Standards and datasets for reporting cancers

Dataset for histopathology reporting of nodal excisions and neck dissection specimens associated with head and neck carcinomas

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	In accordance with the College's pre-publications policy, it was put on The Royal College of Pathologists' website for consultation from 24 October to 21 November 2011. Sixteen items of feedback were received and the authors considered them and amended the document as appropriate. Please email publications@rcpath.org if you wish to see the responses and comments.
	The authors and sub-specialty advisor reviewed this document in November 2013 and made no changes.
	Dr Suzy Lishman
	Vice-President for Advocacy and Communications

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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 lymph node excision specimens and neck dissection specimens that are removed for the assessment and treatment of patients with head and neck malignancies.

The following stakeholder groups have been consulted:

- the British Society for Oral and Maxillofacial Pathology

- 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 neck dissections and nodal metastases associated with 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 or financial implications have been identified that would hinder the implementation of the dataset, which is fully integrated with the Cancer Outcomes and Services Dataset (previously the National Cancer Dataset).

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 guidelines are presented as a proforma that lists the core data items that may be applied across the head and neck region. The proforma 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 to facilitate the recording of data for particular tumour types.

The guidelines should be implemented for the following reasons.

a.   Certain features of metastases to regional lymph nodes are strong predictors of clinical outcome.[1,3-9]

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[10-12]

- 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 patient outcome 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) incorporated primary mucosal malignancies, salivary malignancies and neck dissection specimens. In this revision, the dataset on neck dissection specimens for metastatic disease is presented separately. 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 nodal sites so that appropriate surveillance, surgery, radiotherapy and/or chemotherapy can be delivered to mitigate the effects of recurrence. The UICC TNM staging, in isolation, does not provide sufficient information for management and prognosis[13] and additional factors need to be considered.

The core dataset for neck dissections is unchanged since the second edition in 2005. Minor changes that have been introduced include the addition of a short section on the role of the cytology in the management of nodal disease; the adoption of the 7th edition of the UICC TNM staging system;[14] and the modification of the reporting proforma to provide a simpler layout with easily identified options for transfer to an electronic format.

1.4 Terminology of node groups

Seven major anatomical groups (levels) of lymph nodes are described (see Figure 1).

- Level I: nodes of the submandibular and submental triangles.

- Levels II, III and IV: nodes of the upper, middle, and lower jugular chain. These nodes lie deep to the upper middle and lower thirds of the sternocleidomastoid muscle respectively. The point at which the omohyoid muscle crosses deep to the sternocleidomastoid muscle is a useful landmark separating levels III and IV. Level IV extends from the omohyoid muscle to the clavicle.

- Level V: nodes of the posterior triangle, behind the posterior border of the sternocleidomastoid muscle.

- Level VI: nodes of the anterior compartment, around the midline visceral structures of the neck from the hyoid bone to the suprasternal notch.

- Level VII: nodes in the superior mediastinum.

Imaging studies may subclassify node levels I, II and V.[15] It is not suggested that this should be part of routine pathological practice but, if separate groups are submitted. e.g. IIA and IIB, this should be noted in the pathology report.

Figure 1: Diagrammatic representation of lymph node levels in the neck
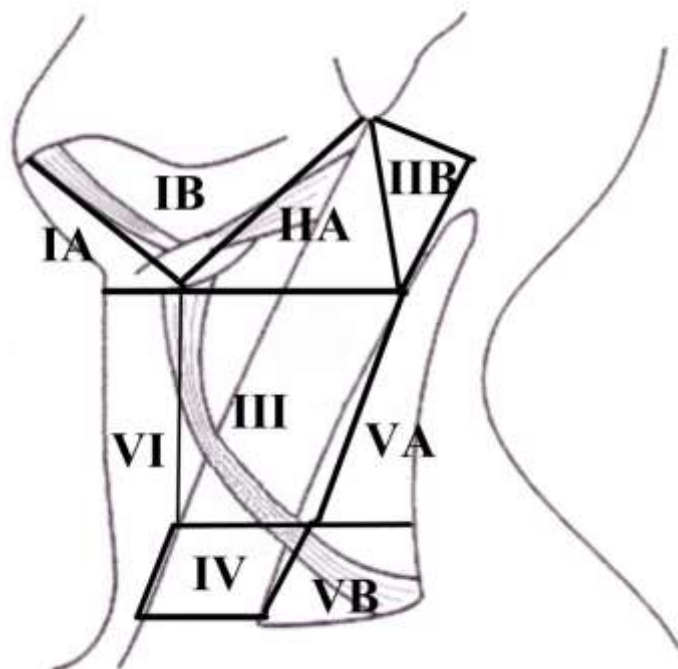
1.5   Terminology of neck dissection specimens

The type of neck dissection and node levels present should be specified by the surgeon using the standard terminology proposed in 2002 by Robbins *et al*[16-17] and modified in 2011 by the International Head and Neck Scientific Group.[18] It may be appropriate to use a request form that encourages the annotation of a schematic diagram to indicate the extent of the dissection. As the terminology applied to modified operations is potentially confusing, dissections should be described by specifying which node groups and non-lymphatic structures the surgeon has dissected and the relevant non-lymphatic structures that have been preserved or removed.

The main types of neck dissection that may be received are:[17]

- **comprehensive neck dissection:** this includes both radical and modified radical (functional) dissections. A radical neck dissection includes removal of cervical lymph nodes (levels I–V), sternocleidomastoid muscle, internal jugular vein, spinal accessory nerve and the submandibular salivary gland, while in a functional dissection, the sternocleidomastoid muscle, internal jugular vein, or the spinal accessory nerve may not be removed

- **selective neck dissection:** this involves removal of the nodal group(s) considered to be the most likely site for metastasis, preserving one or more nodal groups that are routinely removed in a radical dissection

- **extended neck dissection:** when additional lymph node groups or non-lymphatic structures are removed.

To avoid misinterpretation, it is recommended that neck dissections should have three components (for details see reference 18):

1. LND or RND, for left and right neck dissections respectively

2. the levels and/or sublevels removed, e.g. I–III, II–IV

3. any non-lymphatic structures removed, e.g. sternocleidomastoid (SCM), internal jugular vein (IJV), submandibular gland (SG).

1.6 Acknowledgement

For the draft request form, we are grateful to the UICC and Springer-Verlag to use the diagrams of the 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. 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 C). 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 pinned or sutured to cork or polystyrene blocks.

The surgeon should indicate surgically critical margins and identify the general territories of node groups by placing markers such as metal tags or sutures at the centre of each anatomical group.

A practical alternative for selective dissections is for the surgeon to separate the node groups, mark the superior margin of each group with a suture, and place each group in a separately labelled container.

Nodes in addition to the main groups, e.g. parapharyngeal nodes, should be sent as separate specimens.

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 of the specimen may be used to record the nature of the disease and the sites from which tissue blocks are selected. Surgically important margins may be marked with Indian ink or an appropriate dye.

3.2 Dissection and block selection

3.2.1 Identify the component structures. From the outer aspect: the submandibular salivary gland, the sternocleidomastoid muscle, the omohyoid muscle, the external jugular vein, the spinal accessory nerve, the tail of the parotid gland. Some dissections may include skin or other structures such as the stylohyoid and digastric muscles. From the deep aspect, identify the internal jugular vein.

3.2.2 Lymph node identification. Lymph nodes are identified by inspection and palpation around the vein, and around the submandibular gland and adipose tissue of the anterior and posterior triangles, and assigned to the appropriate anatomical level (this should be indicated by surgical markers). Each discrete node is dissected out with attached pericapsular adipose tissue. Larger nodes should be bisected or sliced. If there is obvious metastatic tumour, the half/slice(s) with the more extensive tumour should be processed, together with the perinodal tissues to show the extent of extracapsular spread (ECS). If the node appears negative, all slices should be processed. Small or flat nodes should be processed whole, and several nodes (from the same anatomical level) can be processed in the same cassette. One H&E-stained section from each block is usually sufficient for routine assessment.

3.2.3 An alternative method, which may be particularly useful for selective dissections, is to serially slice the fixed specimen and embed all of the tissue.[19] Care should be taken not to double-count larger nodes that are present in more than one block. Note that large nodes containing obvious metastatic carcinoma only need to be sampled to identify any extracapsular spread.

3.2.4 A radical neck dissection usually yields an average of 20 nodes (range 10–30) in the absence of previous chemotherapy or irradiation, although on occasions 50–100 nodes may be identified. This examination would be expected to include, as a minimum, all palpable nodes greater than 3 mm in diameter.

3.2.5 Other blocks for histology: submandibular gland, jugular vein and sternocleidomastoid if involved by tumour.

4 Core data items to be included in the histopathology report

4.1 Clinical data (provided by the surgeon or oncologist)

Laterality of nodes and anatomical levels of nodes present, together with details of any extranodal structures removed (see section 1.5).

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

4.2 Pathological data

4.2.1 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.[10,12] For practical purposes, the critical factor influencing the use of adjuvant therapy is involvement of levels IV or V.[12]

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

4.2.2 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.[14]

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

4.2.3 Extracapsular spread (ECS)

ECS is a manifestation of the biological aggression of a carcinoma and is associated with a poor prognosis.[1,9-12,20-24] 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.[23] Involvement of adjacent anatomical structures should be recorded separately in the 'Comments' section and, if desired, the extent of ECS may be recorded by direct measurement (in millimetres) from the edge of the residual node when present, or as 'extensive' if residual node is not identified. If histological evidence of ECS 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

4.2.4 Micrometastases

The prognostic significance of micrometastases (2 mm or less in diameter) is not certain.[25-29] Their presence should be included in the number of involved nodes and TNM coded as pN1(mi) or pN2(mi), unless larger metastases are present when the suffix is unnecessary. .

4.2.5 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).[14] The prognostic significance of isolated tumour cells is not known for head and neck cancer.[28-29] At present, it is suggested that dissection and sectioning protocols are not modified to explicitly search for isolated tumour cells.

4.2.6 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.

4.2.7 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.[28,30] Absolute distinction between these possibilities is not always possible and, while the TNM classification[14] 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.

5   Non-core pathological data

These features, which should be included as part of a comprehensive description of a neck dissection specimen, are of uncertain prognostic significance.
- Presence of other pathological changes in cervical nodes.

- Presence of evidence of response of tumour, e.g. keratin debris, to previous therapy. Note that if no viable malignant cells are present then the 'y' prefix is used in TNM staging to indicate that the stage is yN0 post-treatment (see Appendix A). Only if viable malignant cells are present at the time of resection is a node regarded as positive.

- If tumour emboli are present in lymphatics, this should be recorded as a free-text comment; their prognostic significance is uncertain in the absence of established metastases.

6 Diagnostic coding of metastases

pN status should be recorded according to the UICC guidelines[14] (see Appendix A), apart from the designation of isolated nodules of tumour cells (see section 4.2.8).

7 Sentinel node biopsy

Sentinel lymph node biopsy has been suggested as a method to reduce the morbidity associated with cervical node dissections. This is currently being evaluated in clinical trials for head and neck cancer patients and its precise role in patient management has yet to be defined.[31-34]

A standard dissection and sectioning protocol has been defined for current research studies[32, 34-35] and comprises the following:

- bisect or serially slice the node into 2.5 mm slices

- if node is negative on intial H&E sections, then:
    - step serial section at 150 μm intervals
    - one section from each level is stained with H&E
    - if these sections are negative, then immunocytochemical labelling with AE1/AE3 is performed; only morphologically iable, immunoreactive cells are counted as positive
    - cytological imprints and frozen section analysis are not part of the current research protocols
    - sentinel nodes are reported similarly to other node excision specimens
    - molecular analysis of sentinel nodes may be more sensitive than histopathological examination but is still in the research phase.[36-38]

8 Nodal metastasis with no known primary carcinoma

Core needle or excision biopsies of nodes may be received that contain metastatic carcinoma with no known primary carcinoma. If discussion with the clinical team does not suggest the likely primary site, a limited immunocytochemical panel may be considered to identify potentially treatable disease. The components of this panel will depend on the common primary sites for the age and sex of the patient; a College dataset on the appropriate investigation of malignancies with unknown primary site is in preparation. There is a limited range of markers available for head and neck primary sites, although expression of p16 immunocytochemistry +/- in situ hybridisation for high-risk human papillomaviruses may suggest an oropharyngeal primary site, and expression of Epstein-Barr virus protein or RNA may suggest a nasopharyngeal primary site.

9   Cytological diagnosis of neck disease

Fine needle aspiration cytology (FNAC) is an essential technique for the management of patients with head and neck malignancies, allowing rapid and effective triage of patients with neck lumps.[39] Ideally, FNAC should be combined with ultrasound guidance to ensure accurate targeting of lesions. The optimal mode of delivery of a rapid access FNAC service and the resources required to support this are summarised.[40-41]

10   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.

The British Association of Head and Neck Oncologists' (BAHNO) standard for diagnostic FNAC is that 80% of fine needle aspirates should be reported on the day on which the specimen is taken.[42]

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Appendix A TNM classification of malignant tumours[14]

pN	**Regional lymph nodes (for all primary sites, except nasopharynx)**
pNX	Nodes cannot be assessed
pN0	No nodal metastasis
pN0(i+)	Isolated tumour cells only (<0.2 mm)
pN1(mi)	Micrometastasis (2 mm or less) only, in single node
pN1	Metastasis in single ipsilateral node 30 mm or less in diameter
pN2(mi)	Micrometastasis (2 mm or less) only, in multiple or bilateral nodes
pN2a	Metastasis in single ipsilateral node 31–60 mm diameter
pN2b	Metastasis in multiple ipsilateral nodes <61 mm diameter
pN2c	Metastasis in bilateral or contralateral lymph nodes, none more than 60 mm in greatest dimension
pN3	Metastasis in lymph node more than 60 mm diameter.

Notes

(i)   For nasopharyngeal primary carcinomas:

   pN1   Unilateral metastasis <61 mm above the supraclavicular fossa and/or unilateral or bilateral retropharyngeal metastases

   pN2   Bilateral metastases <61 mm above the supraclavicular fossa

   pN3   Metastasis in nodes >60 mm or in supraclavicular fossa

   pN3a   > 60 mm in dimension

   pN3b   Extension in the supraclavicular fossa.

(ii)   Direct extension of a primary tumour into a node is classified as nodal metastasis.

(iii)   Metastasis in any lymph node other than a regional node is classified as distant metastasis.

(iv)   A macroscopic or microscopic tumour nodule in the connective tissue without residual node may represent discontinuous spread, venous invasion or a totally replaced lymph node. If the nodule has a generally smooth contour or is more than 10 mm from the primary carcinoma, it is classified as a nodal metastasis for the purpose of staging.

(v)   When size is a criterion for pN classification, measure the size of the metastasis and not that of the entire node.

(vi)   Cases with micrometastasis only, i.e. no metastasis larger than 0.2 mm, can be designated with the suffix (mi).

(vii) Isolated tumour cells are single tumour cells or small clusters of cells not more than 0.2 mm in greatest dimension or a cluster of less than 200 cells in a single histological cross-section.

(viii) Midline nodes are considered ipsilateral.

(ix) 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.

Sentinel lymph node

pNX(sn)   Sentinel lymph node could not be assessed.

pN0(sn)   No sentinel lymph node metastasis.

pN1(sn)   Sentinel lymph node metastasis.

Appendix B   SNOMED codes

Topographical codes

T08000   Lymph node

T13000   Skeletal muscle

T55200   Submandibular salivary gland.

Morphological codes

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

Metastatic squamous cell carcinoma and variants

M-80706   Squamous cell carcinoma

M-80716   Keratinising squamous cell carcinoma

M-80726   Non-keratinising squamous cell carcinoma

M-80746   Spindle cell squamous cell carcinoma

M-80756   Adenoid squamous cell carcinoma

M-85606   Adenosquamous carcinoma.

Metastic salivary malignancies

M-85506   Acinic cell carcinoma

M-84306   Mucoepidermoid carcinoma

M-82006   Adenoid cystic carcinoma

M-82006   Polymorphous low grade adenocarcinoma

M-85626   Epithelial-myoepithelial carcinoma

M-81476   Basal cell adenocarcinoma

M-84106   Sebaceous carcinoma

M-84506   Papillary cystadenocarcinoma

M-84806   Mucinous adenocarcinoma

M-82906   Oncocytic carcinoma

M-85006   Salivary duct carcinoma

M-81406   Adenocarcinoma, not otherwise specified

M-89826   Malignant myoepithelioma (Myoepithelial carcinoma)

M-89416   Carcinoma arising in pleomorphic adenoma (Malignant mixed tumour)

M-80706   Squamous cell carcinoma

M-80416   Small cell carcinoma

M-80206   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

P1140   Biopsy, not otherwise specified.

Appendix C   Draft request form for 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	

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)		

Right   Left
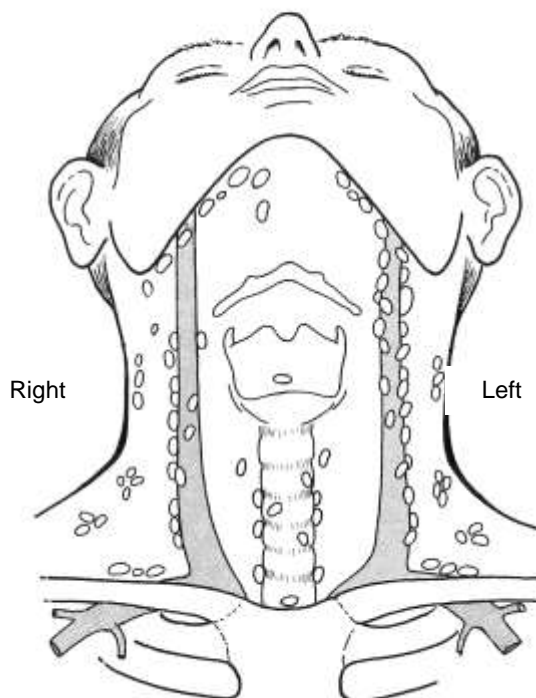
Appendix D   Reporting proforma: Dataset for lymph node excision specimens

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……

SNOMED codes   T……….   M……………..

Tumour type…………………….

Signed: 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
Level 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.
Level 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.
Level 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.
Level 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–D
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.