CARCINOMAS OF THE LARYNX, HYPOPHARYNX AND TRACHEA

STRUCTURED REPORTING PROTOCOL

(1ˢᵗ Edition 2019)

Incorporating the:

International Collaboration on Cancer Reporting (ICCR)

Carcinomas of the Hypopharynx, Larynx and Trachea Dataset
www.ICCR-Cancer.org

Core Document versions:

- ICCR dataset: Carcinomas of the Hypopharynx, Larynx and Trachea Dataset 1st edition
- AJCC Cancer Staging Manual 8th edition
- World Health Organization (WHO). Classification of Head and Neck Tumours. 4th edition.

Disclaimer

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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Contents

Scope

This protocol contains standards and guidelines for the structured reporting of carcinomas of the Larynx, Hypopharynx and Trachea. The protocol has been developed for the reporting of resection and biopsy specimens of mucosal malignancies of the larynx, hypopharynx and trachea. The protocol applies to all invasive carcinomas of the larynx, hypopharynx and trachea (including the supraglottis, glottis, and subglottis). Salivary-type malignancies arising from mucosal glands of the larynx and hypopharynx should be recorded in this dataset; the paucity of prognostic or predictive data suggest that tumour type and grade (as described in the Carcinomas of the major salivary glands protocol), size and margin status should be recorded. Mucosal melanoma is presented in a separate dataset. Lymphomas and sarcomas are not included. Malignancies arising at other sites in the head and neck region, and neck dissections and nodal excisions are dealt with in separate protocols which may be used, as appropriate, in conjunction with this protocol.

Where more than one anatomically or histologically distinct primary tumours occur, a separate cancer checklist should be completed for each tumour.

TRACHEAL CARCINOMAS

Tracheal malignancies are rare and represented in the literature as single case reports and small series of cases. Most reports describe squamous cell carcinomas and carcinomas arising from the salivary glands.[1-5] Too few cases are reported to analyse prognostic or predictive data and there is no TNM classification for tracheal malignancies under either the Union for International Cancer Control (UICC) or American Joint Committee on Cancer (AJCC) systems.

Pragmatically, this protocol suggests that the data from squamous cell carcinomas are recorded using the hypopharyngeal carcinoma dataset as a template. In particular, tumour size (maximum diameter) and depth of invasion should be recorded.

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

Abbreviations

AJCC	American Joint Committee on Cancer
CG	Commentary for a guideline
CS	Commentary for a standard
FISH	Fluorescent in-situ hybridization
HPV	Human papillomavirus
ICCR	International Collaboration on Cancer Reporting
LIS	Laboratory information system
LVI	Lymphovascular invasion
PBS	Pharmaceutical Benefits Scheme
PNI	Perineural invasion
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 National Health and Medical Research Council (NHMRC) level III-2 evidence.[6] 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 e.g., 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 (e.g., 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 histo-morphological 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[6] 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 e.g., 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 (e.g., S1.02).

Structured report	A report format which utilises standard headings, definitions and nomenclature with required information.
Synoptic report	A structured report in condensed form (as a synopsis or precis).
Synthesis	Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.
	The Oxford dictionary defines synthesis as "the combination of components or elements to form a connected whole".
	In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.

Introduction

Carcinomas of the Larynx, Hypopharynx, and Trachea

Malignancies such as squamous cell carcinomas (SCCs) are common in the larynx and hypopharynx. Often associated with the risk factors of smoking and alcohol consumption, they arise from dysplastic surface epithelium, and are more likely to occur in patients older than 60 years.[7]

Transcriptionally active human papillomavirus infection appears to be linked to a small proportion of SCCs, however the prognostic significance is yet to be determined.[8]

Carcinomas of the trachea including tumours arising from the larynx to the carina, are rare. They mostly comprise SCCs or salivary carcinomas arising from mucosal glands. Limited evidence exists to guide management of these malignancies.[1-5]

In the case of co-existent oesophageal cancer, refer to the separate protocol for oesophageal and gastro-oesophageal junction carcinomas.

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[9,10] around the world. Both the United Kingdom,[11] and United States[12] 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 i.e., cancer registries.

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.

International Collaboration on Cancer Reporting

The International Collaboration on Cancer Reporting (ICCR), founded in 2011 by the Australasian (RCPA), United States College of American Pathologists (US CAP) and Royal College of Pathologists United Kingdom (RCPath UK) Colleges of Pathology and the Canadian Association of Pathology - Association Canadienne des Pathologistes (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[13-16] 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 Carcinomas of the Hypopharynx, Larynx and Trachea 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 carcinomas of the Larynx, Hypopharynx and Trachea.

ICCR dataset elements for Carcinomas of the Hypopharynx, Larynx and Trachea are included verbatim. ICCR Core elements are mandatory and therefore represented as standards in this document. ICCR Non-core 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:

![ICCR] S3.01	**The histological tumour type must be recorded.**

Additional commentary by the RCPA expert committee may be added to an ICCR element but is not included in the grey bordered area nor indicated with an ICCR logo e.g.,

![ICCR] 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, Royal College of Pathologists of Austr*alasia, 2009[17]

- *World Health Organization (WHO). Classification of Head and Neck Tumours., 4th Edition. El-Naggar AK, Chan JKC, Grandis JR, Takata T, Slootweg PJ (editors). Lyon, France: IARC Press;2017*[18]

- *AJCC Cancer Staging Manual, 8th edition, American Joint Committee on Cancer, 2016*[19]

Changes 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 – Carcinomas of the Hypopharynx, Larynx and Trachea 1st edition. All ICCR elements from this dataset, both core (mandatory) and non-core (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 e.g., example reports, request information etc, have also been added.

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Stakeholders

ACT Cancer Registry

ACT Health

Australian and New Zealand Head and Neck Cancer Society

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

Health Informatics Society of Australia (HISA)

Independent Review Group of Pathologists

Medical Oncology Group of Australia

Medical Software Industry Association (MSIA)

Ministry of Health, New Zealand

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)

Royal Australasian College of Surgeons (RACS)

Royal Australian and New Zealand College of Radiologists (RANZCR)

Royal Australian College of General Practitioners (RACGP)

Royal College of Pathologists of Australasia (RCPA)

South Australia Cancer Registry

Standards Australia

Tasmanian Cancer Registry

Victorian Cancer Registry

Western Australia Clinical Oncology Group (WACOG)

Western Australian Cancer Registry

Development process

This protocol has been developed following the ten-step process set out in *Guidelines for Authors of Structured Cancer Pathology Reporting Protocols.*[17]

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 carcinomas of the Larynx, Hypopharynx and Trachea, 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.[20] This document specifies the minimum information to be provided by the requesting clinician for any pathology test.

CS1.01b Document whether or not the patient identifies as Aboriginal and/or Torres Strait Islander in Australia, or Māori in New Zealand. This is in support of government initiatives to monitor the health of those who identify as indigenous, 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 In most cases all clinical information should be transcribed: however, in a small number of cases the pathologist may exercise discretion regarding the inclusion of provided clinical information, for instance, possibly erroneous information or information that may impact on patient privacy. In such case reference should be made as to the location of the complete clinical information e.g., "Further clinical information is available from the scanned request form."

G1.01 The copy doctors requested on the request form should 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 principal 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.

G1.02   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.

Tissue banking

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

Specimen handling

> ➢   Detailed fixation and specimen handling instructions are available from the RCPA online Cut-up Manual:
>
> https://www.rcpa.edu.au/Manuals/Macroscopic-Cut-Up-Manual

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

Macroscopic findings

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

S2.02	**The operative procedure must be recorded.**	
	CS2.02a	The nature of the operative procedure will influence the required level of detail in the pathological report. Diagnostic/incisional biopsies will usually generate a limited set of data items compared to excision/resection specimens and, for example, the status of resection margins does not require detailed consideration for diagnostic biopsies except for very small carcinomas where the entire cancer may be present in the diagnostic specimen.
	CS2.02b	If a neck dissection is submitted, then a separate protocol is available to record the information.
S2.03	**The specimen(s) submitted[21,22] must be recorded.**	
	CS2.03a	The pathologist needs to be informed about the nature of surgery (type of specimen) so that their description

| | | and dissection are focused on selecting appropriate tissues to guide accurate cancer staging.

The following commentary is intended to assist pathologists to understand the complex anatomy of the larynx and related structures. Anatomical sites and tissue compartments of the larynx are shown in Figures 1 and 2.

The **supraglottis** includes the epiglottis, aryepiglottic fold (laryngeal aspect), arytenoid (inferior part of it forms the vocal cord), ventricular bands (false cords) and laryngeal ventricles.

The **glottis** extends from the ventricle to approximately 1.0 cm below the free level of the true vocal cord and includes the vocal cords, anterior commissure and posterior commissure, vocal process of arytenoid.

The **subglottis** extends from approximately 1.0 cm below the level of the true vocal cord to the inferior rim of the cricoid cartilage.

Note that transglottic carcinomas cross the ventricles in a vertical direction arising in either the glottic and/or supraglottic larynx.

The **hypopharynx** is the part of the pharynx extending from the plane of the superior border of the hyoid bone (or floor of the vallecula) to the plane corresponding to the lower border of the cricoid cartilage. The contents of the hypopharynx include:

- left and right piriform sinuses which expand bilaterally and forward around the sides of the larynx and lie between the larynx and the thyroid cartilage

- lateral and posterior hypopharyngeal walls

- postcricoid region extending from the level of the arytenoid cartilages, inferior border of arytenoid to the inferior border of the cricoid cartilage.

The **paraglottic space** is a potential space antero-lateral and deep to the ventricles and saccules, and filled with adipose tissue and connective tissue (Figure 1). It is bounded by the conus elasticus inferiorly, the thyroid cartilage laterally, the quadrangular membrane medially, and the piriform sinus posteriorly.

The pre-epiglottic space is anterior to the base of the epiglottis and filled with adipose tissue and connective tissue (Figure 2); it is triangular in shape and is bounded by the thyroid cartilage and thyrohyoid membrane anteriorly, the epiglottis and thyroepiglottic |

			ligament posteriorly, and the hyoepiglottic ligament at its base (Figures 1 and 2). **Trachea** is defined as commencing 1 cm below the free edge of the vocal cord from the inferior border of cricoid to the carina.
ICCR	**S2.04**	**Specimen dimensions must be recorded.**	
ICCR		CS2.04a	The size of a resection specimen is useful as it places the size of the tumour into the operative context. In those rare instances where specimens may be mislabelled, the size of the tissue may help to resolve any discrepancies.
ICCR	**S2.05**	**The macroscopic tumour site(s) must be recorded.**	
ICCR		CS2.05a	Accurate documentation of the laterality and site of the specimen and tumour avoids errors in the delivery of therapy. The site of the primary tumour is a key determinant in clinicopathological staging systems for hypopharynx and larynx. For carcinomas that involve more than one site, the principal site of involvement should be recorded and coded; this may not be the site of origin. If required, the involvement of associated sites can be noted to help in later data analysis. Sites and subsites should be recorded according to the UICC nomenclature.[23]
ICCR	**S2.06**	**Tumour focality must be recorded.**	
ICCR	**S2.07**	**The maximum dimension of largest tumour must be recorded.**	
ICCR		CS2.07a	The macroscopic diameter (in millimetres) should be used unless the histological extent is greater than macroscopically apparent, in which case the microscopic dimension is used. As for other tissues, measurements are made pragmatically, acknowledging distortion of tissues by fixation and processing. For larynx, several sites rely on the presence or absence of vocal cord mobility to determine T stage; in these circumstances, only a provisional pT stage can be offered (at least pT1a, for example).
ICCR	G2.01	Additional dimensions of the largest tumour may be recorded.	

G2.02 Depth of invasion should be recorded.

G2.03 Macroscopic involvement of the thyroid cartilage and anterior soft tissues of the neck should be recorded.

G2.04 A description of the tumour should be recorded.

G2.05 A description of any mucosal surface abnormalities/lesion(s) should be described.

G2.06   A macroscopic distance of tumour to closest margin should be recorded

G2.07   The distance of the edge of tumour to tracheostomy site should be recorded if applicable.

G2.08   Macroscopic involvement of other tissues should be recorded.

S2.08   A differential ink application and block identification key listing the nature and origin of all tissue blocks must be recorded.

CS2.08a   The colours of the ink used to designate the various surfaces (particularly superficial and deep) should be clearly stated in the macroscopic description to guide margin assessment.

CS2.08b   The origin/designation of all tissue blocks should be recorded. This information should be documented in the final pathology report and is particularly important should the need for internal or external review arise. Where appropriate specimen photographs and block diagrams should be utilised. The reviewer needs to be clear about the origin of each block in order to provide an informed specialist opinion. 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.

Recording the origin/designation of tissue blocks also facilitates retrieval of blocks for further immunohistochemical or molecular analysis, research studies or clinical trials.

G2.09   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.

CG2.09a   The traditional macroscopic narrative recorded at the time of specimen dissection is often reported separately from the cancer protocol. Although this remains an option, it is recommended that macroscopic information be recorded within the overall structure of this protocol.

CG2.09b   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.

CG2.09c   A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.

CG2.09d   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.

Figure 1. Coronal section through the larynx to show the main structures and paraglottic space. Copyright ICCR – reproduced with permission.

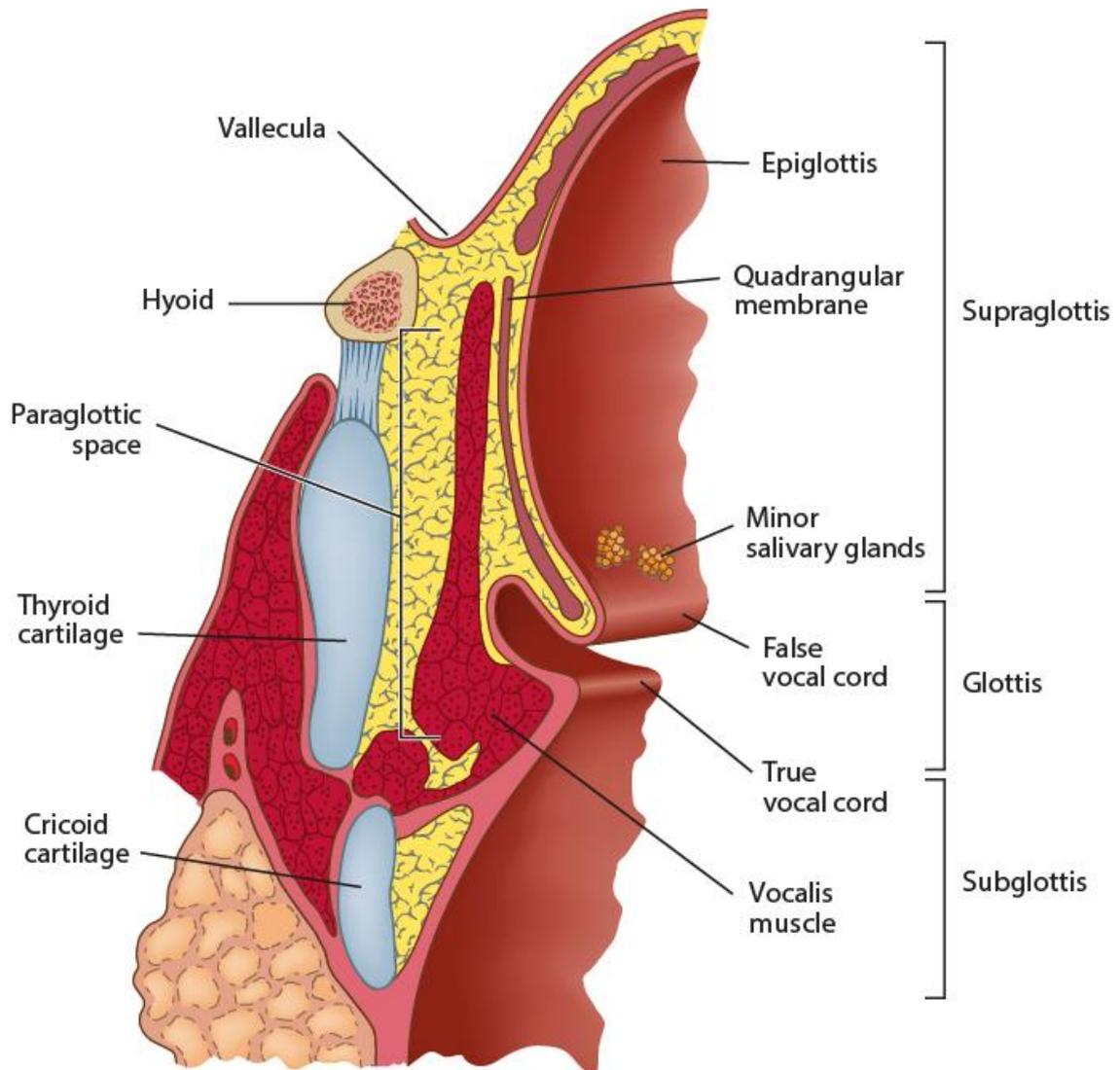**Figure 2. Sagittal section through the larynx to show main structures and the pre-epiglottic space.** Copyright ICCR – reproduced with permission.
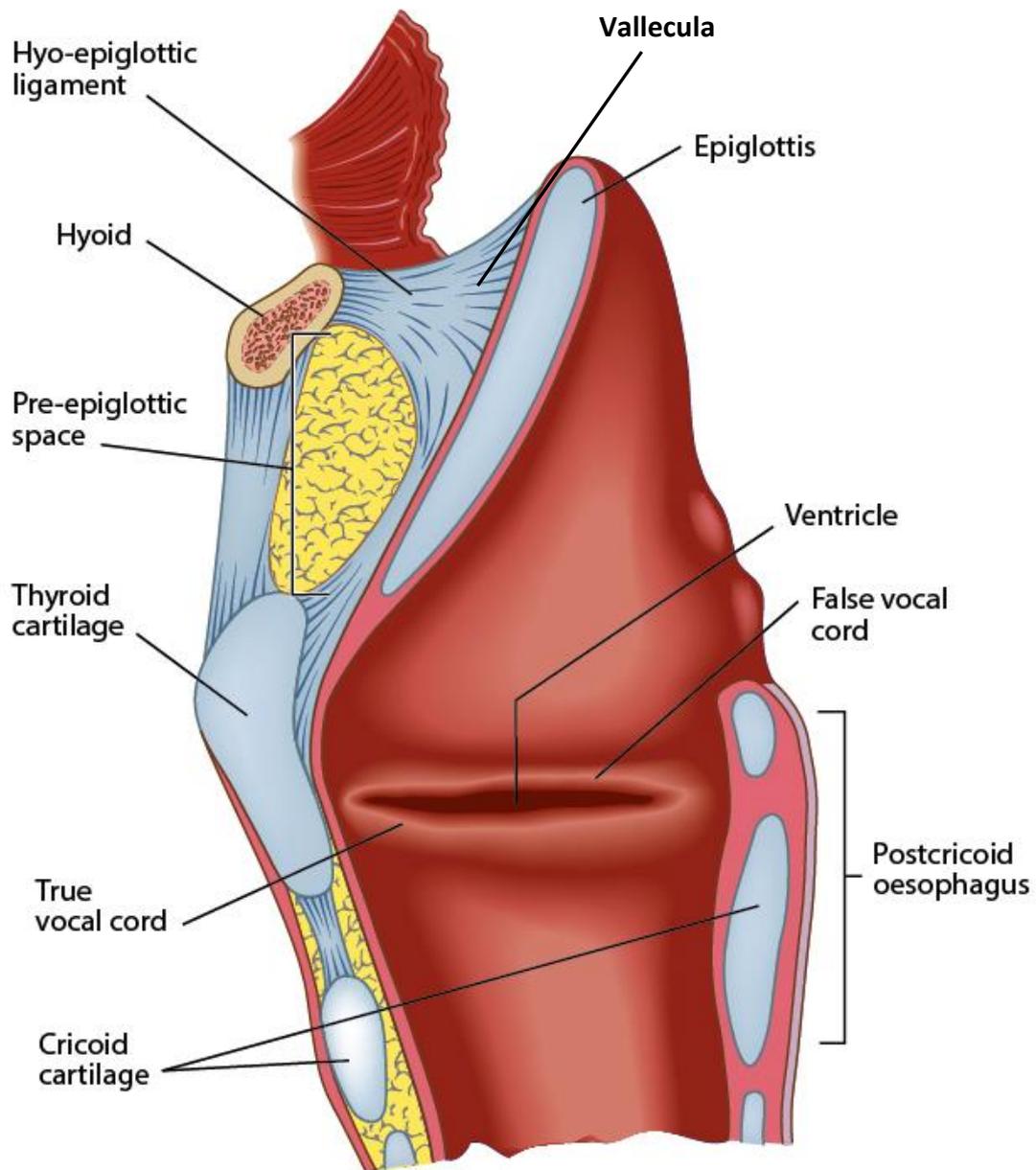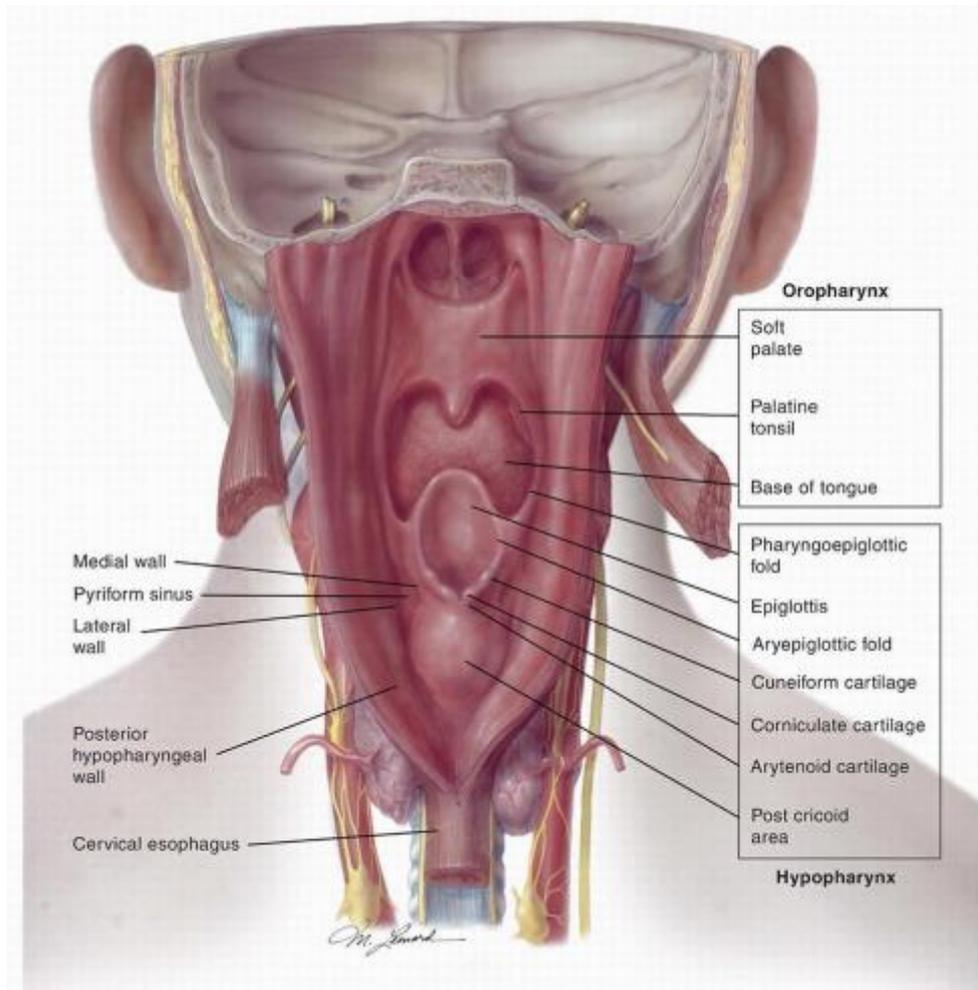
Figure 3. Anatomical subdivisions of the pharynx (posterior view). *This figure was published in Cancer of the Head and Neck, Fifth edition, 2016, Myers J and Hanna E, Copyright Lippincott Williams & Wilkins (2016). Reproduced with permission.*

3   Microscopic findings

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

IC CR S3.01	**The histological tumour type must be recorded.**	
IC CR	CS3.01a	Refer to Appendix 4.
IC CR	CS3.01b	Histopathological type is important for cancer registration and prognosis, with strength of evidence varying for different types. Verrucous and papillary carcinomas tend to have a good prognosis, while adenosquamous carcinomas have a worse prognosis than conventional and spindle cell carcinomas. For most of the variants of squamous cell carcinoma, surgery with adequate margins is the main treatment. In some tumours, such as large cell neuroendocrine carcinomas, a combination of irradiation and chemotherapy is indicated. All tumours of the larynx, hypopharynx and trachea should be given a type based on the most recent edition of the World Health Organization (WHO) Classification of Head and Neck Tumours.[24]
IC CR S3.02	**The Histological tumour grade[24-30] must be recorded.**	
IC CR	CS3.02a	The conventional grading system for classical squamous cell carcinomas should be used for all tumours at these sites. Grading is based on the degree of resemblance of the carcinoma to the normal epithelium and follows the descriptions in the WHO classification. The most aggressive area is graded as well, moderately or poorly differentiated. This system is widely used and prognostically useful, even though it suffers from inter-observer variability and sampling problems. It is important for prognostication to separate tumours based on differentiation. Where a tumour has a varied appearance, then the highest grade (poorest differentiation) is recorded as a core data item, while the predominant pattern may be recorded as non-core data. Squamous cell carcinoma variants (basaloid, adenosquamous, spindle cell) are considered to have intrinsic biological potential and are not graded. Although human papillomavirus (HPV)-associated carcinomas arising in the oropharynx are graded

		differently from conventional (non-HPV) carcinomas (see *Carcinomas of the nasopharynx and oropharynx* protocol), there is insufficient evidence to justify this approach in the hypopharynx and larynx. The recommendation is that HPV assessment should not be performed, except for basaloid carcinomas. For the grading of salivary-type tumour arising from mucosal glands, please refer to the *Carcinomas of the major salivary glands* protocol for descriptors.
IC CR S3.03	**The extent of invasion[21,23,31,32] must be recorded.**	
IC CR	CS3.03a	In the larynx, the invasion of tissue compartments deep to the mucosa is important for staging. The important tissues for staging purposes are the paraglottic space, the pre-epiglottic space and the thyroid and cricoid cartilages. One of the points of distinction between T3 and T4a carcinomas is whether cartilage invasion is minor (partial) or full thickness. The absolute tumour thickness is non-core for larynx and hypopharynx.
IC CR S3.04	**Tumour thickness in mm must be recorded.**	
IC CR G3.01	The pattern of invasive front should be recorded.	
IC CR	CG3.01a	The pattern of invasion[25,33] by the carcinoma at its deep margin is of proven prognostic value for oral and oropharyngeal carcinomas and there is limited evidence that a similar approach may be of value to predict nodal metastasis for hypopharyngeal and laryngeal carcinomas. Note that the response for this data item is based on the most complex ('worst') area of the carcinoma. The pattern of invasion is included as a non-core data item as many head and neck pathologists include this in their personal descriptive assessment of carcinomas at all sites, and it is convenient to use it for larynx and pharynx as well, for consistency with national protocols, even though this is not supported by robust evidence of clinical impact.
IC CR S3.05	**The presence or absence of perineural invasion must be recorded.**	
IC CR	CS3.05a	The presence or absence of perineural invasion[30,33-38] should be recorded, regardless of the size of the nerve. Invasion of the perineural plane is a predictor of local recurrence and nodal metastasis and may prompt consideration of adjuvant chemoradiotherapy. The perineural plane is a potential space between the bundles of axons and the perineurium; the presence of carcinoma around a nerve (external to the perineurium) is not regarded as perineural invasion. There is some evidence that extratumoural perineural invasion is of more importance than intratumoural perineural invasion, but this requires confirmation. For this

		protocol, either intra-tumoural or extra-tumoural invasion is regarded as a positive finding.
ICCR **S3.06**		**The presence or absence of lymphovascular invasion must be recorded.**
ICCR	CS3.06a	Lymphovascular invasion[9,30] is a relatively weak predictor of nodal metastasis.
		The presence of carcinoma cells within an endothelial-lined space is the essential criterion and should be distinguished from retraction artefact. It is not necessary to distinguish between small lymphatics and venous channels.
ICCR **S3.07**		**The surgical margin status must be reported.**
ICCR	CS3.07a	Margin status[39-50] is a predictor of local recurrence and may require consideration of adjuvant therapy. The status of the surgical resection margin should include assessment of both invasive and in situ carcinoma.
		A positive margin is one in which the carcinoma is present at the margin while the definition of a 'close margin' varies between published series, typically being regarded as between 3 and 5 mm. For laser resections of glottic carcinomas even 1 mm may be adequate due to the thermal damage of tissue at the margin.[51] It is recommended that the distance from in situ or invasive carcinoma to the closest margin is recorded in mm, if assessable. Note that comment on the deep resection margin of a laryngectomy specimen may be inapplicable unless the tumour extends close to the base of tongue or into the soft tissues of the neck.[52]
ICCR G3.02		The presence or absence of coexistent pathology should be recorded.
ICCR	CG3.02a	This is a non-core data item to provide the pathologist with the flexibility to record any other diseases that potential impact on clinical management, such as infections.

G3.03   Radiation induced tissue damage can be recorded.

      G3.03a   An observation regarding radiation induced tissue damage can be provided if the request form includes history regarding neoadjuvant radiotherapy or recurrence in a previous radiotherapy field. Currently, there are no internationally standardised guidelines for evaluation of radiotherapy induced damage or whether this should influence any decisions regarding further radiotherapy. However, description of the radiotherapy induced tissue damage will allow collection of this data to develop evidence base for the future. Features such as stromal atypia, hyalinization, interstitial fibrosis,

small vessel endothelial proliferation, and other features may be mentioned.

G3.04 Any additional relevant microscopic comments should be recorded.

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.

IC CR G4.01	Whether or not ancillary tests are performed should be recorded and the results incorporated into the pathology report.	
IC CR	CG4.01a	This is a non-core data item that is intended to allow pathologists to record the use of additional investigations, particularly molecular testing, the prognostic and predictive significance of which is uncertain.
		The literature recognises that a very few HPV associated carcinomas may occur in the hypopharynx and larynx, but prognostic relevance is uncertain.[8]

5 Synthesis and overview

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

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

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

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

ICCR S5.01	**The primary tumour stage (pT) must be recorded according to the AJCC TNM system (8th edition).**[19] 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.
ICCR	CS5.01a	By AJCC/UICC 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 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 lesions. Clinical classification (cTNM) is usually carried out by the referring physician before treatment during initial evaluation of the patient or when pathologic classification is not possible.

Pathologic staging is performed after surgical resection of the primary tumour. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumour has been completely removed. If a biopsied tumour is not resected for any reason (e.g., when technically unfeasible) and if the highest T and N categories or the M1 category of the tumour can be confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.

Primary Tumour: Subglottis |

		Note that the UICC and AJCC staging differs for T3/T4a subglottic carcinomas. In the AJCC system, T3 carcinomas include those limited to larynx with vocal cord fixation and/or invasion of paraglottic space and/or inner cortex of the thyroid cartilage. Larynx: Normal (T1) or impaired (T2) vocal cord mobility and vocal cord fixation (T3) may only be determined clinically. TNM Descriptors For identification of special cases of TNM or pTNM classifications, the "m" suffix and "y" and "r" prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis. The "m" suffix indicates the presence of multiple primary tumours in a single site and is recorded in parentheses: pT(m)NM. The "y" prefix indicates those cases in which classification is performed during or following initial multimodality therapy (i.e., neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a "y" prefix. The ycTNM or ypTNM categorizes the extent of tumour actually present at the time of that examination. The "y" categorization is not an estimate of tumour prior to multimodality therapy (i.e., before initiation of neoadjuvant therapy). The "r" prefix indicates a recurrent tumour when staged after a documented disease-free interval, and is identified by the "r" prefix: rTNM. Additional Descriptors Residual Tumour (R) Tumour remaining in a patient after therapy with curative intent (e.g., surgical resection for cure) is categorized by a system known as R classification, shown below. RX Presence of residual tumour cannot be assessed R0 No residual tumour R1 Microscopic residual tumour R2 Macroscopic residual tumour

		For the surgeon, the R classification may be useful to indicate the known or assumed status of the completeness of a surgical excision. For the pathologist, the R classification is relevant to the status of the margins of a surgical resection specimen. That is, tumour involving the resection margin on pathologic examination may be assumed to correspond to residual tumour in the patient and may be classified as macroscopic or microscopic according to the findings at the specimen margin(s).

S5.02 The year of publication and/or the 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. Specimen(s) submitted

    b. Tumour type

    c. Tumour grade

    d. Tumour stage

    e. Lymphovascular invasion (LVI)

    f. Perineural invasion (PNI)

    g. Margins of resection

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:

- explain the decision-making pathway, or any elements of clinicopathological ambiguity, or factors affecting diagnostic certainty, thereby allowing communication of diagnostic subtlety or nuance that is beyond synoptic capture

- give recommendations for further action or investigation

- document further consultation or results still pending

    CS5.03b   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 XXXXXXX".

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 this cancer. For emphasis, standards (mandatory elements) are formatted in bold font.

S6.01   The structured checklist provided may be modified as required but with the following restrictions:

a. All standards and their respective naming conventions, definitions and value lists must be adhered to.

b. Guidelines are not mandatory but are recommendations and where used, must follow the naming conventions, definitions and value lists given in the protocol.

G6.01   The order of information and design of the checklist may be varied according to the laboratory information system (LIS) capabilities and as described in *Functional Requirements for Structured Pathology Reporting of Cancer* Protocols.[53]

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.

S/G	Item description	Response type	Conditional
Pre-analytical			
S1.01	**Demographic information provided**		
S1.02	**Clinical information provided on request form**	**Not provided** OR **Text** OR **Structured entry as below:**	

	Neoadjuvant therapy	**Single selection value list:**
		
		• Information not provided
		
		• Not administered
		
		• Administered, *specify type (select all that are applicable)*
		    o Chemotherapy
		    o Radiotherapy
		    o Targeted therapy, *specify if available*
		    o Immunotherapy, *specify if available*	

		o Time interval since therapy, *specify*	
	New primary lesion or recurrence	**Single selection value list:** • New primary • Recurrence – regional, *describe* • Recurrence – distant, *describe*	
IC CR	Operative procedure	**TEXT** **OR** **Multi selection value list (select all that apply):** • Biopsy (excisional, incisional), *specify* • Resection, *specify* • Neck (lymph node) dissection*, *specify* • Other, *specify* Note: ** If a neck dissection is submitted, then a separate protocol is used to record the information.*	
G1.01	Copy To doctors recorded	**Text**	
S1.03	**Pathology accession number**	**Alpha-numeric**	
S1.04	**Principal clinician**	**Text**	
G1.02	Comments	**Text**	

	Macroscopic findings			
S2.01	**Specimen labelled as**	**Text**		
ICCR **S2.02**	**Operative procedure**	**Multi selection value list (select all that apply):** • Not specified • Biopsy (excisional, incisional), *specify* • Resection, *specify* • Neck (lymph node) dissection*, *specify* • Other, *specify* Note: ** If a neck dissection is submitted, then a separate protocol is used to record the information.*		

ICCR **S2.03**	**Specimen submitted**	Not specified
		
		OR
		
		Multi selection value list (select all that apply):
		
		• Trachea
		
		• Hypopharynx
		  o Laryngopharyngectomy
		  o Other, *specify*
		
		• Larynx		

			o Transoral laser excision
			o Total laryngectomy
			o Other, *specify*
IC CR	S2.04	**Specimen dimensions**	**Numeric: __x__x__mm** <u>Notes:</u> Record measurements for each specimen submitted

IC CR	S2.05	**Tumour site**	• Cannot be assessed
			
			 • No macroscopically visible tumour
			
			 OR
			
			 Multi selection value list (select all that apply):
			
			 • Trachea
			     o Left
			     o Midline
			     o Right
			     o Laterality not specified
			
			 • Hypopharynx
			     o Left
			     o Midline
			     o Right
			     o Laterality not specified
			     o Piriform sinus

		○ Postcricoid ○ Pharyngeal wall (posterior and/or lateral) ○ Other, *specify* • Larynx, supraglottis ○ Left ○ Midline ○ Right ○ Laterality not specified ○ Epiglottis ▪ Lingual aspect ▪ Laryngeal aspect ○ Aryepiglottic fold ○ Arytenoid ○ False vocal cord/fold ○ Ventricle • Larynx, glottis ○ Left ○ Midline ○ Right ○ Laterality not specified ○ True vocal cord/fold ○ Anterior commissure	

			o Posterior commissure
			• Larynx, subglottis
			   o Left
			   o Midline
			   o Right
			   o Laterality not specified
			• Other, *specify including laterality*	

IC+CR	S2.06	**Tumour focality**	**Single selection value list:** • Cannot be assessed, *specify* • Unifocal • Multifocal*, specify number of tumours in specimen*	
IC+CR	S2.07	**Maximum dimension of largest tumour**	**Cannot be assessed, *specify*** **OR** **Numeric: __mm**	
	G2.01	Additional dimensions of largest tumour	**Numeric: __x__mm**	
	G2.02	Depth of invasion	**Numeric: __mm**	
	G2.03	Involvement of thyroid cartilage and anterior soft tissues of the neck	**Single selection value list:** • Not identified • Present, describe	

G2.04	Tumour description	**Multi selection value list (select all that apply):** • Exophytic • Endophytic • Ulcerated • Polypoid • Nodular	
G2.05	Mucosal surface abnormalities/lesion(s)	**Single selection value list:** • Not identified • Present, *describe and measure*	
G2.06	Macroscopic distance to closest margin(s)	**Numeric:___mm** **AND** *Specify margin(s)*	
G2.07	Distance of edge of tumour to tracheostomy site	**Numeric: ___mm**	
G2.08	Macroscopic involvement of other tissues	**Multi selection value list (select all that apply):** • Laryngeal cartilage, *specify numbers involved* • Extralaryngeal tissues • Other, *describe*	
S2.08	**Ink application and block identification key**	**Text**	

G2.09	Additional macroscopic comments	**Text**	
Microscopic findings			

IC CR S3.01	**Histological tumour type**	**Multi selection value list (select all that apply):**
		
		 • Squamous cell carcinoma, conventional type
		
		 • Squamous cell carcinoma, variant types
		
		      o Adenosquamous carcinoma
		
		      o Basaloid squamous cell carcinoma
		
		      o Papillary squamous cell carcinoma
		
		      o Spindle cell squamous cell carcinoma
		
		      o Verrucous squamous cell carcinoma
		
		 • Lymphoepithelial carcinoma
		
		 • Neuroendocrine carcinoma
		
		      o Well differentiated neuroendocrine carcinoma
		
		      o Moderately differentiated neuroendocrine carcinoma
		
		      o Poorly differentiated neuroendocrine carcinoma	

		▪ Small cell neuroendocrine carcinoma	
		▪ Large cell neuroendocrine carcinoma	
		• Combined (or composite) neuroendocrine carcinoma, with squamous or adenosquamous component	
		• Carcinomas of minor salivary glands	
		o Adenoid cystic carcinoma, *specify grade*	
		o Mucoepidermoid carcinoma, *specify grade*	
		o Other, *specify*	
		• Other, *specify*	
IC✱CR S3.02	**Histological grade**	**Single selection value list:**	
		• Not applicable	
		• GX: Cannot be assessed	
		• G1: Well differentiated	
		• G2: Moderately differentiated	
		• G3: Poorly differentiated	
		• G4: Undifferentiated	
		• Other, *specify*	

ICCR	S3.03	**Extent of invasion**	**Multi selection value list (select all that apply):** **Larynx** • Not identified • Involves mucosa • Involves muscle • Involves paraglottic space • Involves pre-epiglottic space • Partial thickness invasion of cartilage • Full thickness invasion of cartilage • Other, *specify* **Hypopharynx** • Tissue layers involved, *specify*	
ICCR	S3.04	**Tumour thickness**	**Numeric: __mm**	
ICCR	G3.01	Pattern of invasive front *(Resection specimens only, not applicable to biopsies)*	**Single selection value list:** • Cohesive • Non-cohesive	
ICCR	S3.05	**Perineural invasion**	**Single selection value list:** • Cannot be assessed, *specify* • Not identified • Present	

IC CR	S3.06	**Lymphovascular invasion**	**Single selection value list:** • Cannot be assessed, *specify* • Not identified • Present	
IC CR	S3.07	**MARGIN STATUS**		
IC CR		**Invasive carcinoma**	**Single selection value list:** • Not involved • Involved	*If not involved by invasive carcinoma record the distance from closest margin and specify closest margin, if possible* *If involved specify margin(s) if possible*
IC CR		*Distance from closest margin*	**Numeric: ___mm** *OR* **Distance not assessable**	
IC CR		*Closest margin*	*Text*	
IC CR		*Margin(s) involved*	*Text*	
IC CR		**Carcinoma in situ/high-grade dysplasia****	**Single selection value list:** • Not involved • Involved <u>Notes</u>:	*If not involved by Carcinoma in situ/high-grade dysplasia record the distance of tumour from closest margin and the closest margin, if possible.* *If involved specify margin(s) if possible*

			** *High-grade dysplasia is synonymous with moderate/ severe dysplasia.*	
IC CR	G3.02	Coexistent pathology	**None identified** **OR** **Multi selection value list (select all that apply):** • Necrotizing sialometaplasia • Infection, *specify* • Dysplasia, *specify type and grade* • Other, *specify*	
	G3.03	Radiation induced tissue damage	**Single selection value list:** • Not identified • Identified, *specify* • Cannot be assessed, *specify*	*If identified specify a description of induced damage, if possible.* *If cannot be assessed, specify a reason, if possible.*
	G3.04	Additional microscopic comment	**Text**	
Ancillary findings				
IC CR	G4.01	Ancillary studies	**Single selection value list:** • Not performed • Performed, *specify*	
Synthesis and overview				
IC CR	S5.01	**PATHOLOGICAL STAGING (AJCC 8TH EDITION)**		

IC CR	**TNM descriptors**	**Multi select value list :** • m - multiple primary tumours • y - post therapy • r - recurrent	
IC CR	**Primary tumour (T)**	**Single select value list :** **Supraglottis** TX Primary tumour cannot be assessed *Tis* Carcinoma *in situ* T1 Tumour limited to one subsite of supraglottis with normal vocal cord mobility T2 Tumour invades mucosa of more than one adjacent subsite of supraglottis or glottis or region outside the supraglottis (e.g., mucosa of base of tongue, vallecula, medial wall of pyriform sinus) without fixation of the larynx T3 Tumour limited to larynx with vocal cord fixation and/or invades any of the following: postcricoid area, pre-epiglottic space, paraglottic space, and/or inner cortex of thyroid cartilage T4 Moderately advanced or very advanced T4a Moderately advanced local disease. Tumour invades through the outer cortex of the thyroid cartilage and/or invades tissues beyond the	

		larynx (e.g., trachea, soft tissues of neck including deep extrinsic muscle of the tongue, strap muscles, thyroid, or oesophagus)
		T4b Very advanced local disease
		     Tumour invades prevertebral space, encases carotid artery, or invades rnediastinal structures
		
		Glottis
		TX Primary tumour cannot be assessed
		Tis Carcinoma in *situ*
		T1 Tumour limited to the vocal cord(s) (may involve anterior or posterior commissure) with normal mobility
		T1a Tumour limited to one vocal cord
		T1b Tumour involves both vocal cords
		T2 Tumour extends to supraglottis and/or subglottis, and/or with impaired vocal cord mobility
		T3 Tumour limited to the larynx with vocal cord fixation and/or invasion of paraglottic space and/or inner cortex of the thyroid cartilage
		T4 Moderately advanced or very advanced
		T4a Moderately advanced local disease
		     Tumour invades through the outer cortex of the thyroid cartilage and/or invades tissues beyond the larynx (e.g., trachea, cricoid cartilage, soft tissues of neck including deep extrinsic muscle of	

| | | the tongue, strap muscles, thyroid, or oesophagus) |
| | | T4b Very advanced local disease Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures |

Subglottis

TX   Primary tumour cannot be assessed

Tis   Carcinoma *in situ*

T1   Tumour limited to the subglottis

T2   Tumour extends to vocal cord(s) with normal or impaired mobility

T3   Tumour limited to larynx with vocal cord fixation and/or invasion of paraglottic space and/or inner cortex of the thyroid cartilage

T4   Moderately advanced or very advanced

T4a   Moderately advanced local disease. Tumour invades cricoid or thyroid cartilage and/or invades tissues beyond the larynx (e.g., trachea, soft tissues of neck including deep extrinsic muscles of the tongue, strap muscles, thyroid, or oesophagus)

T4b   Very advanced local disease Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures

		Hypopharynx TX Primary tumour cannot be assessed Tis Carcinoma in *situ* Tl Tumour limited to one subsite of hypopharynx and/or 2 cm or smaller in greatest dimension T2 Tumour invades more than one subsite of hypopharynx or an adjacent site, or measures larger than 2 cm but not larger than 4 cm in greatest dimension without fixation of hemilarynx T3 Tumour larger than 4 cm in greatest dimension or with fixation of hemilarynx or extension to oesophagus mucosa T4 Moderately advanced and very advanced local disease T4a Moderately advanced local disease. Tumour invades thyroid/cricoid cartilage, hyoid bone, thyroid gland, esophageal muscle or central compartment soft tissue* T4b Very advanced local disease Tumour invades prevertebral fascia, encases carotid artery, or involves mediastinal structures *Note: Central compartment soft tissue includes prelaryngeal strap muscles and subcutaneous fat	

S5.02	**Year and edition of staging system**	**Numeric:** year **AND** **Text:** Edition e.g.,1st, 2nd etc	
G5.01	Diagnostic summary Include: a. Specimen(s) submitted b. Tumour type c. Tumour grade d. Tumour stage e. LVI f. PNI g. Margins	**Text**	
S5.03	**Overarching comment**	**Text**	
G5.02	Edition/version number of the RCPA protocol on which the report is based	**Text**	

7 Formatting of pathology reports

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

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

Appendix 1   Pathology request form

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 Carcinomas of the Larynx, Hypopharynx and Trachea 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 must 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

- Document whether or not the patient identifies as Aboriginal and/or Torres Strait Islander in Australia, or Māori in New Zealand. This is in support of government initiatives to monitor the health of those who identify as indigenous, 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

IC CR ➢	Any neoadjuvant therapy administered should be recorded.

IC·CR	●	Information from the surgeon about the use of neoadjuvant therapy will help the pathologist interpret correctly the histologic findings. While the extent of tumour necrosis or post-therapy fibrosis are not currently used as an important guide to management for most types of laryngeal cancer, it is good practice to document the effects of previous treatment as part of a free text report. Pragmatically, an estimate of the amount (% tumour volume) of necrosis or fibrosis can be provided as free text.
IC·CR ➢		The operative procedure should be recorded.

➢ Comments should be included, if appropriate.

    ● Space for free text should be included to encourage reporting of ambiguity, or for the addition of other comments.

Example Request Information Sheet

Carcinomas of the Larynx, Hypopharynx and Trachea Histopathology Request Information

Family name

Given name(s)

Date of birth

DD – MM – YYYY

Date of request

DD – MM – YYYY

Patient identifiers
e.g. MRN, IHI or NHI (please indicate which)

Indigenous Status

- ○ Aboriginal but not Torres Strait Islander origin
- ○ Torres Strait Islander but not Aboriginal origin
- ○ Both Aboriginal and Torres Strait Islander origin
- ○ Neither Aboriginal nor Torres Strait Islander origin
- ○ Not stated/inadequately described

Requesting doctor - name and contact details

Copy to doctor name and contact details

CLINICAL INFORMATION

NEOADJUVANT THERAPY

- ○ Information not provided
- ○ Not administered
- ○ Administered, *specify type*
  - ☐ Chemotherapy
  - ☐ Radiotherapy
  - ☐ Targeted therapy, *specify if available*

  - ☐ Immunotherapy, *specify if available*

OPERATIVE PROCEDURE (select all that apply)

- ☐ Biopsy, *specify*

- ☐ Resection, *specify*

- ☐ Neck (lymph node) dissection*, *specify*

- ☐ Other, *specify*

* If a neck dissection is submitted, then a separate dataset is used to record the information.

COMMENTS

V1.0 Request Info from CARCINOMAS OF THE LARYNX, HYPOPHARYNX AND TRACHEA Structured Reporting Protocol 1st Edition

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

56 Carcinomas of the Larynx, Hypopharynx and Trachea Structured Reporting Protocol 1st edition

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 similar data elements under headings and using 'white space' assists in rapid transfer of information.[54]

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

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

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

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

Configure reports in such a way that data elements are 'chunked' into a single unit to help improve recall for the clinician.[54]

Reduce 'clutter' to a minimum.[54] Thus, information that is not part of the protocol (e.g., billing information or SNOMED codes) should not appear on the reports or should be minimised.

Reduce the use of formatting elements (e.g., bold, underlining or use of footnotes) because these increase clutter and may distract the reader from the key information.

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

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

As a report is transferred between systems:

- text characteristics such as font type, size, bold, italics and colour are often lost

- tables are likely to be corrupted as vertical alignment of text is lost when fixed font widths of the LIS are rendered as proportional fonts on screen or in print

- spaces, tabs and blank lines may be stripped from the report, disrupting the formatting

- supplementary reports may merge into the initial report.

Appendix 3   Example of a pathology report

For malignancies arising from lymph node specimens, refer to the protocol for Head and Neck nodal excisions where appropriate, in conjunction with this protocol.

Citizen, Gerald W.
C/O Paradise Close
Wreck Bay Resort
Nar Nar Goon East, 3181

Male

DOB 1/7/1947
MRN M1196785

Lab Ref: **18/P28460**
Referred: 30/8/2019

Copy to: Dr N.G.Chappie
Rainforest Cancer Centre.
46 Smith Road,
Woop Woop, 3478

Referred by: Dr V. Brown
Suite 3, AJC Medical Centre,
Bunyip Crescent
Nar Nar Goon West, 3182

CARCINOMAS OF THE LARYNX, HYPOPHARYNX AND TRACHEA

STRUCTURED REPORT

Diagnostic Summary

Pharyngolaryngectomy and left neck dissection levels II-IV:

Squamous cell carcinoma,

Perineural invasion present

Metastatic squamous cell carcinoma in 2 of 33 lymph nodes (2/33)

Stage pT4a pN3b (AJCC 8th edition, 2016)

Supporting Information

CLINICAL INFORMATION RECEIVED

Neoadjuvant therapy:	Not administered
Operative procedure:	Pharyngolaryngectomy and left neck dissection

MACROSCOPIC

Specimen labelled as:	"left neck dissection with pharyngolaryngectomy"
Operative procedure:	Pharyngolaryngectomy and left neck dissection, Level II-IV
Specimen submitted:	Pharynx, larynx, level II-IV neck dissection
Specimen dimensions:	85 x 60 x 50mm
Tumour site:	Hypopharynx, left
Tumour focality:	Unifocal
Maximum dimension of largest tumour:	35 mm
Additional tumour dimensions:	20 x 35 mm
Depth of invasion:	10 mm
Involvement of thyroid/soft tissue:	Soft tissue
Tumour description:	Located in left hypopharynx, ulcerated tumour nodule, suspicious for involvement of left aryepiglottic fold and thyroid cartilage
Mucosal surface abnormalities/lesions:	Not identified
Macro. dist. To closest margin(s):	1 mm, superior, 3mm right soft tissue margin
Dist. Of tumour to tracheostomy site:	Not applicable

NECK DISSECTION:

Number of lymph nodes:	33
Macroscopic metastatic tumour:	Present
Macroscopic largest metastatic deposit:	35mm
Macroscopic extracapsular spread: Present	
Macroscopic distance to closest margin:	2mm

Ink application & block identification key:

Anterior orange, right lateral blue, left lateral green, posterior back. False margin after hyoid bone removed yellow.

A: inferior tracheal margin, B: Inferior oesophageal margin, C: left epiglottic fold: 1D–a tumour with closest superior margin: 1F–H tumour with closest left circumferential margin: 1I representative section posterior margin: 1J tumour and thyroid cartilage: 1K tumour and cricoid cartilage: 1L hyoid bone closest to tumour (decalcified section)

1M–S level II lymph nodes, 1 T–W level III lymph nodes, 1X–third level IV lymph nodes (lymph nodes according to lymph node protocol nil)

Photograph and blocking diagram attached.

MICROSCOPIC

Histologic tumour type:	Squamous cell carcinoma
Histological grade:	G2: Moderately differentiated, keratinising
Extent of invasion:	Invades aryepiglottic fold, invades into soft tissue of neck
Tumour thickness:	10 mm
Pattern of invasive front:	Cohesive
Perineural invasion:	Present
Lymphovascular invasion:	Not identified

Margin status

Invasive carcinoma:	Not involved
Distance from closest margin:	2 mm superior
Closest margin:	Superior
Margin(s) involved:	nil
Carcinoma in situ/high-grade dysplasia:	Adjacent high grade dysplasia
Coexistent pathology:	None identified
Additional microscopic comments:	nil

Lymph node (LN) status

Lymph node laterality:	Left
Node levels:	II-IV
Number of nodes examined:	33
Number of nodes positive:	2
Level of involved nodes:	Level 2: 2/12
Max dimension of largest LN met:	35 mm
Max dimension of largest involved LN:	35 mm
Extranodal extension (ENE):	ENEma (>2mm)
Number of nodes with ENE:	1
Level of lymph node with ENE:	2
Greatest extent of ENE:	5mm

Margin overlying ENE:	2mm away
Soft tissue metastasis:	Not seen
Non-lymphatic structures involved:	Not applicable

Additional comments: Lymph nodes: as per lymph node protocol
Level 2: 2/12. The largest is 35mm in diameter with 5mm extranodal extension
Level 3: 0 of 7
Level 4: 0 of 14

ANCILLARY TESTS   Nil

Reported by Dr Bernadette Beckstein   Authorised 4/9/2019

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Appendix 4   WHO classification of tumours

WHO classification of tumours of the larynx, hypopharynx and trachea[24]

Descriptor	ICD-O codes[a]
Malignant surface epithelial tumours	
Conventional squamous cell carcinoma	8070/3
Verrucous squamous cell carcinoma	8051/3
Basaloid squamous cell carcinoma	8083/3
Papillary squamous cell carcinoma	8052/3
Spindle cell squamous carcinoma	8074/3
Adenosquamous carcinoma	8560/3
Lymphoepithelial carcinoma	8082/3
Neuroendocrine tumours	
Well-differentiated neuroendocrine carcinoma	8240/3
Moderately differentiated neuroendocrine carcinoma	8249/3
Poorly differentiated neuroendocrine carcinoma	
Small cell neuroendocrine carcinoma	8041/3
Large cell neuroendocrine carcinoma	8013/3

[a] 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.

For salivary-type tumour arising from mucosal glands, please refer to the *ICCR Carcinomas of the major salivary glands* dataset[55] for descriptors and ICD-O codes.

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