving glans and foreskin and invading corpus spongiosum
Margins clear (1mm from the proximal margin).
Focal lymphovascular invasion present.
3 /12 positive right inguinal nodes
1 /12 positive left inguinal nodes
Stage pT2 N2 (AJCC 8th edition, 2016)

Comment: The invasive carcinoma arising in a broader area of warty/basaloid penile intraepithelial neoplasia (PeIN).

Reported by Dr Bernard Beckstein  Authorised 4/5/2017
## Appendix 4 WHO classification of tumours of the penis

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>ICD-O codes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Malignant epithelial tumours</strong></td>
<td></td>
</tr>
<tr>
<td>Squamous cell carcinoma, NOS</td>
<td>8070/3</td>
</tr>
<tr>
<td>Verrucous carcinoma</td>
<td>8051/3</td>
</tr>
<tr>
<td>Adenosquamous carcinoma</td>
<td>8560/3</td>
</tr>
<tr>
<td>Sarcomatoid squamous carcinoma</td>
<td>8074/3</td>
</tr>
<tr>
<td>Mixed squamous cell carcinoma</td>
<td>8070/3</td>
</tr>
<tr>
<td>Basaloid squamous carcinoma</td>
<td>8083/3</td>
</tr>
<tr>
<td>Warty (condylomatous) carcinoma</td>
<td>8054/3</td>
</tr>
<tr>
<td>Papillary carcinoma (NOS)</td>
<td>8050/3</td>
</tr>
<tr>
<td>Lymphoepithelioma-like carcinoma</td>
<td>8082/2</td>
</tr>
<tr>
<td><strong>Precursor lesions</strong></td>
<td></td>
</tr>
<tr>
<td>Penile intraepithelial neoplasia</td>
<td></td>
</tr>
<tr>
<td>Low grade</td>
<td>8077/0</td>
</tr>
<tr>
<td>High grade</td>
<td>8077/2</td>
</tr>
<tr>
<td>Warty PeIN/Basaloid PeIN/Wart-basaloid PeIN</td>
<td></td>
</tr>
<tr>
<td>PeIN differentiated</td>
<td>8071/2</td>
</tr>
<tr>
<td>Paget disease</td>
<td>8542/3</td>
</tr>
</tbody>
</table>

*The morphology codes are from the International Classification of Diseases for Oncology (ICD-O). Behaviour is coded /0 for benign tumours; /1 for unspecified, borderline, or uncertain behaviour; /2 for carcinoma in situ and grade III intraepithelial neoplasia; and /3 for malignant tumours.*

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Appendix 5       AJCC TNM staging

Tumours of the Penis and Foreskin (TNM 8)\textsuperscript{14,23,26,58,59}

Primary Tumour (T)

TX  Primary tumour cannot be assessed.

T0  No evidence of primary tumour.

Tis  Carcinoma \textit{in situ} (Penile intraepithelial neoplasia [PeIN]).

Ta  Non invasive localised squamous cell carcinoma

T1  Glans: Tumour invades lamina propria

- Foreskin: Tumour invades dermis, lamina propria or dartos fascia
- Shaft: Tumour invades connective tissue between epidermis and corpora regardless of location
- All sites with or without LVI or perineural invasion and is or is not high grade

T1a Tumour invades lamina propria or subepithelial connective tissue and is without lymphovascular or perineural invasion and is not high grade (i.e. grade 3 or sarcomatoid)

T1b Tumour invades lamina propria or subepithelial connective tissue and exhibits lymphovascular or perineural invasion and or is high grade (i.e. grade 3 or sarcomatoid)

T2  Tumour invades into corpus spongiosum (either glans or ventral shaft) with or without urethral invasion

T3  Tumour invades into corpora cavernosum (including tunica albuginea) with or without urethral invasion

T4  Tumour invades other adjacent structures.
Regional Lymph Nodes (N)

pNX  Lymph node metastasis cannot be established.
pN0  No lymph node metastasis.
pN1  Two or more inguinal metastases without extranodal extension (ENE)
pN2  Three or more unilateral inguinal metastases or bilateral metastases
pN3  ENE of lymph node metastases or pelvic lymph node metastases.

Distant Metastasis (M)

M0  No distant metastasis (clinical category only).
M1  Distant metastasis present.

M1 includes lymph node metastasis outside of the true pelvis in addition to visceral or bone sites.

Accurate staging and grading of tumours are used to determine subsequent clinical management and follow-up.

The anatomy of the penis is complex and difficulties often arise in distinguishing levels of invasion. The distinction between lamina propria and corpus spongiosum is made on the basis of vascularity. Vessels within erectile tissue are more angular and thin-walled with intervening fibromuscular tissue than those within the lamina propria which are more variably sized and separated by loose connective tissue.

Although there is a category of non-invasive verrucous carcinoma in the primary tumour classifications (Ta) in TNM7, the criteria for the diagnosis of this entity and its distinction from verrucous hyperplasia are unclear to the authors of this dataset and use of this category is not recommended. Although verrucous carcinomas have a pushing rather than infiltrative margin, they are nevertheless invasive. Invasion is often only superficial but more deeply invasive tumours may be observed. Non invasive localised tumours of the penis of any subtype are exceptionally rare in the authors’ experience.

Staging of pT1 is subdivided in TNM7 into pT1a for low-risk tumours and pT1b for high-risk tumours depending on the absence or presence of high-grade tumour and/or LVI. TNM8 also includes perineural invasion as a stratifier between T1a and T1b. The number of unilateral nodes needed upstage from pN1 to N2 has increased from two to three in TNM8. Metastatic tumour in regional lymph nodes with extranodal spread is categorised as pN3.

It was initially proposed that the pT2 primary tumour classification be subdivided to distinguish between invasion into the spongiosum and cavernosum, as some reports show that risk of metastases in increased in patients with invasion of the cavernosa. The RCPath dataset published in 2015 recommend substaging of T2 penile tumours into T2a (corpus spongiosum invasion) and T2b (corpus cavernosum invasion) as this is evidence based. TNM8 now recommends that
involvement of the corpus spongiosum is classified as T2 and involvement of corpora cavernosa is T3 irrespective of urethral involvement.

In the case of multiple tumours, the tumour with the highest T category should be classified and the multiplicity or number of tumours should be indicated in parentheses, e.g. pT2 (m) or pT2.

Use of the category TX is to be avoided and the designation e.g. ‘T (numerical value) at least’ is preferable if full staging is not possible because of the nature of the specimen (e.g. small incision biopsies) or the presence of positive margins.

If deep structures are not sampled and/or the invasive tumour extends to the margins of excision staging should still be attempted but designated as ‘pT1 at least’. The designation of pTX (unstageable) even in small biopsies should be avoided as far as possible as it is clinically unhelpful.

The category M0 should not be used in pathological staging. The term MX is no longer in use.
References


12 RCPA (Royal College of Pathologists of Australasia) (2009). *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols*. RCPA, Surry Hills NSW.


