The Royal College of Pathologists
Pathology: the science behind the cure

Standards and datasets for reporting cancers

Dataset for histopathology reporting of salivary gland neoplasms

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Foreword

The cancer datasets published by The Royal College of Pathologists are a combination of textual guidance and reporting proformas that should assist pathologists in providing a high standard of care for patients and facilitate accurate cancer staging. Guidelines are systematically developed statements to assist the decisions of practitioners and patients about appropriate healthcare for specific clinical circumstances and are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the guidelines in the interests of specific patients and special circumstances. The clinical risk of departing from the guidelines should be assessed by the relevant multidisciplinary team (MDT); just as adherence to the guidelines may not constitute defence against a claim of negligence, so a decision to deviate from them should not necessarily be deemed negligent.

Each dataset contains **core data items** that will be mandated for inclusion in the Cancer Outcomes and Services Dataset (previously the National Cancer Data Set) in England. Core data items are items that are supported by robust published evidence and are required for cancer staging, optimal patient management and prognosis. Core data items meet the requirements of professional standards (as defined by the Information Standards Board for Health and Social Care [ISB]) and it is recommended that at least 90% of reports on cancer resections should record a full set of core data items.

Other, **non-core, data items** are described. These may be included to provide a comprehensive report or to meet local clinical or research requirements. All data items should be clearly defined to allow the unambiguous recording of data.

Authors are aware that datasets are likely to be read by, *inter alia*, trainees, general pathologists, specialist pathologists and clinicians, and service commissioners. The dataset should seek to deliver guidance with a reasonable balance between the differing needs and expectations of the different groups. The datasets are not intended to cover all aspects of service delivery and reference should be made, where possible and appropriate, to guidance on other aspects of delivery of a tumour-specific service, e.g. cytology and molecular genetics.

The dataset has been reviewed by the Working Group on Cancer Services and was placed on the College website for consultation with the Fellowship from 24 October to 21 November 2011. All comments received from the Working Group and Fellowship were addressed by the authors, to the satisfaction of the Chair of the Working Group and the Director of Publications.

This dataset was developed without external funding to the writing group. The College requires the authors of datasets to provide a list of potential conflicts of interest; these are monitored by the Director of Professional Standards and are available on request. The authors of this document have declared that there are no conflicts of interest.

Each year, the College asks the authors of the dataset, in conjunction with the relevant subspecialty adviser to the College, to consider whether or not the dataset needs to be revised.

1 Introduction

1.1 Purpose of the dataset

This document presents the core data that should be provided in histopathology reports on specimens of malignant neoplasms arising in the salivary glands. Malignant neoplasms arising in the minor salivary tissue of the mucosa of the upper aerodigestive tract should be reported using the same staging principles as for other primary mucosal malignancies and including predictive factors associated with specific histological types.

Malignant tumours of the salivary glands are usually removed by partial excision of the gland including the tumour mass, or by total excision of the gland. Parotid tumours may require an extended radical procedure with resection of the subcutis and skin of the pre- or infra-auricular region and upper neck. Resection margins around salivary tumours will be either salivary tissue and/or soft tissue. The most important prognostic features are the histological tumour type, the clinical/pathological stage and the adequacy of the excision, with histological grade influencing prognosis for some malignancies.[1-7]

The dataset does not cover benign salivary neoplasms, although pathology reports on these neoplasms would be expected to include an overall description of the specimen and the tumour, the histology type[8] and the proximity of the neoplasm to the resection margins.

The parotid gland is richly supplied with two networks of lymphatic vessels, paraglandular and intraglandular, which may or may not intercommunicate. Each gland contains 20–30 lymph nodes that may be the site of metastases from salivary and other malignancies, particularly those arising in the head and neck region. The efferent lymphatics from the parotid drain primarily to the superior deep cervical nodes (level II). The submandibular gland does not contain intraglandular lymph nodes and the parenchyma drains to the 2–5 submandibular nodes that lie close to the gland, and then to nodes at level II. The sublingual gland drains to the submandibular, submental and level II nodes.[9]

The following stakeholder groups have been consulted:

- the British Society for Oral and Maxillofacial Pathology (BSOMP)
- the British Association of Head and Neck Oncologists (BAHNO)
- ENT-UK
- the British Association of Oral and Maxillofacial Surgeons
- the UK Association of Cancer Registries
- the National Cancer Intelligence Network.

Comments from specialist and general histopathologists on the draft document that was published on the College website have been considered as part of the review of the dataset.

The authors have searched electronic databases for relevant research evidence and systematic reviews on salivary malignancies up to April 2011. The recommendations are in line with those of other national pathology organisations (College of American Pathologists and The Royal College of Pathologists of Australasia) and the ENT-UK Consensus document for the management of patients with head and neck malignancies [www.entuk.org/publications]. The level of evidence for the recommendations has been summarised according to College guidance (see Appendix D) and indicated in the text as, for example, *[level B*]. No major conflicts in the evidence have been identified and minor discrepancies between studies have been resolved by expert consensus.

No major organisational changes have been identified that would hinder the implementation of the dataset, which is fully integrated with the Cancer Outcomes and Services Dataset, and there are no major financial implications arising from implementation of this guidance.

Optimal reporting of specimens from the head and neck area requires a partnership between the pathologist and surgeon/oncologist.[10] The surgeon can help the pathologist to provide the information necessary for patient management by the appropriate handling and labelling of the specimen in the operating theatre. The regular discussion of cases at clinicopathological meetings and correlation with pre-operative imaging studies are important in maintaining and developing this partnership.[11]

The core pathological data are summarised as a proforma, that may be used as the main reporting format or may be combined with free text as required. Individual centres may wish to expand the detail in some sections, e.g. for sites and subsites or to facilitate the recording of data for particular tumour types.

The guidelines should be implemented for the following reasons:

a. Certain features of salivary malignancies (type, size and grade of the primary carcinoma, and proximity of carcinoma to resection margins) have been consistently shown to be related to the clinical outcome of salivary malignancies at all sites.[1-7,12]

b. These features may therefore be important in:

   - deciding on the most appropriate treatment for particular patients, including the extent of surgery and the use and choice of adjuvant radiotherapy.
   - monitoring changing patterns of disease, particularly by cancer registries.

c. These features provide sufficiently accurate pathological information that can be used, together with clinical data, for the patient to be given a prognosis.

d. To allow the accurate and equitable comparison of surgeons in different surgical units, to identify good surgical and pathological practice, and the comparison of patients in clinical trials.

1.2 Potential users of the dataset

The dataset is primarily intended for the use of consultant and trainee pathologists when reporting biopsies and resection specimens of salivary gland malignancies. Surgeons and oncologists may refer to the dataset when interpreting histopathology reports and core data should be available at multidisciplinary meetings when recommendations for the management of head and neck cancer patients are discussed. The core data items are incorporated into the Cancer Outcomes and Services Dataset and are collected for epidemiological analysis by Cancer Registries on behalf of the National Cancer Intelligence Network.

1.3 Changes since the second edition

The second edition of this dataset (2005) incorporated salivary malignancies and neck dissection specimens. In this revision, the dataset on malignant neoplasms arising in the major salivary glands and the dataset on neck dissection specimens for metastatic disease are presented as separate datasets. For convenience, the section on core data required for nodal disease is replicated in each dataset; users should cross-refer to the more detailed discussion in the separate neck dissection dataset. The guidance has been revised to include recent evidence supporting the inclusion of specific data items.

The strength of the basis in published evidence for the recommended core data items has been reviewed (see Appendix D). The primary reasons for inclusion of core data are the need for accurate classification and staging and the desire to predict those carcinomas that are likely to recur at local, regional (nodal) or distant sites so that appropriate surveillance, surgery, radiotherapy and/or chemotherapy can be delivered to mitigate the effects of recurrence. Inevitably, the strength of evidence varies for the prediction of different patterns of recurrence and for survival, and varies between primary tumour types and sites. To keep the guidance relatively simple, not all possible variations are described in detail and the reader is referred to the cited literature for more information.

The core set of data items for salivary malignancies is unchanged since the second edition in 2005, and the guidance includes adoption of the 7th edition of the UICC TNM staging

system[13] and a short section on cytological assessment. The reporting proforma for neck dissection specimens is that described in the companion dataset and has been modified to provide a simpler layout, with easily identified options for transfer to an electronic format.

2 Specimen request form

The request form should include patient demographic data, the duration of symptoms, whether surgery is palliative or curative, details of previous histology or pathology reports and the core clinical data items (see section 4). Clinical TNM stage is useful. A history of previous radiotherapy or chemotherapy should be included as this may influence the interpretation of the histological changes and should prompt a comment on the extent of any response to treatment. The request form should provide the opportunity for surgeons to provide annotated diagrams of specimens. Copies of reports that are sent to the Cancer Registries should include the patient's address if possible.

3 Specimen handling and block selection

The exposed margin of the excised tissue should be marked with Indian ink or a suitable pigment before the tissue is serially sliced. If a major nerve has been resected, the proximal and distal margins should be indicated by the surgeon, thus facilitating accurate assessment of any perineural or intraneural invasion.

Blocks to be taken:

- representative blocks of tumour (at least one per 10 mm of tissue diameter) to include normal tissue and the relationship between tumour and the nearest resection margin. For smaller tumours (<30 mm), it is often appropriate to block the entire tumour; for larger tumours, macroscopically different areas should be sampled, particular at the edge of the tumour
- lymph nodes within the gland or in peri-glandular soft tissue
- blocks from designated resection margins of nerves.

Neck dissection specimens associated with salivary neoplasms are handled as described in the separate dataset.

4 Core data items to be included in the histopathology report

4.1 Clinical data (provided by the surgeon or oncologist)

4.1.1 Site and laterality of the carcinoma

Sites and subsites should be recorded according to the UICC nomenclature (Appendix A).

4.1.2 Type of specimen

The type of specimen should be described as: incisional biopsy, excisional biopsy or resection. The designation of resection specimens may be refined according to site-specific criteria, e.g. partial, total.

[These data are required for accurate staging and for cancer registration.]

4.2 Pathological data

4.2.1 Histological type of carcinoma

The histological type of carcinoma is required for classification and cancer registration and is a predictor of biological behaviour on univariate analysis in most cohort studies; histological type is less important than stage on multivariate analysis.[1-2,4,14-16] The histological type should be recorded according to the WHO classification.[8]

[Level of evidence, C.]

4.2.2 Histological grade of malignancy (see section 4.3)

4.2.3 Maximum diameter of the tumour

The size of a salivary malignancy (T stage) is consistently reported to be a major prognostic factor for treatment outcome and survival.[1-7,16] The maximum diameter of the tumour should be recorded in millimetres. The macroscopic measurement should be confirmed or amended after microscopy.

[Level of evidence, B.]

4.2.4 Distance from carcinoma to nearest resection margin

The adequacy of surgical clearance is an independent factor in determining local control of disease and survival.[15,17-19.] The distance from the tumour to the nearest resection margin should be measured in millimetres. The macroscopic measurements should be confirmed histologically and, if there is a discrepancy, then the histological distance should be stated in the report. In the report summary, the same criteria as for squamous cell carcinomas at other mucosal sites in the upper aerodigestive tract may be used: >5 mm is clear, 1–5 mm is close and <1 mm is involved.

[Level of evidence, C.]

4.2.5 Macroscopic extraparenchymal extension of carcinoma

Macroscopic extraglandular extension to involve adjacent structures is a predictor of local recurrence and nodal metastasis for parotid carcinomas;[1,14,20] the evidence at other sites is by extrapolation.

[Level of evidence, C/D.]

4.2.6 Perineural invasion

Perineural invasion is a common finding, and may be diagnostically useful in adenoid cystic carcinomas and in polymorphous low-grade adenocarcinomas. Neurological symptoms suggesting invasion of the VII or VIII cranial nerves are predictors of nodal disease and poor outcome[1,18,21] but the independent prognostic relevance of invasion of the perineural space histologically varies between published studies.[4] The predominance of evidence suggests that the presence or absence of perineural space invasion should be recorded.

[Level of evidence, C.]

4.2.7 Lymph node involvement

The involvement of cervical lymph nodes by a salivary malignancy (N stage) is consistently reported to be a major prognostic factor for treatment outcome and survival.[1-7,16,18] The presence or absence of lymph node involvement should be recorded as for squamous cell carcinomas of the upper aerodigestive tract (see section 10).

[Level of evidence, B.]

4.3 Grading of salivary malignancies

The grade of salivary carcinomas is related to the risk of local recurrence, regional and distant metastasis but is of less importance than stage.[1,4,22-23] The histological type of carcinoma is broadly related to grade (see Table 1) and to risk of local or regional recurrence, although it is important to recognise that there are exceptions to the general schema (e.g. low-grade variants of salivary duct carcinoma) and that some carcinomas may show progression to higher grade or may dedifferentiate.[22,24] For some types of carcinoma, a range of grades is observed; these are described in more detail in subsequent sections.

Table 1 General grading categories for salivary adenocarcinomas (adapted)[4]

Salivary adenocarcinomas	Low grade	High grade
Polymorphous low grade adenocarcinoma	+	
Acinic cell carcinoma	+	
Basal cell adenocarcinoma	+	
Cribiriform adenocarcinoma	+	
Mammary analogue secretory carcinoma	+	
Myoepithelial carcinoma	+	+
Cystadenocarcinoma	+	
Epithelial-myoepithelial carcinoma	+	
Mucoepidermoid carcinoma	+	+
Adenoid cystic carcinoma	+	+
Adenocarcinoma, not otherwise specified	+	+
Squamous cell carcinoma	+	+
Carcinoma ex-pleomorphic adenoma		+
Salivary duct carcinoma		+
Oncocytic carcinoma		+
Undifferentiated carcinoma		+

4.3.1 Mucoepidermoid carcinoma

Grading of mucoepidermoid carcinomas is related to metastatic potential and survival, whichever system is used.[25-28] In general, low-grade (cytologically benign) tumours with abundant mucous cells and mucin production are less aggressive and rarely metastasise. Tumours that are predominantly solid and have a preponderance of epidermoid cells have the greatest metastatic potential.

There has been considerable debate around grading criteria and the relative merits of 2 and 3 grade systems and the AFIP system that appears to 'downgrade' some mucoepidermoid carcinomas.[23] A modification of the AFIP grading system[25] has the merit of simplicity and allows good discrimination between tumours with good and poor prognosis. This system scores a range of histological features but, in essence, the presence of two or more poor prognostic features indicates a high-grade tumour (see Table 2). It is good practice to specify in the final diagnostic report which grading system has been used.

Table 2 Prognostic features for mucoepidermoid carcinoma (adapted)[25]

Grade 1	Predominant goblet cell component. Lack of aggressive features.
Grade 2	Predominant intermediate cell component. Aggressive invasion pattern but lacks other features of grade 3.
Grade 3	Predominant squamous cell component. Aggressive invasion pattern plus one or more of the following features: • necrosis • >4 mitoses per 10 high power fields • high-grade nuclear pleomorphism • perineural invasion • vascular invasion • bony invasion.

Although the volume-corrected Ki-67 labelling index correlates with outcome in mucoepidermoid carcinoma,[29] it is uncertain whether or not this provides additional prognostic benefit. The MECT1-MAML2 (also known as CRTC1-MAML2) fusion oncogene has been identified in a prognostically favourable subset of mucoepidermoid carcinomas;[30-32] this test is not currently in routine use.

[Level of evidence, C.]

4.3.2 Acinic cell carcinoma

Acinic cell carcinomas are usually circumscribed but incompletely encapsulated. Cytologically low-grade tumours show several configurations (solid, papillary, follicular, clear-cell), but neither the configuration nor the cytological grade is generally accepted as a useful indicator of behaviour.[33-34] Most acinic cell carcinomas are low grade (low risk of recurrence or metastasis) but a Ki-67 labelling index of >5% probably identifies the minority of more aggressive acinic cell carcinomas.[8,29,35] Carcinomas with more than 20 mitoses/mm^2 should be regarded as high grade.[29]

[Level of evidence, C.]

4.3.3 Adenoid cystic carcinoma

The histological subtype of adenoid cystic carcinoma is related to metastatic potential, with 0–4% of cribriform, hyaline and tubular carcinomas, and 33% of solid (basaloid) carcinomas metastasising to local lymph nodes and distant metastasis being commoner in solid tumours.[22-23,34,36-40] Adenoid cystic carcinoma is recognised as high grade if there is >30% solid pattern.[8,38] Although the volume-corrected Ki-67 index correlates with outcome in mucoepidermoid carcinoma,[29] it is uncertain whether or not this provides additional prognostic benefit.

[Level of evidence, C.]

4.3.4 Carcinoma in pleomorphic adenoma

Carcinomas arising in pleomorphic adenomas may be of any histological type, but are thought to be particularly aggressive and the prognosis of the carcinomatous component is poorer than that of comparable carcinomas developing *de novo.*[34,37,41] Evidence for a pre-

existing adenoma (remnants of myxochondroid stroma, focal scarring, hyalinised nodular 'ghost') should be sought in all carcinomas, particularly those showing multiple histological types and a varied histological appearance.

The extent of invasion should be measured in these tumours as it is prognostically useful, although precise criteria are not defined. Invasion more than 5–6 mm from the capsule of the residual adenoma is associated with a high risk of local recurrence and distant metastasis.[42-44]

[Level of evidence, C.]

4.4 Minor salivary gland tumours

The core data items and grading criteria for malignancies of minor salivary glands are the same as for major glands, although the evidence is less extensive.[45-48] The spectrum of histological types is wider as some carcinomas, e.g. polymorphous low-grade adenocarcinoma, are mainly found in minor glands[49] Multivariate analysis in a large series of minor salivary carcinomas found that the main predictors of nodal disease were T3-T4 carcinomas, high-grade carcinomas and those arising in the pharynx.[50] It is recommended that the dataset for squamous cell carcinomas of the appropriate primary site is used for minor salivary gland malignancies, adapted to include the histological type and, where appropriate, grade of salivary carcinoma.

5 Non-core pathological data

These features should be included as part of a comprehensive description of a carcinoma and the surrounding tissues. Some are preferences of individual centres or are considered to be of uncertain prognostic significance and therefore are not part of the core data set.

5.1 Macroscopic features

- The overall size of the specimen with regard to anatomical features.
- The length of the excretory duct, if obvious.
- The size of the tumour in three dimensions.
- The presence and size of lymph nodes around or within the gland.
- The nature of the tumour: solitary or multifocal; solid or cystic.
- The nature of the edge of the tumour: discrete (well defined) or poorly defined.
- The appearance and texture of the cut surface: translucent or cartilaginous, brown or haemorrhagic, cystic, necrotic, etc.

5.2 Microscopic features

- Mitotic index
- Microscopic encapsulation or invasion of normal tissues (note that macroscopic invasion is a core data item)
- Changes in the macroscopically normal salivary tissue.

5.3 Molecular markers for diagnosis, prediction and prognosis

Immunocytochemical labelling may help to characterise some types of neoplasm that contain myoepithelial cells (e.g. caldesmon, calponin, p63, S-100 protein), luminal cells

(cytokeratins CK 8, 18, 19; CD117) or mitochondria, but diagnosis is based primarily on morphological criteria.[3,24]

As noted above, the Ki67 labelling index may be useful in grading acinic cell, adenoid cystic and mucoepidermoid carcinomas;[29] currently this is recommended only for acinic cell carcinomas. Other immunocytochemical markers such as bcl-2, p53, androgen receptor, HER-2 may have prognostic or predictive value[3,36,51-53] but are not routinely performed.

Gene expression profiling correlates fairly well with the morphological classification of salivary carcinomas,[51] although the MECT1-MAML2 (also known as CRTC1-MAML2) fusion oncogene separates a prognostically favourable subset of mucoepidermoid carcinomas from the more aggressive mucoepidermoid carcinomas.[30-32.]

6 Diagnostic coding of primary carcinomas

6.1 pT status

pT status should be recorded according to the UICC guidelines[13] (see Appendix A).

6.2 SNOMED T codes

SNOMED T code(s) should be recorded for primary site(s). A list of T codes against site and subsite is provided in Appendix B.

6.3 SNOMED M and P codes

SNOMED M and P codes should be used to describe the morphological diagnosis and diagnostic procedure (see Appendix B).

7 Reporting criteria for small diagnostic biopsy specimens

The data that can be obtained from small biopsy specimens will be determined, in part, by their size. The presence or absence of malignancy is the minimum data, although it will usually be possible to define the histological type of carcinoma. The grade of carcinoma is provisional on small biopsies, as salivary malignancies often show variations in architecture and cytological grade in different areas.

8 Frozen section diagnosis

The initial diagnosis of carcinoma will usually be suggested on the basis of fine needle aspiration cytology or core biopsy before definitive surgery is performed. On occasions, intra-operative frozen section diagnosis of the nature of a neoplasm will be required. While it will usually be possible to identify the presence of neoplastic tissue, the nature of a poorly differentiated neoplasm may be impossible to determine on frozen sections.

The assessment of the presence or absence of carcinoma at surgical resection margins may be required to assist surgical management. The surgeon should select the tissue for frozen section diagnosis with care, bearing in mind that it is not usually possible to section material more than 10 mm in diameter.

The report on the frozen section specimen(s) should normally form part of, or accompany, the final diagnostic report on the case.

9 Cytological diagnosis of salivary malignancies

Fine needle aspiration cytology is useful for the diagnostic triage of salivary masses but has well-recognised limitations.[1,54-56] The ability to distinguish inflammatory masses, lymphoid and epithelial proliferations is helpful in a rapid diagnostic clinic, but cytopathologists need to be aware of the complexity of histological patterns in salivary neoplasms that make the precise diagnosis of many carcinomas difficult on limited cytological samples. The cytological opinion on a fine needle aspirate from a salivary mass should always be interpreted in the context of clinical and imaging findings. The requirements for an effective fine needle aspiration service are described elsewhere.[54,57]

10 Core pathological data for neck dissection specimens

A detailed explanation and description of the handling and reporting of neck dissections associated with head and neck malignancies is provided in a companion dataset (see the 'Cancer datasets and tissue pathways' section of www.rcpath.org/publications). For ease of use, the text relating to core pathological data is provided here and the reporting proforma is in Appendix C.

10.1 Total number of nodes and number of positive nodes

At each anatomical level, record the total number of nodes identified and number of nodes involved by carcinoma.

[The number of involved nodes affects staging and the pattern of nodal involvement influences postoperative treatment; level of evidence B.]

10.2 Size of largest metastatic deposit

Note that this is not the same as the size of the largest node. The size of the largest metastasis is a determinant in the TNM staging.[13]

[The size of the largest metastasis is a determinant of TNM stage.]

10.3 Extracapsular spread

Extracapsular spread (ECS) is a manifestation of the biological aggression of squamous cell carcinomas and is associated with a poor prognosis.[10,58-66] The evidence for salivary malignancies is more limited,[15] but extrapolation of evidence from squamous cell carcinoma suggests that ECS reflects more aggressive disease. ECS should be recorded as present or not identified. If present, the node level(s) showing this feature are recorded. Any spread through the full thickness of the node capsule is regarded as ECS and the previous separation into macroscopic and microscopic spread is now considered not to be necessary, as for squamous cell carcinomas.[62] Involvement of adjacent anatomical structures should be recorded separately in the 'comments' section. If histological evidence of extracapsular spread is equivocal, it should be recorded as 'present'. This should prompt the use of adjuvant radiotherapy.

[Level of evidence C (by extrapolation from level B evidence for squamous cell carcinomas).]

Notes on core data items

10.4 Micrometastases

The prognostic significance of micrometastases (2 mm or less in diameter) is not known for salivary malignancies but the general guidance for squamous cell carcinomas should be followed; the presence of micrometastases should be included in the number of involved nodes and TNM coded as pN1(mi) or pN2(mi).

10.5 Isolated tumour cells

The TNM classification includes a category of pN0(i+) for nodes that contain clumps of isolated tumour cells (<0.2 mm diameter or <200 cells in one section).[13] The prognostic significance of isolated tumour cells is not known for salivary malignancies. At present, it is suggested that dissection and sectioning protocols are not modified to explicitly search for isolated tumour cells.

10.6 Fused nodes

If there is obvious metastatic disease with fusion (matting) of lymph nodes, record:

- the level(s) of nodes involved by the mass.
- the maximum dimension.
- an estimate of the number of nodes that might be involved in the mass.

10.7 Isolated nodules of tumour in the connective tissue

Isolated nodules of tumour in the connective tissue may represent discontinuous extensions of the primary tumour, soft tissue metastases or nodal metastases that have destroyed the node.[67-68] Absolute distinction between these possibilities is not always possible and, while the TNM classification[13] recommends regarding all deposits that do not have the contour of a node as discontinuous tumour extension, there does not appear to be any evidence for this approach in the head and neck. As for squamous cell carcinomas, a practical approach is to regard any tumour nodule in the region of the lymphatic drainage as a nodal metastasis, and to only diagnose discontinuous extension of a carcinoma within 10 mm of the primary carcinoma and where there is no evidence of residual lymphoid tissue.

11 Criteria for audit of the dataset

In keeping with the recommended key performance indicators published by The Royal College of Pathologists (www.rcpath.org/index.asp?PageID=35), reports on head and neck cancers should be audited for the following.

- The inclusion of SNOMED or SNOMED-CT codes:
  - standard: 95% reports should have T, M and P codes.
- The availability of pathology reports and data at MDT meetings:
  - standard: 90% of cases discussed at MDT meetings where biopsies or resections have been taken should have pathology reports/core data available for discussion
  - standard: 90% of cases where pathology has been reviewed for the MDT meeting should have the process of review recorded.
- The use of electronic structured reports or locally agreed proformas (it is assumed that these processes will ensure that 90% of core data items are recorded):

- standard: 80% of resection specimens will include 100% data items presented in a structured format.

- Turnaround times for biopsies and resection specimens:
  - standard: 80% diagnostic biopsies will be reported within 7 calendar days of the biopsy being taken
  - standard: 80% of all histopathology specimens (excluding those requiring decalcification) will be reported within 10 calendar days of the specimen being taken.

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Appendix A TNM classification of malignant tumours[13]

Major salivary glands

Tx Primary tumour cannot be assessed.

T0 No evidence of primary tumour.

T1 Tumour 20 mm or less in greatest dimension without extraparenchymal extension.

T2 Tumour more than 20 mm but not more than 40 mm in greatest dimension without extraparenchymal extension.

T3 Tumour more than 40 mm and/or tumour with extraparenchymal extension.

T4a Tumour invades skin, mandible, ear canal or facial nerve.

T4b Tumour invades base of skull, pterygoid plates or encases carotid artery.

Notes:

- Extraparenchymal extension is clinical or macroscopic evidence of invasion of soft tissues or nerve except those listed under T4a or b. Microscopic evidence alone does not constitute extraparenchymal extension for classification purposes.
- If there is doubt as to which category a tumour should be allocated to, then the lower (less extensive) category should be used.

Additional descriptors to be used in special cases

These do not affect the stage groupings but may require 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 (neoadjuvant chemotherapy and/or radiation therapy). The ypTNM categorises the extent of tumour actually present at the time of that examination and is not an estimate of tumour before treatment.

The ‘r’ prefix indicates a recurrent tumour when staged after a documented disease-free interval, and is identified by the ‘r’ prefix: rTNM.

The R classifier for residual tumour is available in the TNM system, but is not recommended for use in the setting of salivary cancers. The method of assessment of margins described in section 4.2 is well-established and current surgical practice does not require the assessment of macroscopic or microscopic residual disease.

For the pN classification of regional lymph nodes, see the dataset on neck dissection specimens.

M Distant metastasis

pM1 Distant metastasis confirmed microscopically.

Note that pM0 and pMX are no longer valid categories.

Appendix B SNOMED codes

Topographical codes

T-55000 Salivary gland, not otherwise specified

T-55100 Parotid gland

T-55200 Submandibular gland

T-55300 Sublingual gland

T-55400 Minor salivary gland.

Morphological codes

Note: This is not a comprehensive list of all malignancies and other codes should be used as necessary.

M-85503 Acinic cell carcinoma

M-84303 Mucoepidermoid carcinoma

M-82003 Adenoid cystic carcinoma

M-82003 Polymorphous low grade adenocarcinoma

M-85623 Epithelial-myoepithelial carcinoma

M-81473 Basal cell adenocarcinoma

M-84103 Sebaceous carcinoma

M-84503 Papillary cystadenocarcinoma

M-84803 Mucinous adenocarcinoma

M-82903 Oncocytic carcinoma

M-85003 Salivary duct carcinoma

M-81403 Adenocarcinoma

M-89823 Malignant myoepithelioma (myoepithelial carcinoma)

M-89413 Carcinoma in pleomorphic adenoma (malignant mixed tumour)

M-80703 Squamous cell carcinoma

M-80413 Small cell carcinoma

M-80203 Undifferentiated carcinoma.

Procedure codes

Note: This is not intended to be a comprehensive list of all procedures and other codes should be used as necessary.

P1100 Resection

P1141 Excisional biopsy

P1340 Endoscopic biopsy

P1140 Biopsy, not otherwise specified.

Appendix C Reporting proformas

In order to provide flexibility in use, separate reporting proformas are provided for the primary carcinoma and for nodal disease.

It is expected that the proformas will be combined if one operation yields tissue from both the primary site and neck dissection, providing one pathological summary and staging.

The nodal proforma should be edited appropriately, depending on the type(s) of specimen received (sentinel nodes, left and/or right neck dissections).

Dataset for salivary carcinoma resections

Surname…… Forenames……..… Date of birth…….. Sex…...
Hospital……..…….…… Hospital no…….……. NHS/CHI no……..
Date of receipt……..…… Date of reporting……..…….. Report no……...
Pathologist……..…… Surgeon……..…….

Site: Parotid □ Submandibular □ Sublingual □

Other site □ (Please specify)……

Laterality: Left □ Right □

Type of specimen: Incisional □ Excisional □ Resection □

Histological type:……

Histological grade (if appropriate)……

Maximum diameter…….(mm)

Extraglandular extension – macroscopic: Yes □ No □

Extraglandular extension – microscopic: Yes □ No □
If present, estimate distance (mm) ……..

Perineural invasion Yes □ No □

Minimum excision margin……(mm)

COMMENTS / ADDITIONAL INFORMATION:

SUMMARY OF PATHOLOGICAL DATA

Tumour site……

Tumour type……

pTNM stage pT….. pN…….

SNOMED codes

T…… M…….

T…… M…….

Resection of primary tumour Clear (>5 mm) □ Close (>1 mm) □ Involved □

Signature: ..... Date: .....

Dataset for lymph node excision specimens

Surname…… Forenames……..… Date of birth…….. Sex…...

Hospital…….…….…… Hospital no…….……. NHS/CHI no……..

Date of receipt…….…… Date of reporting……..…….. Report no……...

Pathologist…….…… Surgeon……..……

Sentinel node(s)			
Levels submitted	I □ IIA □ IIB □ III □ IV □ V □ VI □ other □		
Node level	**No. nodes present**	**No. positive nodes**	**ECS present**
I			Yes □ .. No □
II (total)			Yes □ .. No □
IIA			Yes □ .. No □
IIB			Yes □ .. No □
III			Yes □ .. No □
IV			Yes □ .. No □
V			Yes □ .. No □
VI			Yes □ .. No □
Other			Yes □ .. No □
Totals			**Yes □ .. No □**

Right neck dissection			
Levels submitted	I □ IIA □ IIB □ III □ IV □ V □ VI □ other □		
Node level	**No. nodes present**	**No. positive nodes**	**ECS present**
I			Yes □ .. No □
II (total)			Yes □ .. No □
IIA			Yes □ .. No □
IIB			Yes □ .. No □
III			Yes □ .. No □
IV			Yes □ .. No □
V			Yes □ .. No □
VI			Yes □ .. No □
Other			Yes □ .. No □
Totals			**Yes □ .. No □**

Left neck dissection			
Levels submitted	I □ IIA □ IIB □ III □ IV □ V □ VI □ other □		
Node level	**No. nodes present**	**No. positive nodes**	**ECS present**
I			Yes □ .. No □
II (total)			Yes □ .. No □
IIA			Yes □ .. No □
IIB			Yes □ .. No □
II			Yes □ .. No □
III			Yes □ .. No □
IV			Yes □ .. No □
V			Yes □ .. No □
VI			Yes □ .. No □
Other			Yes □ .. No □
Totals			Yes □ .. No □

COMMENTS/ADDITIONAL INFORMATION

SUMMARY OF PATHOLOGICAL DATA

Neck nodes …… pTNM stage pN……

Tumour type…… SNOMED codes T…… M…….

Signature: ..... Date: .....

Appendix D Summary table – explanation of levels of evidence

(modified from Palmer K *et al. BMJ* 2008;337:1832)

Level of evidence	Nature of evidence
A	At least one high-quality meta-analysis, systematic review of randomised controlled trials or a randomised controlled trial with a very low risk of bias and directly attributable to the target cancer type or A body of evidence demonstrating consistency of results and comprising mainly well-conducted meta-analyses, systematic reviews of randomised controlled trials or randomised controlled trials with a low risk of bias, directly applicable to the target cancer type.
B	A body of evidence demonstrating consistency of results and comprising mainly high-quality systematic reviews of case-control or cohort studies and high-quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relation is causal and which are directly applicable to the target cancer type or Extrapolation evidence from studies described in A.
C	A body of evidence demonstrating consistency of results and including well-conducted case-control or cohort studies and high quality case-control or cohort studies with a low risk of confounding or bias and a moderate probability that the relation is causal and which are directly applicable to the target cancer type or Extrapolation evidence from studies described in B.
D	Non-analytic studies such as case reports, case series or expert opinion or Extrapolation evidence from studies described in C.
Good practice point (GPP)	Recommended best practice based on the clinical experience of the authors of the writing group.

Appendix E AGREE monitoring sheet

The cancer datasets of The Royal College of Pathologists comply with the AGREE standards for good quality clinical guidelines (www.agreecollaboration.org). The sections of this dataset that indicate compliance with each of the AGREE standards are indicated in the table.

AGREE standard	Section of dataset
SCOPE AND PURPOSE	
1. The overall objective(s) of the guideline is (are) specifically described.	1
2. The clinical question(s) covered by the guidelines is (are) specifically described.	1
3. The patients to whom the guideline is meant to apply are specifically described.	1
STAKEHOLDER INVOLVEMENT	
4. The guideline development group includes individuals from all the relevant professional groups.	1
5. The patients' views and preferences have been sought.	Not applicable*
6. The target users of the guideline are clearly defined.	1
7. The guideline has been piloted among target users.	Previous editions
RIGOUR OF DEVELOPMENT	
8. Systematic methods were used to search for evidence.	1
9. The criteria for selecting the evidence are clearly described.	1
10. The methods used for formulating the recommendations are clearly described.	1
11. The health benefits, side effects and risks have been considered in formulating the recommendations.	1
12. There is an explicit link between the recommendations and the supporting evidence.	4
13. The guideline has been externally reviewed by experts prior to its publication.	1
14. A procedure for updating the guideline is provided.	Foreword
CLARITY OF PRESENTATION	
15. The recommendations are specific and unambiguous.	4
16. The different options for management of the condition are clearly presented.	4
17. Key recommendations are easily identifiable.	4
18. The guideline is supported with tools for application.	Appendices A–E
APPLICABILITY	
19. The potential organisational barriers in applying the recommendations have been discussed.	Foreword
20. The potential cost implications of applying the recommendations have been considered.	Foreword
21. The guideline presents key review criteria for monitoring and/audit purposes.	1, 11
EDITORIAL INDEPENDENCE	
22. The guideline is editorially independent from the funding body.	1
23. Conflicts of interest of guideline development members have been recorded.	1

* The Lay Advisory Committee (LAC) of The Royal College of Pathologists has advised the Director of Communications that there is no reason to consult directly with patients or the public regarding this dataset because it is technical in nature and intended to guide pathologists in their practice. The authors will refer to the LAC for further advice if necessary.