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

Standards and datasets for reporting cancers

Dataset for histopathological reporting of primary cutaneous basal cell carcinoma

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Comments	This document will replace the 3rd edition of the dataset for the histological reporting of basal cell carcinoma. This is to incorporate the *TNM Classification of Malignant Tumours (8th edition*) from the Union for International Cancer Control (UICC) published in 2017. In accordance with the College's pre-publications policy, this document was on the College website for consultation from 6 September to 4 October 2018. Responses and authors' comments are available to view on request. **Dr Brian Rous** **Clinical Lead for Guideline Review (Cellular Pathology)**

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NICE has accredited the process used by the Royal College of Pathologists to produce its cancer datasets. Accreditation is valid for five years from 25 July 2017. More information on accreditation can be viewed at www.nice.org.uk/accreditation.

Foreword

The cancer datasets published by the Royal College of Pathologists (RCPath) 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 allowing clinicians to provide a high standard of care for patients and appropriate management for specific clinical circumstances. This guideline has been developed to cover most common circumstances. However, we recognise that guidelines cannot anticipate every pathological specimen type and clinical scenario. Occasional variation from the practice recommended in this guideline may therefore be required to report a specimen in a way that maximises benefit to the patient.

Each dataset contains core data items (see Appendices D and E) that are mandated for inclusion in the Cancer Outcomes and Services Dataset (COSD – previously the National Cancer Dataset) 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 95% 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 were consulted during its preparation and approved the dataset:

- British Association of Dermatologists (BAD; member of RCPath Specialty Advisory Committee on Dermatopathology)
- British Society for Dermatopathology (BSD; member of RCPath Specialty Advisory Committee on Dermatopathology)
- participating members of the National Specialist Dermatopathology External Quality Assessment (NSDEQA) scheme (member of the RCPath Speciality Advisory Committee on Dermatopathology).

This dataset has been constructed taking into account the strong evidence that is contained in, and forms the basis for, the following 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:

- Union for International Cancer Control (UICC)[1]
- American Joint Committee on Cancer (AJCC)[2]
- World Health Organization (WHO) Classification of Skin Tumours[3]
- National Institute for Health and Clinical Excellence (NICE) Guidance and Quality Standards on skin cancer and melanoma[4–6]
- NHS Evidence[7]
- Clinical guidelines published by the BAD and other professional bodies[8]
- Public Health England (PHE) Cancer Outcomes and Services Dataset (COSD)[9]
- NHS England Quality Surveillance Programme (QSP; formerly the National Cancer Peer Review Program)[10]
- National Comprehensive Cancer Network (NCCN)[11]
- Armed Forces Institute of Pathology (AFIP) Atlas of Tumour Pathology (noting AFIP disestablished in 2011 and now under American Registry of Pathology [ARP] Press).[12]

Evidence for the revised dataset was obtained from updates to international tumour grading, staging and classification systems and by electronically searching medical literature databases for relevant research evidence, systematic reviews and national or international publications on uterine sarcomas. The level of evidence for the recommendations has been summarised (Appendix G). Unless otherwise stated, the level of evidence corresponds to 'Good practice point (GPP): Recommended best practice based on the clinical experience of the authors of the writing group'. The sections of this dataset that indicate compliance with each of the AGREE II standards are indicated in Appendix H.

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 new major financial or work implications arising from the implementation, compared to the 2002 dataset.

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 subspecialty 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 members' attention. If members 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.

The dataset has been reviewed by the Clinical Effectiveness department, Lay Governance Group and Working Group on Cancer Services (WGCS) and was placed on the College website for a consultation with the membership from 6 September to 4 October 2018. All comments received from the WGCS and membership wiere addressed by the authors, to the satisfaction of the Chair of the Working Group and Clinical Lead for Guideline Review (Cellular Pathology).

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 Clinical Effectiveness department and are available on request. The authors have declared no conflicts of interest.

1 Introduction

1.1 Target users and health benefits of this guideline

The primary target users of this dataset are consultant and trainee cellular pathologists and biomedical scientists and, on their behalf, the suppliers of IT products to laboratories. Other target users are clinicians in secondary and primary care within the NHS and members of skin cancer multidisciplinary teams (MDTs). Secondary users are NHS England and NHS Scotland, each involved in quality surveillance, cancer networks, cancer alliances and those involved in skin cancer data collection via the NHS, including PHE and in particular the National Cancer Registration and Analysis Service (NCRAS). Standardised cancer reporting and 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. The collection of standardised cancer-specific data also provides information for epidemiologists and facilitates international benchmarking and research.

1.2 Purpose of the dataset

This document provides the dataset for the histological reporting of basal cell carcinoma and replaces the previous edition.

The meticulous diagnosis and reporting of basal cell carcinoma is important because histological parameters play a significant role in defining patient treatment. Similarly, 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 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 NCRAS and to provide feedback for those caring for patients with cancer. It is important to have robust local mechanisms in place to ensure that the MDT clinical leads and NCRAS are apprised of supplementary or revised histology reports that may affect patient treatment and data collection.

1.3 Changes since the previous edition

1.3.1 Pathological tumour, node and metastases (pTNM) stage

It must be noted, in general and whenever possible, that UICC TNM is the version favoured by NCRAS in the UK. UICC is, in essence, the international custodian of TNM, although it is recognised that the AJCC TNM version, although intended for use in the USA, is also favoured elsewhere. UICC and AJCC are, however, common stakeholders in TNM and ideally both versions should be the same. The staging of basal cell carcinoma in the previous edition of this dataset was, however, based on AJCC TNM 7. The latter was selected at the time by the RCPath for skin cancers because of the high number of errors contained in UICC TNM 7, some of which still remained uncorrected in its subsequent supplementary publication.

AJCC TNM 8 has a chapter on staging cutaneous squamous cell carcinoma (cSCC) of head and neck, which incorporates other non-melanoma skin cancers (NMSC), including basal cell carcinoma and adnexal carcinomas but not Merkel cell carcinoma (MCC), as that has its own separate chapter. AJCC TNM 8, however, has no staging system for cSCC on the remainder of the body. By contrast, UICC TNM 8 has not only a chapter on staging skin carcinoma of the head and neck, but also a staging system for carcinoma of the skin for the remainder of the body (essentially limbs and trunk but excluding the eyelid and genitals). These incorporate the same types of NMSC as AJCC TNM 8; the physical boundary between the two body regions is the acromioclavicular joint anteriorly and the upper aspect of the shoulder blade posteriorly. Accordingly, both AJCC and UICC TNM 8 staging systems have been assessed critically to determine which system should be recommended by RCPath for national use in the UK and the RCPath skin cancer datasets, and in particular by PHE, NCRAS and COSD. The UICC and AJCC TNM 8 staging systems for cutaneous melanoma and MCC are now identical, taking into account subsequent website errata (www.wileyanduicc.com; www.cancerstaging.org). Accordingly, the final decision to use UICC TNM 8 and not AJCC TNM 8 has been based on the staging of NMSC.

In general, the terms microscopic and macroscopic have, where appropriate, been replaced in TNM 8 by the respective terms clinically occult and clinically detected.

pT category

The pT category for both UICC and AJCC TNM 8 is entirely different from UICC and AJCC TNM 7.

pT subcategories for T1, T2 and T3 are now defined by stratification of the maximum tumour dimension at 20 mm or 40 mm. T1 and T2 can be upstaged to T3 by the presence of one or more risk factors comprising specifically defined perineural invasion or deep invasion representing either a tumour thickness/depth >6 mm* and/or invasion beyond/further than the subcutaneous fat. AJCC TNM 8 states that these risk factors apply less to basal cell carcinoma,

but does not specifically exclude them as upstaging parameters for basal cell carcinoma. UICC TNM 8 include them in both skin carcinoma of the head and neck and carcinoma of the skin (essentially limbs and trunk but excluding the eyelid and genitals) with no qualification. Hence, they are used in this dataset. T3 is also defined by minor bone erosion, T4a by gross cortical/marrow invasion and T4b by axial skeleton/skull base or foraminal invasion.

This has required a new core entry if deep invasion is present and, if so, if the basal cell carcinoma thickness/depth is >6 mm or the tumour extends beyond the subcutaneous fat.

If perineural invasion is present, an entry is required if it meets the broadly agreed criteria to upstage to T3 (a named nerve or large calibre ≥0.1 mm diameter or beyond the dermis). AJCC TNM 8 contains all the criteria, whereas UICC is confined to a named nerve, which may include clinical or imaging detection. Named nerves and those beyond the dermis are invariably large calibre in type, over 0.1 mm in diameter.

UICC and AJCC versions of TNM 8 are very similar but not identical. Whereas UICC stratifies T1, T2 and T3 at ≤20 mm, >20 mm to ≤40 mm and >40 mm, respectively, AJCC stratifies at <20 mm, ≥20 mm to <40 mm and ≥40 mm, respectively. At the time of writing the dataset, neither UICC nor AJCC have published an erratum on their websites. However, it is more likely that UICC breakpoints are the correct version, as its stratification is identical to that used by both UICC and AJCC TNM 8 for MCC and tumours of the lip and oral cavity, and also in TNM 7. UICC TNM 8 also excludes the vermilion border of the lip (as with UICC and AJCC TNM 7), whereas AJCC TNM 8 includes the site.

AJCC states that the maximum dimension should be a clinical measurement on the evidence available, but a pathological measurement is permitted if a clinical one is not available. UICC are not specific on matters of measurement other than recommending physical examination. This dataset also recommends use of the clinical measurement but supports use of a pathological measurement if the clinical one is absent. Indicating which one is used for staging is a new dataset item. Preferably, this should be the macroscopic measurement, unless in a particular case use of a microscopic one is unavoidable.

It is envisaged that TNM 8 will provide a better prognostic discrimination of the T categories for cSCC than that achieved in TNM 7. In AJCC TNM 7, many cSCCs were placed into the T2 category, and T3 and T4 cases were rare.

*Tumour depth is measured in millimetres from the granular layer of the nearest normal adjacent epidermis to the deepest point of the tumour.

pN category

As with UICC and AJCC TNM 7, UICC and AJCC TNM 8 nodal staging is still based on the size, number and location of positive nodes, although minor differences exist between TNM 7 and TNM 8. Similarly, UICC TNM 8 carcinoma of the skin and skin carcinoma of the head and neck display minor differences. AJCC TNM 8 head and neck, with one minor addition (pT2a includes the presence of extranodal extension [ENE] in a node ≤30 mm), is identical to UICC TNM 8 head and neck.

pN categories of UICC TNM 8 carcinoma of the skin are based purely on ipsilateral nodes. Contralateral nodes are regarded as distant metastases for UICC TNM 8 but not for AJCC TNM 8. For single positive nodes, pN stratification for pN1, pN2 and pN3 is ≤30 mm, >30 mm to 60 mm and >60 mm, respectively. Multiple nodes ≤60 mm are also pN2.

pN categories of UICC TNM 8 skin carcinoma of the head and neck and carcinoma of the skin are similar with regard to the size of nodes and number, although single and multiple nodes below 60 mm in pN2 are defined as pN2a and pN2b, respectively. A bilateral or contralateral node ≤60 mm is defined as pN2c. A positive node >60 mm is defined as pN3a.

A major development in pN3 for both UICC and AJCC TNM 8 head and neck is the recognition of ENE. ENE was not part of staging in TNM 7. ENE can have either clinical or pathological definitions and its presence defines pN3b.

There is an expectation that a minimum of six nodes will be identified in lymphadenectomy specimens for carcinoma of the skin and ten or 15 nodes for selective or radical/modified radical lymphadenectomy, respectively.

pTNM 8 stage group

The TNM 8 stage group is largely similar to TNM 7. UICC TNM 8, however, divides Stage IV into Stage IVA and Stage IVB, depending on absence or presence of a distant metastasis. Stage IV is not subdivided in AJCC.

Selection of UICC TNM 8

For NMSC (except MCC), UICC TNM 8 covers the entire skin surface in two chapters titled 'Carcinoma of the Skin' and 'Skin Carcinoma of the Head and Neck'. By contrast, AJCC has only one chapter titled 'Head and Neck for Cutaneous Squamous Cell Carcinoma'. Overall, however, there are extremely close similarities in the UICC and AJCC TNM 8 staging of skin cancer. Accordingly, the authors of the RCPath datasets were confident to recommend the use of UICC TNM 8 and thereby also ensure coverage of the entire skin surface for NMSC.

TNM stage group in basal cell carcinoma

The pT category of basal cell carcinoma has prognostic and risk status importance and accordingly has been maintained as a dataset item. The national collection of such data for basal cell carcinoma remains essential and can therefore be supported. The data is important for patient prognostic assessment, NHS service planning and development, PHE/NCRAS epidemiological analysis and research.

It is recognised, however, that the pTNM stage group will currently have far less importance in view of the extreme rarity of nodal and metastatic spread. The logic underlying the routine collection of these data by clinicians and MDTs therefore requires national discussion, including by both the NHS and PHE/NCRAS/COSD.

1.3.2 Lymph nodes

Although UICC TNM 8 provides a new nodal staging system for basal cell carcinoma, the metastasis of such tumours to lymph nodes is extremely rare; thus, a specific reporting proforma has not been devised for the dataset. In the eventuality of reporting such a metastasis, the cSCC nodal proforma's title should be modified and used for basal cell carcinoma, as UICC TNM 8 nodal staging is identical for the two cancers.

1.3.3 Pathological risk factors for clinical management

Building on basic anatomical stage, both UICC and AJCC in TNM 7 and 8 have introduced the concept of prognostic/risk stratification by virtue of prognostic grids (covering stage, the tumour, the host and the environment) or prognostic stage groups, respectively. AJCC are also working towards risk assessment models for each site and cancer as personalised medicine develops. Unfortunately, the UICC prognostic grids are still based on UICC TNM 7 and, to date, AJCC has developed no risk assessment models for skin.

The national clinical guidelines for both basal cell and squamous cell carcinoma, however, introduced the concept of risk stratification/status.[7] In broad terms, high risk correlates with significantly greater clinical risk for local recurrence, nodal metastatic disease and reduced disease-specific survival. The evidence base for this has been endorsed by NICE, the previous NHS Cancer Action Team and SIGN in their publications.[4–6,8,9,12] Knowledge of risk status remains vital for the correct clinical management, treatment and skin cancer MDT case discussion.

For basal cell carcinoma, knowledge of risk status is essential to manage margin clearance. High-risk cases with involved margins require skin cancer MDT discussion. Trusts may also prefer to discuss cases with non-involved margins <1 mm (so-called 'clear but close' margins) within the context of an MDT.

Services for low-risk basal cell carcinomas can be commissioned from GPs within the framework of the DES (Directed Enhanced Services) and LES (Local Enhanced Services) under general or personal medical services. High-risk basal cell carcinomas should primarily be managed in secondary care.

On that basis, a new core data item was introduced in the second edition, in the form of an entry as to whether the cancer was of low- or high-risk type, based on pathological parameters relevant to clinical management. It was acknowledged that additional knowledge of clinical high-risk factors, unknown or uncertain at the time of reporting, may have subsequently upgraded low risk to high risk, in particular during skin cancer MDT discussion.

This core item, however, has caused numerous practical and clinical difficulties, reflected in the low level of acceptance and usage identified in the joint BAD–RCPath audit on NMSC.[13] For cSCC, particular confusion was generated by different risk factors being used for TNM upstaging compared with the tumour itself. For example, >2 mm thickness was used in upstaging to pT2, whereas >4 mm was an independent high-risk factor for the cSCC itself. In addition, binary low- and high-risk stratification at times oversimplifed a more complex clinicopathological situation, with intermediate/middle-risk groups appearing not uncommonly, yet remaining unacknowledged by this binary stratification. Furthermore, a summation of the number of high-risk factors present indicated clinical importance but was largely ignored.

It now appears more logical to base the risk status of a patient with squamous or basal cell carcinoma on the judgement of clinicians overseeing care or on skin cancer MDT discussion, considering all known risk factors within each personalised setting. Accordingly, risk factor status has been removed as a core item from this dataset and moved into the non-core section.

The current dataset does, however, still provide all of the relevant raw data relating to core items that constitute risk factors and still provides guidance on the interpretation of these factors. This information is included for use by clinicians and/or skin cancer MDTs.

In summary, as with TNM staging, risk stratification is now considered as an activity that is best undertaken by each patient's clinician and/or by a skin cancer MDT, rather than as a specific core entry in a histopathology report. This also appears to reflect a better approach to personalised medicine.

1.3.4 Changes in 2018

The authors are mindful that significant changes in skin cancer are likely to be published during 2018. These include a new (second) edition of the WHO Classification of Skin Tumours and new national clinical guidelines on NMSC from the BAD. Any such changes will be captured in the first revision of this dataset. After consideration, rather than await these changes, it was agreed that this new dataset would proceed to facilitate use of the new TNM classification from 1 January 2018.

1.4 Core and non-core data items

Data items are now divided into core and non-core types.

As defined in the foreword, core items in RCPath's cancer datasets are robust, evidence-based data items that are required for cancer staging, management and prognosis. These data items are expected to be available routinely for cancer MDT meetings, are recorded by MDT management systems and are used as part of the national QSP.

The foreword also sets out that non-core data items are not considered mandatory on a national basis, but some or all may be included to provide a more comprehensive report or to meet locally agreed clinical or research requirements.

The core pathological data items are summarised in structured proforma style, which may be used as the reporting format or combined with free text as required. There is peer support for the idea that the use of structured proformas (or protocols/checklists) contributes substantially to improving the quality of histopathology reports. An electronic version is also available from RCPath.

2 Clinical information required on the specimen request form

The provision of clinical information is the responsibility of the clinician submitting a specimen for pathological examination. The requirement for clinical information is based on the proposed UK National Histopathology Request Form (Appendix C) and COSD.[8] The information is required for MDT discussion and also conforms to NICE requirements[4–6] for the clinician. As a minimum these include the site of origin and type of specimen. Similarly, for NMSC, it is vital to emphasise that T1, T2 and T3 categories are best based, according to available evidence, on the maximum clinical dimension/diameter of the tumour. This must be recorded on the request form and in the clinical notes by the clinician. The maximum pathological dimension/diameter, however, can be used if the clinical dimension is absent on the request form.

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

The overall size of the specimen received must be measured. When appropriate, and in particular with excision specimens, this should incorporate three dimensions. 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 abnormality to the naked eye must be recorded. When a lesion is apparent, measurements should include the maximum diameter and possible elevation.

Consideration should be given to inking 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 curetted specimens or incisional, shave and punch biopsies as these are not performed for excisional purposes.

During examination of specimens submitted to the laboratory with prior designated orientation (by sutures or inking, for example), different coloured inks must be used on different margins, notching the specimen or inserting coloured agar into the processing cassette.

4 Specimen handling, dissection and block selection

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 be made on each individual case, taking these variables into account, assisted by the following general comments.

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.

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

For specimens that need to be trimmed, 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.

To obtain an accurate assessment of surgical margins, as much of the specimen as possible should be examined. Accordingly, for specimens under 10 mm, it is recommended that most or all of the lesion be 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 predominantly 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 lesion cannot be identified, or there is uncertainty, 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 orientation of the specimen has been identified clinically.

In some very large specimens, as well as sampling the lesion, the peripheral margins at selected points can be sampled, although the limitation in assessing margin clearance should be appreciated.

The dissection of a wedge excision (e.g. ear or lip) can be flexible depending on the nature of the specimen, whether there is a location marker and the position of the lesion. The same flexibility applies to whether the specimen needs to be inked. The selection of blocks taken, however, must be clearly documented and frequently a diagram can be useful. Additionally, if necessary, this should be accompanied by direct liaison between the person dissecting the specimen and the later reporting pathologist. This is the recommended approach to avoid potential problems in block interpretation during subsequent reporting. The blocks selected, however, must be able to measure the lesional margins to the same degree of accuracy stated in the dataset for the type of skin cancer present. Sometimes, there is only one so-called wedge margin and no peripheral and deep margins. If applicable, the presence or absence of cartilage invasion should be stated in the report.

The requirement for step-levels/sections in any type of specimen is dependent on the requirement 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 the processing of more than two pieces of tissue in one cassette, incurs an increased risk of incorrect orientation and sectioning, with a resulting potential loss of diagnostic and margin information.

Re-excision specimens are considered in section 11.2.

5 Core data items

5.1 Clinical

The core clinical data that must be recorded on the pathology report are the site of origin, type of specimen and maximum clinical dimension/diameter. The latter is a primary determinant for establishing TNM 8 subcategories T1, T2 and T3.

[Level of evidence B – Maximum clinical dimension of a lesion is a primary staging determinant.]

If invasion of a named nerve is identified clinically in NMSC, the clinician must advise the pathologist on the request form as this is an upstaging determinant.

[Level of evidence B – Clinical invasion of a named nerve is an upstaging determinant.]

Although rare for basal cell carcinoma, when identified in head and neck NMSC (excluding MCC), the clinician should inform the pathologist on the request form that ENE has been demonstrated clinically. This can be the presence of skin involvement or soft tissue invasion with deep fixation/tethering to underlying muscle or adjacent structures or clinical signs of nerve involvement.

[Level of evidence B – Clinical ENE is a primary staging determinant in head and neck NMSC (excluding MCC).]

5.2 Pathological: macroscopic

5.2.1 Specimen and lesion size

The three-dimensional size of the specimen should be recorded in millimetres. The overall size of the specimen can, at times, assist clinical discussion on a case. Specimen size can also be occasionally vitally useful in specimen identification and distinction, if there are issues relating to multiple specimens in one or multiple specimen containers.

The maximum dimension/diameter of all lesions must be recorded in millimetres. This can be used to establish T categories in the absence of a maximum clinical dimension.

5.3 Pathological: microscopic

5.3.1 Histopathological subtype

Some subtypes of basal cell carcinoma are regarded as clinically high-risk variants, in national clinical guidelines by NICE and national quality surveillance for skin cancer MDT discussion.[4–6,8,10] High risk clinically correlates with a significantly increased risk for local recurrence and very occasionally metastasis. These high-risk subtypes comprise those with infiltrating and/or sclerosing/morphoeic and/or micronodular growth patterns. It also includes basosquamous carcinoma, perceived as a high-risk variant of basal cell carcinoma showing squamous differentiation.

Any classification of basal cell carcinoma should be based on the ability to relate different subtypes to biological behaviour. The classification should be relatively easy to use and be reasonably reproducible at the intra- and inter-observer levels. The WHO classification of basal

cell carcinoma fulfils many of these requirements and is used in several national clinical guidelines.[3,11] Accordingly, the WHO classification is used as the basis for this dataset. This recognises morphology, which correlates with low- and high-risk behaviour and also correlates with the aforementioned NICE, clinical and quality surveillance guidelines. This also represents an updated version of the classification and approach used in the first edition of this dataset.

The two morphological/histological components correlating with biological risk represent tumour growth pattern and differentiation.

Growth pattern
This can be usefully divided into subtypes of low (non-aggressive/indolent) or high (aggressive) biological risk status.

Low-risk subtypes

- Superficial basal cell carcinoma. This type is also termed 'multicentric' or 'multifocal basal cell carcinoma', although this is recognised to be a misnomer as in many cases there is histological continuity of the lesions. This type is characterised by multiple small collections of follicular germ cells in contact with the epidermis or hair follicles. This type of malignancy is often associated with a focal stromal reaction in the upper dermis that includes increased vascularity and fibrosis. At times this may reflect tumour regression. The presence of this stromal reaction may be the only abnormality in a biopsy and should prompt examination of multiple levels of the tissue left in the paraffin block for potential basal cell carcinoma. There is no consensus as to whether superficial basal cell carcinoma represents in situ or invasive carcinoma. For that reason, the term 'invasive basal cell carcinoma' is specifically not used in the title or proforma of this dataset. Similarly, there is no consensus as to the exact definition of superficial basal cell carcinoma. Specifically, the distinction between superficial and nodular basal cell carcinoma has been variably defined with respect to the level and/or depth of tumour present. The most widely supported definition of superficial basal cell carcinoma is that it should not extend beyond the papillary dermis. Studies have also quoted various degrees of thickness in millimetres for the definition of superficial basal cell carcinoma but to date, there appears to be no consensus. All studies, however, have suggested figures of less than 1 mm.
- Nodular basal cell carcinoma displays nodules of varying size. The nodules can be cystic or pseudoadenoid/pseudoglandular in appearance and display follicular differentiation or keratin cysts. Rippled patterns are also described. By definition, the nodules are greater in size than those defined in micronodular basal cell carcinoma (see 'High-risk subtypes', part b below).
- Fibroepithelial basal cell carcinoma (of Pinkus). Although there is considerable debate about the nosological status of this entity, and specifically whether it represents a basal cell carcinoma or benign trichoblastoma, the WHO regards it as a low-risk basal cell carcinoma. RCPath has adopted the WHO approach, as the lesion can certainly occur frequently in association with high-risk variants of basal cell carcinoma.

High-risk subtypes

- Infiltrating or sclerosing/morphoeic basal cell carcinoma. The infiltrating variant is characterised by irregular groups of tumour cells that comprise islands and strands with a jagged or spiky appearance. The sclerosing/morphoeic variant of infiltrating basal cell carcinoma is accompanied by stromal fibrosis with increased fibroblasts. At times, the fibrosis can be of keloidal type.
- Micronodular basal cell carcinoma. The nodules are small, round and of follicular bulb size. They are defined as being less than 0.15 mm in diameter. As an approximate guide, the islands have fewer than 25 cells in their maximum transverse diameter. Some basal cell carcinomas seem very well circumscribed, in a manner comparable to nodular basal cell carcinoma, but appear to be composed of smaller nodules, seemingly akin to micronodules. It is not yet definitively established whether the latter compromise true micronodules, are the effect of tangential cutting of interwoven ribbons and/or represent

irregularity at the edge of macronodules. It is recommended, however, that the term 'micronodular basal cell carcinoma' is confined to tumours displaying a degree of infiltration at the edge.

There is no clinical value, with regard to management or treatment, in distinguishing between high-risk infiltrating, sclerosing and micronodular variants. These often co-exist in the same tumour with overlapping forms. There has therefore been a recent proposal to combine all three high-risk subtypes under one generic term: 'infiltrative basal cell carcinoma'. This logical proposal has been adopted in this dataset.[14] Specifying the different subtypes individually remains a non-core option.

In practice, many basal cell carcinomas contain both low- and high-risk patterns (so-called 'composite basal cell carcinoma'). Unfortunately, however, no robust evidence is available to assist in assessing when a certain percentage or location of a subtype is biologically significant. On that basis, the current dataset has taken the pragmatic approach of simply identifying the different type of subtypes present under low-risk or high-risk headings. The overall clinical risk status of a basal cell carcinoma is best judged from the highest risk subtype(s) present, irrespective of percentage or location. This approach is also supported internationally by the NCCN and conforms to tumour grading in general.[11] Accordingly, if high-risk components are present, any accompanying low-risk components need not be recorded, for the purpose of reporting whether the basal cell carcinoma is of low-risk or high-risk type.

Although many basal cell carcinomas are clearly invasive, it is interesting to consider whether in situ variants occur. As already discussed, this raises a particular query as to whether superficial basal cell carcinoma is truly invasive.

Consideration was given to whether basal cell carcinomas can simply be designated histologically as pure low-risk (non-aggressive) or high-risk (aggressive) type with no mention of histological type.

This approach has not been adopted as many clinicians deploy different treatment strategies for superficial and nodular basal cell carcinoma, especially when they involve surgical margins. It was deemed appropriate to omit the collection of data items not relevant to superficial basal cell carcinoma, i.e. the level of invasion and perineural invasion. However, these data must be collected for nodular basal cell carcinoma because although rare, this subtype may display perineural invasion.

Differentiation

There has been a suggestion that basal cell carcinoma could be divided into differentiated and undifferentiated types. This proposal, however, has had limited support; furthermore, it is widely accepted that the multitude of types of histological differentiation of basal cell carcinoma need not be recorded in a report. The reported types are extensive and include pigmented, adamantinoid, granular cell, clear cell, giant cell, signet cell, adenoid, keratotic and pleomorphic variants. Basal cell carcinomas with variable ductal, glandular and adnexal differentiation have been described including eccrine, apocrine, sebaceous, infundi-bulocystic, follicular or matricial components. Basal cell carcinomas with myoepithelial or neuroendocrine differentiation are also reported. Furthermore, basal cell carcinoma can be associated with a benign pseudocarcinomatous squamous cell proliferation in the adjacent epidermis. However, atypical squamous differentiation in basal cell carcinoma appears to have greater biological significance, although the topic has been complicated by variable definitions of the term 'basosquamous carcinoma'. For example, it has been used to describe collision tumours, keratotic and follicular basal cell carcinomas and also the controversial metatypical type of basal cell carcinoma. The latter, in particular, is poorly defined and represents a possible intermediary tumour with features of both basal and squamous cells. Despite these problems, there is reasonable evidence that basal cell carcinoma associated with moderate/severe squamous atypia or squamous malignancy is associated with a higher incidence of recurrence and metastatic spread. On that basis, it is recommended that basal cell carcinomas admixed

with a moderate/severely atypical or malignant squamous component are identified as such by the term 'basosquamous carcinoma'. To date, no minimum percentage of atypical squamous epithelium has been set in the diagnosis of basosquamous carcinoma. This approach is consistent with that adopted by the WHO.[3] A minor degree of squamous atypia is not unusual in basal cell carcinomas that show follicular differentiation and this is not biologically significant. In view of the metastatic potential of basosquamous carcinoma, there has also been debate as to whether the entity is best categorised under basal cell or squamous cell carcinoma. This dataset adopts the approach used by the WHO and categorises the entity as a high-risk variant of basal cell carcinoma.[3]

Although not a core dataset item, there is the option for both basal and squamous components of the tumour to be described separately. In particular, the percentage of squamous cell carcinoma can be described together with the associated squamous cell dataset parameters. Basosquamous carcinoma is the variant most likely to be associated with vascular invasion.

[Level of evidence C – Classification of basal cell carcinoma according to growth pattern and differentiation correlates with risk of local recurrence and metastasis and clinical high- and low-risk status.]

5.3.2 Level of invasion

Level of invasion is a primary staging determinant for T3 and T4 categories.[1,2]

T3 is signified by minor bone erosion, T4a by gross cortical/marrow invasion and T4b by axial/skull base or foraminal invasion. In addition, TNM 8 has introduced the principle of upstaging from T1 or T2 to T3, in the presence of so-called deep invasion. The latter is defined as tumour thickness of more than 6 mm and/or invasion beyond/further than the subcutaneous fat. Tumour thickness is measured from the granular layer of adjacent normal epidermis to the deepest point of the tumour. AJCC state that upstaging relates more to cSCC rather than basal cell carcinoma, but both UICC and AJCC have retained upstaging in TNM 8 for basal cell carcinoma cases; accordingly, it is used in the dataset. This information is not required for superficial basal cell carcinoma.

[Level of evidence B/C – Level of invasion is a primary staging and upstaging determinant.]

5.3.3 Thickness/depth

Unlike melanoma and cSCC, tumour thickness of basal cell carcinoma in millimetres has had limited known primary prognostic value. Accordingly, it did not feature as a core item in the TNM 7 dataset but could be entered as a non-core item.

However, as explained previously, TNM 8 has introduced the principle of upstaging from T1 or T2 to T3, in the presence of so-called deep invasion. The latter is defined as tumour thickness/depth of more than 6 mm and/or invasion beyond/further than the subcutaneous fat. AJCC states that upstaging relates more to cSCC rather than basal cell carcinoma, but both UICC and AJCC have retained upstaging in TNM 8 for cases of basal cell carcinoma. Accordingly, it is used in the dataset. A core entry is therefore now required with respect to whether or not the thickness of basal cell carcinoma is >6 mm.

In TNM 7 and TNM 8, the terminology used for this parameter, by both UICC and AJCC, is variable and guidance is limited in UICC TNM 8. The terms used most frequently are thickness and/or depth, although thickness appears favoured. Depth of invasion (DoI) is also used by AJCC and would be a logical twin to the term level of invasion. Unfortunately, however, DoI receives varying usage, sometimes even meaning level of invasion. Breslow thickness is now universally used in melanoma and is defined in relation to the granular layer over the tumour. Furthermore, in TNM 7, Breslow thickness was also used for NMSC. In TNM 8, however, although the measurement of thickness/depth is also recommended to be made from the granular layer to the base of the tumour, the granular layer of the adjacent normal epidermis is now used instead. This could be regarded as a modified Breslow thickness. AJCC explain that this change has been instigated to avoid various issues. They state that, in tumours, the

granular layer can be lost and simply measuring from the surface of the tumour to the base may overestimate prognostic impact because the dead keratotic surface of some tumours may contribute little prognostically.

Therefore, to achieve uniformity in terminology, the RCPath recommend that the most appropriate term to use in NMSC is also thickness, although accepting it has the same interchangeable meaning in this context as depth. On that basis, thickness or thickness/depth (in section 1.3 relating to new changes) are the terms used in this dataset. Furthermore, the RCPath also acknowledges that this means no term is currently uniformly available to describe the maximum vertical distance, from the top to bottom, of the malignant cells within a tumour. Accordingly, it is recommended that the term absolute thickness (stated in millimetres) is used for this dimension.

The reason for implementing the new method of measuring thickness in TNM 8 appears to have logic and RCPath Figures 1 and 2 illustrate the measuring methodology in tumours of either classic ulcerative or endo-exophytic type. In the consultation on the datasets, however, RCPath Fellows have highlighted not uncommon difficulties in the practical application of this method. This may lead to variable and inconsistent practice and over- or under-rating thickness measurements, thereby potentially impacting on pathological stage and clinical risk status. It is evident that numerous architectural variations of tumour and adjacent epidermis can occur, which are not adequately covered by the TNM 8 guidance. Advice has been sought from both the UICC and AJCC but this enquiry is still under active consideration. Therefore, in the interim, the RCPath consider it appropriate to provide provisional guidance, to reduce the subjectivity and variation in the measurement of tumour thickness, in these problematical areas. These difficulties occur more commonly with cSCC but can also occur with basal cell carcinoma. They are easier to accommodate, however, with basal cell carcinoma since measurements are only recorded in relation to 6 mm thickness

Although basal cell carcinoma is often of follicular origin, the problematical cup-shaped and crateriform lesions of follicular-derived SCC fortunately appear to occur far less commonly with basal cell carcinoma. In some cases, all of an exophytic tumour may originate at the level of or above the granular layer of the adjacent normal epidermis. As a zero or negative thickness value could be viewed as lacking credibility, the RCPath recommends that these cases are recorded as simply <6 mm.

In other not uncommon cases, the appearance may fail to conform to any architectural model. In some instances the adjacent normal epidermis is sloping, irregular or has undulating crests and troughs. In others, there may be gradations between reactive squamous epithelium and the basal cell carcinoma, either at the edge or over the tumour. This may give rise to sloping squamous epithelium along the edge and onto the top of the tumour and furthermore, sometimes the granular layer can be absent. Basosquamous carcinoma can also create its own measuring difficulties with combined squamous and basal cell elements. Use of classic Breslow thickness in this situation would appear inappropriate for the reasons already explained by AJCC. Measuring from the base of the epidermis would be confronted with the same problems and estimating a theoretical average height of normal granular layer could be difficult to apply in practice. Accordingly, until definitive guidance is available, the RCPath recommend that absolute thickness in millimetres (as defined above) is recorded in this situation. In particular, it is believed that this approach will not falsely under-rate the thickness measurement. If absolute thickness is used for this measurement, it would appear appropriate to mention its use as free text in the comments section of the report, particularly to inform colleagues who review the case for MDT purposes. It is believed that the gain in uniformity with this interim approach will outweigh the variation in measurement by using the TNM 8 guidance in an ad hoc, subjective and variable manner. In view of these acknowledged difficulties, measuring thickness of NMSC may, at times, require a pragmatic approach to the problem.

Tumour thickness can be measured using an ocular micrometer, Vernier scale or an eye-piece measurement graticule.

The absence of specific measurement requirements, other than in relation to 6 mm, should simplify measurement of thickness.

Depth ≤6 mm or >6 mm can be recorded as a whole integer as a non-core item.

[Level of evidence C – Tumour thickness/depth is a staging determinant.]

Figure 1: Measuring the thickness/depth of an ulcerative tumour

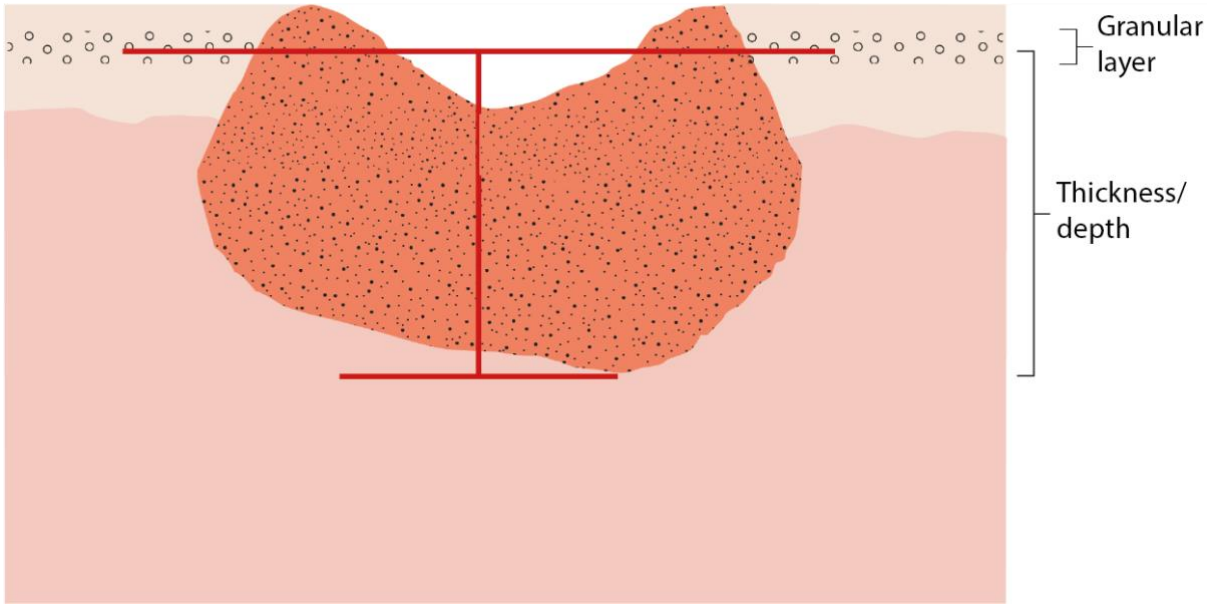
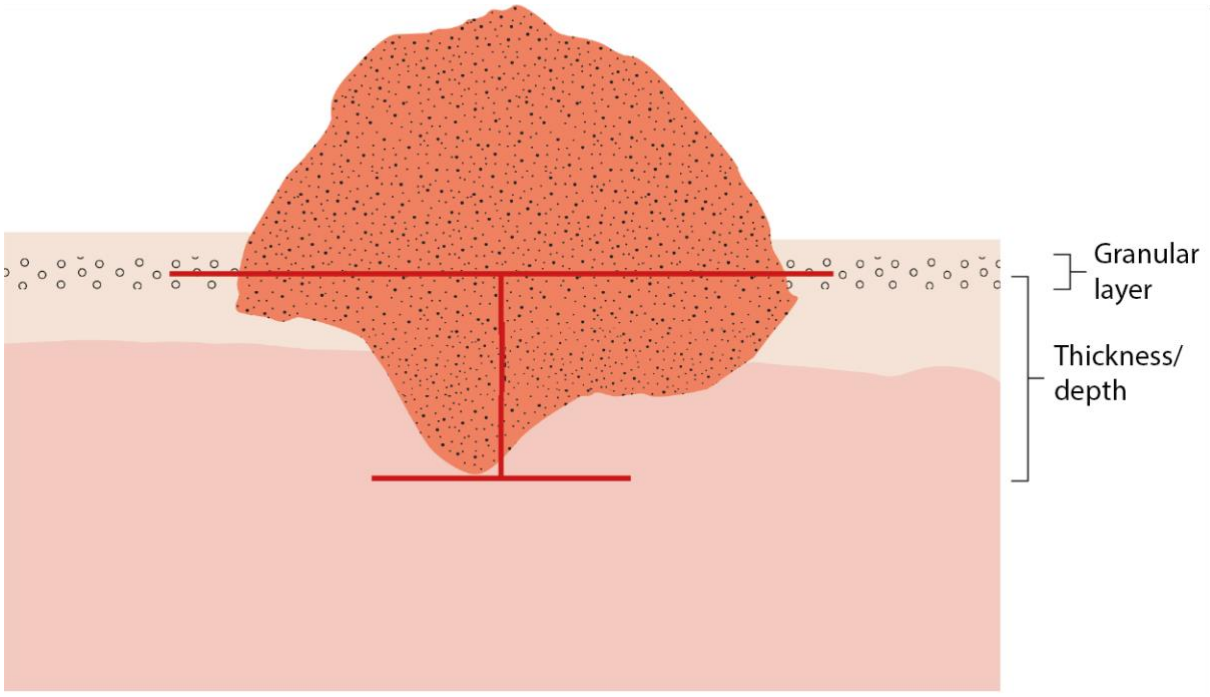


Figure 2: Measuring the thickness/depth of an endo-exophytic tumour



5.3.4 Perineural and lymphovascular invasion

National clinical guidelines and NICE both recognise perineural invasion as a clinical high-risk factor for skin cancer MDT management.[4,8] Perineural invasion is also a site-specific item in the COSD.[9] Invasion of the perineural sheath is most often a feature of high-risk basal cell carcinoma, including infiltrative/morphoeic, micronodular and basosquamous variants. This results in difficulty in achieving clearance at primary excision and is an important cause of tumour recurrence.

Perineural invasion, when conforming to specified defined criteria, is a high-risk feature that upstages T1 or T2 to T3. The criteria include a named nerve or large calibre ≥0.1 mm diameter or beyond the dermis. AJCC TNM 8 contains all the criteria, whereas UICC TNM 8 is currently confined to a named nerve, which may include clinical or imaging detection. Named nerves and those beyond the dermis are invariably large calibre in type, ≥0.1 mm in diameter. On that basis, it appears appropriate to apply all of the criteria.

Tumour cells within the actual nerve constitutes significant neural invasion, but occurs too infrequently to know whether this should also be an upstaging criterion

There is no evidence to indicate whether the term 'in skin' applies to intratumoral or extratumoral invasion, including perineural invasion at the invading front. Some restrict the use of this term to the latter situation. 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'. 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. Immunohistology can be used to make the distinction.[15]

[Level of evidence B/C – Perineural invasion is a primary upstaging determinant and also correlates with local recurrence.]

The evidence base to suggest that vascular invasion correlates with recurrence, metastasis or prognosis is less strong. Lymphovascular invasion is, however, a collection variable in AJCC TNM 7,[2] a clinical high-risk factor in the national clinical guidelines and supported by NICE for skin cancer MDT management.[4,8] The presence of an endothelial-lined space is an essential criterion for lymphovascular invasion, because it is important to distinguish it from retraction artefact. As indicated by the AJCC term, it is not necessary to distinguish lymphatic from venous invasion.

Lymphovascular invasion is a feature of basosquamous carcinoma and not basal cell carcinoma. It is, however, stated to be a high-risk feature of basal cell carcinoma by both the BAD and NICE, although neither clarifies whether lymphovascular invasion applies to basosquamous carcinoma and/or basal cell carcinoma. There must, however, be a presumption that it can only accurately apply to basosquamous carcinoma. On that basis, RCPath regards it as reasonable to restrict lymphovascular invasion as a core item to only basosquamous carcinoma. If lymphovascular invasion is ever detected in pure basal cell carcinoma, this must be entered in the 'Comments' section.

[Level of evidence C – Lymphovascular invasion in basosquamous carcinoma can indicate increased risk of metastasis.]

5.3.5 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 histopathological reports. Unless all of the margins have been examined, it is difficult to be certain about the completeness of excision. Traditionally, the term 'complete' has been more acceptable in the context of Mohs surgery,

where the peripheral margin has been examined in virtually its entirety. This view is now significantly weakened in the context of modern paraffin wax histology, with its considerably more thorough sampling of margins, and with the more recent methods of specimen handling, as advocated in this and previous datasets. Adequacy/inadequacy usually incorporates a degree of clinicopathological subjective judgement and is therefore more applicable in the context of skin cancer MDT discussion. However, it is well recognised that in a significant number of cases where tumour extends to a margin, there is no residual tumour present on re-excision. This indicates that the term 'incomplete' is inappropriate in this situation. Similarly, lesions not at the margin can occasionally recur and therefore may not be completely excised as originally thought. In non-excision specimens with therapeutic intent (e.g. double curettage and cautery), the term 'edge' is increasingly favoured. This is to aid distinction from the normal use of the term margin, as here the true surgical margin lies beyond the zone of cautery not represented in the specimen. Accurate margin assessment in this situation requires clinical input with regard to the nature of the procedure undertaken and the degree of certainty that therapeutic intent was achieved. This often requires discussion within the context of a skin cancer MDT.

Although evidence is more robust for peripheral margins, there is broad peer agreement that comments are necessary about the clearance of both peripheral and deep excision margins. The words 'peripheral' or 'radial' rather than 'lateral' are 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 not involved or involved by tumour. Although all RCPath datasets are standardised to the term 'not involved' ('uninvolved' internationally), the term 'clear' is preferable to minimise potentially important errors in the use of 'involved' and 'not involved'. These occur not uncommonly in reports dictated from a template. Although less frequently used, 'negative' or 'positive' correlates acceptably with 'not involved' (clear) and 'involved', respectively. Clinicians invariably also wish to know whether the tumour is 'close' to the nearest margin to evaluate the potential risk of recurrence, the necessity for further treatment and follow-up. 'Close' is, however, a poorly defined term and used inconsistently for skin cancer treatment and management. The evidence base for the term is also limited.

Guidance on adequate clinical margins is available in the national clinical guidelines. Adequacy of clearance is essentially a risk assessment of percentage chance of recurrence, based on margin clearance and low/high-risk status of the tumour. For basal cell carcinoma and clinical margins, this varies between 3 and 15 mm.[8] Information on histological margins is 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.[16,17] The figures vary according to growth pattern; approximately 10% of infiltrative basal cell carcinomas with margins greater than 0.75 mm will recur. Few, if any, basal cell carcinomas will recur with a histological margin beyond 0.84 mm. It is interesting that the Cancer Council of Australia and the Australian Cancer Network defined histological margins of less than 0.5 mm for basal cell carcinoma as inadequate. On that basis a robust evidence-based histological definition of 'close' is still awaited and use of the term therefore remains somewhat subjective. Although some information is available for basal cell carcinoma, less is available for cSCC. Accordingly, the reporting of margins below 1 mm to one decimal point is supported as a non-core rather than core item.

Consultation between the RCPath and BAD in 2001 revealed strong support (for clinical purposes) in knowing whether basal (and squamous cell) carcinoma excision margins are histologically involved (0 mm), not involved (or clear) below 1 mm and not involved (or clear) above 1 mm. Although accepted as having a degree of subjectivity, both the BAD and RCPath agreed that non-involved margins below 1 mm can usefully be termed 'clear but close'.

As a core data element for skin cancer, the COSD records whether skin tumour excision margins are clear by more than 5 mm, clear by at or greater than 1 mm but less than or equal to 5 mm, or less 1 mm but without tumour reaching the margin.[9] Skin cancer margins should therefore be measured in relation to both 1 mm and 5 mm breakpoints. There is also additional peer support for auditing the excision margins of all skin cancer specimens between different Trusts and general practices within a cancer network/alliance and between different clinical specialities and clinicians. Measuring resection margins over 1 mm histologically to within 1 mm is one way to facilitate this objective; this could also represent a reasonable surrogate marker for clinical margins as defined in national guidelines. This dataset recommends measuring peripheral and deep margins histologically as <1 mm, 1–5 mm and >5 mm. Measuring to a whole millimetre integer over 1 mm is included as a non-core item.

It is important that assessment of a margin below 1 mm is undertaken on blocks selected in accordance to the RCPath protocol, 'full-face' sections, with a low threshold to request additional levels to increase the accuracy of assessment.

It should be noted that margin definitions used for mucosal malignancies of the oral cavity, including vermilion lip (>5 mm clear, 1–5 mm close and <1 mm involved), are not regarded as applicable to cSCC, including hair-bearing lip.

This dataset defines margin clearance that is either involved or not involved but <1 mm as high risk. Using <1 mm as the definition takes into account the limited evidence base in this area and errs on the side of clinical safety to incorporate different variables such as tumour type, fixation shrinkage, lesion sampling and levels.

Although not listed in NICE guidance, there is increasing clinical practice for so-called clear but close margins to receive skin cancer MDT review. This can then take into account the degree of histological closeness to within 0.1 mm, the growth pattern, the extent of closeness and its position, especially in the event of an orientated specimen. In the previous edition of the dataset, this information was a non-core item. Consideration has therefore been given as to whether this should now become a core item in the current dataset. Consideration has also been given as to whether the information could be better assessed by the pathologist reviewing the case for a skin cancer MDT. Certainly, the microscopical demonstration of these histological features facilitates MDT discussion and permits a team consensus on the possible degree of clearance of the lesion, adequacy of treatment and whether further treatment is indicated. Although equivocal, the RCPath consider that there is still insufficient evidence or clinical guidance to alter the approach in the previous dataset, taking into account that this information can still be currently provided as a non-core item in the report. It is recommended that if this approach is adopted, however, that the minimum non-core information needs to be distance to 0.1 mm and growth pattern of the basal cell carcinoma. The RCPath are aware that new clinical guidelines on basal cell carcinoma and SCC will be published by the BAD in 2019 and this may include a recommendation to refer all cases with clear but close margins to a skin cancer MDT. In this eventuality, the RCPath are likely to support clear but close margins below 1 mm, being reported as core items, to include at least a margin measurement to the nearest 0.1 mm and growth pattern. This could be included in the first revision of the dataset. This addition could also necessitate consideration of an increase in workload scoring for basal cell carcinomas in this group.

[Level of evidence C – Margin status correlates with the risk of clinical recurrence.]

5.3.6 Maximum dimension/diameter

The maximum dimension/diameter is the major breakpoint determinant to define T categories in TNM 8: ≤20 mm, >20 mm to ≤40 mm and >40 mm defines T1, T2 and T3 categories respectively, although T1 and T2 can be upstaged to T3 by the presence of one or more defined high-risk factors (see Appendix A).

AJCC states that the maximum dimension should be a clinical measurement on the evidence base available, but permitting a pathological measurement if the clinical one is not available. UICC are not specific on this point other than recommending that the measurement be assessed by physical examination. This dataset also recommends the use of clinical measurement but supports the use of pathological measurement if the clinical type is absent. Indicating the one used for staging is a new dataset item. Preferably, this should be the macroscopic measurement, unless in a particular case use of a macroscopic and/or microscopic one is unavoidable.

NICE has also defined parameters to indicate which basal cell carcinomas may be managed and treated in the community/primary care by appropriate practitioners, by virtue of being low risk according to defined criteria. A diameter of <10 mm is one definition of a low-risk basal cell carcinoma.

[Level of evidence B – Maximum diameter is a primary staging determinant and a determinant of risk permitting excision in community care by general practitioners.]

6 Non-core data items

These can be included to provide a more comprehensive report, taking into account the local cancer alliance, clinical preferences, audit and research. These data items were supported during the informal consultation on the dataset.

6.1 Basal cell carcinoma pathology risk status/stratification

This has been integrated from AJCC TNM 8,[2] BAD,[8] NICE,[4–7] QSP,[10] WHO,[3] AFIP[12] and NCCN.[11] Risk status/risk stratification is required for skin cancer MDT discussion, based on NICE Skin Cancer Guidance and QSP requirements for the following reasons:

- to decide whether treatment in primary or secondary care is appropriate (competence and thereby permission to treat basal cell carcinoma in primary care has formal professional restrictions and these are defined by the type of practitioner contract)
- to assess the extent of desirable margin clearance to facilitate skin cancer MDT action and decision-making as necessary
- to help decide on follow-up: duration and primary/secondary care.

Risk status/risk stratification has been classically divided in a polarised binary fashion into low and high risk. Increasingly, however, there is a realisation that an intermediate-/middle-risk status is not unusual. In addition, a summation of the number of high-risk factors present should also, logically, have clinical importance.

Risk status for basal cell carcinoma relates primarily to risk of persistent or recurrent local disease. The risk of metastasis is rare except in basosquamous carcinoma (WHO/AFIP). Risk status incorporates both clinical and histological features. The clinical features are covered in clinical non-core items. A recurrence rate of 5% or greater is generally agreed to be regarded as high risk; the pathological features that constitute high risk by the RCPath are listed below.

Pathological risk status can be reported as a non-core item under the two subheadings of the basal cell carcinoma tumour with stage and margin clearance. This provides clinical guidance relating to management, treatment and prognosis but does not necessarily indicate a requirement for MDT referral or additional treatment. One or both of the latter possibilities must be decided on an individual case basis, either by the clinician overseeing the patient and/or in an MDT setting. Some specific situations for MDT referral for discussion are covered by NICE and QSP guidance.

It must be noted that a low-risk basal cell carcinoma based on histological criteria may be upgraded to an overall high-risk lesion when summated with any clinical high-risk features present (as supplied by a clinician and/or emerging at an MDT).

High-risk pathological factors (see Appendix F)
Any one equals high risk.

i. Basal cell carcinoma and stage

- Growth pattern:

Infiltrative (infiltrating/morphoeic and/or micronodular)	BAD/NICE/WHO/NCCN
High-risk component in any part of lesion	NCCN

  RCPath: High-risk component in any part of lesion

- Differentiation:

Basosquamous carcinoma	BAD/NICE/WHO

  RCPath: Basosquamous carcinoma

- Level of invasion:

Clark level 5 and beyond	NICE/WHO
Beyond the subcutaneous fat for TNM upstaging	TNM 8

  In general, Clark level 5 is regarded as weak evidence, so this dataset has adopted the more robust 'beyond the subcutaneous fat'.

  RCPath: Beyond the subcutaneous fat

- Thickness

>6 mm for TNM 8 upstaging	TNM 8

  RCPath: >6 mm

- Perineural invasion:

Present	BAD/NICE/WHO/QSP
Present below dermis	NICE update
Specified perineural invasion for TNM 8 upstaging (named nerve, ≥0.1 mm, below dermis)	TNM 8

  RCPath: Perineural invasion

- Lymphovascular invasion

Present	BAD

  This is, however, regarded as weak evidence except in the context of basosquamous carcinoma.

  RCPath: Lymphovascular invasion present in basosquamous carcinoma

- TNM pathological (p) stage:

T2, T3, T4	BAD/NICE

  RCPath: pT2, pT3, pT4

ii. Margins

- Histological margins:

  Margins that are involved (0 mm) or not involved <1 mm BAD
  (so-called 'clear but close')

  RCPath: Margins that are involved (0 mm) or not involved <1 mm

[Level of evidence B – Knowledge of defined high-risk pathological features is required for appropriate clinical management, treatment and MDT discussion.]

6.2 Non-core clinical items

These are based on the national clinical guidelines, core and site-specific items in COSD and the draft UK National Histopathology Request Form (Appendix C).

They also conform to NICE requirements and can be captured if provided by the clinician. They include:

- grade of clinician undertaking procedure
- clinical diagnosis/description
- procedure intention of clinician (diagnostic or therapeutic biopsy)
- measured surgical clinical peripheral margin (millimetres)
- a tumour recurrence
- previous histology reference number(s)
- an immunocompromised patient
- a tumour arising in an area of radiation or thermal injury, chronic draining sinus, chronic ulcer or chronic inflammation
- a tumour arising in an individual genetically predisposed to cancer
- a tumour previously treated using topical medication (this may reduce the likelihood of finding the tumour histologically).

Clinical high-risk factors for basal cell carcinoma for skin cancer MDT treatment and management
(any one equals high risk):

- anatomic location – central face, around eyes, nose, lip or ears BAD
- recurrent at site BAD
- persistent at site NICE update
- reduced immune status BAD
- genetic (e.g. Gorlin's) BAD

Definition of low-risk basal cell carcinoma for management in the community (NICE)

- >24 years old
- no immunosuppression/genetic syndrome
- below clavicle
- <10 mm
- not recurrent/persistent

- not morphoeic/infiltrating/basosquamous
- not over-important anatomical structure
- primary closure not difficult
- not an area with poor cosmetic results
- not a highly visible anatomical site with cosmetic risk.

Note that some parameters for management in the community (such as tumour diameter) are different from those that are used for pathological and clinical risk stratification and MDT referral in secondary care. Whereas the above NICE guidance was originally applicable to all suitably trained practitioners in primary care who had demonstrated competency, there have been subsequent modifications of the practitioner contract. On a DES/LES contract, the above list is still applicable.

For a GPwSI (General Practitioner with a Specialist Interest) who was contracted and accredited as a Model 1 practitioner, the diameter increases up to 20 mm but only when below the clavicle. Lesions above the clavicle, and not over 10 mm diameter, can be treated if located on the chin, cheeks, forehead, temples, neck and sides of the face.

The Royal College of General Practitioners/BAD have jointly developed a national accreditation process that recognises the importance of diagnostic skill for all skin cancers and not just surgical skill for basal cell carcinoma. In addition, the accreditation process recognises that individual GPs may have skills, supported by their clinical supervisor, that exceed those defined by NICE.

To delineate those GPs who have been through this accreditation process the term General Practitioners with an Extended Role (GPwER) has been adopted. Those accredited to undertake skin cancer management will be Group 2 (Skin Lesion Management) or Group 3 (General Dermatology and Skin Lesion Management).

Model 2 practitioners operate under acute Trust governance on lesions already selected through discussion with a core member of the skin MDT, thus the above list and limitations are not applicable.

6.3 Non-core pathological items

The following are non-core items:

- comment on the presence of infiltrating and/or sclerosing and/or micronodular components in high-risk infiltrative basal cell carcinoma
- margins: <1 mm measure to nearest 0.1 mm
- margins: >1 mm to nearest 1 mm whole integer
- margins: information on nearest peripheral and deep margins in relation to designated specimen orientation
- growth pattern at involved or not involved margin <1 mm (‘clear but close’)
- extent of involvement or closeness at a margin. It is useful to know if the tumour abuts or transects a margin and whether the involvement is focal or more widespread. This can be expressed for a distance in millimetres
- differentiation: basosquamous carcinoma – percentage of squamous component present and squamous carcinoma dataset information where relevant
- perineural invasion: location and whether intratumoral, extratumoral or multifocal; distance to nearest margin

- thickness: ≥1 mm to the nearest whole integer
- whether dermal regression is present and distance to nearest margin in mm
- in incisional biopsies, whether subcutaneous fat is present
- clearance/completeness of excision: RCPath recognises that many clinicians and MDTs look for guidance from their histopathologists regarding the probability/likelihood of incompleteness/completeness of tumour clearance. As already discussed, this is a subjective area and accordingly cannot be included as a core item. A locally agreed statement of probability of clearance is, however, not unreasonable and is therefore included as a non-core item, with possible suggested terminology. If used, however, 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. In many instances, it may be appropriate/helpful to convey this opinion at a skin cancer MDT, with microscopic demonstration of the features, to facilitate MDT discussion.

  Suggested terminology for a subjective probability statement on the likelihood of tumour clearance could include:
  - clearance appears apparently complete
  - clearance appears close but probably complete
  - clearance appears close but possibly complete
  - clearance appears uncertain
- high-risk status score: a summation system of the number of high-risk factors present.

7 Diagnostic staging and coding

TNM and SNOMED are required for the COSD.[8]

7.1 pTNM stage and stage group

By TNM convention, TNM/cTNM (c meaning clinical) refers to staging a primary tumour that has not been previously treated. Clinical staging can therefore incorporate some pathological diagnostic information but the T category is still referred to as T and not pT. Similarly, by convention, pTNM (p meaning pathological) refers to staging after surgical treatment. The pathological information for pTNM is designated pT, pN and pM with reference to the three component TNM categories.

pTNM stage/stage group for skin cancer must be recorded according to UICC and not AJCC TNM 8.[1]

pTNM staging/stage grouping must be deferred until all TNM information is available and, if appropriate, during or after skin cancer MDT discussion.

A pTNM stage/stage group can be added to a histopathology report as a non-core item, but the report should indicate that this is the minimum stage based on the information in the report.

The pTNM stage categories are broadly condensed into four stage groups:

- stage 0: in situ
- stage I: localised disease
- stage II: more extensive localised disease
- stage III: regional nodal disease

- stage IV: metastasis.

Although pTNM classically refers to the anatomic extent of disease, more recently this has, at times, incorporated additional non-anatomic prognostic information, giving rise to so-called prognostic groups (UICC) or prognostic stage groups (AJCC).

pTNM stage is based on three anatomical categories: pT (Tumour), pN (Node), M or pM (Metastasis).

- pT – Primary tumour
  - pTx: Primary tumour cannot be assessed
  - pTis: Carcinoma – in situ
  - pT has multiple subcategories, i.e. pT0, pT1, pT2, pT3, pT4, reflecting increasing pT stages
- pN – Regional lymph nodes
  - pN has multiple subcategories, i.e. pN0, pN1, pN2, pN3
  - for melanoma and MCC, isolated tumour cells are defined as N1
- M – Distant metastasis
  - M/pM (if confirmed histopathologically) has two categories, i.e. M0, M1/pM1
  - it should be noted that there is no MX nor pM0
- Additional descriptors can be used:
  - the suffix ‘m’ indicates the presence of multiple synchronous primary tumours in a single organ (i.e. skin) within four months of diagnosis and is recorded in parentheses, e.g. pT1 (m). The highest T category should be used. Beyond four months they are regarded as new metachronous tumours and staged separately.
  - the suffix 'sn' indicates a sentinel lymph node biopsy and is shown in parentheses, e.g. pN1 (sn)
  - the prefix 'r' indicates a recurrent tumour with a disease-free interval or disease that has progressed with no interval. This can be designated ‘rp’ if based on pathological information.
  - the TNM R classification for residual tumour is not used as margin status; information is provided in more detail elsewhere in the dataset.

Full details are available in Appendix A.

7.2 SNOMED codes

SNOMED Topography (T) code should be recorded for the site.

SNOMED Morphology (M) code should be recorded for the diagnosis/tumour morphology.

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.

However, it is noted that SNOMED is now in a practical transition phase as part of the intended full implementation by the NHS and PHE of SNOMED CT. SNOMED ceased to be licensed by the International Health Terminology Standards Development Organisation from 26 April 2017.

A list of applicable T and M SNOMED and SNOMED CT codes is provided in Appendix B. Mapping SNOMED CT terminology is provided.

8 Reporting of small biopsy specimens

When a procedure is carried out with the clear intention of establishing a diagnosis (e.g. punch biopsies, incisional biopsies and some shave or curettings), data items can be restricted to diagnosis and indicators of a high-risk status.

A full dataset should, however, be completed when a procedure is undertaken with therapeutic intent. This could include curettings, a punch excision or shave. It is, however, appreciated that perhaps all dataset items cannot be provided.

9 Reporting of frozen sections

Frozen sections should be limited to Mohs micrographic surgery where horizontal sections are used to accurately assess margin status. 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 usually cannot be supported as this circumvents the desirable standard of prospective skin cancer MDT discussion and potential patient involvement in the decision-making process.

10 Cytological diagnosis

Cytology has only a limited role in the diagnosis of cutaneous basal cell carcinoma. Imprints or aspirates for cytological diagnosis can be used in clinics on a ‘one-stop’ basis. Basal cell carcinoma may be characterised by so-called ‘elephant trunk’ cellular clusters.

11 Specific aspects of individual tumours not covered elsewhere

11.1 Recommendation for MDT referral

Low-risk basal cell carcinomas can only be treated in primary care by appropriately trained and accredited practitioners. All other basal cell carcinomas must be treated in secondary care or by a Model 2 practitioner in primary care.[4–7]

Basal cell carcinoma cases requiring local skin cancer MDT referral:[4–7]

- high-risk basal cell carcinomas that involve the excision margins
- patients for Mohs surgery
- immunocompromised patients.

Patients requiring specialist skin cancer MDT referral:[4–7]

- metastatic basal cell carcinomas
- immunocompromised patients or those with a genetic susceptibility.

MDT referral can be included in a report as a non-core data item.

The MDT referral status of lesions with histologically non-involved (clear) margins <1 mm remains an individual clinical decision or a locally agreed MDT decision. Non-involved margins <1 mm are, however, a defined high-risk pathological parameter. This indicates that the case must have special clinical consideration, with a low threshold to request MDT advice if considered appropriate.

11.2 Re-excision specimens

There has been considerable debate as to the extent of the examination that is required of wider local excision specimens for skin cancer. Macroscopic examination is essential. This is the most reliable means to record that the re-excision has been undertaken while noting the measurements of the wider excision. The fixed specimen should be sliced every 2–4 mm to detect any macroscopic abnormalities such as potential metastases. Each slice with a macroscopic abnormality must be examined histologically to ensure that margin status can be assessed.

The debate centres on the cost efficiency of examining an entire specimen that is macroscopically normal when abnormalities were not present at 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. 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 one to four cassettes of tissue. Clinicians require information about whether the specimen contains a scar and whether the scar is completely excised.

If abnormalities were reported to extend to the resection margins in the index specimen, the re-excision 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

12.1 Recommended by NICE[4]

- Skin cancer excision margins between specialities and clinicians.
- Skin cancer specimens in primary care.
- Histopathology reporting times (see section 12.2).
- Audit of all basal cell carcinomas and squamous cell carcinomas not discussed at the MDT meeting.

12.2 Recommended by the RCPath as key performance indicators

See *Key Performance Indicators – Proposals for implementation* (July 2013) on http://www.rcpath.org/profession/quality-improvement/kpis-for-laboratory-services.html:

- 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 were required to implement the structured recording of core pathology data in the COSD by January 2016 and to update their systems in line with subsequent COSD updates.
  - standard: 95% of reports must contain structured data

- histopathology cases must be reported, confirmed and authorised within seven to 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

Phillip McKee and Maureen Walsh are acknowledged for their contributions to the first and second editions of this dataset. The numerous other colleagues who offered useful advice during the extensive informal professional consultation about this dataset are also acknowledged; their views have been listened to carefully.

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

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Appendix A UICC TNM 8 pathological staging of primary cutaneous carcinoma

This combines the UICC TNM 8 chapter guidance for skin carcinoma of the head and neck and carcinoma of the skin (essentially limbs and trunk but excluding the eyelid, vulval, penile or perianal skin).

This includes basal cell carcinoma, squamous cell carcinoma and adnexal carcinoma, but excludes Merkel cell carcinoma and carcinomas of the eyelid, vulva, penis, non-hair-bearing lip or non-hair-bearing perianal skin (within 5 cm of the perianal margin).

The clinico-pathological implications of TNM 8 for skin cancer have been jointly reviewed by the BAD and RCPath.[18]

Definitions of pTNM

Primary tumour (pT)

pTX	Primary tumour cannot be assessed
pT0	No evidence of primary tumour
pTis	Carcinoma in situ
pT1	Tumour ≤20 mm or less in maximum dimension (this is the clinical dimension but the pathological dimension, usually macroscopic, can be used if the clinical is not available)
pT2	Tumour >20 mm to ≤40 mm in maximum dimension (this is the clinical dimension but the pathological dimension, usually macroscopic, can be used if the clinical is not available)
pT3	Tumour >40 mm in maximum dimension (this is the clinical dimension but the pathological dimension, usually macroscopic, can be used if the clinical is not available) OR pT1 or pT2 can be upstaged to pT3 by one or more high-risk clinical/pathological features including deep invasion,* specifically defined perineural invasion* or minor bone erosion
pT4a	Tumour with gross cortical/marrow invasion
pT4b	Tumour with axial skeleton/skull base/foraminal invasion

*High-risk features in relation to pT1 and pT2 upstaging to pT3.

Definitions
Deep invasion: this is defined as a level beyond/further than the subcutaneous fat and/or tumour thickness >6 mm. Thickness is measured in millimetres from the granular layer of the nearest adjacent normal epidermis to the deepest point of the tumour.

UICC TNM 8 currently defines upstaging/specified perineural invasion by either clinical or imaging criteria or histological invasion of a named nerve. However, as discussed in section 5.3.4 the RCPath consider it appropriate to extend the definition of specified perineural invasion to include invasion of a nerve ≥0.1 mm diameter and/or or a nerve deeper than the dermis.

Comment: UICC TNM 8 states pT is identical to T.

Regional lymph nodes (pN)

The division between head and neck and non-head and neck (trunk and limbs) regions anteriorly represents the level of the acromio-clavicular joint and posteriorly the level of the upper margin of the shoulder blade.

Carcinoma of the skin (essentially limbs and trunk but excluding the eyelid, vulva, penis or perianal area)

pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastasis
pN1	Metastasis in a single ipsilateral lymph node ≤30 mm in greatest dimension
pN2	Metastasis in a single ipsilateral lymph node >30 mm but not >60 mm in greatest dimension or in multiple ipsilateral lymph nodes, but not >60 mm in greatest dimension
pN3	Metastasis in a lymph node >60 mm in greatest dimension

A contralateral nodal metastasis (unlike with skin carcinoma of head and neck; see below) represents a distant metastasis.

There is an expectation that at least six lymph nodes will be identified in a lymphadenectomy specimen.

Skin carcinoma of head and neck (excluding vermillion lip)

pNX	Regional lymph nodes cannot be assessed
pN0	No regional lymph node metastasis
pN1	Metastasis in a single ipsilateral lymph node ≤30 mm in greatest dimension, without extranodal extension
pN2a	Metastasis in a single ipsilateral lymph node, >30 mm but not >60 mm in greatest dimension, without extranodal extension
pN2b	Metastasis in multiple ipsilateral lymph nodes, none >60 mm in greatest dimension, without extranodal extension
pN2c	Metastasis in bilateral or contralateral lymph nodes, none >60 mm in greatest dimension, without extranodal extension
pN3a	Metastasis in a lymph node, >60 mm in greatest dimension, without extranodal extension.
pN3b	Metastasis in a lymph node with extranodal extension

Extranodal extension can be defined by clinical or pathological criteria.

There is an expectation that at least ten lymph nodes will be identified by selective lymphadenectomy and at least 15 in radicle or modified radicle lymphadenectomy.

Distant metastasis (M)

M0	No distant metastasis
M1/pM1	Distant metastatic disease.

Comment: MX and pM0 do not exist.

pTNM stage group

Stage	T	N	M
Stage 0	Tis	N0	M0
Stage I	T1	N0	M0
Stage II	T2	N0	M0
Stage III	T3	N0	M0
	T1, T2, T3	N1	M0
Stage IV	T1, T2, T3	N2, N3	M0
	T4	N Any	M0
	T Any	N Any	M1

Appendix B Basal cell carcinoma SNOMED coding

Topographical codes	SNOMED	SNOMED CT terminology	SNOMED CT code
Skin	T01000	Skin structure (body structure)	39937001

Morphological codes	SNOMED	SNOMED CT terminology	SNOMED CT code
Basal cell carcinoma, NOS	M80903	Basal cell carcinoma (morphologic abnormality)	1338007
Superficial basal cell carcinoma	M80913	Multifocal superficial basal cell carcinoma (morphologic abnormality)	61098004
Infiltrating basal cell carcinoma	M80923	Infiltrating basal cell carcinoma (morphologic abnormality)	56665009
Morphoeic basal cell carcinoma	M80923	Basal cell carcinoma – morphoeic (morphologic abnormality)	134152008
Basosquamous cell carcinoma	M80943	Basosquamous carcinoma (morphologic abnormality)	37304002
Nodular/micronodular basal cell carcinoma	M80973	Basal cell carcinoma, nodular (morphologic abnormality)	128636006
Fibroepithelial tumour of Pinkus	M80933	Basal cell carcinoma, fibroepithelial (morphologic abnormality)	43369006

Procedure

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 PHE Skin Site-Specific Reference Group and kindly provided for RCPath dataset information by PHE. Permission for use should be sought from the PHE. This histopathology request form has been approved by the BAD; the mode of national implementation is under consultation. This could be useful to ensure that the maximum clinical dimension of a lesion is always recorded.

Date of surgical procedure

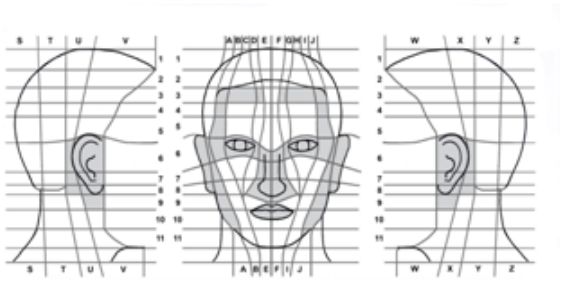
Please attach patient details

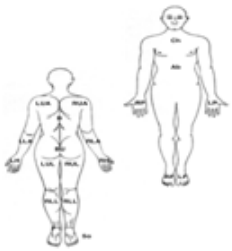
Name of surgeon

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

Clinical diagnosis: free text

Mandatory for Clinician to complete:	First biospy	Second	Third	Fourth
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?	Y/N	Y/N	Y/N	Y/N
Is the pateint immunocompromised?	Y/N			
Is this a tumour arising in areas of radiation or thermal injury, chronic draining sinuses, chronic ulcers, chronic inflammation or Bowen's Disease	Y/N	Y/N	Y/N	Y/N
Is this a tumour arising in a genetically predisposed individual?	Y/N			





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 8E). Where a lesion lies across grid lines then that grid reference in which the greater part of the tumour lies should be used OR 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 LIP 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 LLA).

Free text

Appendix D Reporting proforma for cutaneous basal cell carcinoma removed with therapeutic intent

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

Clinical data

Clinical site …….....
Maximum clinical dimension/diameter.....mm
Specimen type†:
Not stated □
Incision Diagnostic □
Excision Diagnostic □ Therapeutic □ Uncertain □ Re-excision □ Wider local excision □
Punch Diagnostic □ Therapeutic □ Uncertain □
Curettings Diagnostic □ Therapeutic □ Uncertain □
Shave Diagnostic □ Therapeutic □ Uncertain □
Other □ Specify ….....

Macroscopic description

Dimension of specimen: Length ……mm Breadth….mm Depth …….mm
Maximum dimension/diameter of lesion†: ....……mm Uncertain □ No lesion seen □

Histological data

Low risk subtype: Superficial □ Nodular □ Fibroepithelial □
OR high risk if present: Infiltrative (infiltrating/sclerosing/micronodular) □ Basosquamous carcinoma □

For pure superficial basal cell carcinoma, invasive entries can be omitted

Deep invasion: Criteria to upstage to pT3***** Present □ Not identified □ ***If present:***
Thickness >6 mm Present □ (**pT3**) Not identified □ *and/or*
Level of invasion beyond subcutaneous fat Present □ (**pT3**) Not identified □ ***If present:***
Specify tissue: Fascia □ Muscle □ Perichondrium □ Cartilage □
Paratendon/tendon □ Periosteum □ Bone □

If bone invasion present:
Minor bone erosion Present □ (**pT3**) Not identified □ Uncertain □ Cannot be assessed □
Gross cortical/marrow invasion: Present □ (**pT4a**) Not identified □ Uncertain □ Cannot be assessed □
Axial/skull base/foraminal invasion: Present □ (**pT4b**) Not identified □ Uncertain □ Cannot be assessed □

Perineural invasion†:** Present □ Not identified □ Uncertain □ Cannot be assessed □
If present: Meets criteria to upstage pT1/pT2 to pT3?****** Yes □ (**pT3**) No □
If yes: Named nerve □ ≥0.1 mm □ Beyond dermis □

Lymphovascular invasion (basosquamous carcinoma only)†:
Present □ Not identified □ Uncertain □ Cannot be assessed □

Margins†:

	Involved	Not involved			Uncertain	Not applicable
		<1 mm	1–5 mm	>5 mm		
Peripheral	□	□	□	□	□	□
Deep	□	□	□	□	□	□

Maximum dimension/diameter of lesion

Indicate which used:

Clinical □ OR Macroscopic □ OR Microscopic □

Dimension†

≤20 mm □ >20 – ≤40 mm □ >40 mm □ Uncertain □ Cannot be assessed □

---

pTNM pT..... (UICC TNM 8)

SNOMED codes……..

COMMENTS

Pathologist……..... **Date……**

*Depth of invasion >6 mm or level of invasion beyond subcutaneous fat.
**Specified perineural invasion: named nerve or diameter ≥0.1 mm or location beyond dermis.
†Data items that are part of the Cancer Outcomes and Services Dataset (COSD) version 8.

Appendix E Reporting proforma for cutaneous basal cell carcinoma removed with therapeutic intent in list format

Element name	Values	Implementation comments
Clinical site	Free text	
Maximum clinical dimensions/diameter	Size in mm	
Specimen type	Single selection value list: • Not stated • Incision, Diagnostic • Excision, Diagnostic • Excision, Therapeutic • Excision, Uncertain • Re-excision • Wider local excision • Punch, Diagnostic • Punch, Therapeutic • Punch, Uncertain • Curettings, Diagnostic • Curettings, Therapeutic • Curettings, Uncertain • Shave, Diagnostic • Shave, Therapeutic • Shave, Uncertain • Other	
Specimen type, Other, Specify	Free text	Only applicable if 'Specimen type, Other' is selected.
Dimension of specimen, Length	Size in mm	
Dimension of specimen, Breadth	Size in mm	
Dimension of specimen, Depth	Size in mm	
Maximum dimension/diameter of lesion	Size in mm	
Lesion dimension not given, reason	Single selection value list • Uncertain • No lesion seen • Not applicable	Not applicable if value given for 'Maximum dimension/diameter of lesion'.

Subtype and risk	Multiple selection value list: • Superficial (low risk) • Nodular (low risk) • Fibroepithelial (low risk) • Infiltrative (infiltrating/sclerosing/ micronodular; high risk) • Basosquamous carcinoma (high risk)	
Deep invasion, Criteria to upstage to pT3	Single selection value list: • Present • Not identified • Not applicable	Not applicable if subtype and risk is 'Superficial' (low risk) only.
Thickness >6 mm	Single selection value list: • Present • Not identified • Not applicable	Not applicable if subtype and risk is 'Superficial' (low risk) only, or if 'Deep invasion, Criteria to upstage to pT3' is 'Not identified'.
Level of invasion beyond subcutaneous fat	Single selection value list: • Present • Not identified • Not applicable	Not applicable if subtype and risk is 'Superficial' (low risk) only, or if 'Deep invasion, Criteria to upstage to pT3' is 'Not identified'.
Level of invasion beyond subcutaneous fat, Specify	Multiple selection value list: • Fascia • Muscle • Perichondrium • Cartilage • Paratendon/tendon • Periosteum • Bone • Not applicable	Only applicable if 'Level of invasion beyond subcutaneous fat, Present' is selected.
Minor bone erosion	Single selection value list: • Present • Not identified • Uncertain • Cannot be assessed • Not applicable	Only applicable if 'Level of invasion beyond subcutaneous fat, Specify, Bone' is selected.
Gross cortical/marrow invasion	Single selection value list: • Present	Only applicable if 'Level of invasion beyond

	• Not identified • Uncertain • Cannot be assessed • Not applicable	subcutaneous fat, Specify, Bone' is selected.
Axial/skull base/foraminal invasion	Single selection value list: • Present • Not identified • Uncertain • Cannot be assessed • Not applicable	Only applicable if 'Level of invasion beyond subcutaneous fat, Specify, Bone' is selected.
Perineural invasion	Single selection value list: • Present • Not identified • Uncertain • Cannot be assessed • Not applicable	Not applicable if subtype and risk is 'Superficial' (low risk) only.
Perineural invasion, criteria to upstage to pT3	Single selection value list: • Yes • No	Only applicable if 'Perineural invasion, Present' is selected.
Perineural invasion, features	Multiple selection value list: • Named nerve • ≥0.1 mm • Beyond dermis	Only applicable if 'Perineural invasion, criteria to upstage to pT3, Yes' is selected.
Lymphovascular invasion	Single value selection list: • Present • Not identified • Uncertain • Cannot be assessed	Only applicable if 'Basosquamous carcinoma' is selected for subtype and risk.
Margins, Peripheral	Single selection value list: • Involved • Not involved but <1 mm • Not involved 1–5 mm • Not involved >5 mm • Uncertain • Not applicable	
Margins, Deep	Single selection value list: • Involved	.

	• Not involved but <1 mm • Not involved 1–5 mm • Not involved >5 mm • Uncertain • Not applicable	
Basis of diameter measurement	Single selection value list: • Clinical • Macroscopic • Microscopic	
Dimension	Single selection value list: • ≤20 mm • >20 – ≤40 mm • >40 mm • Uncertain • Cannot be assessed	
pT category	Single selection value list: • X • 0 • 1 • 2 • 3 • 4a • 4b	
TNM version	UICC8	UICC8 automatically selected.
SNOMED codes	May have multiple codes. Look up from SNOMED tables.	

Appendix F Table of high-risk pathological features for clinical management

A. Basal cell carcinoma and stage

At least one required for high-risk pathology status.

Growth pattern	Infiltrative (infiltrating/sclerosing/micronodular)
Differentiation	Basosquamous
Level of invasion	Beyond subcutaneous fat
Depth/thickness	>6 mm
Perineural invasion	Present
Lymphovascular invasion (basosquamous only)	Present

TNM T category	T2, T3, T4

B. Margins Involved (0 mm) or not involved <1 mm

NB: Low-risk pathological status may be upgraded to overall high risk when summated with clinical risk features as provided by a clinician or within an MDT setting.

Appendix G 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 H AGREE II compliance monitoring sheet

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

AGREE standard	Section of guideline
Scope and purpose	
1 The overall objective(s) of the guideline is (are) specifically described	Foreword, 1
2 The health question(s) covered by the guideline is (are) specifically described	Foreword, 1
3 The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described	Foreword
Stakeholder involvement	
4 The guideline development group includes individuals from all the relevant professional groups	Foreword
5 The views and preferences of the target population (patients, public, etc.) have been sought	Foreword
6 The target users of the guideline are clearly defined	1
Rigour of development	
7 Systematic methods were used to search for evidence	Foreword
8 The criteria for selecting the evidence are clearly described	Foreword
9 The strengths and limitations of the body of evidence are clearly described	Foreword
10 The methods for formulating the recommendations are clearly described	Foreword
11 The health benefits, side effects and risks have been considered in formulating the recommendations	Foreword, 1
12 There is an explicit link between the recommendations and the supporting evidence	1–11
13 The guideline has been externally reviewed by experts prior to its publication	Foreword
14 A procedure for updating the guideline is provided	Foreword
Clarity of presentation	
15 The recommendations are specific and unambiguous	1–11
16 The different options for management of the condition or health issue are clearly presented	1–11
17 Key recommendations are easily identifiable	1–11
Applicability	
18 The guideline describes facilitators and barriers to its application	Foreword
19 The guideline provides advice and/or tools on how the recommendations can be put into practice	Appendices A–F
20 The potential resource implications of applying the recommendations have been considered	Foreword
21 The guideline presents monitoring and/or auditing criteria	12
Editorial independence	
22 The views of the funding body have not influenced the content of the guideline	Foreword
23 Competing interests of guideline development group members have been recorded and addressed	Foreword