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

Standards and datasets for reporting cancers

Dataset for the histological reporting of primary cutaneous basal cell carcinoma

May 2014

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Unique document number	G123
Document name	Dataset for the histological reporting of primary cutaneous basal cell carcinoma
Version number	3
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Date active	May 2014
Date for abridged review	May 2015
Date for full revision	May 2016
Comments	This dataset has been revised to include a redesign of the coding appendix, standardisation of terminology in the reporting proformas and improved clarity of the proforma to better conform to the NCIN Clinical Outcomes and Services Dataset (COSD) for skin, in particular the COSD data collection for AJCC7 staging. In accordance with the College's pre-publications policy, this document was on the College website for an abridged consultation from 4–18 February 2014. Twenty-six items of feedback were received. The authors considered them and amended the document as appropriate. Please email publications@rcpath.org if you wish to see the responses and comments. **Dr Suzy Lishman** **Vice-President for Advocacy and Communications**

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Registered charity in England and Wales, no. 261035

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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 and allowing clinicians to provide a high standard of care for patients and appropriate management for specific clinical circumstances. It may rarely be necessary or even desirable to depart from the guidelines in the interests of specific patients and special circumstances. The clinical risk of departing from the guidelines should be assessed by the relevant multidisciplinary team (MDT); just as adherence to the guidelines may not constitute defence against a claim of negligence, so a decision to deviate from them should not necessarily be deemed negligent.

Each dataset contains **core data items** that are mandated for inclusion in the Cancer Outcomes and Services Dataset (COSD – previously the National Cancer Data Set) in England. Core data items are items that are supported by robust published evidence and are required for cancer staging, optimal patient management and prognosis. Core data items meet the requirements of professional standards (as defined by the Information Standards Board for Health and Social Care [ISB]) and it is recommended that at least 90% of reports on cancer resections should record a full set of core data items. Other, **non-core, data items** are described. These may be included to provide a comprehensive report or to meet local clinical or research requirements. All data items should be clearly defined to allow the unambiguous recording of data.

The following organisations were consulted during its preparation and approved the dataset:

- British Association of Dermatologists (BAD) (co-institutional member of the RCPath Joint Specialty Advisory Committee on Dermatopathology)
- British Society for Dermatopathology (BSD) (institutional member of the RCPath Joint Specialty Advisory Committee on Dermatopathology)
- Participating Members in the National Specialist Dermatopathology External Quality Assessment Scheme (NSDEQA) (member of the RCPath Joint Subcommittee of Dermatopathology)
- National Cancer Intelligence Network (NCIN).

This dataset has been constructed taking into account the new strong evidence base that is contained in, and forms the basis for, the following new national and international publications. All publications have widespread national and/or international peer acceptance and reflect the current accepted professional standards and practice in skin cancer.

- COSD published by NCIN[5]
- Clinical guidelines published by the BAD and other professional bodies[6]
- World Health Organization (WHO) Classification of Skin Tumours[7]
- Armed Forces Institute of Pathology (AFIP) Atlas of Tumour Pathology[8]
- National Institute for Health and Clinical Excellence (NICE) Guidance on Cancer Series[9,10]
- National Cancer Peer Review (NCPR) Program by the Department of Heath Cancer Action Team[11]
- NHS Evidence[12]
- National Comprehensive Cancer Network (NCCN)[13]

As well as peer-reviewed scientific publications, consideration has also been given to published evidence and expert opinion on the internet, such as Dermpedia (www.Dermpedia.com).

Evidence for the revised dataset was also obtained by electronically searching medical literature databases for relevant research evidence, systematic reviews and national or international publications on skin cancer up to November 2013. This identified no evidence to alter the views or conclusions of the publications listed above. The evidence has been evaluated according to the modified SIGN guidance and the level of evidence for the recommendations has been summarised according to College guidance (see Appendix F). Most of the supporting evidence is grade C or D or meets the GPP (Good Practice Point) criteria. No major conflicts in the evidence have been identified and any minor discrepancies between evidence have been resolved by expert consensus.

No major organisational changes have been identified that would hinder the implementation of the dataset, which is fully integrated with the Cancer Outcomes and Services Dataset, 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 sub-specialty adviser to the College, to consider whether or not the dataset needs to be updated or revised. A full consultation process will be undertaken if major revisions are required, i.e. revisions to core data items (the only exception being changes to international tumour grading and staging schemes that have been approved by the Specialty Advisory Committee on Cellular Pathology and affiliated professional bodies; these changes will be implemented without further consultation). If minor revisions or changes to non-core data items are required, an abridged consultation process will be undertaken whereby a short note of the proposed changes will be placed on the College website for two weeks for 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. All changes will be documented in the 'data control' section of the relevant dataset.

The dataset has been reviewed by the WGCS and was placed on the College website for an abridged consultation with the membership from 4–18 February 2014. All comments received from the WGCS and membership were addressed by the authors, to the satisfaction of the WGCS Chair and the Vice-President for Advocacy and Communications.

This dataset was developed without external funding to the writing group. The College requires the authors of datasets to provide a list of potential conflicts of interest; these are monitored by the Clinical Effectiveness Department and are available on request.

1 Introduction

1.1 Purpose of the dataset

This document provides the dataset for the histological reporting of basal cell carcinoma. Although the data items remain largely unchanged from the previous edition, in some instances their usage now has revised implications for the treatment, management and prognosis.

The meticulous diagnosis and reporting of basal cell carcinoma is important because histological parameters play a major role in defining patient treatment. Although the mortality from basal cell carcinoma is low, its morbidity level can be very high and its potential adverse cosmetic effects can be distressing to patients. Similarly, the recording of pathological parameters in the dataset has direct implications for the prognosis of individual patients.

The use of datasets (and the background information that forms part of the datasets) in the context of the multidisciplinary team (MDT) meeting is advocated to optimise decisions related to patient treatment, to facilitate regular audit and review of all aspects of the service,

to enable the collection of accurate data for Cancer Registries and to provide feedback for those caring for patients with cancer. It is important to have robust local mechanisms in place to ensure that the MDT Clinical Leads and Cancer Registries are apprised of supplementary or revised histology reports that may affect patient treatment and data collection.

1.2 Changes since the previous edition

The revised dataset is largely based on the previous edition. The main alterations are as follows.

a) Staging

It is essential to accommodate the changes in the international staging of basal cell carcinoma introduced in 2010.

Ideally, staging of basal cell carcinoma should be based on the latest published edition of the tumour, node and metastasis (TNM) categorisation of malignant tumours published by the International Union against Cancer (UICC).[1] It has been internationally agreed that this should be identical to the same staging edition published by the American Joint Committee on Cancer (AJCC).[2] When published, however, it was clear that the UICC 7th edition contained significant differences in relation to skin cancer. These differences, in particular in relation to melanoma, have been partly corrected in a subsequent TNM supplement.[3] The preface contains a statement of policy that the 7th edition of the UICC TNM Classification and Staging is still intended to correspond to the 7th edition of AJCC. Furthermore, in 'Frequently asked questions', UICC states for the sake of uniformity that it has adopted AJCC criteria for skin cancer and specifically acceptance of 2 mm tumour thickness as a high-risk feature for non-melanoma skin cancer (except basal cell carcinoma and Merkel cell carcinoma). In the main text, however, UICC has failed to incorporate AJCC high-risk factors, states 4 mm in error, and uses different staging definitions for T3 and T4 disease.[3] This difference is of importance as UICC has thereby failed to align cutaneous squamous cell carcinoma of the head and neck with cutaneous squamous cell carcinoma at other sites. On that basis, after widespread consultation, The Royal College of Pathologists advised its members to use the AJCC 7th edition for skin cancer.[4] For the same reason, a similar decision was made by the NCIN.

Several important differences occur in the new AJCC 7th edition compared to the 6th edition.

1. Non-melanoma skin cancer is now divided into two separate chapters with different staging criteria. The two chapters are titled 'Merkel cell carcinoma' and 'Cutaneous squamous cell carcinoma and other cutaneous carcinomas'.

2. There is now no additional tumour staging breakpoint based on diameter for lesions over 20 mm diameter for non-melanoma skin cancer (except Merkel cell carcinoma).

3. As many basal cell carcinomas occur on the head and neck, staging of cutaneous tumours has been aligned with the previous AJCC Head and Neck Staging System. In particular, this has resulted in changes to T3 and T4 staging criteria.

4. Clinical and histological high-risk features are now defined that can upstage from T1 to T2 for cutaneous squamous cell carcinoma and an aggressive subset of non-melanoma skin cancer. AJCC, however, states that these rarely apply to basal cell carcinoma. Accordingly, after national and international consultation, the RCPath and NCIN have adopted the view that currently these will not be applied to basal cell carcinoma as no evidence base or advice to indicate when these items should collected has been published. Routine collection would entail considerable extra time and cost for such a common malignancy, with no known current clinical benefit. There may some logic to include any squamous cell carcinoma high-risk features present in basosquamous

carcinoma and these can be entered as either non-core data items or free-text comments.

5. There is now a new nodal staging system based on the diameter of metastatic deposits and the number and location of nodes involved. In view of their extreme rarity, however, this has not been included in the current dataset and, if necessary, reference should be made to the identical AJCC nodal staging system in the RCPath's 2014 cutaneous squamous cell carcinoma dataset.

b) Core and non-core data items

In contrast to the first edition of this dataset, data items are now divided into core and non-core types. As defined in the foreword, core items in the RCPath 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 part of the Clinical Lines of Enquiry for the NCPR Program. The core and non-core pathological data items are summarised in proforma style, which may be used as the main reporting format or combined with free text as required. The use of proformas and checklists significantly improves the quality of skin cancer histopathology reports.

c) Lymph nodes

Although there is a new nodal staging system for basal cell carcinoma, in view of the great rarity of metastasis of such tumours to lymph nodes, a specific reporting proforma has not been devised. In the eventuality of this occurrence, the cutaneous squamous cell carcinoma nodal proforma should be modified, as AJCC nodal staging is identical for the two cancers.

d) Risk status

National clinical guidelines on both basal and squamous cell carcinoma have introduced the concept of risk status. In broad terms, high risk correlates with significantly greater clinical risk for recurrent disease and/or metastatic potential. The evidence base for this has been endorsed by both NICE and the NHS Cancer Action Team in its publications. Knowledge of risk status is now vital for the correct clinical management and 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. High-risk cases can only be managed in primary care by a Model 2 practitioner, after discussion with a core member of the skin cancer MDT.

Accordingly a new data item is required in the form of an entry as to whether the cancer is of low- or high-risk type, based on pathological and known clinical parameters. It is acknowledged that subsequent additional knowledge of clinical high-risk factors, unknown or uncertain at the time of reporting, may upgrade low risk to high risk at a later point in time and in particular during skin cancer MDT discussion.

e) Margins

In the previous edition of the dataset, peripheral and deep margins over 1 mm were measured as whole integers. This remains as a non-core item in this edition. The new core requirement is measuring <1 mm, 1–5 mm and >5 mm.

1.3 Target users and health benefits of this guideline

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

2 Clinical information required on the specimen request form

The clinical data are based on the National Clinical Guidelines[6] core and site-specific items, COSD[5] and the draft UK National Histopathology Request Form (Appendix C), and are required by NICE.[9] Provision of clinical information is the responsibility of the clinician submitting a specimen. This will be required to complete the COSD and for MDT discussion to consider any clinical high-risk factors in relation to both management and treatment.

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

3 Preparation of specimens before dissection

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 naked eye must be recorded. When a lesion is apparent, measurements should include the maximum diameter and 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, incisional, shave and punch biopsies as these are not performed for excisional purposes.

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

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 is 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.

The more of the specimen that is examined, the more accurate the assessment of the surgical margins will be. Accordingly, for specimens under 10 mm, it is recommended that most or all of the lesion is examined. For specimens over 10 mm, the extent of sampling should take into account the proximity of the lesion to the margins, maximum lesional thickness, lesional uniformity and any unusual features. When the lesion can be clearly identified, sampling the polar margins of skin ellipses should be discretionary and based 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 cruciate margins at 3, 6, 9 and 12 o’clock can be sampled, although the limitation in assessing margin clearance should be appreciated.

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 should be recorded on the pathology report are the site and type of specimen.

5.2 Pathological

5.2.1 Macroscopic

Specimen and lesion size

The three dimensional size of the specimen should be recorded in millimetres. The maximum diameter of all lesions should be recorded in millimetres.

5.2.2 Microscopic

a) Histopathological subtype

Some subtypes of basal cell carcinoma are regarded as clinically high-risk variants, in National Clinical Guidelines, by NICE and NCPR for skin cancer MDT discussion.[6,9,11] 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.[7,6,13] 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 clinical and NCPR 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 (i) growth pattern and (ii) differentiation.

i. Growth pattern

This can be usefully divided into subtypes of low (indolent) or high (aggressive) biological risk status.

Low-risk subtypes

A. 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 agreement 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 agreement 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 mm for the definition of superficial basal cell carcinoma but, to date, there appears to be no consensus agreement. All, studies, however, have suggested figures less than 1 mm.

B. 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 in part B below).

C. Fibroepithelial basal cell carcinoma (of Pinkus). Although there is debate about the nosological status of this entity, and specifically whether it represents a basal cell carcinoma or benign trichoblastoma, the WHO regard it as a low-risk basal cell carcinoma. The Royal College of Pathologists has similarly adopted the WHO approach, as the lesion can certainly occur in association with high-risk variants of basal cell carcinoma.

High-risk subtypes

A. 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.

B. 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 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, to distinguish between high-risk infiltrating, sclerosing and micronodular variants. These often co-exist in the same tumour with overlap forms. There has therefore been a recent proposal to combine all three high-risk subtypes under the one generic term of 'infiltrative basal cell carcinoma'. Accordingly, this logical proposal has been adopted in this dataset.[14] Reporting the different subtypes individually, however, remains as 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 know 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) that is present, irrespective of percentage or location. This

approach is also supported internationally by the National Comprehensive Clinical Network and conforms to tumour grading in general.[13] Accordingly, if high-risk components are present, any accompanying low-risk components need not be recorded.

Although many basal cell carcinomas are clearly invasive, there is an interesting consideration as to 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- or high-risk 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.

ii. Differentiation

The types of histological differentiation of basal cell carcinoma need not be recorded in the 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, infundibulocystic, follicular or matricial components. Basal cell carcinomas with myoepithelial or neuroendocrine differentiation are also reported. Also, basal cell carcinoma can be associated with a benign pseudocarcinomatous squamous cell proliferation in the adjacent epidermis. The importance, however, of atypical squamous differentiation in basal cell carcinoma appears to have greater biological significance although the topic has been complicated by variable use of definitions for 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.[7] 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’. This approach is consistent with that adopted by the WHO.[7] 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.[7]

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.

[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 – Level of evidence C.]

b) Level of invasion

Invasion of basal cell carcinoma into facial or cranial bones (maxilla, mandible, orbit and temporal bone) is a determinant for pT3 in AJCC7.[2] Invasion into the skull base or invasion of skeleton (axial or appendicular) is a determinant for pT4 in AJCC7.[2] In addition, NICE regards invasion into the subcutaneous fat (Clark level 5) or beyond as a clinical high-risk factor in the context of skin cancer MDT management.[9] This is also supported by the WHO.[7] This information is not required for superficial basal cell carcinoma.

[Level of invasion is a primary staging determinant – Level of evidence B.]

c) Perineural and lymphovascular invasion

Perineural invasion of the skull base is a determinant of stage pT4 in AJCC7.[2] Perineural invasion is a clinical high-risk factor in the National Clinical Guidelines and by NICE for skin cancer MDT management.[6,9] Perineural invasion is also a site-specific item in the COSD.[5] 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. 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' (RPI). This reflects the presence of benign perineural epithelial cells in previously biopsied areas, most likely representing reactive/reparative proliferation of traumatised eccrine sweat gland ducts into a plane of lower resistance.[15] Immunohistology can be used to make the distinction.

The evidence base to suggest that vascular invasion correlates with recurrence, metastasis or prognosis is less strong. Lymphovascular invasion is, however, an additional descriptor in AJCC7,[2] a clinical high-risk factor in the National Clinical Guidelines and supported by NICE for skin cancer MDT management.[6,9] The presence of an endothelial-lined space is an essential criterion for lymphovascular invasion, because it is important to distinguish 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, though the latter organisations do not clarify 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, The Royal College of Pathologists 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 Comment section.

Perineural invasion is a primary staging determinant and also correlates with local recurrence – Level of evidence B.]

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

d) 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. The term 'complete' is more acceptable in the context of Mohs' surgery where the peripheral margin has been examined in its entirety. 'Adequacy' implies a degree of clinicopathological judgement and is therefore more applicable in the context of skin cancer MDT discussion. It is well recognised, in a significant number of cases where tumour extends to a margin, that there is no residual tumour present on re-excision. This confirms that the term 'incomplete' can be inappropriate in this situation. In non-excision specimens (such as curettings), the term 'edge' may be more appropriate, as the edge may not reflect the true surgical margin.

Although evidence is more robust for peripheral margins, there is broad peer agreement that comments are necessary about the clearance 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 clear or involved by tumour. 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 and 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 this varies between 3 and 15 mm.[6] 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. The figures vary according to growth pattern and approximately 10% of infiltrative basal cell carcinomas with margins greater than 0.75 mm will recur. On that basis an evidence-based histological definition of 'close' is still awaited. Accordingly, the reporting of margins below 1 mm to one decimal point cannot be supported as a core item, although this is a non-core option.

Consultation with the BAD has revealed strong support for clinical purposes, to know whether basal (and squamous cell) carcinoma excision margins are histologically involved
(0 mm), 'close' as defined below 1 mm, and 'clear' above 1 mm. Approximately one-third of dermatologists in the East Midlands SHA, when audited, regarded histological margins below 1 mm as effectively involved, although this was not sufficiently consistent to justify adopting the approach in the current dataset.

As a core data element for all cancers, the COSD records whether tumour excision margins are clear by more than 5 mm, clear by greater than 1 mm but less than or equal to 5 mm, or present less than or equal to 1 mm but without tumour reaching the margin.[5.] Skin cancer margins should therefore be measured in relation to both 1 mm and 5 mm breakpoints. There is also additional peer support to audit the excision margins of all skin cancer specimens between different Trusts and general practices

within a Cancer Network and between different clinical specialities and clinicians. Measuring resection margins over 1 mm histologically to within 1 mm is one way to facilitate this objective and this could also represent a reasonable surrogate marker for clinical margins 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 mm 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 '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 cutaneous squamous cell carcinoma, including hair-bearing lip.

This dataset defines margin clearance that is either involved or less than 1 mm as high risk. Using less than 1 mm as the definition takes into account the absence of a strong 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.

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

e) Maximum diameter

A diameter of greater than 20 mm is the break-point determinant in distinguishing pT1 and pT2 in AJCC7.[2] It is uncertain from AJCC7 whether the diameter measurement is based on clinical or histopathological measurements, although there is a possibility that the AJCC database may be based on clinical measurements. This dataset has adopted the broad approach of using pathological measurements for pT staging of non-melanoma skin cancer. A pragmatic approach is recommended for each individual case as to whether the measurement is based on macroscopic and/or microscopic dimensions. This should be in millimetres.

NICE has also defined parameters to indicate which basal cell carcinomas may be managed and treated in the community/primary care. These are defined by the degree of specialist training and resulting practitioner contracts (DES/LES, Model 1 and Model 2). These include basal cell carcinomas with a diameter <10 mm. For this reason, the size of basal cell carcinomas below, at or greater than 10 mm must be recorded. This stratification for clinical management in the community is slightly different from the risk stratification for MDT referral.

[Maximum diameter is a primary staging determinant – Level of evidence B.]

f) BCC pathology risk status

This has been integrated from AJCC7,[2] BAD,[6] NICE,[9] NICE Update,[10] NCPR,[11] WHO,[7] AFIP[8] and National Comprehensive Clinical Network (NCCN).[13.] Risk status is required for skin cancer MDT discussion, based on NICE Skin Cancer Guidance and NCPR requirements for the following reasons:

i. to decide whether treatment in primary or secondary care is appropriate; competence and thereby permission to treat BCC in primary care has formal professional restrictions and these are defined by the type of practitioner contract (see section 6.1)

ii. to assess the extent of desirable margin clearance

iii. to facilitate skin cancer MDT action and decision making as necessary

iv. to help decide on follow-up: duration and primary/secondary care.

High-risk status relates to risk of persistent or recurrent local disease. 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. High-risk pathological features are listed below.

The pathology risk status is reported as a core item, under the two subheadings of BCC and stage and margin clearance, to provide clinical guidance relating to management, treatment and prognosis. It 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 a clinician and/or in an MDT setting.

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 (supplied by a clinician and/or emerging at an MDT).

High-risk pathological factors (see Appendix E)

A. BCC and stage

Any one equals high risk.

i. Growth pattern: infiltrating/morphoeic and/or micronodular
   BAD/NICE/WHO/NCCN
   NCCN – High-risk component in any part of lesion
   RCPath: High-risk component in any part of lesion

ii. Differentiation: basosquamous carcinoma
   BAD/NICE/WHO
   RCPath: Basosquamous carcinoma

iii. Level of invasion to Clark level 5 or beyond
   NICE/WHO
   RCPath: Clark level 5 or beyond

iv. Perineural invasion present
   BAD/NICE/WHO/NCCN
   Perineural invasion present below dermis NICE Update
   RCPath: Perineural invasion

v. Lymphovascular invasion present
   BAD
   RCPath: Lymphovascular invasion present in basosquamous carcinoma

vi. TNM pathological (p) stage T2, T3, T4
   BAD/NICE
   RCPath: pT2, pT3, pT4.

B. Margins

Margins that are involved (0 mm) or less than 1 mm
BAD
RCPath: Margins that are involved (0 mm) or less than 1 mm.

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

6 Non-core data items

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

6.1 Clinical

These are based on the National Clinical Guidelines,[6] core and site-specific items in COSD[5] and the draft UK National Histopathology Request Form (Appendix C).

They also conform to NICE requirements[9] and can be captured if provided by the clinician.

- Date of surgical procedure.
- Grade of clinician undertaking procedure.
- Clinical diagnosis/description.
- Procedure intention of clinician (diagnostic or therapeutic biopsy).
- Measured surgical clinical peripheral margin (mm).
- Is this a tumour recurrence?
- Previous histology reference number(s).
- Is the patient immunocompromised?
- Is this a tumour arising in an area of radiation or thermal injury, chronic draining sinus, chronic ulcer or chronic inflammation?
- Is the tumour arising is an individual genetically predisposed to cancer?
- Has the tumour been previously treated using topical medication? The latter may reduce the likelihood of finding tumour histologically.
- Clinical high-risk factors for BCC for skin cancer MDT treatment and management[9,10,11] (any one equals high risk):

anatomic location – central face, around eyes, nose, lip or ears	BAD[6]
recurrent at site	BAD[6]
persistent at site	NICE update[11]
reduced immune status	BAD[6]
genetic (e.g. Gorlins)	BAD.[6]

NICE update: Definition of low-risk BCC for management in the community [11]

- >24 years.
- 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 risk stratification and MDT referral in secondary care. Whereas originally applicable to all suitably trained and accredited practitioners in primary care, there have been subsequent modifications of the practitioner contract. On a DES/LES contract, the above list is still applicable. On a Model 1 contract, the diameter now 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. On a Model 2 contract, the above list and limitations are not applicable.

6.2 Pathological

- Comment on the presence of infiltrating and/or sclerosing and/or micronodular components in high-risk infiltrative basal cell carcinoma.
- Margins: below 1 mm measure to nearest 0.1 mm or 0.5 mm.
- Margins: over 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 close margin.
- 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 mms.
- Differentiation: basosquamous carcinoma – percentage of squamous component present and squamous carcinoma dataset information.
- Perineural invasion: location and whether intratumoral, extratumoual, below dermis or multifocal, and distance to nearest margin. The diameter of nerves involved.
- Thickness: (a) below 1 mm to the nearest 0.1 mm (b) at or over 1 mm to the nearest whole integer.
- Whether dermal regression present and distance to nearest margin in mm.
- In incisional biopsies whether subcutaneous fat present.
- The Royal College of Pathologists recognises that many clinicians and MDTs look for guidance from their histopathologists regarding the probability/likelihood of 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 not unreasonable though 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.

  Suggested terminology for a subjective probability statement on the likelihood of tumour clearance could include:
  - clearance appears 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 coding and staging

TNM and SNOMED are required for the COSD.[5]

7.1 pTNM status

pTNM status must be recorded according to the 7th edition AJCC.[2]

TNM stage grouping should be deferred until all current TNM information is available and if appropriate after skin cancer MDT discussion.

A 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 group based on the information in the report.

General principles

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

Additional descriptors can be used.

The suffix 'm' indicates the presence of multiple primary tumours in a single site and is recorded in parentheses: pT(m) N M

The 'r' prefix indicates a recurrent tumour when staging is carried out after a documented disease-free interval. 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. These are audited as part of the RCPath key performance indicators (KPIs). P codes vary according to the SNOMED system in use in different organisations, therefore local P codes should be recorded and used for audit purposes.

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

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.

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 BCCs can only be treated in primary care by appropriately trained and accredited practitioners. All other BCCs must be treated in secondary care or by a Model 2 practitioner in primary care.[9,10]

BCC cases requiring local skin cancer MDT referral:[9]

- high-risk BCCs that involve the excision margins
- patients for Mohs surgery
- immunocompromised patients.

Patients requiring specialist skin cancer MDT referral:[9]

- metastatic BCCs
- 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 histological margins less than 1 mm remains an individual clinical decision or a locally agreed decision. Margins less than 1 mm are, however, a defined high-risk pathological parameter, indicating 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 and 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 which 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 1–4 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 of the dataset

12.1 Recommended by NICE: [9]

- skin cancer excision margins between specialities and clinicians
- skin cancer specimens in primary care
- histopathology reporting times (see below)
- audit of all BCCs and SCCs not discussed at the MDT.

12.2 Recommended by the RCPath as key performance indicators (KPIs)

(see *Key Performance Indicators – Proposals for implementation* (July 2013) on www.rcpath.org/clinical-effectiveness/kpi/KPI):

- Cancer resections must be reported using a template or proforma, including items listed in the English COSD which are, by definition, core data items in RCPath cancer datasets. English Trusts are required to implement the structured recording of core pathology data in the COSD by January 2014.

  Standard: 95% of reports must contain structured data

- Histopathology cases that are reported, confirmed and authorised within seven and ten calendar days of the procedure.

  Standard: 80% of cases must be reported within seven calendar days and 90% within ten calendar days.

13 Acknowledgements

Phillip McKee is acknowledged for his contribution to the first edition of this dataset. The numerous colleagues who offered useful advice during the extensive informal professional consultation about this dataset are acknowledged; their views have been listened to carefully.

The late A Bernard Ackerman MD is acknowledged and 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 AJCC7 pathological staging of basal cell carcinoma

Basal cell carcinoma, squamous cell carcinoma and adnexal carcinoma but excluding Merkel cell carcinoma and carcinomas of eyelid, vulva and penis

Definitions of TNM

Primary tumour (T)*

TX Primary tumour cannot be assessed

T0 No evidence of primary tumour

Tis Carcinoma *in situ*

T1 Tumour 20 mm or less in greatest dimension and (*with the exception of BCC**) with less than two high-risk features*

T2 Tumour greater than 20 mm in greatest dimension *or* (*with the exception of BCC**) any size and with two or more high-risk features*

T3 Tumour with invasion of maxilla, mandible, orbit or temporal bone

T4 Tumour with invasion of skeleton (axial or appendicular) or perineural invasion of skull base

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

Depth/invasion	>2 mm thickness
	Clark level ≥4
	Perineural invasion
Anatomic location	Primary site ear
	Primary site non-hair-bearing lip
Differentiation	Poorly differentiated or undifferentiated

* Stated in AJCC7 to rarely apply to BCC and therefore not included in the staging of basal cell carcinoma by the RCPath and NCIN.

Regional lymph nodes (N)

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

Distant metastasis (M)

M0	No distant metastases
M1	Distant metastases

Anatomic stage/prognostic groups

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	N1	M0
	T2	N1	M0
	T3	N1	M0
Stage IV	T1	N2	M0
	T2	N2	M0
	T3	N2	M0
	T Any	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	M80943	Infiltrating basal cell carcinoma (morphologic abnormality)	56665009
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 NCIN Skin Site Specific Reference Group and kindly provided for the RCPath dataset information by the NCIN. Permission for use should be sought from the NCIN.

This histopathology request form is approved by the BAD; the mode of national implementation is under consultation.

The UK National Histopathology Request form for skin biopsies

Date of surgical procedure

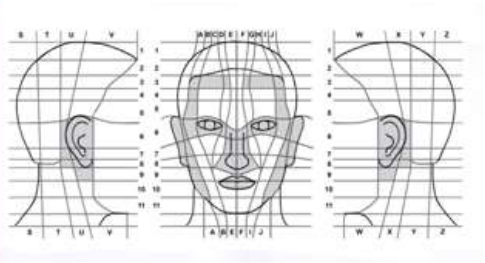
Please attach patient details

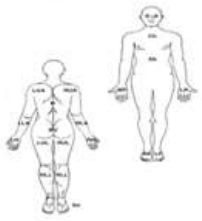
Name of surgeon

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 Histology reporting proforma for basal cell carcinoma

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

Clinical data

Clinical site ……

Specimen type:

Excisional biopsy □ Incisional (diagnostic) biopsy □ Punch biopsy □ Shave □
Curettings (Therapeutic) □ Curettings (Diagnostic) □ Curettings(Not specified) □
Other □ Please specify ……

Macroscopic description

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

Histological data

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

Level of invasion*: Dermis □ Extradermal □

If extradermal specify tissue: Fat □ Muscle □ Fascia □ Perichondrium □
Cartilage □ Paratendon/tendon □ Periosteum □ Bone □

If bone invasion present:

Invasion of maxilla, mandible, orbit or temporal bone: No □ Yes (pT3) □ Uncertain □ Cannot be assessed □
Invasion of skeleton (axial or appendicular): No □ Yes (pT4) □ Uncertain □ Cannot be assessed □

Perineural invasion*: Not identified □ Present □ Uncertain □ Cannot be assessed □

If perineural invasion present:

Perineural invasion of skull base: No □ Yes (pT4) □ Uncertain □ Cannot be assessed □

Lymphovascular invasion (basosquamous carcinoma only):

Not identified □ Present □ Uncertain □ Cannot be assessed □

Margins:

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

Maximum diameter (macroscopic and/or microscopic):

<10 mm □ 10–20 mm □ >20 mm □ Uncertain □ Cannot be assessed □

TNM pathological (p) stage

(AJCC7).....

Pathological risk status for clinical management

BCC and stage Low □ High □
Margins Low □ High □

SNOMED codes……..

COMMENTS

Pathologist……..... **Date……**

*** Not required for pure superficial BCC**

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

A. BCC and stage

At least one required for high-risk pathology **status**.

Growth pattern	Infiltrative (infiltrating/sclerosing/micronodular)
Differentiation	Basosquamous
Level of invasion	Subcutaneous fat and beyond
Perineural invasion	Present
Lymphovascular invasion (basosquamous only)	Present
TNM stage	pT2, T3, T4

B. Margins

Involved (0 mm) or < 1 mm

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

Appendix F 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 G AGREE compliance monitoring sheet

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

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

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