

**CARCINOMAS OF THE MAJOR
SALIVARY GLANDS
STRUCTURED REPORTING
PROTOCOL
(2nd Edition 2019)**

Incorporating the:

International Collaboration on Cancer Reporting (ICCR)

Carcinomas of the Major Salivary Glands Dataset

www.ICCR-Cancer.org

Core Document versions:

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

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Contents

Scope	vi
Abbreviations	vii
Definitions	viii
Introduction	1
Authority and development	4
1 Pre-analytical	7
2 Specimen handling and macroscopic findings	9
3 Microscopic findings	12
4 Ancillary studies findings	17
5 Synthesis and overview	18
6 Structured checklist	21
7 Formatting of pathology reports	36
Appendix 1 Pathology request information and surgical handling procedures	37
Appendix 2 Guidelines for formatting of a pathology report	41
Appendix 3 Example of a pathology report	43
Appendix 4 WHO histological classification of tumours	45
References	46

Scope

This protocol contains standards and guidelines for the reporting of resection and biopsy specimens of malignant neoplasms and associated carcinoma in situ arising from the major salivary glands. The protocol applies to all carcinomas of the parotid, submandibular and sublingual glands; metastases are excluded. Melanomas, lymphomas, and sarcomas are dealt with in separate protocols. Minor salivary gland malignancies arising in the oral cavity, nasal cavity and paranasal sinuses, trachea, nasopharynx, oropharynx and hypopharynx and odontogenic specimens are staged according to their anatomical sub-site and are dealt with in separate protocols. In addition, neck dissections and nodal excisions are dealt with in a separate protocol, and this protocol should be used in conjunction, where applicable.

For bilateral tumours, a separate cancer checklist should be completed for each tumour.

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 any salivary gland neoplasms, whether as a minimum data set or fully comprehensive report.

Abbreviations

AJCC	American Joint Committee on Cancer
ICCR	International Collaboration on Cancer Reporting
IHC	Immunohistochemistry
IHI	Individual health identifier
LIS	Laboratory Information System
MRN	Medical Record Number
NHI	National Health Index number (NZ)
PBS	Pharmaceutical Benefits Scheme
RCPA	Royal College of Pathologists of Australasia
TALP	Tumour associated lymphoid proliferation
TNM	Tumour-node-metastasis
UHI	Unique Health Identifier
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 (eg how does the item assist with clinical management or prognosis of the specific cancer).
- cite published evidence in support of the standard or guideline
- 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 (eg 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.¹ 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 evidence¹ 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).

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	<p>Synthesis is the process in which two or more pre-existing elements are combined, resulting in the formation of something new.</p> <p>The Oxford dictionary defines synthesis as “the combination of components or elements to form a connected whole”.</p> <p>In the context of structured pathology reporting, synthesis represents the integration and interpretation of information from two or more modalities to derive new information.</p>

Introduction

Salivary gland carcinomas

Malignant salivary gland neoplasms are derived from the gland parenchyma and are generally uncommon lesions.^{2,3} When they do occur there is wide variation in their histological features and also in their clinical behaviour.⁴ The frequency of salivary gland malignancies ranges from 0.4 to 13.5 cases per 100000 population.² They account for between 5 - 6% of head and neck cancers and 0.3-1% of malignancies of all body sites.^{2,3} They can arise in the major salivary glands, minor glands or rarely ectopic sites. Malignant neoplasms arising in minor salivary glands are classified using the same staging principle as for other primary mucosal malignancies and include predictive factors associated with the specific histological type.⁴ Surgical removal of salivary gland neoplasms usually involves partial excision of the gland including the tumour mass or, alternatively by complete excision of the entire gland.

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^{5,6} around the world. Both the United Kingdom,⁷ and United States⁸ 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.

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 capture⁹⁻¹² 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 Major Salivary Glands 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 Major Salivary Glands.

ICCR dataset elements for Carcinomas of the Major Salivary Glands 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:

 S3.01	The histological tumour type must be recorded.
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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 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, Royal College of Pathologists of Australasia, 2009*¹³
- *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.*¹⁴
- *AJCC Cancer Staging Manual, 8th edition, American Joint Committee on Cancer, 2016*¹⁵

Changes since the last edition

- Rework of formatting in line with new Structured Pathology Reporting protocols framework.
- Rework of the checklist in Ch 6.
- Inclusion of ICCR agreed CORE and NON-CORE elements.

Authority and development

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

This 2nd edition of the protocol is an amalgam of two separate processes:

1. This protocol is based on the ICCR dataset – carcinomas of the major salivary glands 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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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)

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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

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Public Pathology Australia

Queensland Cooperative Oncology Group (QCOG)

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Representatives from laboratories specialising in anatomical pathology across Australia

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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*.¹³

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 major salivary glands 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.¹⁶ 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 a 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 eg "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 ie 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 must be recorded.

	S2.02 The operative procedure must be recorded.
	<p>CS2.02a The wide distribution of subsites that are involved by salivary gland carcinomas results in a wide complexity of procedural types, and necessitates open communication between the operating surgeon and the pathologist. The exact type of procedure (ie excisional biopsy versus resection) will be interpreted in discussion with the multidisciplinary team, especially since procedural nomenclature is constantly evolving.^{17,18} In the context of recurrent disease, there may be nodules of recurrent carcinoma without any surrounding salivary gland tissue, and the best procedure designation would require dialog between pathologist and surgeon.¹⁹</p>
	S2.03 The specimen(s) submitted must be recorded.
	<p>CS2.03a The salivary sites, particularly the parotid have a nuanced, oncologically relevant compartmentalization that should be represented appropriately under specimen type and tumour type.¹⁷ Tissue types and</p>

		<p>microanatomic structures encountered histologically are dependent on this specimen type and site. Thus, as with procedure type, open communication is necessary to maximize accuracy.</p> <p>Laterality is a standard identifying parameter for specimen types that should rarely be left not specified. Reporting of laterality provides supporting information to ensure that the correct site is recorded, and is a common quality assurance metric.²⁰ Not specified should be used rarely and only after best efforts have been made to obtain the requisite information.</p>
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G2.01 The integrity of the specimen should be recorded as intact or fragmented.

S2.04 Record if the specimen is received fresh or in formalin.

S2.05 The specimen must be measured in 3 dimensions.

	S2.06	The macroscopic tumour site(s) must be recorded.
	S2.07	Tumour focality must be recorded.
	CS2.07a	Truly multifocal salivary carcinomas are rare. The most common multifocal malignancy is acinic cell carcinoma. ²¹ Rarely multifocality in basal cell adenocarcinoma may raise the possibility of a cylindromatosis (<i>CYLD</i>) associated syndrome (ie Brooke Spiegler syndrome). ²²
	S2.08	The maximum dimension of largest tumour must be recorded.
	CS2.08a	Tumour size, specifically the largest dimension is a key staging element for American Joint Committee on Cancer (AJCC) and is prognostically critical. ^{23,24} Tumour measurement should ideally be performed macroscopically on the fresh specimen if possible, since formalin fixation may cause tumour shrinkage. ²⁵ Occasionally, the microscopic extent of tumour should be used to record tumour size, for example, when the size significantly exceeds macroscopic estimates.

CS2.08b The prognosis of stage III or IV neoplasms is poor regardless of histological grade.

	G2.02	Additional dimensions of the largest tumour may be recorded.
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S2.09 Macroscopic evidence of extraparenchymal extension of the tumour must be recorded.

CS2.09a In the AJCC staging system, extraparenchymal extension qualifies for a T3 tumour. Extension into the skin, mandible, ear canal, facial nerve, base of skull, pterygoid plates or encasement of the carotid artery, which are classified as T4 tumours.

In most instances the ear canal, portion of the

mandible, proximal end of the facial nerve, or soft tissues around the carotid may be received in separate jars.

S2.10 A block identification key listing the nature and origin of all tissue blocks must be recorded.

CS2.10a 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. 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.

G2.03 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.

CG2.03a 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.

CG2.03b 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.

CG2.03c A traditional macroscopic description may be required when the Laboratory Information System (LIS) does not allow a structured approach.

CG2.03d 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.

 S3.01	The histological tumour type must be recorded.	
	CS3.01a	Refer to Appendix 4.
	CS3.01b	<p>Salivary carcinoma histologic type essentially defines its biologic behaviour and thus influences prognosis, patterns of recurrence and thus clinical management.^{26,27} Some carcinoma types (ie basal cell adenocarcinoma, conventional acinic cell carcinoma) are more indolent with locoregional recurrence but low nodal and distant metastatic rates.²⁸ Other tumour types are aggressive even at early T stage, aggressive lesions (such as conventional salivary duct carcinoma) show high rates of nodal metastasis and worse 5-year overall survival.^{29,30}</p> <p>Carcinoma ex pleomorphic adenoma is subclassified by type and extent of invasion. Non-invasive cancers are completely confined within the capsule of the adenoma. The definition for minimally invasive carcinomas varies, ranging from 1.5 mm to 6 mm (this distance should be specified when possible). Invasive carcinomas extend beyond 6 mm; non-invasive cancers are completely confined to within the capsule without evidence of penetration into extracapsular tissue. Prior to diagnosing a non-invasive carcinoma ex pleomorphic adenoma, sectioning of the entire lesion for histologic evaluation is recommended in order to exclude the presence of invasive growth. Prognosis has been linked to degree of invasion with non-invasive and minimally invasive cancers apparently having a better prognosis than invasive cancers.^{31,32} For salivary duct carcinoma arising from pleomorphic adenoma, intracapsular lesions behave indolently. But once invasive, the concept of minimal invasion may be less relevant since cases with extracapsular invasion ≤ 2 mm have still been reported to be clinically aggressive.²⁹</p> <p>Metastasizing pleomorphic adenoma, despite its aggressive behaviour is not included here since it is technically considered benign under the recent World Health Organization (WHO) classification of tumours.³³</p> <p>In the 2017 WHO classification of tumours, cribriform adenocarcinoma of (minor) salivary gland origin is a subcategory of polymorphous adenocarcinoma.³⁴ This is a controversial area and the recommendation is to separate classical and cribriform pattern polymorphous adenocarcinomas in the dataset to allow acquisition of prognostic information. Unlike classic polymorphous</p>

		<p>adenocarcinoma, cribriform adenocarcinomas of minor salivary gland are more frequently extrapalatal, commonly at base of tongue, and have a higher propensity for nodal metastasis. Histologically they have more pronounced vesicular nuclei and tend to have a papillary glomeruloid and cribriform growth rather than a targetoid fascicular pattern seen in classic polymorphous adenocarcinoma.³⁵ They tend to demonstrate translocations involving the <i>protein kinase D (PRKD)</i> family of genes,³⁶ rather than the <i>PRKD1</i> point mutations³⁷ seen in classic polymorphous adenocarcinoma. For the purposes of reporting, differentiating between these entities may be helpful given the noticeably different behavioural profile.</p> <p>Note: The diagnosis of primary squamous cell carcinoma of the salivary gland should be used sparingly as it is typically a metastasis from another site.</p>
 S3.02	The Histological tumour grade³⁸⁻⁴⁴ must be recorded (when applicable).	
	CS3.02a	<p>The histologic (microscopic) grading of salivary gland carcinomas has been shown to be an independent predictor of behaviour and plays a role in optimizing therapy. Further, there is often a positive correlation between histologic grade and clinical stage.^{31,45-47} However, as alluded to above, most salivary gland carcinoma types have an intrinsic biologic behaviour and attempted application of a universal grading scheme is not recommended.³¹ Thus by assigning a histologic type the tumour grade itself is often implied. Thus a generic grading scheme is no longer recommended for salivary gland carcinomas.²³</p> <p>Carcinoma types for which grading systems exist and are relevant are incorporated into histologic type. The major categories that are amenable to grading include adenoid cystic carcinoma, mucoepidermoid carcinoma, and adenocarcinoma, not otherwise specified.^{31,46,48} Additionally, with the new WHO classification, polymorphous adenocarcinoma is another tumour type that is to be graded,³⁴ with the understanding that a validated grading scheme has not yet been established.</p> <p>In adenoid cystic carcinoma histologic grading is based on growth pattern.⁴⁸ Those adenoid cystic carcinomas showing 30% or greater of solid growth pattern are considered to be histologically high grade carcinomas. However, recent studies suggest that any solid component may still be of prognostic relevance.⁴⁹ The histologic grading of mucoepidermoid carcinoma includes a combination of growth pattern characteristics (eg cystic, solid, neurotropism) and cytomorphologic findings (eg anaplasia, mitoses, necrosis).⁵⁰⁻⁵² Adenocarcinomas, not otherwise specified, do not have a formalized grading scheme and are graded intuitively based on cytomorphologic features.³¹ Similarly, as the</p>

		<p>concept of grading polymorphous adenocarcinomas will be a new one,³⁴ as these also lack a formalized grading scheme. Currently, the recommendation is to grade these intuitively based on cytomorphologic features, acknowledging that the majority will be low grade.</p> <p>High grade transformation has evolved into an important concept of tumour progression in salivary gland carcinomas. Historically designated as 'dedifferentiation', it describes progression of a typically monomorphic carcinoma into a pleomorphic high grade carcinoma.⁵³ The importance of this phenomenon is that tumours demonstrating high grade transformation show an aggressive clinical course that deviates drastically from the usual behaviour for a given tumour type, thus alerting to the potential need for more aggressive clinical management. Tumours for which this phenomenon is well characterized include acinic cell carcinoma, adenoid cystic carcinoma, and epithelial-myoeipithelial carcinoma. Secretory carcinoma and polymorphous adenocarcinoma also rarely undergo high grade transformation.^{54,55}</p>
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CS3.02b Refer to WHO for further [information](#).^{14,56}

S3.03 Microscopic tumour size must be recorded.

CS3.03a Neoplasm size is an important factor relating to the outcome of salivary gland neoplastic disease.⁵⁷ The prognosis of stage III or IV neoplasms is poor regardless of histological grade. Lesions that are less than 4cm in size generally have a better prognosis.⁵⁷

 S3.04	The extent of invasion must be recorded.	
	CS3.04a	<p>Macroscopic extraparenchymal extension is the parameter required to upstage a tumour to T3 and is thus more important than microscopic extraparenchymal extension.</p> <p>Bone, skin and facial nerve involvement are parameters that define stage T4a.²³ While microscopic extraparenchymal extension is not a stage defining parameter, in certain instances it may yield useful information for post-operative clinical management.</p>

CS3.04b Extraparenchymal extension for pT3 is based on macroscopic examination and requires macroscopic extension of the tumour beyond the confines of the salivary gland into the attached soft tissues and skeletal muscle. This assessment may also require clinical and radiologic correlation.

CS3.04c Involvement of skin, mandible, ear canal or facial nerve confers a T4a classification while encasement of the carotid artery or invasion of the skull base and pterygoid plates indicates T4b disease.

 S3.05	The presence or absence of perineural invasion must be recorded.	
	CS3.05a	Perineural invasion is diagnostically useful since it usually indicates a malignant categorization. The value of perineural invasion as a prognosticator varies depending on tumour type and literature. ⁵⁸ While this has not been as well studied for salivary gland as for head and neck squamous cell carcinoma, much of the literature supports the importance of recording this feature as a data element. ⁵⁹⁻⁶² Select named nerve (ie facial nerve) involvement is incorporated into staging and assigned a more advanced stage. ²³ But even beyond this, a more granular documentation, extent of perineural invasion, localization and size of involved nerves may be prognostically relevant as well, though not well studied, hence their inclusion as non-core elements.
 G3.01	If perineural invasion is present, nerve size, location and degree of extent should be recorded.	

CG3.01a From a radiation oncology perspective, it is important to specify if perineural invasion involves a named nerve, the size or diameter of the involved nerve and the length of involvement. This provides useful information for risk assessment in determining whether to include the nerve back to the base of skull in the radiation target volume.

 S3.06	The presence or absence of lymphovascular invasion must be recorded.	
	CS3.06a	Lymphovascular invasion is diagnostic of malignancy in salivary gland tumours. Existing data are limited but support its prognostic value although this varies by tumour type and study. ^{61,63,64} As with other organ sites, the significance of the distinction between vascular and lymphatic invasion as well as the extent of vascular invasion is not known.
 S3.07	The surgical margin status must be reported.	
	CS3.07a	In addition to the distance of tumour from the excision margin, documentation regarding the site of the positive or narrow margin should also be reported.
	CS3.07b	Complete surgical excision to include cancer-free surgical margins is the primary mode of therapy for salivary gland cancers, as retrospective studies have shown an increased risk for recurrence and decreased survival with positive surgical margins. ⁶⁵⁻⁶⁷ Unlike mucosal sites, there are no data to indicate a specified critical distance of tumour from margin indicative of a prognostic difference. Indeed this may be dependent on tumour type, major salivary gland involved, and border as well. Based on current level of evidence, reporting of

		<p>distances to margins constitute a non-core element.</p> <p>For illustration, adenoid cystic carcinoma usually has an infiltrative border and high propensity for local recurrence. The “safe distance” for this tumour will be intuitively greater than for a more indolent carcinoma such as epithelial myoepithelial carcinoma, for instance. Limited data suggest that even with >5 mm clearance, approximately 20% of adenoid cystic carcinomas recur, which is still less than the recurrence rate for close (<5 mm) and positive margins.⁶⁸ In contrast, almost all epithelial- myoepithelial carcinomas are cured if margins are negative, even without a stipulation in distance to margin.⁶⁹</p> <p>Occasionally, even salivary carcinomas may show encapsulation similar to that of pleomorphic adenoma. In superficial parotid gland tumours, this tumour capsule rests on the facial nerve and may thus be resected conservatively (ie via extracapsular dissection) in order to spare and minimize injury to the facial nerve. Thus it is not uncommon for such tumours to be “close” with the tumour capsule forming the deep margin. It is not clear whether this scenario indicates an increased risk of local recurrence. Limited data on extracapsular dissection for salivary carcinomas suggest a favourable outcome even with close margins, though this may be influenced by tumour type, since most carcinomas with this configuration are slow growing and low grade.⁷⁰</p>
 G3.02	The presence or absence of coexistent pathology should be recorded.	
	CG3.02a	<p>For salivary epithelial malignancies, non-neoplastic salivary pathology is of interest but not currently oncologically relevant overall. For some tumours however a tumour associated lymphoid proliferation (TALP)⁷¹ may be mistaken for a lymph node and this distinction is important for staging. For acinic cell carcinomas, those with a prominent TALP may actually be more indolent.⁷²</p>

G3.03 Any additional relevant 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. Research continues into various prognostic biomarkers, however at the present time there are no specific molecular markers that are used in routine clinical practice to assist clinicians in predicting the neoplasms behaviour or response to therapy for salivary gland neoplasms.

The few ancillary tests that may be required in certain situations will be listed by technique. No ancillary tests are currently used on a routine basis for the diagnosis of salivary gland neoplasms.

 G4.01	Whether or not ancillary tests are performed should be recorded and the results incorporated into the pathology report.	
	CG4.01a	<p>Ancillary studies encompass immunohistochemistry as well as molecular analysis. The main use of ancillary testing in salivary gland is to refine diagnosis. While there may be some prognostic and therapeutic applications, they are not yet strongly validated as standard of care, and thus no ancillary study is currently required as a data element in salivary cancers.</p> <p>Understanding of salivary gland cancer biology has increased tremendously and is largely characterized by a preponderance of chromosomal translocations that frequently define certain tumour types. These are testable by many methodologies. A detailed review of each relevant marker in each salivary gland cancer type is beyond the scope of this dataset.⁵⁶ Alterations in benign tumours such as pleomorphic adenoma and basal cell adenoma may be retained in their malignant counterparts.</p>

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.

 S5.01	The primary tumour stage (pT) must be recorded according to the AJCC TNM system (8th edition).¹⁵	
	CS5.01a	<p>By AJCC/Union for International Cancer Control (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 based on clinical stage information supplemented/modified by operative findings and gross and microscopic evaluation of the resected specimens.⁷³ pT entails a resection of the primary tumour or 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 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.</p> <p>Pathologic staging is usually 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 (eg 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.</p> <p>TNM Descriptors</p> <p>For identification of special cases of TNM or pTNM</p>

		<p>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.</p> <p><u>The "m" suffix</u> indicates the presence of multiple primary tumours in a single site and is recorded in parentheses: pT(m)NM.</p> <p><u>The "y" prefix</u> indicates those cases in which classification is performed during or following initial multimodality therapy (ie 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 (ie before initiation of neoadjuvant therapy).</p> <p><u>The "r" prefix</u> indicates a recurrent tumour when staged after a documented disease-free interval, and is identified by the "r" prefix: rTNM.</p>
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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. Type of operation
- b. Anatomical site / laterality
- c. Tumour type
- d. Histological grade
- e. Tumour dimensions
- f. Extraglandular extension of tumour
- g. Lymphovascular invasion
- h. Perineural invasion
- i. Involved or close margins with measurements
- j. Tumour stage

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 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 neoplasms of the salivary glands. For emphasis, standards (mandatory elements) are formatted in bold font.

S6.01 The structured checklist provided below 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*.⁷⁴

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.

Values 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:	
	Operative procedure	TEXT OR Multi select value list (select all that apply): <ul style="list-style-type: none"> • Biopsy (excisional, incisional), <i>specify</i> • Resection, <i>specify</i> • Neck (lymph node) dissection*, <i>specify</i> • Other, <i>specify</i> <u>Note:</u> * <i>If a neck dissection is submitted, then a separate dataset is used to record the information.</i>	

S/G	Item description	Response type	Conditional
	Anatomical site of neoplasm	Multi select value list (choose all that apply): <ul style="list-style-type: none"> • Parotid gland - whole • Parotid gland - superficial lobe • Parotid gland - deep lobe • Submandibular gland • Sublingual gland • Other, <i>specify</i> 	
	Laterality of the lesion	Single selection value list: <ul style="list-style-type: none"> • Left • Right • Midline • Not specified 	
	Clinical history	Text	
	Clinical TNM stage	Text	
	Clinical diagnosis or differential diagnosis	Text	
	New primary cancer or recurrence	Single selection value list: <ul style="list-style-type: none"> • New primary • Recurrence – regional (local) • Recurrence – distant metastasis, <i>specify</i> 	
	Pre-operative or prior	Single selection value list:	

S/G	Item description	Response type	Conditional
	radiotherapy	<ul style="list-style-type: none"> None administered Administered, <i>specify details</i> 	
	Any involvement of adjacent structures	Text	
G1.01	Copy to doctor	Text	
S1.03	Pathology accession number	Alpha-numeric	
S1.04	Principal clinician caring for the patient	Text	
G1.02	Other clinical information received	Text	
Macroscopic findings			
S2.01	Specimen labelled as	Text	
 S2.02	Operative procedure	<p>Not specified</p> <p>OR</p> <p>Multi select value list (select all that apply):</p> <ul style="list-style-type: none"> Biopsy (excisional, incisional), <i>specify</i> Resection, <i>specify</i> Neck (lymph node) dissection*, <i>specify</i> Other, <i>specify</i> <p><u>Note:</u> * If a neck dissection is submitted, then a separate dataset is used to record the</p>	

S/G	Item description	Response type	Conditional
		<i>information.</i>	
 S2.03	Specimens submitted	Not specified OR Multi select value list (select all that apply): <ul style="list-style-type: none"> • Parotid gland <ul style="list-style-type: none"> ○ Superficial lobe only ○ Deep lobe only ○ Total parotid (superficial and deep lobe) • Submandibular gland • Sublingual gland • Other (eg partial gland excision), specify 	
G2.01	Specimen integrity	Single selection value list: <ul style="list-style-type: none"> • Intact • Fragmented 	
S2.04	Specimen received	Single selection value list: <ul style="list-style-type: none"> • Fresh • Formalin 	
S2.05	Specimen measurements	Numeric: __x__x__mm	

S/G	Item description	Response type	Conditional
 S2.06	Macroscopic tumour site(s)	<p>Cannot be assessed</p> <p>OR</p> <p>Multi select value list (choose all that apply):</p> <ul style="list-style-type: none"> • Parotid gland <ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Parotid gland - superficial lobe only <ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Parotid gland - deep lobe only <ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Total parotid (superficial and deep lobe) <ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Submandibular gland 	

S/G	Item description	Response type	Conditional
		<ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Sublingual gland <ul style="list-style-type: none"> ○ Left ○ Right ○ Laterality not specified • Other, <i>specify including laterality</i> 	
 S2.07	Tumour focality	Single selection value list: <ul style="list-style-type: none"> • Cannot be assessed, <i>specify</i> • Unifocal • Multifocal, <i>specify number of tumours in specimen</i> 	
 S2.08	Maximum dimension of largest tumour (largest focus in a single specimen)	Cannot be assessed, <i>specify</i> OR Numeric: __mm	
 G2.02	Additional dimensions (largest tumour)	Numeric: __x__mm	
S2.09	Macroscopic evidence of extraparenchymal extension	Single selection value list: <ul style="list-style-type: none"> • Absent • Present 	

S/G	Item description	Response type	Conditional
S2.10	Block identification key	Text	
G2.03	Other macroscopic comment	Text	
Microscopic findings			
IC ⁺ CR	S3.01 Histological tumour type	<p>Cannot be assessed, <i>specify</i></p> <p>OR</p> <p>Multi select value list (choose all that apply):</p> <p>(World Health Organization Classification of Head and Neck Tumours [2017]).</p> <ul style="list-style-type: none"> • Acinic cell carcinoma • Secretory carcinoma • Mucoepidermoid carcinoma <ul style="list-style-type: none"> ○ Low grade ○ Intermediate grade ○ High grade • Adenoid cystic carcinoma <ul style="list-style-type: none"> ○ Tubular/cribriform pattern predominant ○ Solid pattern • Polymorphous adenocarcinoma 	<p>If Adenoid cystic carcinoma - Tubular/cribriform pattern predominant or Solid pattern, record the % of solid component, if any.</p> <p>If Carcinoma ex pleomorphic adenoma, minimally invasive, record the distance from capsule</p>

S/G	Item description	Response type	Conditional
		<ul style="list-style-type: none"> ○ Classic, <i>specify grade</i> ○ Cribriform • Epithelial-myoepithelial carcinoma • (Hyalinizing) Clear cell carcinoma • Basal cell adenocarcinoma • Sebaceous adenocarcinoma • Myoepithelial carcinoma • Intraductal carcinoma <ul style="list-style-type: none"> ○ Low grade ○ High grade • Cystadenocarcinoma <ul style="list-style-type: none"> ○ Low grade ○ High grade • Adenocarcinoma, not otherwise specified (NOS) <ul style="list-style-type: none"> ○ Low grade ○ Intermediate grade ○ High grade • Salivary duct carcinoma, <i>specify variants</i> • Carcinoma ex pleomorphic adenoma, <i>specify tumour type(s) eg salivary duct adenocarcinoma, NOS</i> 	

S/G	Item description	Response type	Conditional
		<ul style="list-style-type: none"> ○ Intracapsular ○ Minimally invasive ○ Widely invasive • Carcinosarcoma • Poorly differentiated carcinoma: <ul style="list-style-type: none"> ○ Neuroendocrine and non-neuroendocrine ○ Undifferentiated carcinoma ○ Large cell neuroendocrine carcinoma ○ Small cell neuroendocrine carcinoma • Lymphoepithelial carcinoma • Squamous cell carcinoma • Oncocytic carcinoma • Other, <i>specify</i> 	
	% of solid component, if any	Numeric: __%	
	Distance from capsule	Numeric: __mm	
 S3.02	Histological tumour grade	Single selection value list: <ul style="list-style-type: none"> • Not applicable • High grade transformation 	

S/G	Item description	Response type	Conditional
		<ul style="list-style-type: none"> Cannot be assessed, <i>specify</i> 	
S3.03	Microscopic tumour size	Numeric: ___x__x__mm	
 S3.04	Extent of invasion	<ul style="list-style-type: none"> Not identified Cannot be assessed, <i>specify</i> <p>OR</p> <p>Multi select value list (choose all that apply):</p> <ul style="list-style-type: none"> Macroscopic extraparenchymal extension Bone Skin Facial nerve Other, <i>specify</i> 	
 S3.05	Perineural invasion	<p>Single selection value list:</p> <ul style="list-style-type: none"> Not identified Present Cannot be assessed, <i>specify</i> 	If present, consider recording G3.01
 G3.01	<i>Nerve size, if known</i>	Numeric: ___mm	

S/G	Item description	Response type	Conditional
	<i>Location</i>	Single selection value list: <ul style="list-style-type: none"> • <i>Intratumoural</i> • <i>Extratumoural</i> <i>Note: only extratumoural is of prognostic value</i>	
	<i>Degree of extent</i>	Single selection value list: <ul style="list-style-type: none"> • <i>Focal</i> • <i>Extensive</i> 	
 S3.06	Lymphovascular invasion	Single selection value list: <ul style="list-style-type: none"> • Not identified • Present • Cannot be assessed, <i>specify</i> 	
 S3.07	Margin status	Single selection value list: <ul style="list-style-type: none"> • Involved by carcinoma • Not involved by carcinoma • Cannot be assessed, <i>specify</i> 	If involved by carcinoma, record the specific margin(s), if possible If not involved, specify the margin and distance of tumour from closest margin.
	<i>Involved margin(s), if possible</i>	Text	
	<i>Distance of tumour from closest margin</i>	Distance not assessable OR Numeric: ___mm	

S/G	Item description	Response type	Conditional
	<i>Closest margin, if possible</i>	Text	
 G3.02	Coexistent pathology	None identified OR Multi select value list (choose all that apply): <ul style="list-style-type: none"> • Sialadenitis • Tumour associated lymphoid proliferation (TALP) • Benign tumour(s), <i>specify</i> • Other, <i>specify</i> 	
G3.03	Other microscopic comment	Text	
Ancillary test findings			
 G4.01	Ancillary studies	Single selection value list: <ul style="list-style-type: none"> • Not performed • Performed, <i>specify</i> 	
Synthesis and overview			
 S5.01	PATHOLOGICAL STAGING (AJCC 8TH EDITION)		
	TNM descriptors	Multi select value list :	

S/G	Item description	Response type	Conditional
		<ul style="list-style-type: none"> • m - multiple primary tumours • y - post therapy • r - recurrent 	
	Primary tumour (T)	Single selection value list: TX Primary tumour cannot be assessed T0 No evidence of primary tumour Tis Carcinoma <i>in situ</i> T1 Tumour 2 cm or smaller in greatest dimension without extraparenchymal extension* T2 Tumour larger than 2 cm but not larger than 4 cm in greatest dimension without extraparenchymal extension* T3 Tumour larger than 4 cm and/or tumour having extraparenchymal extension* T4 Moderately advanced or very advanced disease T4a Moderately advanced disease Tumour invades skin, mandible, ear canal, and/or facial nerve T4b Very advanced disease Tumour invades skull base and/or pterygoid plates and/or encases carotid artery *Extraparenchymal extension is clinical or macroscopic evidence of invasion of soft tissues. Microscopic evidence alone does not constitute extraparenchymal extension for classification purposes.	

S/G	Item description	Response type	Conditional
S5.02	Year of publication and edition of cancer staging system	Numeric: year AND Text: Edition eg 1 st , 2 nd etc.	
G5.01	Diagnostic summary Include: a) Type of operation b) Anatomical site / laterality c) Tumour type d) Histological grade e) Tumour dimensions f) Extraglandular extension of tumour g) Lymphovascular invasion h) Perineural invasion i) Involved or close margins with measurements j) Tumour stage	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 interpretation 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 carcinomas of the major salivary glands 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
 - 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 ie 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



➤ **The operative procedure should be recorded.**

- The type of operation performed will influence the subsequent handling of the specimen in the laboratory.

➤ **The anatomical site of the neoplasm should be recorded.**

- This may include:
 - Parotid gland - whole
 - Parotid gland - superficial lobe
 - Parotid gland - deep lobe
 - Submandibular gland
 - Sublingual gland
 - Minor salivary gland (specify site)
 - Other (specify)
- Site is an important identifier especially when multiple biopsies are performed. For carcinomas that may involve more than one site it is recommended that the clinician identify all sites involved and that if possible the principal site of involvement be recorded.
- Sufficient information is required to localise the lesion for subsequent therapy. A diagram or photograph can facilitate this.
- Prognostic significance – the association between anatomical site and survival may be explained by the tumour site's influence on metastasis to cervical lymph nodes.^{75,76}

➤ **The laterality of the lesion should be recorded.**

- Laterality information is needed for identification purposes.

➤ **Clinical history should be recorded.**

- The clinical TNM stage should be recorded.
- The clinical diagnosis or differential diagnosis should be recorded.
 - Providing the provisional clinical diagnosis or differential diagnosis improves clinico-pathological correlation and improves diagnostic accuracy.

- **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.
- **If pre-operative or prior radiotherapy has been administered, this should be recorded.**
 - Pre-operative radiotherapy significantly alters the gross and microscopic appearance of the neoplasm.
 - This information would prompt a comment on the extent of any response to the treatment.
- **Any involvement of adjacent structures should be recorded.**
 - With regard to extension of disease into areas that either have or have not been resected, it is the responsibility of the surgeon to report these deposits and, if indicated, mark these areas with a suture or other marker.

Surgical handling

- **The specimen must be handled in a systematic and thorough fashion by the surgeon and theatre staff.**
 - The pathological findings from examination of a surgical specimen are important in guiding the patient's subsequent management. Hence the surgeon should handle the specimen in a systematic and thorough fashion to ensure accuracy of pathological data, resection margin status and pathological stage.
- The specimen should be correctly labelled, orientated or be capable of orientation. The status of specific surgical margins is critical in determining the need for, or extent of, further surgery or other

adjuvant therapies.⁷⁷

- Where there are no anatomical landmarks, specimen orientation should be indicated with marking sutures or other techniques. If a specimen is orientated, the orientation should be indicated on the specimen request form (this may be facilitated by the use of a diagram).

Example Request Information Sheet

CARCINOMAS OF THE MAJOR SALIVARY GLANDS Histopathology Request Information 	
Family name <input type="text"/>	Ethnicity <input type="radio"/> Unknown/inadequately described <input type="radio"/> Aboriginal/Torres Strait Islander (AU) <input type="radio"/> Māori (NZ) <input type="radio"/> Other ethnicity: <input type="text"/>
Given name(s) <input type="text"/>	
Date of birth <input type="text" value="DD - MM - YYYY"/>	Date of request <input type="text" value="DD - MM - YYYY"/>
Patient identifiers e.g. MRN, IHI or NHI (please indicate which) <input type="text"/>	Requesting doctor - name and contact details <input type="text"/>
Copy to doctor name and contact details <input type="text"/>	
OPERATIVE PROCEDURE <input type="checkbox"/> Biopsy (excisional, incisional), <i>specify</i> <input type="text"/> <input type="checkbox"/> Resection, <i>specify</i> <input type="text"/> <input type="checkbox"/> Neck (lymph node) dissection*, <i>specify</i> <input type="text"/> <input type="checkbox"/> Other, <i>specify</i> <input type="text"/> * If a neck dissection is submitted, then a separate dataset is used to record the information.	CLINICAL TNM STAGE <input type="text"/> CLINICAL DIAGNOSIS OR DIFFERENTIAL <input type="text"/> NEW PRIMARY CANCER OR RECURRENCE <input type="checkbox"/> New primary <input type="checkbox"/> Recurrence - regional <input type="checkbox"/> Recurrence - distant Details: <input type="text"/>
ANATOMICAL SITE OF NEOPLASM <input type="checkbox"/> Parotid gland <input type="checkbox"/> whole <input type="checkbox"/> Submandibular gland <input type="checkbox"/> superficial lobe <input type="checkbox"/> Sublingual gland <input type="checkbox"/> deep lobe Other anatomical site ▶ <input type="text"/>	PRE-OPERATIVE OR PRIOR RADIOTHERAPY <input type="radio"/> None administered <input type="radio"/> Administered <input type="text"/>
LATERALITY OF THE LESION <input type="checkbox"/> Left <input type="checkbox"/> Right <input type="checkbox"/> Midline <input type="checkbox"/> Not specified	INVOLVEMENT OF ADJACENT STRUCTURES <input type="text"/>
CLINICAL HISTORY <input type="text"/>	PRINCIPAL CLINICIAN <input type="text"/>
	OTHER COMMENTS <input type="text"/>

Version 2.0 Request Information from Carcinomas of the Major Salivary Glands Structured Reporting Protocol 2nd Edition

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 Laboratory Information System (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.⁷⁸

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

When reporting on different neoplasm 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 group data elements into a single unit will help to improve recall for the clinician.⁷⁸
- 'Clutter' should be reduced to a minimum.⁷⁸ Thus, information that is not part of the protocol (eg billing information, SNOMED codes, etc.) should not appear on the reports or should be minimized.
- Injudicious use of formatting elements (eg 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

Citizen, Georgina W. C/O Paradise Close Wreck Bay Resort Nar Nar Goon East, 3181 Female DOB 1/7/1951 MRN FMC1096785	Lab Ref: 19/P28460 Referred: 30/2/2019
Copy to: Dr N.G. Chapman Rainforest Cancer Centre, 46 Smith Road, Woop Woop, 3478	Referred by: Dr V. Smith Suite 3, AJC Medical Centre, Bunyip Crescent Nar Nar Goon West, 3182

SALIVARY GLAND CANCER STRUCTURED REPORT Page 1 of 2

Diagnostic Summary

LEFT PAROTIDECTOMY:

Adenoid cystic carcinoma, solid variant

Tumour 32 X 25 X 20 mm, perineural invasion present, lymphovascular invasion absent, tumour is present at multiple margins of resection.

pT2 (AJCC 8th edition)

Supporting Information

CLINICAL

Anatomical site of neoplasm:	Parotid gland
Laterality of lesion:	Left
New primary/recurrence:	New primary
Pre-operative/prior radiotherapy:	None administered

MACROSCOPIC

Specimen label:	"Left Parotid Gland, Single Suture Superior; Double Suture Anterior; Loop Suture Facial Nerve"
Operative procedure:	Resection, parotid gland
Specimens submitted:	Parotid Gland
Specimen integrity:	Intact
Specimen received:	Formalin
Specimen measurements:	40 x 30 x 30mm
Macroscopic tumour site(s):	Parotid gland, left
Tumour focality:	Unifocal
Max dimension of largest tumour:	25mm
Add'l dimensions (largest tumour):	25 x 20 mm
Extraparenchymal extension:	Absent

Additional Macroscopic comments: Specimen inked superficial blue, deep black and area of suture over facial nerve inked red. The specimen is serially sectioned into 10 slices from superior to inferior. A grey white infiltrative tumour is seen in slices 3-8.

Block identification key:

- 1 = Superior margin
- 2 = Tumour in slice 3 with red inked facial nerve area.
- 3 = Tumour in slice 5 with anterior margin
- 4 = Tumour in slice 7 with posterior margin
- 5 = Tumour in slice 8 with superficial margin
- 6 = Inferior margin

MICROSCOPIC

Histological tumour type: Adenoid cystic carcinoma

Histological grade: High grade, approximately 40-50% of the tumour shows solid morphology.

Microscopic size: 32 mm (Tumour present in 8 slices, each approximately 4mm in thickness)

Extent of invasion: Tumour is limited to the parotid gland.

Perineural invasion: Present

Lymphovascular invasion: Absent

Margin status: Involved by carcinoma

Closest margin: Tumour is seen at the inferior margin and at the deep margin.

Additional Microscopic Comments: The tumour reaches 0.5mm from the area with loop suture over the facial nerve.

ANCILLARY TEST FINDINGS: Nil

Reported by Dr Bernadette Mg

Authorised 4/3/2019

Appendix 4 WHO histological classification of tumours

WHO classification of tumours of the salivary glands^{a44}

Descriptor	ICD-O codes
Malignant tumours	
Mucoepidermoid carcinoma	8430/3
Adenoid cystic carcinoma	8200/3
Acinic cell carcinoma	8550/3
Polymorphous adenocarcinoma	8525/3
Clear cell carcinoma	8310/3
Basal cell adenocarcinoma	8147/3
Intraductal carcinoma	8500/2
Adenocarcinoma, NOS	8140/3
Salivary gland carcinoma	8500/3
Myoepithelial carcinoma	8982/3
Epithelial-myoepithelial carcinoma	8562/3
Carcinoma ex pleomorphic adenoma	8941/3
Secretory carcinoma	8502/3
Sebaceous adenocarcinoma	8410/3
Carcinosarcoma	8980/3
Poorly differentiated carcinoma	
Undifferentiated carcinoma	8020/3
Large cell neuroendocrine carcinoma	8013/3
Small cell neuroendocrine carcinoma	8041/3
Lymphoepithelial carcinoma	8082/3
Squamous cell carcinoma	8070/3
Oncocytic cell carcinoma	8290/3
Uncertain malignant potential	
Sialoblastoma	8974/1

^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.

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