Standards and datasets for reporting cancers

Dataset for the histological reporting of primary cutaneous adnexal carcinomas and regional lymph nodes

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Comments
This dataset, which supersedes the February 2013 version, has been revised to include a redesign of the coding appendix and changes to the reporting proformas, including standardisation of terminology and improved clarity to better reflect AJCC7 staging for non-melanoma skin cancer, as used by COSD for basal and squamous cell carcinoma. In accordance with the College’s pre-publications policy, this document was on the Royal College of Pathologists’ website for an abridged consultation from 10–24 June 2014. Seventeen items of feedback were received. Please email publications@rcpath.org to see the responses and comments.

Dr Suzy Lishman
Vice-President for Advocacy and Communications
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NICE has accredited the process used by The Royal College of Pathologists to produce its Cancer Datasets and Tissue Pathways guidance. Accreditation is valid for 5 years from July 2012. More information on accreditation can be viewed at www.nice.org.uk/accreditation. For full details on our accreditation visit: www.nice.org.uk/accreditation.
Foreword

The cancer datasets published by The Royal College of Pathologists (RCPPath) are a combination of textual guidance, educational information and reporting proformas. The datasets enable pathologists to grade and stage cancers in an accurate, consistent manner in compliance with international standards and provide prognostic information thereby and allowing clinicians to provide a high standard of care for patients and appropriate management for specific clinical circumstances. It may rarely 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 are mandated for inclusion in the Cancer Outcomes and Services Dataset (COSD – 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.

The following organisations have been consulted during its preparation and have approved the dataset:
- British Association of Dermatologists (BAD) (as a co-institutional member of The Royal College of Pathologists’ Specialty Advisory Committee on Dermatopathology)
- British Society for Dermatopathology (BSD) (as an institutional member of The Royal College of Pathologists’ Specialty Advisory Committee on Dermatopathology)
- National Specialist Dermatopathology External Quality Assessment Scheme (NSDEQA) (as a member of The Royal College of Pathologists’ Specialty Advisory Committee on Dermatopathology)
- National Cancer Intelligence Network (NCIN)
- College of American Pathologists (CAP).

This dataset has been constructed taking into account the new strong evidence base that is contained in and forms the basis for the following new national and international publications. All publications have widespread national and/or international peer acceptance and reflect the current accepted professional standards and practice in skin cancer.
- COSD published by NCIN
- World Health Organization (WHO) Classification of Skin Tumours
- Armed Forces Institute of Pathology (AFIP) Atlas of Tumour Pathology
- National Institute for Health and Clinical Excellence (NICE) Guidance on Cancer Series
- National Cancer Peer Review (NCPR) Program by the Department of Heath Cancer Action Team
- NHS Evidence
- CAP.

As well as peer-reviewed scientific publications, consideration has also been given to published evidence and expert opinion on the internet, such as on Dermpedia (www.Dermpedia.org).
Evidence for the dataset was also obtained by electronically searching medical literature databases for relevant research evidence, systematic reviews and national or international publications on skin cancer up to May 2014. This identified no evidence to alter the views or conclusions of the publications listed above. The evidence has been evaluated according to the modified SIGN guidance and the level of evidence for the recommendations has been summarised according to College guidance (see Appendix E). Most of the supporting evidence is grade C or D or meets the GPP (Good Practice Point) criteria. No major conflicts in the evidence have been identified and any minor discrepancies between evidence 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 COSD, and there are no major financial or work implications arising from its implementation.

A formal revision cycle for all cancer datasets takes place on a three-yearly basis. However, each year, the College will ask the author of the dataset, in conjunction with the relevant sub-specialty adviser to the College, to consider whether or not the dataset needs to be updated or revised. A full consultation process will be undertaken if major revisions are required, i.e. revisions to core data items (the only exception being changes to international tumour grading and staging schemes that have been approved by the Specialty Advisory Committee on Cellular Pathology and affiliated professional bodies; these changes will be implemented without further consultation). If minor revisions or changes to non-core data items are required, an abridged consultation process will be undertaken, whereby a short note of the proposed changes will be placed on the College website for two weeks for Fellows’ attention. If Fellows do not object to the changes, the short notice of change will be incorporated into the Dataset and the full revised version (incorporating the changes) will replace the existing version on the College website. All changes will be documented in the ‘data control’ section of the relevant dataset.

The dataset has been reviewed by the WGCS and will be placed on the College website for an abridged consultation with the membership from 10–24 June 2014. All comments received from the WGCS and membership will be addressed by the author to the satisfaction of the WGCS Chair and the Vice-President for Advocacy and Communications.

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.

1 Introduction

1.1 Purpose of the dataset

This document provides the dataset for the histological reporting of cutaneous adnexal carcinoma and associated regional lymph nodes.

The diagnosis and reporting of cutaneous adnexal carcinoma is important because histological parameters play a significant role in defining patient treatment. In addition, recording of pathological parameters in the dataset has direct implications for the staging and prognosis of individual patients. The use of datasets (and the background information that forms part of the datasets) in the context of the multidisciplinary team (MDT) meeting is advocated to optimise decisions related to patient treatment, to facilitate regular audit and review of all aspects of the service, to enable the collection of accurate data for Cancer Registries, and to provide feedback for those clinicians caring for patients with cancer. It is important to have robust local mechanisms in place to ensure that the MDT Clinical Leads and Cancer Registries are informed of supplementary or revised histology reports that may affect patient treatment and data collection.
1.2 Staging

It is essential to implement the changes in the international staging of skin cancer that were introduced in 2010.

Ideally, staging for skin cancer is based on the latest published edition of the Tumour, Node and Metastasis (TNM) categorisation of malignant tumours published by the International Union against Cancer (UICC). International it has been agreed that this should be identical to the same staging edition published by the American Joint Committee on Cancer (AJCC). When published, however, it was clear that the UICC 7th edition contained significant discrepancies in relation to skin cancer. Some of these remain unaddressed in the 4th Supplement. On that basis, after widespread consultation, the use of AJCC 7th edition was recommended for skin cancer by the RCPath.

Several important differences occurred in the AJCC 7th edition.

a) Non-melanoma skin cancer (NMSC) is divided into two separate chapters with different staging criteria. The chapters comprise Merkel cell carcinoma and other types of NMSC. The latter includes non-aggressive NMSC such as basal cell carcinoma and aggressive NMSC, including cutaneous squamous cell carcinoma and some types of sebaceous and eccrine neoplasms. The AJCC database relating to adnexal carcinoma is not yet currently available in the public domain and the AJCC definition of aggressive tumour growth (local, nodal or more distant metastatic spread) is not well defined. To facilitate staging and cancer registration, each primary malignant adnexal carcinoma (eccrine, apocrine, follicular and sebaceous subtypes) should be staged using AJCC7 NMSC criteria. These usually show some degree of local, nodal or metastatic spread. A similar approach is recommended by CAP. This ensures that each aggressive adnexal carcinoma is recorded by the Cancer Registries.

b) There is no additional tumour stage breakpoint based on maximum diameter for NMSC lesions over 20 mm diameter (except Merkel cell carcinoma; see the College’s Dataset for the histological reporting of primary cutaneous Merkel cell carcinoma and regional lymph nodes – www.rcpath.org/publications).

c) As many NMSC occur on the head and neck, staging of cutaneous tumours (except Merkel cell carcinoma) is aligned with the previous AJCC head and neck staging system. In particular this has resulted in changes to T3 and T4 staging criteria.

d) Clinical and histological high-risk features are now defined in AJCC7 for NMSC (except Merkel cell carcinoma) that upstage from T1 to T2.

e) The nodal staging system for NMSC (excluding Merkel cell carcinoma) is based on the maximum diameter of metastatic deposits and the number and location of nodes involved.

f) AJCC is ambiguous in its definition as to which part of lip is subject to NMSC staging. In sections on anatomic site, prognostic factors and summary, AJCC states that it is hair-bearing lip to which NMSC staging applies, but in the section on high-risk features, AJCC states that it is the non-hair-bearing lip. The latter is interpreted as a typographical error as AJCC7 specifically defines carcinoma of the lip and oral cavity under head and neck TNM staging, to commence at the vermilion border of the non-hair-bearing lip. Head and neck histopathologists should note this anatomical boundary to decide whether to apply the staging for cutaneous or head and neck NMSC (excluding Merkel cell carcinoma). AJCC7 lymph node staging for both, however, is similar.
g) AJCC7, and accordingly, this dataset, excludes eyelid, penis, vulva and vermilion lip from cutaneous NMSC staging (except Merkel cell carcinoma).

1.3 Evidence base

Apart from two publications on primary cutaneous eccrine porocarcinoma and apocrine carcinoma,13,14 there are few publications that deal with sufficiently large numbers of patients with primary adnexal carcinomas to be considered scientifically robust in relation to prognosis.

For eccrine porocarcinoma recognised aggressive features include:
- greater than 14 mitoses per high power field
- lymphovascular invasion
- depth >7 mm.

For apocrine adenocarcinoma, a recognised poor prognostic feature is a grade 3 tumour defined by mitotic index, pleomorphism and percentage tubules using a modified Bloom-Richardson method for the scoring of breast carcinoma.15

Although histopathologists and MDTs should be aware of the above publications, core data collection should be limited to what is required for AJCC7 staging. Some data items in apocrine adenocarcinoma can be of value in assessing the tumour grade for AJCC staging.14

1.4 Core and non-core data items.

The core pathological data items are summarised in proforma style, which may be used as the main reporting format or included with a free-text report. There is strong peer support that the use of proformas or checklists contributes significantly to achieving defined standards in respect to report content.

1.5 Target users and health benefits of this guideline

The target primary users of the dataset are trainee and consultant cellular pathologists and, on their behalf, the suppliers of IT products to laboratories. The secondary users are surgeons and oncologists, cancer registries and the National Cancer Intelligence Network. Standardised cancer reporting and multidisciplinary team (MDT) working reduce the risk of histological misdiagnosis and help to ensure that clinicians have all of the relevant pathological information required for tumour staging, management and prognosis. Collection of standardised cancer specific data also provides information for healthcare providers, epidemiologists, and facilitates international benchmarking and research.

2 Clinical information required on the specimen request form

Provision of clinical information is the responsibility of the clinician submitting a specimen for pathological examination. A range of clinical information, as indicated in the proposed UK National Histopathology Request Form (Appendix C) is required for both the COSD and MDT discussion relating to management, treatment and prognosis. A draft National Request Form, which is awaiting implementation, has been developed by the NCIN and endorsed by the BAD.

The minimum clinical items regarded as core for the pathology report constitute the site of origin and the type of specimen. Other clinical items are recognised to be important but since their provenance is not the primary responsibility of the pathologist, they are listed as non-core items to encourage their collection and inclusion in the histology report.
3 Preparation of specimens before dissection

3.1 Skin specimens

The overall size of the submitted specimen received must be measured. When appropriate, and in particular with excision specimens, this should incorporate three-dimensional details. Any unusual features that could be diagnostically important should also be recorded.

The presence, absence or any uncertainty about the existence of a lesion or abnormalities to naked eye must be recorded. When a lesion is apparent, measurements should include the maximum diameter and elevation.

Consideration should be given to inking or notching the margins of all skin specimens with potential skin cancer. Standard techniques include the use of substances such as Indian ink, silver nitrate, alcian blue, crayon or commercial preparations. Excepting Mohs' surgery, inking is the best way to obtain a reasonably accurate assessment of surgical margins and thereby lesional clearance. Discretion and flexibility should, however, be applied in this decision. The potential for dye to track and give rise to false margins should be taken into account in the final histopathological assessment. Its routine use in large specimens, especially with a clearly visible small central lesion, is more debatable. Even in these circumstances, however, inking may be useful because of the possibility of unexpected microscopic extension of the lesion. It is not necessary to ink specimens that are submitted for diagnostic purposes, i.e. when there is no clinical intent to excise.

The examination of specimens submitted to the laboratory with prior designated orientation, by sutures or inking for example, can be facilitated by the use of different coloured inks on different margins, notching the specimen or the insertion of coloured agar into the processing cassette.

3.2 Regional lymphadenectomy specimens

The generalities of macroscopic neck and axillary block dissection, described for head and neck cancer and breast cancer (www.rcpath.org/publications), apply equally to skin cancer. Inguinal dissections can be approached as axillary dissections.

The overall dimensions of the fixed tissue must be measured, with particular note of any designated orientation and in particular, any apical node. Nodes should be identified by inspection and palpation. The use of clearing agents is time consuming and increases cost. Accordingly this is not regarded as essential.

3.3 Sentinel lymph node biopsy

AJCC7 does not contain specific advice about sentinel lymph node biopsy for NMSC. Where appropriate, the dataset guidance contained in nodal excisions of head and neck carcinomas can be used (www.rcpath.org/publications) and modified according to general advice in UICC7. Alternatively, the bread-loaf or bivalve techniques described in Merkel cell carcinoma or malignant melanoma datasets respectively (www.rcpath.org/publications) can be used, but omitting their immunohistochemical component.

4 Specimen handling, dissection and block selection

4.1 Skin specimens

Very small specimens may not require trimming. In this situation, however, it must be appreciated that a histological section along the longitudinal axis may not accurately reflect the nearest peripheral margin.
The method of handling excisional biopsies depends on the size of the specimen, whether the lesion can be seen, the position of the lesion on the specimen, the uniformity of the lesion and the type of processing technology. It is recommended that a separate judgement is made on each individual case, taking these variables into account, assisted by the following general comments.

Laboratories using rapid processing technology must ensure that sections are no more than 2–3 mm in maximum thickness, whereas those using conventional processing technology can increase this to 4–5 mm.

In specimens that require trimming and in which the lesion can be seen, the specimen should be cut at regular intervals so that the nearest naked-eye margin to the lesion can be assessed histopathologically. For many skin ellipses, this will require transverse rather than longitudinal sectioning. When multiple sections are required, this should be undertaken by the 'sliced bread/toast rack' method.

The more of the specimen is examined, the more accurate the assessment of the surgical margins will be. Accordingly, for specimens under 10 mm, it is recommended that most or all of the lesion is examined. For specimens over 10 mm, the extent of sampling should take into account the proximity of the lesion to the margins, maximum lesional thickness, lesional uniformity and any unusual features. When the lesion can be clearly identified, sampling the polar margins of skin ellipses should be discretionary and based on whether the lesion is close (under 1–2 mm) to the margin or is less than that in the short transverse axis.

When the periphery of the lesion is indistinct, the whole of the specimen should be sampled. In this situation, the polar ends from the long axis of a skin ellipse should be examined. These can be placed in one or two cassettes, depending on whether the specimen has been orientated clinically.

In some very large specimens, as well as sampling the lesion, the cruciate margins at 3, 6, 9 and 12 o’clock can be sampled, although the limitations of assessing margin clearance should be appreciated.

Step-levels/sections may be required in any type of specimen in order to identify a lesion, achieve full face assessment, establish a diagnosis and assess the margins. Requests for levels at cut-up can be used flexibly but with the proviso that laboratory protocols and technical experience must ensure that sufficient material remains in the paraffin block for further investigations if subsequently proved necessary.

Trimmed pieces of tissue of different thickness, or more than two pieces of tissue in one cassette, incurs an increased risk of incorrect orientation and sectioning, with potential loss of diagnostic and margin information.

Re-excision specimens are covered in section 11.

4.2 **Regional lymphadenectomy specimens**

Inking of the specimen surface is not regarded as essential.

The three-dimensional size of the overall specimen should be recorded.

Any localising marker should be recorded.

All potential lymph nodes must be removed, blocked and recorded in a manner that permits an accurate microscopic count of lymph nodes, the number involved and measurement of
the maximum diameter of the largest metastasis. Nodes can be bisected or sliced at 4–5 mm intervals.

The largest metastatic deposit identified macroscopically should be recorded. Representative sampling is acceptable, taking into account the necessity to measure the largest metastasis, ascertain whether more than one node is involved and to identify extracapsular invasion. The maximum diameter of the largest metastasis should be ascertained pragmatically, using both macroscopic and microscopic information. The lymph node or tumour closest to the surgical margin, within a macroscopic distance of 5 mm, should be identified and sampled.

If skin accompanies the specimen, any abnormal areas must be sampled. In the absence of a macroscopic abnormality, one random block of skin is adequate.

5 Core data items

5.1 CLINICAL

The minimum clinical items regarded as essential for the pathology report are the type and site of specimen.

5.2 PATHOLOGICAL

5.2.1 Macroscopic

a) Skin

The three-dimensional size of the overall specimen and the maximum diameter of all lesions must be recorded in millimetres.

b) Lymph node

The three-dimensional size of the overall specimen must be recorded in millimetres.

Localising markers attached by the clinician must be recorded.

The maximum diameter of the largest lesion must be recorded in millimetres.

[Maximum diameter of the skin lesion and largest metastatic deposit are primary staging determinants – Level of evidence B.]

5.2.2 Microscopic

a) Diagnostic subtype of adnexal carcinoma

Where possible the diagnosis should conform to the WHO classification of malignant adnexal tumours and the appropriate M code should be applied.6 There is a correlation between tumour subtype and clinical outcome. It is recognised that in some instances diagnostic entities may be reported in other publications (for example, the Armed Forces Institute of Pathology or specialist textbooks) and the latter diagnoses may not be included in the WHO classification.7,16

The presence of a benign adnexal tumour in the background should be recorded.

[The diagnostic subtype adnexal carcinoma has a correlation with clinical outcome – Level of evidence C.]
b) Grade

The term ‘differentiation’ has two main meanings with respect to adnexal neoplasms.

First, the lineage of differentiation, i.e. whether the tumour is, for example, eccrine, apocrine, follicular or sebaceous.

Second, the histological grade of tumour differentiation, i.e. whether the tumour is well, moderately or poorly differentiated. It is this tumour differentiation to which the core data item relates. A poorly differentiated adnexal carcinoma is a joint high-risk feature and contributes to upstaging from pT1 to pT2 in AJCC7.\(^2\) Tumour differentiation is a core item for all tumours in the Cancer Outcomes and Services Dataset.\(^3\) Evidence indicates that increasing de-differentiation correlates with an increasing risk of recurrence and metastasis.\(^2\)

Although AJCC7 lists poor differentiation as a high-risk feature for staging, its definitions are broad. They are summarised below.

- Low-grade tumours are defined as tumours that show considerable cellular differentiation, uniform cell size, infrequent cellular mitoses and infrequent nuclear irregularity.
- High-grade tumours are described as showing poor differentiation, necrosis and high mitotic activity.

After consultation, a decision was taken to modify the classification used for squamous cell carcinoma and to incorporate the three elements of comparison against normal epithelium (here adnexal type). These comprise the degree of adnexal differentiation, nuclear pleomorphism and mitotic activity.\(^17\)

Three grades can then be identified as follows.

- Well-differentiated tumours are characterised by epithelium easily recognisable as adnexal in origin. The tumours display little nuclear pleomorphism and mitotic figures are sparse. The adnexal elements predominantly comprise ducts and/or lumina in apocrine or eccrine tumors, sebaceous cells in sebaceous tumours and follicular elements in follicular tumours.
- Moderately differentiated tumours show rather more architectural disorganisation and an adnexal lineage is less obvious. Nuclear and cytoplasmic pleomorphism are more pronounced and mitotic figures (including abnormal forms) are much more common.
- In poorly differentiated variants, it is more difficult to identify adnexal lineage and there is significant cytological and nuclear pleomorphism. The mitotic index is high. In this group, the diagnosis may rely on the results of immunohistochemistry. Antibodies against CAM 5.2, cytokeratin 7, EMA, CEA, HMFG1, GCPFP-15 and BerEP4 may be helpful. The absence of a myoepithelial component can be demonstrated using antibodies against smooth muscle actin and S100.

Apocrine adenocarcinomas can be graded using a modified Nottingham breast system.\(^15,16\)

<table>
<thead>
<tr>
<th>Mitosis/mm(^2)</th>
<th>Pleomorphism</th>
<th>Tubules</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>0–6</td>
<td>Mild</td>
<td>&gt;75%</td>
<td>1</td>
</tr>
<tr>
<td>7–12</td>
<td>Moderate</td>
<td>10–75%</td>
<td>2</td>
</tr>
<tr>
<td>&gt;12</td>
<td>Severe</td>
<td>&lt;10%</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Score</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>3–5</td>
<td>Well differentiated</td>
</tr>
<tr>
<td>6–7</td>
<td>Moderately differentiated</td>
</tr>
<tr>
<td>8–9</td>
<td>Poorly differentiated</td>
</tr>
</tbody>
</table>
The grading system for cutaneous sebaceous carcinoma based on growth pattern that is recommended by the WHO has not been adopted in this dataset.\textsuperscript{5} Although the WHO states that this grading system is based on a publication by Rao et al, the grading system that is provided is misquoted and does not appear in Rao’s publication.\textsuperscript{18} In addition, the publication by Rao et al relates purely to sebaceous carcinoma of the ocular adnexa. High-risk features reported by Rao et al include vascular and lymphatic invasion, orbital invasion, involvement of upper and lower eyelids, poor differentiation, multicentric origin, diameter greater than 10 mm, infiltrative growth pattern and pagetoid invasion of the adjacent epithelium.

AJCC7 provides no guidance on the percentage of differentiated components required to establish tumour grade. On that basis, this dataset has adopted the widely recognised approach that a tumour should be classified according to its most poorly differentiated region, irrespective of the percentage present.\textsuperscript{17} This approach is also advocated by the National Comprehensive Cancer Network and is used in other RCPath cancer datasets (such as mucosal malignancies of the oral cavity). The reporting proforma requires an entry about whether a poorly differentiated component is present. The percentage of different differentiated components can be entered as a non-core dataset item.

\textit{[Increasing dedifferentiation correlates with increasing risk of recurrence and metastasis – Level of evidence C.]}

c) Thickness

Tumour thickness of greater than 2 mm in a cutaneous adnexal carcinoma is a joint high-risk feature and contributes to upstaging from pT1 to pT2 in AJCC7.\textsuperscript{2}

In order to conform to the requirements of AJCC7, tumour thickness must be measured in the same way as Breslow thickness for invasive malignant melanoma (\textit{Dataset for the histological reporting of primary cutaneous malignant melanoma and regional lymph nodes [2\textsuperscript{nd} edition}, see www. rcpath.org/publications). It should be measured from the granular layer or, when present, the ulcer base, to the deepest extent of invasion by contiguous tumour cells. Tumour thickness can be measured using an ocular micrometer, Vernier scale or an eye-piece measurement graticule. Difficulties in measurement may be encountered in polypoid, exophytic or endophytic tumours. In addition, some adnexal carcinomas arise as a result of malignant transformation in a benign tumour and the malignant component can be variably positioned within the tumour mass or, more commonly, at the edge of the benign tumour. In this situation, a pragmatic approach should be adopted and the difficulty should be mentioned briefly in the report. Although it would be useful to standardise the practice in some other clinical sites and measure thickness from the base of the epithelium, this would conflict with the use of AJCC7 and its staging system which is based on Breslow thickness for squamous cell and adnexal carcinomas.

The single core measurement required for this dataset is a statement as to whether the thickness is greater than 2 mm. Statistically this is taken as 2.0 mm.

\textit{[Tumour thickness is a pT staging parameter – Level of evidence B.]}

d) Level of invasion

It is a requirement to state whether the adnexal carcinoma is \textit{in situ} or invasive. Invasive cutaneous adnexal carcinoma invading into or beyond the reticular dermis (Clark level 4) is a joint high-risk feature and contributes to upstaging pT1 to pT2 in AJCC7.\textsuperscript{2} The degree of extension beyond the reticular dermis must be specified and, in particular, any extension into the bone/s listed below. These are staging determinants for pT3 and pT4 in AJCC7.
These stages are defined as:

- invasion into facial or cranial bone (maxilla, mandible, orbit, temporal bone) is a solitary determinant to define stage pT3
- invasion of skull base or skeleton (axial or appendicular) is a solitary determinant to define stage pT4.

Information about invasion into the papillary dermis (Clark level 2) or invasion to the interface between the papillary and reticular dermis (Clark level 3) does not need to be specified in this dataset.

The same problems may be encountered in assessing some cutaneous adnexal carcinomas as described in the section on tumour thickness. A similar pragmatic approach is recommended.

Clark levels are defined in the College’s Dataset for the histological reporting of primary cutaneous malignant melanoma and regional lymph nodes (www.rcpath.org/publications).

[The presence and level of invasion is a pT staging parameter – Level of evidence B.]

e) Lymphovascular invasion

Evidence to indicate that lymphovascular invasion correlates with recurrence, metastasis or prognosis is limited. Lymphovascular invasion is a descriptor in AJCC7. The presence of an endothelial-lined space is an essential criterion for lymphovascular invasion, as it is essential to distinguish retraction artefact. As indicated by the AJCC, it is not necessary to separately identify lymphatic and venous invasion.

Unlike malignant melanoma, there are no international definitions for satellite, microsatellite or in-transit metastasis for cutaneous adnexal cell carcinoma. In particular, there are no definitions with regard to size or distance from the primary tumour. As with Merkel cell carcinoma in the skin, it is recommended that the term in-transit metastasis is used empirically for any metastasis between the primary tumour and regional nodes. If present, this can be specified in the lymphovascular section.

[Lymphovascular invasion can indicate a worse prognosis – Level of evidence C.]

f) Perineural invasion

Perineural invasion is a recommended site-specific prognostic factor in AJCC7. Perineural invasion into the skull base is one specific determinant for stage pT4 in AJCC7. Perineural invasion correlates with a high risk of local recurrence and high clinical morbidity. There is no evidence to indicate whether the term in skin applies to intratumoural or extratumoural invasion, including tumour at the invading front. Some pathologists restrict the term to the latter. This information can be included as a non-core item.

In re-excision specimens it is important to ensure that apparent perineural invasion is not so-called re-excision perineural invasion (RPI). This reflects the presence of benign perineural epithelial cells in previously biopsied areas, most likely representing reactive/reparative proliferation of traumatised eccrine sweat gland ducts into a plane of lower resistance. Immunohistochemistry can be used to make the distinction.

[Perineural invasion is a pT staging parameter and correlates with a high risk of local recurrence – Level of evidence B.]
g) Margins

Tumour recurrence and clinical morbidity are influenced by the completeness and adequacy of primary excision. In general, however, use of the words ‘complete/incomplete’ and ‘adequate/inadequate’ should be avoided in routine histopathology reports. Unless all of the margins have been examined, it is difficult to be certain about the completeness of excision. The term ‘complete’ is more acceptable in the context of Mohs’ surgery, where the peripheral margin has been examined in its entirety. Adequacy implies a degree of clinicopathological judgement and is therefore more applicable in the context of skin cancer MDT discussion. It is well recognised in a significant number of cases where tumour extends to a margin, that there is no residual tumour present on re-excision. This confirms that the term ‘incomplete’ can be inappropriate in this situation. In non-excision specimens (such as curettings), the term ‘edge’ may be more appropriate, as the edge may not reflect the true surgical margin.

Although evidence is more robust for peripheral margins, there is broad peer agreement that comments are necessary about the clearance at both peripheral and deep excision margins. The word peripheral rather than lateral is generally preferred, to avoid problems by possible inference of a medial margin. The words lateral and medial may be applicable to specifically defined and designated margins in orientated specimens. Careful consideration has been given as to whether the extent of peripheral and deep clearance should be measured in quantitative terms. It is certainly clinically necessary to have information about whether the peripheral and deep excision margins are clear or involved by tumour. Clinicians invariably also wish to know whether the tumour is close the nearest margin to evaluate the potential risk of recurrence, the necessity for further treatment and follow-up. ‘Close’ is, however, a subjective term and used inconsistently for skin cancer treatment and management. For squamous and basal cell carcinoma this ranges from 3 mm to 6 mm for clinical margins. Information on histological margins is much more limited. For basal cell carcinoma, the histological definition of ‘close’, based on recurrence, is variable and has included measurements between 0.31 mm and 0.84 mm, or less than 1 high power field. Little information is available for close histological margins in squamous cell carcinoma. No national clinical guidelines are yet available for cutaneous adnexal carcinoma and site–specific data items for adnexal carcinoma are not contained in the current COSD. Little evidence-based information on clinical margins for adnexal carcinoma is published and the histological definition of close for adnexal carcinoma is awaited. Accordingly, the reporting of margins below 1 mm to one decimal point cannot be routinely supported, although provision of this information is a local non-core option.

Consultation with BAD has revealed strong support for clinical reasons to know whether squamous and basal cell carcinoma excision margins are histologically involved (0 mm), ‘close’ as defined below 1 mm, and above 1 mm. When audited, approximately one-third of dermatologists in the East Midlands Strategic Health Authority regarded histological margins below 1 mm as effectively involved, although this was not sufficiently consistent to justify adopting the approach in the current dataset. The same broad approach is considered to apply to adnexal carcinoma.

As a core data element for all cancers, the COSD records whether tumour excision margins are clear by more than 5 mm, clear by greater than 1 mm but less than or equal to 5 mm, or less than or equal to 1 mm but without tumour reaching the margin. Skin cancer margins should therefore be measured in relation to both 1 mm and 5 mm breakpoints. This dataset recommends measuring peripheral and deep margins histologically as <1 mm, 1–5 mm and >5 mm. There is also additional peer support to audit the excision margins of all skin cancer specimens between different Trusts and general practices within a Cancer Network and between different clinical specialties and clinicians. Measuring resection margins over 1 mm histologically to within 1 mm is one way to facilitate this objective and this could also represent a reasonable surrogate marker for clinical margins. Measuring to a whole mm integer over 1 mm is accordingly included as a non-core item. The development of
databases that include margin measurements is encouraged to allow assessment of the biological behaviour of adnexal carcinomas.

It is important that assessment of a margin below 1 mm is undertaken on ‘full-face’ sections, with a low threshold to request additional levels to increase the accuracy of assessment.

The margin definitions used for mucosal malignancies of the oral cavity, including vermillion lip (>5 mm clear, 1–5 mm close and <1 mm involved) are not applicable to tumours of the hair-bearing lip.

[Margin involvement by tumour or the degree of clearance correlates with the risk of clinical recurrence – Level of evidence C.]

h) **Maximum diameter**

A maximum tumour diameter of greater than 20 mm is a primary determinant in the distinction between stage pT1 and pT2 in AJCC7. A diameter greater than 20 mm is an important threshold for increased risk of recurrence and metastatic potential. In contrast to AJCC6, there is now considered to be insufficient evidence for an additional 50 mm threshold staging break-point. Advice on how to measure diameter is not provided in AJCC7. It is unclear whether the AJCC7 database uses clinical or histological measurements. To achieve standardisation, this dataset advocates a pragmatic approach using both macroscopic and microscopic measurements as deemed appropriate and applicable to each individual case. A pragmatic approach should be taken when measuring adnexal carcinomas arising from a background benign lesion.

[Maximum tumour diameter is a principal pT staging determinant – Level of evidence B.]

i) **Number of nodes involved and maximum diameter of metastatic deposit**

The number of nodes involved and size of largest metastatic deposit are primary pN staging determinants. There are staging breakpoints at 30 and 60 mm. The maximum size relates to the metastatic deposit and not the lymph node. The number of nodes identified and involved is a core requirement in the COSD.

[The number of nodes involved and maximum diameter of metastatic deposit are primary staging determinants – Level of evidence B.]

j) **Lymph nodes – highest/apical node**

Clinicians frequently identify the highest/apical lymph node in lymphadenectomy specimens. If identified, the report must indicate whether this contains a metastatic tumour deposit.

[This information is frequently requested by the clinician and considered to have some prognostic value – Level of evidence D.]

k) **Lymph nodes – margin clearance of lymphadenectomy specimen**

Clinicians require information as to whether the peripheral margins of lymphadenectomy specimens are clear of tumour.

[The presence of positive margins instigates consideration of adjuvant chemotherapy – Level of evidence D.]
I) Lymph node extracapsular invasion (spread/extension)

This feature is widely regarded as a manifestation of potential biological aggression and is considered to be associated with a worse prognosis. This finding prompts consideration of the use of adjuvant chemotherapy.

[The presence of extracapsular invasion instigates consideration of adjuvant radiotherapy – Level of evidence C.]

6 Non-core data items

All or some of these items can be included to create a more comprehensive report, taking into account local Cancer Network and clinical preferences, audit and research requirements.

6.1 Clinical

These are based on the draft UK National Histopathology Request Form (Appendix C) and can be captured if provided by the clinician.

- Date of surgical procedure.
- Grade of clinician undertaking procedure.
- Clinical diagnosis/description.
- Clinical size of lesion (maximum diameter in mm).
- Procedure intention of clinician:
  - diagnostic biopsy
  - therapeutic.
- Measured surgical/clinical peripheral margin (mm).
- Is this a recurrent tumour?
- Previous histology reference number(s).
- Is the patient immunocompromised?
- Is this a tumour arising in an individual who is genetically predisposed to cancer?

6.2 Pathological

- Mitotic index/mm².
- Tumour differentiation, other than core information.
- Whether well and/or moderately differentiated components present.
- % tumour component of each different tumour grade (well, moderately or poorly differentiated).
- Character of tumour periphery closest to margin:
  - circumscribed/cohesive
  - infiltrative/non-cohesive.
- Tumour thickness over 2 mm to the nearest whole integer in mm.
- Margins below 1 mm measure to nearest 0.1 mm or 0.5 mm.
- Margins over 1 mm measured to whole mm integer.
Margins: information about nearest peripheral and deep margins if specimen has been orientated.

Perineural/lymphovascular invasion: intratumoural, extratumoural, multifocal.

Distance of perineural/lymphovascular invasion to nearest resection margin.

Incisional biopsies: whether subcutaneous fat is present.

Distance of metastatic nodal deposit to margin in mm.

Blood vessel invasion in lymphadenectomy specimens.

Analysis of mismatch repair gene products in sebaceous carcinoma for potential Muir-Torre syndrome.

TNM stage group: minimum on the information available.

The Royal College of Pathologists recognises that many clinicians and MDTs look for guidance from their histopathologists with regard the probability/likelihood of completeness of tumour clearance. As already discussed, this is a subjective and somewhat visionary area and accordingly cannot be included as a core item. An individually or locally agreed statement of probability of clearance is, however, not unreasonable and accordingly is included as a non-core item, with possible suggested terminology. If used, it must be firmly understood by the clinician and/or MDT that this is a subjective and not objective assessment, with variation in the degree of potential accuracy. Suggested terminology could include:

- clearance appears complete
- clearance appears close but probably complete
- clearance appears close but possibly complete
- clearance appears uncertain.

7 Coding – TNM and SNOMED

Both are core requirements for COSD.¹

pTNM status

pTNM status should be recorded according to AJCC 7th edition.²

TNM stage grouping should be deferred until all current TNM information is available and if applicable after skin cancer MDT discussion. A stage group can be added to a histopathology report as a non-core item but should usually be stated to be the minimum stage group based on the information in the report.

General principles

pT Primary tumour
pTx Primary tumour cannot be assessed
pTis Carcinoma in situ
pT1, pT2, pT3, pT4 – increasing pT stages.

Additional descriptors can be used. The suffix ‘m’ indicates the presence of multiple primary tumours in a single site and is recorded in parentheses: pT(m) NM.
The ‘r’ prefix indicates recurrent tumour when restaged after a documented disease-free interval. This is described in detail in Appendix A.

**SNOMED codes**

SNOMED Topography (T) code should be recorded for the tumour site.
SNOMED Morphology (M) code should be recorded for the tumour morphology/diagnosis.
SNOMED Procedure (P) codes should be recorded for the procedure. P codes vary according to the SNOMED system in use in different organisations, therefore local P codes should be recorded and used for audit purposes.

A list of T and M codes is provided in the Appendix B.

8 **Small biopsy specimens**

Procedures that are carried out for the purpose of establishing only diagnosis (e.g. some punch biopsies, incisional biopsies and some shave or curettings) data items that should be recorded are restricted to providing a diagnosis and indicating any features of high-risk status.

9 **Reporting of frozen sections**

Frozen sections should be limited to Mohs’ micrographic surgery where horizontal sections are used to assess margin status accurately. Vertical frozen sections should not be used to assess margins as they are insufficiently representative of the entire margin.

The use of frozen sections for a specific clinical diagnostic problem cannot usually be supported as this would circumvent the desirable standard of prospective skin cancer MDT discussion and potential patient involvement in the decision-making process.

Frozen sections have little role in lymph node assessment of cutaneous adnexal carcinoma.

10 **Cytological diagnosis**

Cytology has little role in the primary diagnosis of cutaneous adnexal carcinoma.

Fine needle aspiration cytology is an appropriate modality to investigate clinically and/or radiologically abnormal regional lymph nodes to exclude the possibility of metastatic cutaneous adnexal carcinoma. This modality of investigation is also discussed in the College’s *Dataset for histopathology reporting of nodal excisions and neck dissection specimens associated with head and neck carcinomas* (www.rcpath.org/publications).

11 **Specific aspects of individual tumours not covered elsewhere**

11.1 **MDT referral**

All cases of difficult, borderline or malignant cutaneous adnexal tumours must be reviewed by a specialist skin cancer MDT histopathologist and all cases that are confirmed to be malignant must be discussed at a specialist skin cancer MDT.8,10

MDT referral can be included in a report as a non-core item.
11.2 Re-excision specimens

There has been considerable debate as to the extent wider local excision specimens for skin cancer require examination. Macroscopic examination is essential. This is the most reliable means to record that a re-excision has been undertaken and also the measurements of the wider excision. The fixed specimen should be sliced every 2–4 mm to identify any macroscopic abnormalities such as potential satellite lesions. Each of these must be examined histologically and the status of the margin must be assessed.

The debate centres on the cost-efficiency of examining an entire macroscopically normal specimen, when abnormalities were absent from the margins of the index specimen. Some peers consider that this is the only guaranteed way to ensure that residual disease or metastases are not overlooked. Some also consider that the specimen should always be examined in its entirety with a biomedical scientist led cut-up. Certain clinicians require information about whether the specimen contains a scar and whether it is completely excised. There is considerable latitude for discretion in this area. An acceptable compromise would be to sample the specimen in its shortest transverse axis, incorporating the area where the scar appears closest to the margin. This can generally be achieved in 1–4 cassettes.

If tumour in the index specimen was reported to extend to the margin, the specimen should be examined more extensively. For specimens up to 10 mm, the entire specimen should be sampled. Specimens over 10 mm should be sampled pragmatically according to the nature of the original margin involvement.

12 Criteria for audit linked to the dataset

12.1 Recommended by NICE:³

Histopathology reporting times (see below).

12.2 Recommended by the RCPath as key performance indicators (KPIs) (see Key Performance Indicators – Proposals for implementation (July 2013) on www.rcpath.org/clinical-effectiveness/kpi/KPI):

- Cancer resections must be reported using a template or proforma, including items listed in the English COSD which are, by definition, core data items in RCPath cancer datasets. English Trusts are required to implement the structured recording of core pathology data in the COSD by January 2014.
  
  Standard: 95% of reports must contain structured data.
- Histopathology cases that are reported, confirmed and authorised within seven and ten calendar days of the procedure.
  
  Standard: 80% of cases must be reported within seven calendar days and 90% within ten calendar days.

13 Acknowledgements

To the numerous colleagues who offered useful advice during the extensive informal professional consultation about this dataset – their views have been listened to carefully.

To the late A Bernard Ackerman MD for his infectious enthusiasm for dermatopathology and for facilitating intellectual thought in debating the necessity for and content of datasets/checklists.
References


Appendix A  AJCC7 pathological staging of cutaneous adnexal carcinoma and regional lymph nodes

Definitions of TNM

Primary tumour (T)*

TX  Primary tumour cannot be assessed
T0  No evidence of primary tumour
Tis  Carcinoma in situ
T1  Tumour 20 mm or less in greatest dimension and with less than two high-risk features*
T2  Tumour greater than 20 mm in greatest dimension or any size and with two or more high-risk features*
T3  Tumour with invasion of maxilla, mandible, orbit or temporal bone
T4  Tumour with invasion of skeleton (axial or appendicular) or perineural invasion of skull base

* High-risk features for the primary tumour (T) staging

Depth/invasion                   >2 mm thickness
                                 Clark level ≥4
                                 Perineural invasion

Anatomic location Primary site ear
                                 Primary site hair-bearing lip

Differentiation Poorly differentiated or undifferentiated

Regional lymph nodes (N)

NX  Regional lymph nodes cannot be assessed
N0  No regional lymph node metastases
N1  Metastasis in a single ipsilateral lymph node, 30 mm or less in greatest dimension
N2  Metastasis in a single ipsilateral lymph node, more than 30 mm but not more than 60 mm in greatest dimension; or in multiple ipsilateral lymph nodes, none more than 60 mm in greatest dimension; or in bilateral or contralateral lymph nodes, none more than 60 mm in greatest dimension
N2a Metastasis in a single ipsilateral lymph node, more than 30 mm but not more than 60 mm in greatest dimension
N2b Metastasis in multiple ipsilateral lymph nodes, none more than 60 mm in greatest dimension
N2c Metastasis in bilateral or contralateral lymph nodes, none more than 60 mm in greatest dimension
N3  Metastasis in a lymph node, more than 60 mm in greatest dimension
**Distant metastasis (M)**

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<td>M0</td>
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<td>M0</td>
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Appendix B  Cutaneous adnexal cell carcinoma SNOMED coding

<table>
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<th>Topographical codes</th>
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<th>SNOMED CT terminology</th>
<th>SNOMED CT code</th>
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<tr>
<td>Skin</td>
<td>T01000</td>
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<th>SNOMED CT terminology</th>
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<tr>
<td>Primary cutaneous adnexal carcinoma</td>
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<tr>
<th>Subtypes</th>
<th>Malignant tumours with apocrine and eccrine differentiation</th>
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<tr>
<td>Tubular carcinoma</td>
<td>M82113 Tubular adenocarcinoma (morphologic abnormality)</td>
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<tr>
<td>Malignant mixed tumour</td>
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<tr>
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<td>Mucinous carcinoma</td>
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<tr>
<td>Adenoid cystic carcinoma</td>
<td>M82003</td>
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<tr>
<td>Apocrine carcinoma</td>
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<td>Extramammary Paget disease</td>
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**Malignant tumours with follicular differentiation**

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**Tumours with sebaceous differentiation**

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</table>

**Procedure codes**

Local P codes should be recorded. At present, P codes vary according to the SNOMED system in use in different institutions.
Appendix C  Draft UK National Histopathology Request Form for Skin Biopsies

Devised by the NCIN Skin Site Specific Reference Group and kindly provided for RCPath dataset information by the NCIN. Permission for use should be sought from the NCIN. This histopathology request form is approved by the BAD; the mode of national implementation is under consultation.

The UK National Histopathology Request form for skin biopsies

<table>
<thead>
<tr>
<th>Date of surgical procedure</th>
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<tbody>
<tr>
<td>Name of surgeon</td>
</tr>
<tr>
<td>Clinical diagnosis: free text</td>
</tr>
</tbody>
</table>

Please attach patient details

Grade of surgeon: Nurse, Specialist trainee, Consultant, Hospital Practitioner, Other

Mandatory for Clinician to complete:
- Site Code as per image (insert LUL etc.)
- Clinical Diagnosis (select either BCC, SCC, Melanoma, Atypical Mole, other tumour or other). For inflammatory lesions add clinical details as free text.
- Clinical size of lesion sampled (max diameter) (mm)
- Intention of the surgeon (select biopsy, excision or curative curettage)
- Procedure (select curettage, shave biopsy, punch, incisional biopsy or excision)
- For tumours give measured surgical clinical margin (mm)
- Is this a recurrent tumour?
- Is the patient immunocompromised?
- Is this a tumour arising in areas of radiation or thermal injury, chronic draining sinuses, chronic ulcers, chronic inflammation or Bowen's Disease?
- Is this a tumour arising in a genetically predisposed individual?

Please mark site of samples taken on the above images. For head and neck skin cancers the site code will be made up of the number in the horizontal grid and the letter from the vertical grid (e.g. for a tumour in the middle of the nose that might be code SE). If a lesion lies across grid lines then that grid reference in which the greater part of the tumour lies should be used. If the lesion impacts on a grey shaded area or on the lips then that code should be used. Where the tumour is on the marked lips then the code LP should be used. For tumours outside the head and neck the letters are indicated on the body map (e.g. a tumour on the left lower arm is LA).

Free text
Appendix D1  Reporting proforma for cutaneous adnexal cell 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
Clinical site ........................................................................................................................................
Specimen type:  Excisional biopsy □ Incisional (diagnostic) biopsy □ Punch biopsy □ Shave □
               Curettings (therapeutic) □ Curettings (diagnostic) □ Curettings (not specified) □
               Other □ Please specify ………………………………………………………………………..

Macroscopic description
Size of specimen:  Length ……mm  Breadth…..mm  Depth …….mm
Maximum diameter of lesion: …………..mm  Uncertain □  No lesion seen □

Histological data
Histological type:  Extramammary Pagets disease □ Porocarcinoma □ Hidradenocarcinoma □ Spiradenocarcinoma □
               Microcystic adnexal carcinoma □ Malignant mixed tumour □ Mucinous carcinoma □ Apocrine carcinoma □
               Adenoid cystic carcinoma □ Digital papillary carcinoma □ Sebaceous carcinoma □ Pilomatrical carcinoma □
               Other □ Please specify ………………………………………………………………………..

Invasive component:  Not identified (in situ) □ Present □
If invasive component present:
Grade:  Poorly differentiated component present  No □  Yes □
Lesion Thickness:  ≤ 2 mm □  >2 mm □  Uncertain □  Cannot be assessed □
Level of invasion ≥ reticular dermis (Clark level 4):  No □  Yes □  Uncertain □  Cannot be assessed □
               If yes, specify tissue/level:  Fat (Clark level 5) □  Muscle □  Fascia □  Perichondrium □
               Cartilage □  Paratendon/tendon □  Periosteum □  Bone □

If bone invasion present:
               Invasion of maxilla, mandible, orbit or temporal bone:  No □  Yes (pT3) □  Uncertain □  Cannot be assessed □
               Invasion of skeleton (axial or appendicular):  No □  Yes (pT4) □  Uncertain □  Cannot be assessed □
Lymphovascular invasion  Not identified □  Present □  Uncertain □  Cannot be assessed □
Perineural invasion  Not identified □  Present □  Uncertain □  Cannot be assessed □
               If perineural invasion present:
               Perineural invasion of skull base:  No □  Yes (pT4) □  Uncertain □  Cannot be assessed □
Background benign adnexal tumour present:  No □  Yes □  If yes, specify type:………………………………………………
Margins:

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<tr>
<td>Deep</td>
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</tbody>
</table>

Maximum diameter >20 mm (macroscopic and/or microscopic)  No □  Yes □  Uncertain □  Cannot be assessed □

TNM pathological (p) stage   (AJCC7) ......................................................
SNOMED code…………..
Comments

Pathologist ……………………  Date…………………………

PSU  210714  26  V10  Final
### Reporting proforma for regional lymph nodes associated with cutaneous adnexal cell carcinoma

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

**Hospital**……………………… **Hospital no**……………………… **NHS/CHI no**………………………

**Date of receipt**…………………. **Report no**……………………… **Surgeon**………………………

### Clinical data
- **Anatomical site**
  - Axillary ☐
  - Inguinal ☐
  - Other ☐ (specify): ...................................

- **Laterality**
  - Right ☐
  - Left ☐

### Macroscopic description
- Three-dimensional size of overall specimen ............mm
- **Macroscopic abnormality**
  - No ☐
  - Yes ☐
  - Uncertain ☐
- If yes, diameter of largest abnormality ............mm
- **Localising marker**
  - No ☐
  - Yes ☐

### Histological data

#### LYMPHADENECTOMY
- **Number of nodes identified**.............................
- **Nodes involved**
  - No ☐
  - Yes ☐
- **Highest/apical node involved**
  - No ☐
  - Yes ☐
  - Not identified clinically ☐

#### If nodes are involved

**IPSILATERAL**
- **Number involved**.............................
- **Maximum size of metastasis**
  - ≤30 mm ☐
  - >30 mm – ≤60 mm ☐
  - >60 mm ☐
- **Extracapsular invasion**
  - No ☐
  - Yes ☐
  - Uncertain ☐
  - Cannot be assessed ☐
- **Margin not involved**
  - No ☐
  - Yes ☐
  - Uncertain ☐
  - Cannot be assessed ☐

**CONTRALATERAL**
- **Number involved**.............................
- **Maximum size of metastasis**
  - ≤30 mm ☐
  - >30 mm – ≤60 mm ☐
  - >60 mm ☐
- **Extracapsular invasion**
  - No ☐
  - Yes ☐
  - Uncertain ☐
  - Cannot be assessed ☐
- **Margin not involved**
  - No ☐
  - Yes ☐
  - Uncertain ☐
  - Cannot be assessed ☐

#### TNM pathological (p) stage (AJCC7)
- **N**........

#### SNOMED code
- ........................................

### Comments
- ........................................

**Pathologist**……………………….. **Date**………………………..
### Appendix E  Summary table – explanation of levels of evidence

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

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Nature of evidence</th>
</tr>
</thead>
</table>
| **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 compliance 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.

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

* 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.