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

Standards and datasets for reporting cancers

Dataset for histopathology reporting of mucosal malignancies of the nasal cavities and paranasal sinuses

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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 mucosal malignancies originating in the nasal cavities and paranasal sinuses. Malignancies arising in the oral cavity, nasopharynx, oropharynx and hypopharynx, and larynx are described in companion datasets, although the guidance is similar for each site. The guidance is mainly derived from data on squamous cell carcinomas, which account for >90% of malignancies, but similar principles may be applied to the reporting of other mucosal malignancies arising in this anatomical area including adenocarcinomas and

neuroendocrine epithelial neoplasms, which are important considerations in the differential diagnosis but are not described in detail. Important site-specific and diagnosis-specific recommendations are included as appropriate.

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 head and neck mucosal malignancies up to April 2011. The recommendations are in line with those of other national pathology organisations (College of American Pathologists, 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 E) 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 (COSD) 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.[1] 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.[2]

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, to facilitate the recording of data for particular tumour types.

The guidelines should be implemented for the following reasons.

a) Certain features of invasive mucosal carcinomas (type, size and grade of the primary carcinoma, the pattern of invasion and proximity of carcinoma to resection margins) have been shown to be related to clinical outcome.[3-13]

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 or chemotherapy.[14]
    - 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 mucosal malignancies of the head and neck region. Surgeons and oncologists may refer to the dataset when interpreting histopathology reports and core data should be available at multidisciplinary meetings to inform discussions on the management of head and neck cancer patients. 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) encompassed mucosal and salivary malignancies and neck dissection specimens. In this revision, a separate dataset on mucosal malignancies at each of the main head and neck sites has been produced, alongside datasets on malignant neoplasms arising in the major salivary glands and the dataset on neck dissection specimens for metastatic disease. 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 E). 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. TNM staging, in isolation, does not provide sufficient information for management and prognosis[12] and additional factors need to be considered. Inevitably, the strength of evidence varies for the prediction of different patterns of recurrence and for survival, and varies between primary tumour 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 dataset for squamous cell carcinomas is largely unchanged since the second edition in 2005, although site-specific variations are now more explicitly presented, acknowledging the lack of evidence to support recording tumour thickness in the nasal region and larynx and incorporating evidence of human papillomavirus infection as a core data item for oropharyngeal carcinomas.

The 7th edition of the UICC TNM staging system is recommended,[15] including the section on mucosal melanomas.

The reporting proforma has been modified to provide a simpler layout, with easily identified options for transfer to an electronic format. For ease of access, the generic head and neck request form and the proforma summary for neck dissections are included with each of the site-specific documents.

1.3 Acknowledgements

For the draft request forms, we are grateful to the late Professor DG McDonald, University of Glasgow, for permission to use the diagrams of the oral cavity and jaws, and to the UICC and Springer-Verlag to use the diagrams of the larynx and neck that are adapted from the *TNM Atlas (3rd edition)*, 1989.

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 for correlation with pathological findings. 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, either as free-hand drawings or on standard diagrams (see Appendix D). Copies of reports that are sent to the Cancer Registries should include the patient's address if possible.

3 Specimen handling and block selection

3.1 Preparation of the specimen before dissection

Resection specimens should be orientated by the surgeon and, if appropriate, pinned or sutured to cork or polystyrene blocks. The surgeon should indicate surgically critical margins using metal tags or sutures. Fixation is in a formaldehyde-based solution for 24–48 hours in a container of adequate size (the volume of fixative should be ten times that of the tissue).

Photography and radiography of the specimen may be used to record the nature of the disease and the sites from which tissue blocks are selected. Surgical margins should be painted with Indian ink or an appropriate dye to facilitate the later recording of the proximity of carcinoma to the margin.

3.2 Site-specific considerations and block selection

A detailed dissection protocol is beyond the scope of these guidelines, but a brief summary of dissection methods and block selection is included to facilitate recording of the core data items.

Resection specimens should be carefully orientated to identify surgically important resection margins. For specimens with friable margins, it may be advantageous to take blocks from resection margins before completely slicing the specimens (to avoid disruption of the margins). It is often impossible to label margins for small specimens and laser resections in multiple pieces. Major resection specimens may require decalcification before slicing.

Selection of blocks for histology:

- Tumour: at least one block per 10 mm diameter of tumour, including one selected to demonstrate the maximum depth of invasion; the whole tumour if less than 10 mm
- blocks of defined mucosal and soft tissue margins
- non-neoplastic mucosa, if present (one block)
- bone surgical margins (if applicable)

- bone, if involvement by tumour is suspected clinically or on imaging studies.

[The basis in evidence for block selection is extrapolated from the need to provide microscopic confirmation or evaluation of prognostic and predictive factors; level C.]

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

For carcinomas that involve more than one site, the principal site of involvement should be recorded and coded; this may not be the site of origin. If required, the involvement of associated sites can be noted to help in later data analysis. Sites and subsites should be recorded according to the UICC nomenclature (see 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

These guidelines specifically apply to conventional squamous cell carcinomas. Subtypes of squamous carcinoma – such as papillary, verrucous, basaloid, adenosquamous, acantholytic and spindle cell carcinomas – should be recognised[16] and listed in the core dataset and potential prognostic implications noted in the 'Comments' sections. Basaloid squamous cell carcinomas tend to present with more extensive disease but are also more radiosensitive than conventional squamous cell carcinomas and should be diagnosed using standard criteria.[16-17] Comments on adenocarcinomas are made in section 10.

[Histopathological type is important for cancer registration and prognosis, with strength of evidence varying for different types; level C/D.]

4.2.2 Degree of differentiation (grade)

Grading is based on the degree of resemblance of the carcinoma to the normal epithelium and follows the descriptions in the WHO classification.[16] The most aggressive area (at x100 magnification field) is graded as well, moderately or poorly differentiated. This system is widely used and prognostically useful,[1,18-20] even though it suffers from inter-observer variability and sampling problems.[8,21] While most squamous carcinomas will be moderately differentiated, it is important for prognostication to separate well-differentiated and poorly-differentiated tumours. Where a tumour has a varied appearance, then the highest grade (poorest differentiation) is recorded as core data, while the predominant pattern may be recorded as non-core data. See section 10 for comments on adenocarcinomas.

[Histological grade is important for prognostication and prediction of response to adjuvant radiation and/or chemotherapy; level B/C.]

4.2.3 Maximum diameter of tumour

The macroscopic diameter (millimetres) should be used (Figure 1) unless the histological extent is greater than macroscopically apparent, in which case the microscopic dimension is used. As for other tissues, e.g. breast, measurements are made pragmatically, acknowledging distortion of tissues by fixation and processing.

[Tumour size is not a staging criterion for the nasal cavies and paranasal sinuses. Size is retained as a core data item for correlation with imaging studies.]

4.2.4 Distance from invasive carcinoma to surgical margins

Measure the distance (in millimetres) histologically for both mucosal and deep margins. From a surgical point of view, >5 mm is clear, 1–5 mm is close and <1 mm is involved. Incomplete resection or the presence of dysplasia at the margin is associated with a significantly increased risk of local recurrence.[22-25] In the 'Comments' section it may be noted that if the tumour has an infiltrating pattern of invasive front (or vascular or perineural spread ahead of the invasive front) and a close margin, this may be associated with a high risk of local recurrence. Conversely, it may be acceptable to have a close margin for a well-circumscribed tumour with a cohesive growth pattern.

[Margin status is a predictor of local recurrence and may require consideration of adjuvant therapy; level B.]

4.2.5 Vascular invasion

The presence or absence of vascular invasion should be mentioned if it is an obvious feature on medium magnification examination of the tumour. The presence of carcinoma cells within an endothelial-lined space is the essential criterion and should be distinguished from retraction artefact. It is not necessary to distinguish between small lymphatics and venous channels. Vascular invasion is a relatively weak predictor of nodal metastasis.[26-27]

[Level of evidence D.]

4.2.6 Nerve invasion

The presence or absence of invasion of the perineural plane ahead of the invasive front of the carcinoma should be recorded, regardless of the size of the nerve. Perineural invasion predicts local recurrence, nodal metastasis and survival and may indicate a need for adjuvant therapy.[20,28-31]

[Perineural invasion predicts more aggressive disease; level B.]

4.2.7 Bone invasion

The involvement of maxillary or mandibular bone may be by non-invasive erosion of the cortex, or diffuse infiltration of medullary intertrabecular and perineural tissues.[15] If bone invasion is present, the presence or absence of carcinoma at the bone margins should be recorded.

[The presence of bone involvement is important for accurate staging; level B.].

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 at most sites in the head and neck region, and therefore are not part of the data set at present.

- Macroscopic growth pattern of carcinoma: exophytic, polypoid, ulcerated or endophytic.
- Pattern of growth of carcinoma. Unlike other head and neck sites, the microscopic pattern of growth does not have consistent prognostic value in the nasal cavities and paranasal sinuses.
- Severe squamous or glandular epithelial dysplasia. Dysplasia is uncommonly seen except in association with invasive carcinoma. The presence of dysplasia may be recorded but is not of verified prognostic importance.

- Type and intensity of inflammatory infiltrate and desmoplastic stromal response.
- Response to previous therapy such as necrosis, dystrophic calcification and a foreign body reaction to debris (if applicable).
- Results of other investigations, e.g. flow cytometry, molecular and immunocyto-chemical studies.

5.1 Molecular markers

Molecular markers including measures of cell proliferation and nuclear DNA content, the expression of involucrin, blood group antigens, cell adhesion molecules and oncogenes, and the intensity of neoangiogenesis have been investigated as potential prognostic factors. These features generally correlate with cellular differentiation but do not provide any consistent independent prognostic information.[9,11,22,32-36] While molecular markers predictive of tumour behaviour or response to therapy may be required pathological data in the future, current surgical practice does not demand their inclusion in the core data set.[11,22,34]

Molecular genetic studies indicate that squamous cell carcinomas show marked molecular heterogeneity, offering the possibility for improved prognostic classification and targeted therapies in the future.[37-39]

Molecular methods may be used to assess the status of surgical margins;[23,40] these methods may identify histologically inapparent residual carcinoma or preneoplastic field cancerisation but require further validation and assessment of clinical relevance.

Immunocytochemical studies may help to resolve differential diagnostic problems. Most antibodies lack a precise tissue or neoplastic specificity, so that a combination of appropriate results is required to make a diagnosis. These results should always be consistent with the haematoxylin and eosin appearances.

6 Diagnostic coding of primary carcinomas

6.1 pT status

pT status should be recorded according to the UICC guidelines[15] (see Appendix 1).

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 type of carcinoma and its grade are the minimum data, as these may determine treatment. It is recognised that, in large tumours, the grade in superficial biopsy material may not be representative of the most aggressive part of the invasive front. If severe dysplasia/*in situ* carcinoma is present, this should be recorded as it may influence

the siting of excision margins. It is not realistic to assess reliably the tumour thickness or presence of vascular invasion in small biopsies.

8 Frozen section diagnosis

The initial diagnosis of carcinoma will usually be made 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 is the most common indication for intra-operative frozen section diagnosis. 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 mucosal malignancies

Exfoliative or fine needle aspiration of mucosal lesions is rarely used as most lesions are susceptible to conventional biopsy techniques.[41] Cytological diagnosis of lymph node aspirates is covered in the dataset on neck dissections for head and neck cancer.

10 Specific aspects of individual tumours not covered elsewhere

10.1 Mucosal melanoma

The majority of mucosal malignant melanomas arise in the sinonasal tract with approximately 25% in the oral cavity and a few at other sites.[16] Even small melanomas tend to behave aggressively with high rates of recurrence and death. Melanoma should be considered in the differential diagnosis of any poorly differentiated mucosal malignancy and immunocytochemical analysis performed when appropriate.[42-43] The 7th edition of the TNM staging system[15] reflects this aggressive behaviour by designating primary melanomas limited to the mucosa as T3 lesions. Advanced and very advanced mucosal melanomas are classified as T4a and T4b respectively (see Appendix A). *In-situ* mucosal melanomas are excluded from staging as they are extremely rare.

10.2 Adenocarcinomas

Sinonasal adenocarcinomas are classified into salivary type carcinomas, intestinal and non-intestinal adenocarcinomas.[16] Histological type and grade are of prognostic importance.

Intestinal type carcinomas are morphologically and immunophenotypically similar to colonic neoplasms (usually expressing CK20 and CDX2, but not CK7) and are aggressive neoplasms with papillary, exophytic tumours having a better prognosis than colonic pattern, solid and mucinous carcinomas.[16,44-45] Genetic studies suggest a different pattern of chromosomal abnormalities from colorectal neoplasms, but this methodology is not yet in routine diagnostic use.[46]

Non-intestinal adenocarcinomas are not immunoreactive for colonic markers and are grouped as low-grade, indolent tumours and more aggressive, high-grade

adenocarcinomas on the basis of marked cytological atypia, a high mitotic rate and/or necrosis.[44-45]

[Histological type and grade are important for prognostication; level B.]

10.3 Sinonasal undifferentiated carcinoma

Sinonasal undifferentiated carcinomas (SNUC) are highly aggressive epithelial malignancies composed of nests, lobules or sheets of atypical cells with a high mitotic rate, necrosis and apoptosis. They show minimal, if any, squamous or glandular differentiation and immunocytochemical expression of neuroendocrine markers is uncommon.[16,47] Differentiation from other poorly differentiated, non-epithelial malignancies is important[47] and, in children and young adults particularly, SNUC should be distinguished from NUT midline carcinomas which are characterised by translocations that involve the nuclear protein in testis (NUT).[48]

[Histological type is important for prognostication; level C.]

10.4 Olfactory neuroblastoma (esthesioneuroblastoma)

Olfactory neuroblastoma is an uncommon neuroectodermal malignancy that usually arises from the olfactory membrane of the upper nasal cavity, although origin at other sites has been described.[16] The tumours typically have a lobular architecture and a highly vascular fibrous stroma, and express neuroendocrine markers (synaptophysin, neurofilament protein and chromogranin) on immunocytochemistry. Histological grading (Hyams' grade) is of prognostic significance;[13,16] the key histological criteria of which are provided in Table 1.

[Histological grade is important for prognostication; level C.]

Table 1: Main histological criteria for grading olfactory neuroblastoma (adapted)[16]

Histological feature	Grade 1	Grade 2	Grade 3	Grade 4
Lobular architecture	Present	Present	Partial	Partial
Pleomorphism	Minimal	Present	Prominent	Marked
Neurofibrillary matrix	Prominent	Present	May be present	Absent
Rosettes	Present	Present	May be present	May be present
Mitoses	Absent	Present	Prominent	Marked
Necrosis	Absent	Absent	Present	Prominent

11 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 D.

Lymph node metastases are a poor prognostic factor for malignancies of the paranasal sinuses, although the incidence of metastasis is low, particularly for ethmoid neoplasms.[49]

11.1 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.[24,30] For practical purposes, the critical factor influencing the use of adjuvant therapy is involvement of levels IV or V.[30]

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

11.2 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.[15]

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

11.3 Extracapsular spread

Extracapsular spread (ECS) is a manifestation of the biological aggression of a carcinoma and is associated with a poor prognosis.[1,9,24-25,30,50-54] 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.[52] 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 B.]

Notes on core data items

11.4 Micrometastases

The prognostic significance of micrometastases (2 mm or less in diameter) is not certain,[55-59] their presence should be included in the number of involved nodes and TNM coded as pN1(mi) or pN2(mi).

11.5 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).[15] The prognostic significance of isolated tumour cells is not known for head and neck cancer.[58-59] At present, it is suggested that dissection and sectioning protocols are not modified to explicitly search for isolated tumour cells.

11.6 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.

11.7 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.[58,60] Absolute distinction between these possibilities is not always possible and, while the TNM classification[15] 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. 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.

12 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[15]

General principles

pT Primary tumour

pTX Primary tumour cannot be assessed

pT0 No evidence of primary tumour

pTis Carcinoma *in situ*

pT1, pT2, pT3, pT4 – increasing size and/or local extent of the primary tumour (see specific sites)

Note that 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 head and neck cancers. The method of assessment of margins described in section 4.2.6 is well-established and current surgical practice, particularly the use of laser resection, 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.

Site-specific T codes

Maxillary sinus

T1 Tumour limited to antral mucosa with no bone involvement.

T2 Tumour causing bone erosion or destruction, except for posterior wall.

T3 Tumour invades posterior wall of sinus, subcutaneous tissues, floor or medial wall of orbit, infratemporal fossa, pterygoid plate, ethmoid sinuses.

T4a Tumour invades anterior orbital contents, skin of cheek, pterygoid plates, infratemporal fossa, cribriform plate, sphenoid or frontal sinuses

T4b Tumour invades any of the following: orbital apex, dura, brain, middle cranial fossa, cranial nerves other than maxillary division of trigeminal nerve (V_2), nasopharynx, or clivus

Nasal cavity and ethmoid sinus

T1 Tumour restricted to one subsite in the nasal cavity or ethmoid sinus, with or without bone erosion.

T2 Tumour involves two subsites** within one site or extends to involve an adjacent site within the nasoethmoidal complex, with or without bone erosion.

T3 Tumour extends to involve the medial wall or floor of the orbit, maxillary sinus, palate or cribriform plate.

T4a Tumour invades any of the following: anterior orbital contents, skin of nose or cheek, minimal extension to anterior cranial fossa, pterygoid plates, sphenoid or frontal sinuses.

T4b Tumour invades any of the following: orbital apex, dura, brain, middle cranial fossa, cranial nerves other than maxillary division of trigeminal nerve (V2), nasopharynx, or clivus

**Sites for classification are the individual maxillary and ethmoidal sinuses and the nasal cavity. The nasal cavity is divided in the following subsites: septum, floor, lateral floor and vestibule.

Mucosal malignant melanoma

T3 Mucosal disease

T4a Moderately advanced disease. Tumour involving deep soft tissue, cartilage, bone, or overlying skin.

T4b Very advanced disease. Tumour involving brain, dura, skull base, lower cranial nerves (IX, X, XI, XII), masticator space, carotid artery, prevertebral space, or mediastinal structures.

Note that the classification of regional lymph node metastasis differs from that used for squamous cell carcinomas.

NX Regional lymph nodes cannot be assessed

N0 No regional lymph node metastases

N1 Regional lymph node metastases present

Appendix B SNOMED codes

Topographical codes

T-21000	**Nose**
T-21030	Olfactory region of nose
T-21320	Nasal vestibule
T-21340	Nasal septum
T-21360	Nasal turbinate
T-22000	**Paranasal sinuses**
T-22100	Maxillary sinus
T-22200	Frontal sinus
T-22300	Ethmoid sinus
T-22400	Sphenoid sinus

Morphological codes

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

M-80702	Squamous carcinoma *in situ*
M-80703	Squamous carcinoma
M-80705	Microinvasive squamous carcinoma
M-80713	Keratinising squamous carcinoma
M-80723	Non-keratinising squamous carcinoma
M-80743	Spindle cell squamous carcinoma
M-80753	Adenoid squamous carcinoma
M-85603	Adenosquamous carcinoma
M87203	Malignant melanoma
M81403	Adenocarcinoma, not otherwise specified
M84803	Adenocarcinoma, mucinous
M80203	Undifferentiated carcinoma
M95233	Olfactory neuroblastoma

Procedure codes

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

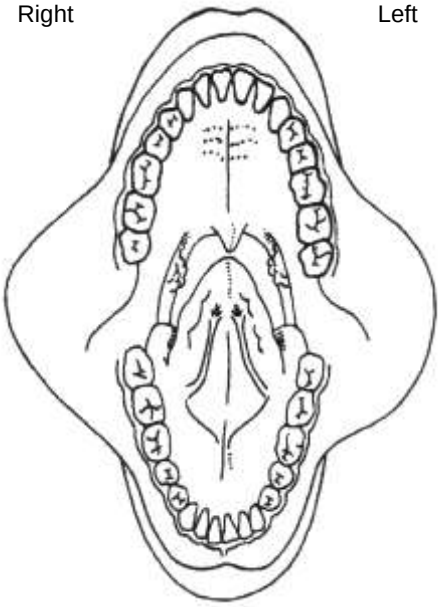
P1100	Resection
P1141	Excisional biopsy
P1340	Endoscopic biopsy
P1140	Biopsy, not otherwise specified

Appendix C Draft request forms for primary mucosal carcinomas and node dissections

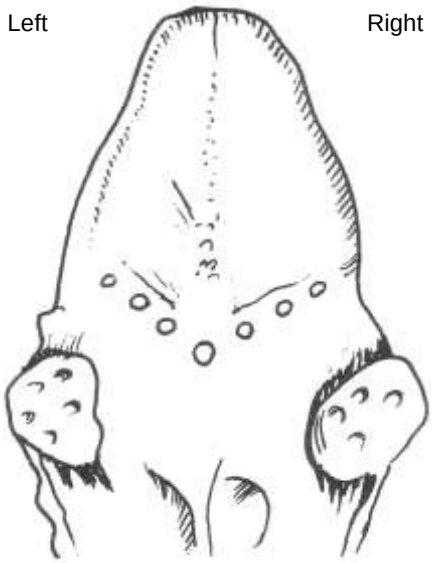
Surname	**Consultant**
Forename	**Location**
Date of birth	
Sex	
Hospital no.	**NHS/CHI no.**

Relevant medical or dental history	**Clinical diagnosis:**
Site of lesion	Previous reports (lab no. if known)
Duration of symptoms	
Predisposing factors	Other information:
Date of operation	
Signature	

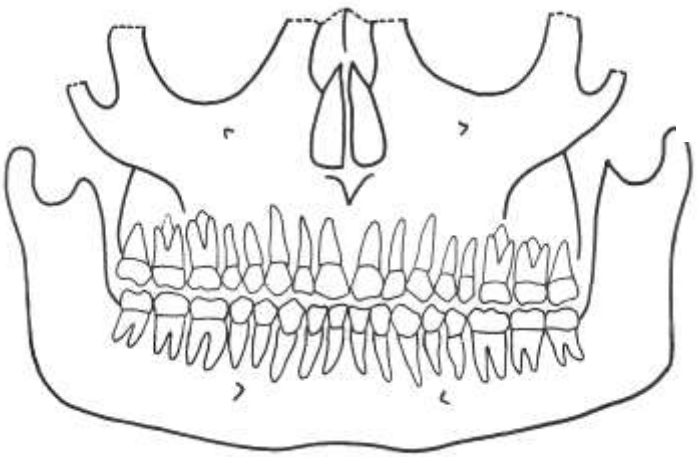
Right Left



Left Right

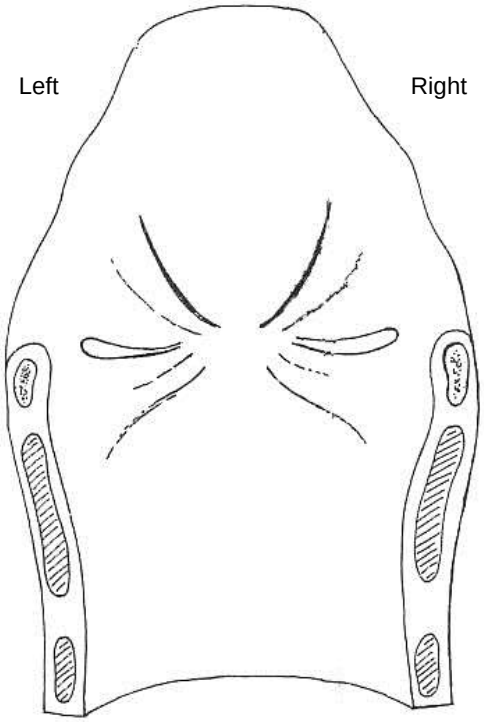


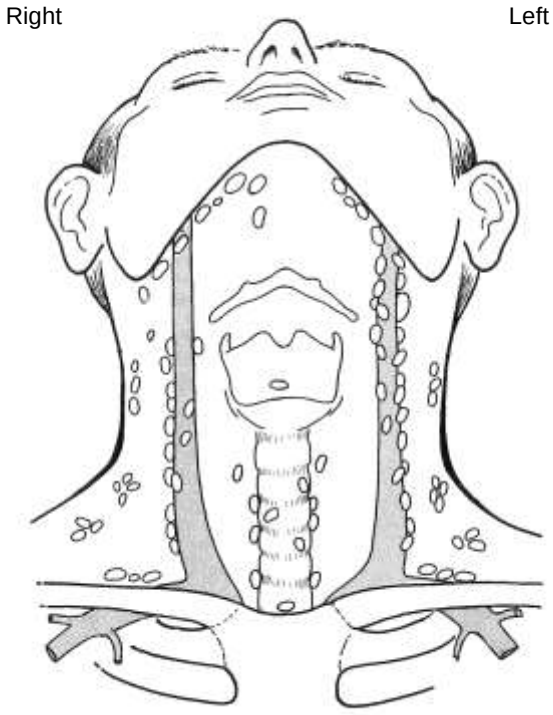
Right Left



Please tick appropriate boxes:

	Right neck dissection	Left neck dissection
Levels submitted		
I		
II (total)		
IIA		
IIB		
III		
IV		
V		
VI		
Other (specify)		
Non-nodal structures		
Sternomastoid		
Submandibular gland		
Internal jugular vein		
Other (specify)		





Appendix D 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 primary nasal cavity and paranasal sinus carcinoma

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

CLINICAL DATA

Type of specimen Incisional biopsy □ Excisional biopsy □
Resection Yes □ No □ If yes, Partial □ Total □
Clinical TNM stage…… T…… N…… M……
New primary □ Recurrence □ Not known □
Previous radiotherapy Yes □ No □ Not known □
Previous chemotherapy Yes □ No □ Not known □

Primary tumour

Site…… Subsite(s)……..
Right □ Left □ Midline □
Histological type: squamous cell carcinoma □
Conventional □ Verrucous □ Papillary □ Acantholytic □ Other (specify) …….
Other malignancy (specify).. ……
Differentiation/grade Well □ Moderate □ Poor □
Maximum diameter …….(mm)
Distance from invasive tumour to
mucosal margin ……..(mm) deep margin ……(mm)
Vascular invasion Yes □ No □
Nerve invasion Yes □ No □
Bone/cartilage invasion Yes □ No □
If present: Erosive □ Infiltrating □ Carcinoma at margin: Yes □ No □

COMMENTS/ADDITIONAL INFORMATION

SUMMARY OF PATHOLOGICAL DATA

Tumour site…… pTNM stage pT…..... pN……...
Tumour type…… SNOMED codes T…… M……
T…… M……

RESECTION OF PRIMARY TUMOUR Clear □ Close □ 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 E 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 F 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.