Improving outcomes for people with skin tumours including melanoma (update):

The management of low-risk basal cell carcinomas in the community
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Foreword

The importance of basal cell carcinoma (BCC) is underestimated, probably because it is rarely fatal. However, BCC is the commonest type of cancer in England and Wales.

Patients want their low-risk BCCs to be treated effectively the first time, with minimal risk of recurrence and the best cosmetic result possible. Should surgery be required, patients want their healthcare professionals to ensure that the risk of damaging important, proximate anatomical features, such as nerves, is kept to a minimum if possible.

Patients and their carers want their low-risk BCCs to be accurately diagnosed and then to be treated by healthcare professionals who:

- have been adequately trained
- are aware of the full range of treatment options
- have met prescribed standards
- participate in audit
- undertake continuing professional development (CPD) in this clinical area
- keep a ‘fail-safe’ log of samples sent to the laboratory, reports received and action taken.

Following consideration of the range of clinical presentations of low-risk BCCs, the volume of work they produce and the evidence from clinical audit studies, three models for the management of low-risk BCC in the community have been recommended in this updated guidance. These match the risk of inadequate excision and poor cosmetic results to increasing skill levels of healthcare professionals. Underpinning the clinical governance arrangements is the need for all practitioners to be accredited and to participate in audit and CPD.

It is hoped that implementation of this guidance will lead to improvements in the quality of the management of low-risk BCC in the community.

I would like to thank the members of the Guidance Development Group (GDG) for their wisdom and patient-centred approach to the guidance update and to the staff at the National Collaborating Centre for Cancer (NCC-C) for their hard work and attention to detail during development of this guidance.

Dr Julia Verne, GDG Chair
Methodology

Background

In February 2006, the National Institute for Health and Clinical Excellence (NICE) published service guidance on skin cancer, ‘Improving outcomes for people with skin tumours including melanoma’ (NICE guidance on cancer services)\(^1\). Many of the recommendations in this guidance were converted into peer review measures published in the ‘Manual for cancer services 2008: skin measures’\(^2\).

Early in 2009, NICE was made aware of concerns about the implementation of some aspects of its guidance on skin cancer services. These were in relation to the arrangements under which GPs could remove ‘low-risk’ basal cell carcinomas (BCCs) and how services for skin cancer patients were being commissioned. In April 2009, the National Collaborating Centre for Cancer (NCC-C) was commissioned by NICE to update the 2006 guidance to specifically address the management of low-risk BCCs in the community.

This document updates the recommendations on the management of low-risk BCCs in the community. All recommendations on this topic contained within the original guidance\(^3\) have been withdrawn and are superseeded by the recommendations presented in this update. However all remaining recommendations in the original guidance are still valid and can be accessed via the NICE website (www.nice.org.uk/XX). [Note: these details will apply when the guidance update is published.]

It has been agreed that the 2007 Department of Health guidance relating to General Practitioners with a special interest (GPwSIs) in dermatology and skin surgery\(^4\) will be updated to take account of the recommendations presented in this update. This work is scheduled to start in July 2010 and will be funded by the Department of Health.

What is service guidance?

Service guidance is a series of recommendations for the organisation and delivery of care for individuals in specific clinical conditions or circumstances – from prevention and self-care through to primary and secondary care and onto more specialised services. NICE service guidance is based on the best available evidence of clinical and cost effectiveness, and is produced to help commissioners, healthcare professionals and patients make informed choices about appropriate healthcare. It should be noted that most of the published research on cancer topics focuses on clinical evaluations of treatment; little direct research has been carried out on the organisation and delivery of services.

This service guidance is intended to guide health organisations (for example, primary care trusts, local health boards, cancer networks and trusts), and their managers and healthcare

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professionals, in improving the effectiveness and efficiency of services for people with low-risk BCC being managed in the community. The information and recommendations in this update are based on reviews of the best available evidence, including service delivery.

Who is the guidance intended for?

This guidance is relevant to all commissioners and healthcare professionals who are responsible for the planning and delivery of the management of low-risk BCC in the community, as well as to the patients themselves and their carers. It is also expected that this guidance will be of significant value to those involved in clinical governance in both primary and secondary care to help ensure that arrangements are in place to deliver appropriate care in these settings.

The remit of the guidance update

The following remit for this guidance update was received from NICE:

- ‘To update the ‘Improving outcomes guidance for people with skin tumours including melanoma’ relating specifically to the management of low-risk basal cell carcinomas in the community’.

The purpose of this remit was to:

- provide an overview of what the update would include (and exclude)
- identify the key aspects of care that must be included
- set the boundaries of the development work and provide a clear framework to enable work to stay within the priorities agreed by NICE and the NCC-C and the remit
- inform the development of the search strategy.

The remit was then translated into the following well-defined clinical question by the GDG Chair and staff at the NCC-C:

- ‘Do outcomes differ when the excisional surgery of a suspicious skin lesion is performed by a general practitioner compared with a specialist in secondary care?’.

Involvement of stakeholders

Details of the guideline development process can be found on the NICE website or in the ‘NICE guidelines manual 2009’. The relevant professional and patient/carer organisations that register as stakeholders are key to the development of all NICE guidance. In brief, their contribution involves submitting relevant evidence and commenting on the draft version of the guidance during the consultation period. A full list of all stakeholder organisations who registered for this update can be found in Appendix 1.2.


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The process of guidance development

Overview

Unlike clinical guidelines developed by NICE, there is no expectation to update the set of 'Improving outcomes guidance' on cancer services developed by the Department of Health and NICE between 1998 and 2006. However due to reasons described earlier in this section, this update represents an 'exceptional update' as defined in the 'NICE guidelines manual 2009' and follows the same methodology as that described for a partial guideline update. It should be noted that development of the original guidance was in accordance with the NICE guidelines manual in use at that time.

The GDG (a team of healthcare professionals, lay members and technical experts, see Appendix 1.1), with support from the NCC-C staff (Appendix 1.3), undertook the development of this update. The basic steps in the process of developing an update are:

- using the remit and defining the clinical question, which sets the parameters of the update
- forming the GDG
- systematically searching for the evidence
- critically appraising the evidence
- incorporating health economic evidence (if appropriate)
- distilling and synthesising the evidence and writing recommendations
- agreeing the recommendations
- structuring and writing the guidance.

The Guidance Development Group (GDG)

The GDG for this guidance update was recruited in line with the existing NICE methodology as set out in the 'NICE guidelines manual 2009'. The first step was to appoint a Chair. It was agreed by NICE that the Chair of the original GDG, Dr Julia Verne, should chair the new GDG. The NCC-C Director and GDG Chair identified a list of specialties that needed to be represented on the GDG. An open advertisement was placed on the NICE website and requests for applications were also sent to the main stakeholder organisations and patient

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10 http://www.nice.org.uk/Guidance/CSG/Published
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organisations/charities (see Appendix 1.2) and all cancer networks in England and Wales.

Individual GDG members were selected by the NCC-C Director and GDG Chair, based on their application forms.

The guidance development process was supported by staff from the NCC-C, who undertook the literature searches, reviewed and presented the evidence to the GDG, managed the process and contributed to drafting the guidance. At the start of the guidance development process all GDG members’ interests were recorded on a standard declaration form that covered consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared new, arising conflicts of interest, which were always recorded (see Appendix 1.1).

Guidance Development Group meetings

Two GDG meetings were held on 9–10 November 2009 and 21 January 2010. During the first GDG meeting (held over two days) the clinical evidence was reviewed, assessed and recommendations drafted. At the second meeting the GDG reviewed and responded to stakeholder comments and produced the final draft of the guidance.

Patient/carer members

Individuals with direct experience of skin cancer gave an integral user focus to the GDG and the guidance development process. The GDG included two patient/carer members. They contributed as full GDG members to addressing the clinical question, helping to ensure that the evidence addressed their views and preferences, highlighting sensitive issues and terminology relevant to the guidance, and bringing service-user research to the attention of the GDG.

Developing the clinical evidence-based question

Background

The remit for this update was very clear about which patient groups were included and which areas of clinical care should be considered. The clinical question and search strategy that covered this topic within the original skin cancer guidance was updated and the evidence search re-run from 19 May 2005.

All the evidence used to inform this update is summarised in the accompanying full evidence review ‘Improving outcomes for people with skin tumours including melanoma (update): the management of low-risk basal cell carcinomas in the community – evidence review’, which includes details of all the studies appraised.

Method

For the clinical question within this update the PICO framework was used. This structured approach divides each question into four components: the patients (the population under study – P), the interventions (what is being done – I), the comparisons (other main treatment options – C) and the outcomes (the measures of how effective the interventions have been – O).
Care pathway

During the development process the GDG prepared a care pathway (or algorithms) in order to explore how patients with low-risk BCC in the community might access treatment and be treated in the NHS (see ‘Algorithms’ pages 13–14).

Review of clinical literature

At the beginning of the development phase, searches were carried out to identify any relevant guidelines (local, national or international) produced by groups or institutions, since 2006. Additionally, stakeholder organisations and cancer networks across England and Wales were invited to submit evidence for consideration by the GDG, including audits, abstracts and local care pathways. All relevant evidence was appraised and included in the evidence review.

In order to answer the clinical question, the NCC-C information specialist developed an updated search strategy (based on the strategy for the original 2006 guidance) to identify relevant published evidence. Papers that were published or accepted for publication in peer-reviewed journals from 19 May 2005 were considered as evidence. No language restrictions were applied to the search; however, foreign language papers were not requested or reviewed (unless of particular importance to the clinical question).

The following databases were included in the literature search:

- The Cochrane Library
- Medline and Premedline
- Excerpta Medica (Embase)
- Cumulative Index to Nursing and Allied Health Literature (Cinahl)
- Allied & Complementary Medicine (AMED)
- British Nursing Index (BNI)
- Psychinfo
- Web of Science (specifically Science Citation Index Expanded [SCI-EXPANDED] and Social Sciences Citation Index [SSCI])
- System for Information on Grey Literature In Europe (SIGLE)
- Biomed Central
- National Research Register (NRR)
- Current Controlled Trials.

The information specialist sifted and removed any irrelevant material from the literature search results obtained from this list of databases (based on the title or abstract) before passing to the researcher. All the remaining articles were then stored in a Reference Manager electronic library.

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Searches were updated and re-run 6 weeks before the stakeholder consultation, thereby ensuring that the latest relevant published evidence was included in the database. Any evidence published after this date was not included. For the purposes of updating this topic, 12 October 2009 should be considered the starting point for searching for new evidence. Further detail of the search strategy is provided in the full evidence review that accompanies this guidance.

**Critical appraisal**

Following the literature search, one researcher independently scanned the titles and abstracts of every article and full publications were obtained for any studies considered relevant or where there was insufficient information from the title and abstract to make a decision. The researcher then individually applied the inclusion/exclusion criteria to determine which studies would be relevant for inclusion and subsequent appraisal. Lists of excluded papers were generated and the rationale for the exclusion was presented to the GDG when required.

The researcher then critically appraised the full papers. Critical appraisal checklists were compiled for each paper and one researcher undertook the critical appraisal and data extraction.

For all the relevant appraised studies, data on the type of population, intervention, comparator and outcomes (PICO) were recorded in evidence tables and an accompanying evidence summary prepared for the GDG (see the full evidence review that accompanies this guidance update). All the evidence was considered carefully by the GDG for accuracy and completeness. All procedures were fully compliant with NICE methodology as detailed in the ‘NICE guidelines manual 2009’ \(^{15}\). No formal contact was made with authors.

**Agreeing the recommendations**

For the clinical question, the GDG were presented with a summary of the clinical evidence derived from the studies reviewed and appraised. From this information the GDG were able to derive the guidance recommendations. The link between the evidence and the view of the GDG in making each recommendation is made explicit in the ‘Linking evidence to recommendations’ section.

**Explaining the link between evidence and recommendations**

Recommendations were developed using, and linked explicitly to, the evidence that supported them. Because of the way service guidance is currently presented, there is limited scope for expressing how and why a GDG made a particular recommendation from the evidence. The ‘Linking evidence to recommendations’ section is intended to make this process more transparent to the reader by explaining:

- the strength of evidence about benefits and harms for the intervention being considered

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The degree of consensus within the GDG

- the costs and cost effectiveness (if formally assessed by the health economics team).

Where evidence was weak or lacking, the GDG agreed the final recommendations through informal consensus and used their collective experience and expertise to identify good practice.

Developing research priorities

When areas for which good evidence was lacking were identified, the GDG considered making recommendations for future research. Decisions about inclusion were based on factors such as the importance to patients or the population, national priorities and the potential impact on the NHS.

Health economics

The original guidance did not contain a de novo economic model, therefore this could not be updated and it was not feasible to build a new model to inform this update. An economic model would have proved difficult to construct due to the lack of clear clinical effectiveness evidence, lack of quality of life data and the difficulty in trying to capture differences in costs between surgical procedures carried out by a GP, a GPwSI and a dermatologist, particularly given the wide variation in payment for GPwSIs across the country. A health economist attended all GDG meetings and was able to remind the group of the need to consider both costs and benefits when making their recommendations.

The report assessing the potential economic impact of the original guidance was updated using standard NICE costing methodology, methods for which are explained in the costing statement (available from www.nice.org.uk[XX]. [Note: these details will apply when the guidance update is published.])

Consultation and validation of the guidance

The draft of the guidance was prepared by NCC-C staff in partnership with the GDG Chair and all GDG members. This was then discussed and agreed with the GDG and subsequently forwarded to NICE for consultation with stakeholders.

Registered stakeholders (see Appendix 1.2) had one opportunity to comment on the draft guidance, which was posted on the NICE website between 23 November and 21 December 2009. The Guideline Review Panel (GRP) also reviewed the guidance and checked that stakeholder comments had been addressed.

The pre-publication check process

Following stakeholder consultation and subsequent revision, the draft guidance underwent a pre-publication check (for details see the ‘NICE guidelines manual 2009’[16]). The pre-publication check provides registered stakeholders with the opportunity to raise any

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concerns about factual errors and inaccuracies that may exist in the revised guidance after consultation.

During the pre-publication check the guidance was posted on the NICE website for 10 working days, together with the consultation table that listed comments received during consultation from stakeholders and responses from the NCC-C and GDG.

All stakeholders were invited to report factual errors using a standard proforma. NICE, the NCC-C and the GDG Chair considered the reported errors and responded only to those related to factual errors. A list of all corrected errors and the revised guidance were submitted to NICE, and the revised guidance was then signed off by the NICE Guidance Executive. The list of reported errors from the pre-publication check and the responses from the NCC-C were subsequently published on the NICE website.

The final document was then submitted to NICE for publication on their website. The other versions of the guidance (see below) were also discussed and approved by the GDG and published at the same time.

Other versions of the guidance

Full guidance

The full version of the original skin cancer guidance (with the recommendations on the management of low-risk BCC in the community withdrawn) and this updated guidance are available to download free of charge from the NICE website (www.nice.org.uk/XX) and the NCC-C website (www.wales.nhs.uk/nccc). [Note: these details will apply when the guidance update is published.]

Understanding NICE guidance

A summary of the updated guidance on the management of low-risk BCCs in the community for patients and carers (‘Understanding NICE guidance’) is available from www.nice.org.uk/XX. [Note: these details will apply when the guidance update is published.]

All the other advice in the ‘Understanding NICE guidance’ for people with skin tumours and their families or carers that accompanied the 2006 guidance remains the same and is available from www.nice.org.uk/XX [Note: these details will apply when the guidance update is published.]

Funding

The NCC-C was commissioned by NICE to carry out this update. Health economic advice for this guidance was provided by the London School of Hygiene and Tropical Medicine and funded by the NCC-C.

Disclaimer

The NCC-C disclaims any responsibility for damages arising out of the use or non-use of this guidance and the literature used in support of this guidance.
Patient with skin lesion presents to GP: thought to be a low-risk BCC

Does the GP meet the requirements to perform skin surgery within the framework of the Direct Enhanced Services and Local Enhanced Services under General Medical Services or Personal Medical Services? Has the GP demonstrated surgical competency?

YES

Is GP confident of the diagnosis of a low-risk BCC

YES

NO

NO

There is no diagnostic uncertainty that the lesion is a primary nodular low-risk BCC and it meets the following criteria:

- The patient with BCC is not:
  - aged 24 years or younger (that is, a child or young adult)
  - immunosuppressed or has Gorlin’s syndrome
- The lesion:
  - is located below the clavicle (that is, not on the head or neck)
  - is less than 1 cm in diameter with clearly defined margins
  - is not a recurrent BCC following incomplete excision
  - is not a persistent BCC that has been incompletely excised according to histology
  - is not morphoeic, infiltrative or basosquamous in appearance
  - is not located:
    - over important underlying anatomical structures (for example, major vessels or nerves)
    - in an area where primary surgical closure may be difficult (for example, digits or front of shin)
    - in an area where difficult excision may lead to a poor cosmetic result
    - at another highly visible anatomical site (for example, anterior chest or shoulders) where a good cosmetic result is important to the patient.

If the BCC does not meet the above criteria, or there is any diagnostic doubt, the patient should be referred to the LSMDT.

If the lesion is thought to be a superficial BCC the GP should ensure that the patient is offered the full range of medical treatments, including photodynamic therapy, and this may require referral to the LSMDT.

Incompletely excised BCCs should be discussed with a member of the LSMDT.

YES

Manage low-risk BCC appropriately

REFER to the LSMDT

Primary Care Trust/ Local Health Board governance
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**MODEL 1 PRACTITIONERS**
(SEE BOX 2)

Patient referred to accredited Model 1 practitioner (*‘Group 3 GPwSI in dermatology and skin surgery’ or new ‘Group 3a GPwSI in skin lesions and skin surgery’) with a suspected low-risk BCC

Services should be commissioned from Model 1 practitioners for the management and excision of low-risk BCC where the definition of a low-risk BCC is made after excluding the following:

- **Patients who are:**
  - aged 24 years or under (that is, a child or young adult)
  - immunosuppressed or have Gorlin’s syndrome.

- **Lesions that:**
  - are on the nose and lips (including nasofacial sulci and nasolabial folds), or around the eyes (periorbital) or ears
  - are greater than 2 cm in diameter below the clavicle or greater than 1 cm in diameter above the clavicle unless they are superficial BCCs that can be managed non-surgically
  - are morphoeic, infiltrative or basosquamous in appearance
  - have poorly defined margins
  - are located
    - over important underlying anatomical structures (for example, major vessels or nerves)
    - in an area where primary surgical closure may be difficult (for example, digits or front of shin)
    - in an area where excision may lead to a poor cosmetic result.

If any of the above exclusion criteria apply, or there is any diagnostic doubt, the patient should be referred to the LSMDT.

If the lesion is thought to be a superficial BCC the GP should ensure that the patient is offered the full range of medical treatments, including photodynamic therapy, and this may require referral to the LSMDT.

Incompletely excised BCCs should be discussed with a member of LSMDT.

- **Primary Care Trust/Local Health Board governance**

**MODEL 2 PRACTITIONERS**
(SEE BOX 3)

Unable to confirm low-risk BCC

REFER for management by the LSMDT

Is the ‘Group 3 GPwSI in dermatology and skin surgery’ also a **Model 2 practitioner**?

- **Acute trust governance**

**Primary Care Trust/Local Health Board governance**

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The management of low-risk basal cell carcinomas in the community

The epidemiology of basal cell carcinoma

The importance of BCC is underestimated, probably because it is rarely fatal. However, BCC is the commonest type of cancer in the UK, with an average of 48,000 new cases registered each year in England between 2004 and 2006. The incidence of BCC in the South West region is 2.9 times higher than that of lung cancer and places a significant burden on NHS resources.

Furthermore, the current number of registered cases is likely to be a significant underestimate of the true incidence of BCC, with modelling estimates indicating that the number of new cases per year is more likely to be between 55 and 60,000. This is partly because the Thames Cancer Registry, which covers all of London and much of the South East region, has until recently not been registering BCCs. Other reasons why the true burden is significantly underestimated include the fact that most cancer registries do not register multiple BCCs in the same individual and that not all BCCs are submitted for histology, which is the major source of registration data.

People diagnosed with one BCC are at increased risk of having further BCCs diagnosed at the same time, or of developing them subsequently. Studies from Scotland suggest that the risk of developing a second BCC within 3 years of the first presentation is approximately 44%. Not all ‘low-risk’ BCCs are subject to histology before medical treatment. Of greater concern is the failure to submit excised BCCs for histology. One audit submitted under the 2009 skin cancer peer review process in England indicated that up to 50% of GPs removing suspected BCCs do not submit them for histology. This contravenes the NICE guidance on skin cancer services and the NICE ‘Referral guidelines for suspected cancer’, which made it clear that all excised skin lesions should be sent for histological examination.

The main risk factor for BCC is sun (ultraviolet light) exposure. This is reflected in the number of tumours that people develop and the predominance of BCCs in sun-exposed areas, for example the head, neck, forearms, hands, lower legs and feet, and trunk. Individuals with fair skin are at more risk of developing BCC.

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17 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
18 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
20 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
22 National Cancer Peer Review: North Zone Reports 2009
Regional variation in the UK incidence rates of BCC exists. For example, the registered age-standardised incidence rate of BCC in the South West of England (121.3 per 100,000 population) is much higher than in England as a whole (93.7 per 100,000 population, excluding London and the South East Coast Strategic Health Authorities where registration of BCCs was minimal). The incidence rate also varies by age and gender. The incidence rates of BCC increase with age, and over the age of 55 the age-specific incidence rates are higher in males than females. This gap increases with age and is greatest for the 85 and older age group, where the incidence for men is 80% higher than that for women in the South West region.

BCCs also arise in people with a genetic predisposition, for example Gorlin’s syndrome. These people may have dozens of BCCs, should be referred to and managed by the local skin cancer multidisciplinary team (LSMDT) or the specialist skin cancer multidisciplinary team (SSMDT) (as recommended in the NICE guidance on skin cancer services), and should not have their BCCs treated with radiotherapy.

The incidence of BCC is rising, with evidence suggesting an estimated annual percentage increase of 1.4% for males and 1.9% for females between 1992 and 2003. The largest reported increase in incidence was seen in the 30–39 age group. Unless population attitudes to sun exposure and skin protection change, the numbers of BCCs are likely to rise. The rise in incidence is predicted to be particularly great up to 2030 because of the large increase in the elderly population that will arise as the ‘baby boom’ population ages.

Therefore numbers would rise even if the incidence rates stayed the same.

BCC is rarely fatal, however it can metastasise in a very small number of cases. The majority of BCCs can be treated in an out-patient, day-case setting or community/primary-care setting. However, failure to diagnose early and/or inadequate treatment can result in tumours that destroy important anatomical structures (such as the nose, eye, ear and lip). Such tumours are very challenging to treat, making it difficult to obtain a good cosmetic result. In England, the number of in-patient bed days devoted to managing BCCs is comparable to those devoted to in-patient management of malignant melanoma. A recent study also showed high rates of complex repair operations compared with melanomas.

Increased public awareness of the risk of excess sun exposure, combined with a change in behaviour towards greater skin protection, could reduce the incidence of BCC. Raising public awareness as advocated in the National Awareness and Early Diagnosis Initiative

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26 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
27 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
33 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)
34 South West Public Health Observatory Skin Cancer Hub (www.swpho.nhs.uk/skincancerhub/)

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(NAEDI)\textsuperscript{35} programme could reduce the proportion of people presenting with advanced disease.

### Types of BCC

There are a range of different clinical presentations and histological variants of BCC – a brief summary of these is included in table 1.

Superficial BCCs are important to distinguish clinically from other types of BCCs because they can frequently be managed medically, avoiding the need for excision.

| Table 1 Clinical presentations and histological variants of BCC |
|--------------------------|------------------------------------------------------------------|
| Nodular                  | • Commonly on the face  
                           | • Cystic, pearly, telangiectasia  
                           | • May be ulcerated  
                           | • Micronodular and microcystic types may infiltrate deeply |
| Superficial              | • Often multiple  
                           | • Usually on upper trunk and shoulders  
                           | • Erythematous well-demarcated scaly plaques, often larger than 20 mm at presentation  
                           | • Slow growth over months or years  
                           | • May be confused with Bowen’s disease or inflammatory dermatoses  
                           | • Particularly responsive to medical rather than surgical treatment |
| Morphoeic                | • Also known as sclerosing or infiltrative BCC  
                           | • Usually found in mid-facial sites  
                           | • Skin-coloured, waxy, scar-like  
                           | • Prone to recurrence after treatment  
                           | • May infiltrate cutaneous nerves (perineural spread) |
| Pigmented                | • Brown, blue or greyish lesion  
                           | • Nodular or superficial histology  
                           | • May resemble malignant melanoma |
| Basosquamous             | • Mixed basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) |

\textsuperscript{35} The National Awareness and Early Diagnosis Initiative. Available from: \url{http://www.ncin.org.uk/outcomes/naedi.shtml}
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- Potentially more aggressive than other forms of BCC

2 Burden of disease

The epidemiology and health services epidemiology of BCC, described above, demonstrates that the number of cases is rising significantly. The management of BCCs imposes a significant workload on both primary- and secondary-care services. The management of high-risk BCCs requires expertise to ensure curative treatment is combined with a good cosmetic result and low risk of complications.

Published data indicate that 24% of primary-care consultations in England and Wales are related to the diagnosis and management of skin conditions, including skin lesions (1.7%)\(^\text{36}\). The burden of skin lesion management in dermatology out-patient services is also great, with 35–45% of specialist referrals relating to the diagnosis and management of skin lesions\(^\text{37}\). This figure is as high as 60% in some areas\(^\text{38}\). Furthermore, approximately 88% of 2-week wait urgent referrals for suspected skin cancer turn out to be non-malignant\(^\text{39}\), highlighting a need for better training in primary care on the recognition of skin cancer. The epidemiology of BCC, especially the predictions for the next two decades, means that there will be a requirement for better trained healthcare professionals to diagnose and manage BCCs.

3 Management options

There are a range of management options for BCC. The choice offered to the patient will depend on the anatomical location, size, clinical appearance, histological diagnosis and ease of access to treatments. The ultimate decision should be taken by the patient having been fully informed about the advantages and disadvantages of management options, including outcomes in terms of likelihood of complete eradication and cosmetic result.

Treatment, provided the diagnosis is confirmed, may include:

- monitoring – observation rather than immediate treatment
- surgical excision
- curettage and cautery/electrodesiccation
- cryotherapy/cryosurgery
- topical treatment (for example, imiquimod)
- photodynamic therapy (PDT)
- Mohs micrographic surgery
- radiotherapy.

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\(^{36}\) Schofield J, Grindlay D and Williams H (2009). Skin conditions in the uk: a health care needs assessment. Centre of Evidence Based Dermatology, University of Nottingham

\(^{37}\) Schofield J, Grindlay D and Williams H (2009). Skin conditions in the uk: a health care needs assessment. Centre of Evidence Based Dermatology, University of Nottingham


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For treatments where tissue is not obtained for histological confirmation (such as cryotherapy, PDT, imiquimod or radiotherapy) it is expected that the histological diagnosis will have been confirmed prior to treatment.

**Patient perspective**

Patients and their families or carers want BCC to be accurately diagnosed and then to be treated by healthcare professionals who:

- have been adequately trained
- are aware of the full range of treatment options
- have met prescribed standards
- participate in audit
- undertake continuous professional development (CPD) in this clinical area
- keep a 'fail-safe' log of samples sent to the laboratory, reports received and action taken.

Patients want their BCC(s) to be treated effectively the first time, with minimal risk of recurrence and the best cosmetic result possible. Should surgery be required, patients want their healthcare professionals to ensure that the risk of damaging important, proximate anatomical features, such as nerves, is kept to a minimum where possible.

Before making a decision about the management of their BCC, patients want to be fully informed by a healthcare professional who:

- is up to date with the choice of treatments available and appropriate for the BCC under consideration
- will give them full information on the advantages and disadvantages of management options and the likely outcome of these options both in terms of successful treatment and cosmetic outcome.\(^{40}\)

Most importantly, patients want to be clearly informed of their diagnosis and involved in the decision on choice of treatment and where this is delivered. A randomised controlled trial found that factors related to a negative cosmetic impact were severity of scar and the extent to which patients were unprepared for the actual size of their scars.\(^{41}\) As with any other area of clinical practice, the healthcare professional’s advice and choice of management, including no treatment, should not be influenced by a person’s age, gender or disabilities unless these have a direct clinical relationship with the success of certain forms of treatment.

While many patients are prepared to travel for specific treatments some prefer to have their care provided close to home. This should not mean a compromise on the quality of care they receive.

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receive\textsuperscript{42}. This emphasis on equity of access to high-quality care is reinforced in the recent Darzi review\textsuperscript{43}.

\textbf{Patient-centred care}

Treatment and care should take into account patients’ needs and preferences. Patients with low-risk BCC should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals. If patients do not have the capacity to make decisions, healthcare professionals should follow the Department of Health’s advice on consent\textsuperscript{44} and the code of practice that accompanies the Mental Capacity Act\textsuperscript{45}. In Wales, healthcare professionals should follow advice on consent from the Welsh Assembly Government\textsuperscript{46}.

If the patient is under 16, healthcare professionals should follow the guidelines in “Seeking consent: working with children”\textsuperscript{47}.

Good communication between healthcare professionals and patients is essential. It should be supported by evidence-based written information tailored to the patient’s needs. Treatment and care, and the information patients are given about it, should be culturally appropriate. It should also be accessible to patients with additional needs such as physical, sensory or learning disabilities, and to patients who do not speak or read English.

If the patient agrees, families and carers should have the opportunity to be involved in decisions about treatment and care.

Families and carers should also be given the information and support they need.

\textbf{Training and accreditation}

It is recognised that the training of healthcare professionals in dermatology is limited\textsuperscript{48,49}. This includes undergraduate and postgraduate medical, nursing and pharmacy training. In particular, undergraduate medical training may be as little as 2 weeks, with no formal skin surgery training or assessment. No requirement for compulsory dermatology training or assessment of skills in the diagnosis and management of skin diseases is included in the specialist registrar GP training programme. Similarly, there is no formal requirement for training or assessment of newly trained GPs in skin surgery skills\textsuperscript{50}.

The evidence review carried out for this update found a number of studies/audits that demonstrated higher levels of incomplete excision of BCCs by GPs than hospital specialists.

\textsuperscript{44} Available from www.dh.gov.uk/consent
\textsuperscript{45} Summary available from www.publicguardian.gov.uk
\textsuperscript{46} Available from www.wales.nhs.uk/consent
\textsuperscript{47} Available from www.dh.gov.uk
\textsuperscript{48} All Party Parliamentary Group on Skin (1998) Enquiry into the training of healthcare professionals who come into contact with skin diseases. London
\textsuperscript{50} Schofield J, Grindlay D and Williams H (2009). Skin conditions in the uk: a health care needs assessment. Centre of Evidence Based Dermatology, University of Nottingham
The management of low-risk basal cell carcinomas in the community: NICE guidance on cancer services update DRAFT (April 2010)
Studies suggest that GPs’ skills in the diagnosis of skin lesions could be improved. Further training and assessment in these areas is therefore essential if GPs are to diagnose and manage skin lesions, including low-risk BCCs, appropriately. Furthermore, there is currently no mandatory system of accreditation that includes ongoing continuing professional development (CPD) and participation in audit.

**Existing guidance**

There are three key national documents that guide service development and quality assessment for services for patients with BCC. These are the NICE ‘Improving outcomes for people with skin tumours including melanoma’ guidance, the Department of Health ‘Guidance and competencies for the provision of services using GPs with a special interest (GPwSIs)’ and the ‘Manual for cancer services: skin measures’. The British Association of Dermatologists has also issued ‘Guidelines for the management of basal cell carcinoma’. Early results from the peer review of skin cancer services in England show generally poor levels of compliance with the standards, especially with respect to the primary-care component and commissioning, although there are many notable exceptions across the country.

Key obstacles identified from the 2009 skin cancer peer review process include:

- weak commissioning
- inadequate clinical governance arrangements across the primary-/secondary-care interface
- issues with finance transfer across the primary-/secondary-care interface
- inadequate understanding of the models under which GPs can manage ‘low-risk’ BCCs
- in some circumstances, poor adherence to the appropriate guidance on ‘high-risk’ BCCs.

This updated guidance will seek to address these areas and provide clarification for patients, commissioners of services and providers of care.

**Definition of low- and high-risk basal cell carcinoma**

The review of the systems for classifying high- and low-risk BCCs (see the full evidence review that accompanies this guidance update) showed that some incorporate histological...
features that would only be available after biopsy or excision. For the purposes of the clinical recognition of high-risk BCCs, criteria were defined for the ‘Manual for cancer services 2008: skin measures’\textsuperscript{57}. However, there is a need for a clear clinical triage definition for low- and high-risk BCCs to ensure simple and efficient referral to appropriate healthcare professionals for management.

A range of definitions and criteria for defining low- and high-risk BCC were reviewed by the GDG (see the full evidence review that accompanies this guidance update). The GDG concluded that the clinical triage definitions for the face and scalp (head) for GPs without specialist training needed to be simplified because:

- there is a lack of precision regarding the H-zone (the high-risk zone on the face)
- a 10 mm low-risk BCC resected with margins may make primary closure challenging and lead to a poor cosmetic result
- proximity to facial structures presents a challenge to achieving both a good cosmetic result and adequate resection margins.

These factors are not independent, particularly in lesions on the face and head. Therefore the GDG decided to recommend new clinical criteria for the definition of low- and high-risk BCC presenting in the community that take into account:

- risk of incomplete excision
- the skill and experience required by the healthcare professional to achieve a good cosmetic result
- risk caused by underlying anatomical structures (for example major blood vessels or nerves)
- other management risks (for example, children and young people, recurrent BCC, Gorlin’s syndrome, immunosuppression).

In addition, having reviewed the evidence, the GDG considered which groups of healthcare professionals can safely treat which types of BCCs and what the accreditation, CPD and audit requirements should be to provide the best outcomes for patients.

These new clinical criteria and considerations about the groups of healthcare professionals have guided the development of a new framework for the management of high- and low-risk BCCs that will facilitate optimal matching of clinical risk to the knowledge and skills of healthcare professionals.

The size and clinical type of the low-risk BCC will influence the choice of healthcare professional, with some services providing a fuller range of services (such as Group 3 community cancer GPwSIs, Model 2 and specialist outreach services) than others (GPs working according to the Directed Enhanced Services [DES] framework or Local Enhanced Services [LES] under General Medical Services or Personal Medical Services). This guidance makes specific recommendations in relation to the different groups of potential healthcare professionals.


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Recommendations

Training, education and accreditation

All healthcare professionals managing skin lesions in the community should have specialist training in the diagnosis and management of skin lesions appropriate to their role.

Primary Care Trusts (PCTs) or Local Health Boards (LHBs) should ensure that all GPs who diagnose, manage and excise low-risk BCCs in the community are fully accredited to do so and undergo continuous professional development in the diagnosis and management of skin lesions to maintain their accreditation.

Commissioning

Commissioners should use the commissioning cycle and follow the process outlined in the NHS primary care contracting guidance when commissioning services for BCC.

Commissioners should undertake a full needs assessment of low-risk BCC for their specific population and this should:

- include projections of the likely increase in the number of cases over the next two decades
- consider local issues such as population demographics, access to services and patient preferences.

Commissioners should:

- ensure that the management of low-risk BCCs by GPs in the community is subject to the quality standards and requirements outlined in this guidance
- consider quality of care and value for money in commissioning services for the management of low-risk BCCs
- consider innovative approaches to the diagnosis of low-risk BCCs so that patients are not inconvenienced with unnecessary travel/access arrangements.

Provided quality standards are ensured, commissioners should commission services from the range of healthcare professionals described in this guidance.

PCTs or LHBs should ensure that services procured/commissioned (by practice-based commissioning) for low-risk BCCs for their population adhere to national cancer peer review measures.

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All children and young people (aged 24 or below) with a suspected skin cancer including BCC should be referred to a member of the skin cancer multidisciplinary team (MDT) regardless of suspected lesion diagnosis, size or anatomical location.

BCC patients who are immunosuppressed or have Gorlin’s syndrome should be referred to a member of the LSMDT or SSMDT.

**Superficial BCCs**

Patients with superficial BCCs (not usually classified as high-risk) should be referred to doctors with experience of the full range of medical treatments, including photodynamic therapy.

Doctors managing superficial BCC in the community should have experience and knowledge of this condition.

**Models of care**

The recommendations below specify the new clinical criteria for triage that should be used to identify those BCCs that should be managed by one of three different groups of GPs in primary care:

- **Low-risk BCCs for DES/LES** – GPs performing skin surgery within the framework of the Directed Enhanced Services and Local Enhanced Services under General Medical Services or Personal Medical Services (see Box 1).

- **Model 1 practitioners** – as defined in the ‘Manual for cancer services 2008: skin measures’. These practitioners are ‘Group 3 GPwSI in dermatology and skin surgery’ as defined by the Department of Health guidance, and include a new ‘Group 3a GPwSI in skin lesions and skin surgery’ (see Box 2).

- **Model 2 practitioners** – as defined in the ‘Manual for cancer services 2008: skin measures’. This comprises outreach community skin cancer services provided by acute trusts linked to the LSMDT (see Box 3).

**Low-risk BCCs for DES/LES**

*GPs performing skin surgery within the framework of the DES and LES under General or Personal Medical Services*

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Only those low-risk BCCs in anatomical sites where excision is easy and in patients who do not have other associated risk factors should be managed by GPs with no special interest or training in skin cancer. The types of low-risk BCC that these GPs can excise and the requirements for their accreditation by the PCT or LHB are outlined in Box 1.

<table>
<thead>
<tr>
<th>Box 1 Low-risk BCCs for DES/LES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services for the removal of low-risk nodular BCCs can be commissioned from GPs within the framework of the DES and LES under General or Personal Medical Services where the following criteria are fulfilled:</td>
</tr>
<tr>
<td>There is no diagnostic uncertainty that the lesion is a primary nodular low-risk BCC and it meets the following criteria:</td>
</tr>
<tr>
<td>• The patient with BCC is not:</td>
</tr>
<tr>
<td>o aged 24 years or younger (that is, a child or young adult)</td>
</tr>
<tr>
<td>o immunosuppressed or has Gorlin’s syndrome</td>
</tr>
<tr>
<td>• The lesion:</td>
</tr>
<tr>
<td>o is located below the clavicle (that is, not on the head or neck)</td>
</tr>
<tr>
<td>o is less than 1 cm in diameter with clearly defined margins</td>
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<tr>
<td>o is not a recurrent BCC following incomplete excision</td>
</tr>
<tr>
<td>o is not a persistent BCC that has been incompletely excised according to histology</td>
</tr>
<tr>
<td>o is not morphoeic, infiltrative or basosquamous in appearance</td>
</tr>
<tr>
<td>o is not located:</td>
</tr>
<tr>
<td>– over important underlying anatomical structures (for example, major vessels or nerves)</td>
</tr>
<tr>
<td>– in an area where primary surgical closure may be difficult (for example, digits or front of shin)</td>
</tr>
<tr>
<td>– in an area where difficult excision may lead to a poor cosmetic result</td>
</tr>
<tr>
<td>– at another highly visible anatomical site (for example, anterior chest or shoulders) where a good cosmetic result is important to the patient.</td>
</tr>
<tr>
<td>If the BCC does not meet the above criteria, or there is any diagnostic doubt, the patient should be referred to the LSMDT.</td>
</tr>
<tr>
<td>If the lesion is thought to be a superficial BCC the GP should ensure that the patient is offered the full range of medical treatments, including photodynamic therapy, and this may require referral to the LSMDT.</td>
</tr>
<tr>
<td>Incompletely excised BCCs should be discussed with a member of the LSMDT.</td>
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</tbody>
</table>

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### Criteria for accreditation of GPs within the framework of the DES and LES under General or Personal Medical Services

GPs performing skin surgery on low-risk BCCs within the framework of the DES and LES under General or Personal Medical Services should:

- demonstrate competency in performing local anaesthesia, punch biopsy, shave excision, curettage and elliptical excision using the direct observation of procedural skills (DOPS) assessment tool in the Department Health Guidance for GPwSIs in dermatology and skin surgery[^69] and then follow a program of revalidation
- send all skin specimens removed to histology for analysis
- provide information about the site of excision and provisional diagnosis on the histology request form
- maintain a 'fail-safe' log of all their procedures with histological outcome to ensure that patients are informed of the final diagnosis, and whether any further treatment or follow-up is required
- provide quarterly feedback to their PCT or LHB on the histology reported as required by the national skin cancer minimum dataset[^70], including details of all proven BCCs
- provide details to their PCT or LHB of all types of skin cancer removed in their practice as described in the 2006 NICE guidance on skin cancer services[^71] and should not knowingly remove skin cancers other than low-risk BCCs
- provide evidence of an annual review of clinical vs histological accuracy in diagnosis for the low-risk BCCs they have managed
- attend, at least annually, an educational meeting (organised by the Skin Cancer Network Site Specific Group), which should:
  - present the 6-monthly BCC network audit results, including a breakdown of individual practitioner performance
  - include one CPD session (a total of 4 hours) on skin lesion recognition and the diagnosis and management of low-risk BCCs
  - be run at least twice a year.

[^69]: Department of Health (2007) Guidance and competencies for the provision of services using GPs with special interests (GPwSIs). Available from: [Department of Health](http://www.nhs.uk/)


Model 1 practitioners

‘Group 3 GPwSIs in dermatology and skin surgery’ and a new ‘Group 3a GPwSI in skin lesions and skin surgery’

The current GPwSI in dermatology and skin surgery guidance requires that Group 3 GPwSIs are trained in the management of the full range of skin diseases, including both inflammatory dermatoses and skin lesion diagnosis and management. To increase the number of healthcare professionals in primary care able to manage suspected skin cancer, a new ‘Group 3a GPwSI in skin lesions and skin surgery’ is proposed with less onerous training and accreditation requirements than ‘Group 3 GPwSI in dermatology and skin surgery’.

Model 1 practitioners should be trained and accredited in the management and excision of low-risk BCCs in the community. They should manage an expanded range of low-risk BCCs, including some on the head and neck, as outlined in Box 2.

Box 2 Model 1 practitioners

Low-risk BCCs that can be operated on by Model 1 practitioners in the community (existing ‘Group 3 GPwSI in dermatology and skin surgery’ and new ‘Group 3a GPwSI in skin lesions and skin surgery’)

Services should be commissioned from Model 1 practitioners for the management and excision of low-risk BCC where the definition of a low-risk BCC is made after excluding the following:

- Patients who are:
  - aged 24 years or younger (that is, a child or young adult)
  - immunosuppressed or have Gorlin’s syndrome
- Lesions that:
  - are on the nose and lips (including nasofacial sulci and nasolabial folds), or around the eyes (periorbital) or ears
  - are greater than 2 cm in diameter below the clavicle or greater than 1 cm in diameter above the clavicle unless they are superficial BCCs that can be managed non-surgically
  - are morphoeic, infiltrative or basosquamous in appearance
  - have poorly defined margins
  - are located:
    - over important underlying anatomical structures (for example, major vessels or nerves)
    - in an area where primary surgical closure may be difficult (for example, digits

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or front of shin)
-
- in an area where excision may lead to a poor cosmetic result.

If any of the above exclusion criteria apply, or there is any diagnostic doubt, the patient should be referred to the LSMDT.

If the lesion is thought to be a superficial BCC the GP should ensure that the patient is offered the full range of medical treatments, including photodynamic therapy, and this may require referral to the LSMDT.

Incompletely excised BCCs should be discussed with a member of LSMDT.

**Criteria for accreditation of Model 1 practitioners by PCTs or LHBs**

GPwSIs performing skin surgery as ‘Group 3 GPwSI in dermatology and skin surgery’ should follow the framework for the training and accreditation of Model 1 practitioners, which is defined by the Department of Health as follows:

- they are accredited by PCTs or LHBs according to national guidance appropriate to their role as GPwSIs
- the GPwSI is linked to a named skin cancer MDT and attends four MDT meetings per year, skin cancer clinical practice is audited annually as defined in the GPwSI guidance
- clinical governance arrangements are with the PCT or LHB and the GPwSI meets the continuing professional development requirements for community skin cancer clinicians specified in the dermatology and skin surgery GPwSI guidance
- In addition they should:
  - provide evidence of an annual review of clinical vs histological accuracy in diagnosis of the low-risk BCCs they have managed
  - attend, at least annually, an educational meeting (organised by the Skin Cancer Network Site Specific Group), which should:
    - present the 6-monthly BCC network audit results, including a breakdown of individual practitioner performance
    - include one CPD session (a total of 4 hours) on skin lesion recognition and the diagnosis and management of low-risk BCCs
    - be run at least twice a year.

A new ‘Group 3a GPwSI in skin lesions and skin surgery’ should be developed whose role is as follows:

- training and accreditation to the same standard as the ‘Group 3 GPwSI in dermatology and skin surgery’ but for skin lesions only (excluding the inflammatory skin disorders)
- all other criteria, including referral pathways, link to the MDT, clinical governance

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arrangements and CPD requirements, to match the ‘Group 3 GPwSI in dermatology and skin surgery’

- managing low-risk BCCs only within the framework described above for the ‘Group 3 GPwSI in dermatology and skin surgery’.

[The 2007 Department of Health guidance relating to ‘GPwSIs in dermatology and skin surgery’\(^{76}\) will be reviewed and updated following publication of this updated NICE guidance and will take account of this new ‘Group 3a GPwSI in skin lesions and skin surgery’. Commissioners and practitioners should be fully conversant with this document and take into account the future changes.]

**Model 2 practitioners**

*Outreach community skin cancer services provided by acute trusts linked to the LSMDT*

A Model 2 practitioner should be one of the following:

- a medical practitioner performing skin surgery in a community setting
- a suitably trained specialist nurse.

The ‘Manual for cancer services 2008: skin measures’\(^{77}\) identifies Model 2 practitioners (doctors or nurses) who can perform surgery on **pre-diagnosed** lesions (Box 2). These Model 2 practitioners can undertake surgery on the full range of BCCs as well as other types of skin cancer provided that:

- they have demonstrated surgical competence
- surgery is performed after the lesions have been diagnosed by an MDT member and a management plan identified.

Model 2 services sit within acute trust clinical governance framework.

**Overlap between Model 1 (‘Group 3 GPwSI in dermatology and skin surgery’) and Model 2 practitioners**

As a requirement of the GPwSI guidance\(^{78}\), ‘Group 3 GPwSI in dermatology and skin surgery’ have a mentoring session (as a minimum, monthly) with a local dermatology specialist team linked to an MDT. Most ‘Group 3 GPwSI in dermatology and skin surgery’ will, in addition to their PCT or LHB governance arrangements, have a documented link with an acute trust clinical governance framework. Provided this is the case, then the healthcare professional can work as both a Model 1 ‘Group 3 GPwSI in dermatology and skin surgery’ and a Model 2 practitioner excising the full range of skin cancers, provided the patient has been discussed and a management plan agreed with a core member of the MDT.


Box 3 Model 2 practitioners

Criteria for accreditation of Model 2 practitioners

Model 2 practitioners should sit within acute trust clinical governance frameworks and should:

- be trained in and have demonstrated competency in skin surgery techniques (as per SS1 and SS2 frameworks in the GPwSI guidance79)
- be associated with a named MDT
- perform surgery on pre-diagnosed skin cancers, receiving referrals from core MDT members with an agreed treatment plan.

If they are ‘Group 3 GPwSI in dermatology and skin surgery’ then they should provide evidence of an annual review of clinical vs histological accuracy in diagnosis of the low-risk BCCs they have managed.

GPs should attend, at least annually, an educational meeting (organised by the Skin Cancer Network Site Specific Group), which should:

- present 6-monthly BCC network audit results, including a breakdown of individual practitioner performance
- include one CPD session (a total of 4 hours) on skin lesion recognition and the diagnosis and management of low-risk BCCs
- be run at least twice a year.

Hospital specialists working in the community

Consultants and speciality and associate specialist [SAS] doctors working in the community should provide the full range of skin cancer services, including the management of low-risk BCCs.

Quality assurance

Histopathology

All skin lesion samples (excision, incision, punch biopsy and curettage) should be sent for histological examination as recommended in the NICE ‘Referral guidelines for suspected cancer’80. If a person has more than one lesion, samples should be sent in separate specimen pots with referral forms.

Histology request and reporting forms, and the electronic recording of these data items, should be improved to capture the national skin cancer minimum dataset requirements.


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All healthcare professionals should have a fail-safe mechanism in place to ensure that they receive results for the skin lesion samples they send for histological assessment and act upon the results. This means that:

- all samples sent to the laboratory should be accompanied with a numerical checklist
- any sample not received by the laboratory should be immediately notified to the operating GP
- all results should be cross checked to ensure they have been seen and actioned.

Healthcare professionals should take appropriate action if the histology result reclassifies the lesion as a high-risk BCC or a SCC, malignant melanoma or other rare skin tumour and refer to approved specialists as recommended in ‘Improving outcomes for people with skin tumours including melanoma’ (NICE guidance on cancer services). The following histological criteria denote high-risk BCC:

- incomplete excision margins
- morphoeic, infiltrative, micronodular or basosquamous
- perineural invasion below the dermis.

Each PCT or LHB should commission histopathology skin cancer services that clearly identify each individual healthcare professional. Audit data should be presented in an anonymised fashion using individual identifier numbers, but individual healthcare professionals and PCTs or LHBs should be given data that is identifiable.

GPs operating under DES/LES should send their low-risk BCC samples to the main histopathology laboratory(ies) that are linked to their local MDT(s).

Data collection and audit

Healthcare professionals managing low-risk BCCs in the community should maintain a written or electronic record of the suspected and actual skin cancers they have managed in their individual caseload.

As required by the ‘Manual for cancer services 2008: skin measures’ all BCCs excised by healthcare professionals in the community should be audited. The PCT or LHB should make these audit results available to the multidisciplinary team (MDT), cancer network, PCT or LHB and the individual practitioner on a quarterly basis and they should be included in the

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cancer network annual audit (cancer standards 08-6A-103J\textsuperscript{85}). The quarterly dataset should be a standard PCT or LHB contract monitoring item for the DES.

Individual healthcare professionals should be responsible for collating their individual audit data for revalidation.

All GPs managing low-risk BCCs in the community should attend at least one educational meeting. This meeting should:

- be organised by the Cancer Network Site Specific Group
- present the 6-monthly BCC network audit results along with a breakdown of individual healthcare professional data
- include one CPD session (a total of 4 hours) on the diagnosis and management of low-risk BCCs
- be run at least twice a year.

GPs should provide evidence of an annual review of clinical vs histological accuracy in diagnosis for the low-risk BCCs they have managed.

The MDT should source suitable patient reported outcome measures for the treatment of BCCs.

Quality standards against which performance can be managed/monitored should be reflected in the national skin cancer minimum dataset.

Improved quality of data collection for BCC should be implemented by cancer peer review following the publication of the national skin cancer minimum dataset\textsuperscript{85}.

All BCCs should be registered by cancer registries to allow national, regional and local epidemiology and health service epidemiological studies to take place.

**Clinical governance**

All community dermatology services that include skin cancer should ensure that:

- Clinical governance arrangements are in place for all healthcare professionals providing these services (including private providers contracted to treat NHS patients) and they are accredited to perform skin lesion excisions.
- All healthcare professionals providing these services work to agreed local clinical protocols for referral, treatment and follow-up. These should be coherent with network-wide clinical protocols and signed off by the network site specific lead for skin cancer.

Healthcare professionals managing skin lesions in the community should obtain informed consent before any treatment is undertaken\textsuperscript{86,87,88}.

\textsuperscript{85} Available from the National Cancer Intelligence Network (NCIN): [http://www.ncin.org.uk/index.shtml](http://www.ncin.org.uk/index.shtml)


\textsuperscript{87} General Medical Council (GMC) guidance on informed consent. Available at: [http://www.gmc-uk.org/static/documents/content/Consent_2008.pdf](http://www.gmc-uk.org/static/documents/content/Consent_2008.pdf)
The recommendations in this guidance and other national clinical guidelines\(^8^9\) should be used in the development of local protocols and guidelines at the cancer network level.

**Communication**

All healthcare professionals managing BCCs in the community should provide information, advice and support for patients and their families or carers.

\(^8^8\) Welsh Assembly Government Guidance on informed consent. Available at: [www.wales.nhs.uk/consent](http://www.wales.nhs.uk/consent)


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Research priorities

The GDG has made the following priorities for research, based on its review of evidence, to improve NICE guidance and patient care in the future.

- What is the true nature of the epidemiology and health service epidemiology of BCC?
- For patients with low-risk BCC treated in the community, what are the factors that predict recurrence of treated BCC and what factors predict a good cosmetic result?
- Is there a difference in outcome for patients whose low-risk BCCs are resected by the different groups of healthcare professionals proposed in this guidance?

Linking evidence to recommendations

The GDG reviewed a number of types of evidence in the process of assessing the fitness for purpose of the existing NICE guidance on skin cancer services pertaining to the identification, referral and management of low-risk BCC. This included:

- an overview of the epidemiology of BCC and its health service epidemiology
- a summary of methods for defining high- and low-risk BCC, including the clinical definitions included in the ‘Manual for cancer services: skin measures’
- preliminary data from the 2009 skin cancer services peer review process, presented by the National Cancer Action Team
- undergraduate and postgraduate training requirements for GPs in skin lesion recognition and management
- an evidence review undertaken to examine the question ‘Do outcomes differ when the excisional surgery of a suspicious lesion is performed by a GP compared with a specialist in secondary care?’.

There was no high-quality evidence comparing the management of BCC by GPs working in the community with specialists in secondary care, so the GDG considered lower quality evidence such as audit data. The GDG was aware of the need to provide high-quality care close to the patient’s home wherever possible. The evidence available suggested that better education and training for GPs was required, so the recommendations specify three models of competency with clear definitions of the types of skin lesion that can be managed within each model. The majority of recommendations were based on GDG consensus and their collective experience and expertise to identify good clinical practice.

The management of low-risk basal cell carcinomas in the community: NICE guidance on cancer services update DRAFT (April 2010) Page 34 of 49
Evidence summary

[References for this evidence summary are listed at the end of this section]

The evidence base for this topic consists of one randomised controlled trial (RCT), non-randomised observational studies (both prospective and retrospective), meeting abstracts presenting audit data, some audit data from specific health services and published correspondence. Almost half the evidence was generated from within the UK, with the other half generated from Australia and one paper published from New Zealand. Applicability of the Australian and New Zealand evidence is limited in the UK setting. This is due to the different health systems operating in New Zealand and Australia compared with the UK (in particular the way skin cancer lesions are managed in primary and secondary care).

In order to accurately evaluate the outcomes from excisional surgery of a suspicious skin lesion performed by a GP compared with a specialist in secondary care, the ideal study would require the randomisation of patients to either of these settings and then assessment of the outcomes. The evidence body is limited in this sense, with only one study attempting to evaluate this question in this way (George et al. 2008). The remaining evidence comes from observational studies, mainly retrospective series, which involve potential bias with respect to data collection processes or patient/lesion selection criteria. Furthermore, this evidence did not consistently describe if the GP groups included were GPs with a special interest or not, therefore making it difficult to draw conclusions about the performance of GPs with a special interest or GPs (with no specialised training).

Overall, 11 studies (Carter et al. 2009; Dabrera 2007; De La Roche et al. 2008; George et al. 2008; Goulding et al. 2009; Khalid et al. 2009; Macbeth et al. 2009; Murchie et al. 2008; Neal et al. 2008; Su et al. 2007; Youl et al. 2007) with varying levels of potential methodological bias compared dermatologists with GPs or other clinical specialists. Eight of these studies indicated that margin clearance or complete excision is more adequately achieved by (‘hospital’ or ‘specialist’) dermatologists than GPs (Carter et al. 2009; Dabrera 2007; De La Roche et al. 2008; Goulding et al. 2009; Khalid et al. 2009; Macbeth et al. 2009; Murchie et al. 2008; Neal et al. 2008).

Three of the 11 studies reported the following:

- The equivalence study by George et al. (2008) compared three outcomes of minor surgery, including the excision of suspected skin cancers, and was conducted in primary care or at a hospital in the south of England. Statistically, hospital doctors scored higher marks than GPs in surgical quality (odds ratio [OR] = 1.64, 95% confidence interval [CI] 0.997–2.69%) but, as this was an equivalence study, the authors found the clinical significance of this result difficult to interpret. GPs failed to recognise a malignant lesion about one third of the time but were good at recognising benign lesions. Hospital doctors achieved more adequate excisions than GPs but the difference was not significant and, with such a low patient number, firm conclusions should not be drawn from this result. Patients were more satisfied with treatment in primary care and found it less inconvenient than attending hospital.

- Su et al. (2007) reported the incidence of incomplete excision at a tertiary referral public hospital. There was no significant difference in the percentage of incomplete
excision between consultants, registrars and the clinical assistant, but the low
numbers of cases performed by consultants may have contributed to this result.

- Youl et al. (2007) compared the ability of GPs or hospital doctors to correctly
recognise malignant skin lesions. Hospital doctors were statistically better in the
detection of BCCs and malignant melanomas but not SCCs. GPs and hospital
doctors were of equal ability in the detection of benign skin lesions.

Importantly, the evidence body lacked sufficient evidence of difference between GPs and
dermatologists in terms of long-term patient outcomes. Recurrence is one key outcome and
was addressed by only one study in this update (Wyile et al. 2009). The study compared
guideline recommendations and actual current practice. Fifty-three dermatologists were
involved in an anonymous online questionnaire. When asked to respond to a clinical case
example, which asked for the likely excision margin (1 mm to > 4 mm) for a primary well-
defined nodular BCC measuring 1 cm on the mid-forehead, 33% suggested they would
excise with a margin of 2 mm or less and only 32% gave 4 mm or greater as their response.
Similarly wide variations in practice were found with examples for high- and low-risk SCC
and also for initial primary melanoma excision. Higher grade of operator and frequency of
surgery were linked with smaller margins. The largest margins (more closely following
recommended guidelines) came from British Society of Dermatology Surgery members,
although not exclusively. Overall it was concluded that, in terms of providing adequate
clearance and reducing recurrence rates, the results indicated marked discrepancies.

In conclusion, the retrospective studies, although flawed, do indicate a consistent trend of
current practices and outcomes in favour of specialist care in this setting. The controlled
study by George et al. (2008) provides an important framework for further research which,
along with more well-conducted studies using reliable audit data, should lead to more
adequate reporting of the outcomes of excisional surgery in future.

[The full evidence review is presented as a separate document that accompanies this
guidance update]

References for evidence summary

Carter, E. J., L. R. Whittam, and D. A. Buckley. 2009. Failure of adherence to NICE

Dabrera G 2007. Is the adequacy of excision of basal cell carcinoma related to operator
experience?. *Clin Exp Dermatol* 32: 103-104.

De La Roche, H. M. and T. Lucke. 2008. Audit of excision rates of BCCs in primary and

George S., Pockney P., Primrose J., Smith H., Little P., Kinley H., Kneebone R., Lowy A.,
Leppard B., Jayatilleke N and McCabe C 2008. A prospective randomised comparison of
minor surgery in primary and secondary care. The MiSTIC trial. *Health Technology
Assessment (Winchester, England)* 12: 23.


Appendices

Appendix 1.0: People and organisations involved in production of the guidance

1.1 Members of the Guidance Development Group (GDG)
1.2 Organisations invited to comment on guidance development
1.3 Individuals carrying out literature reviews and complementary work
1.4 Members of the Guideline Review Panel
Appendix 1.1: Members of the Guidance Development Group (GDG)

GDG Chair
Dr Julia Verne  Deputy Regional Director of Public Health and South West Public Health Observatory Director

Group members
Mrs Fiona Bonas  Director, 3 Counties Cancer Network
Dr Timothy Cunliffe  GPwSI in Dermatology and Skin Surgery, Middlesborough Specialist Skin Service
Dr Bruce Eden  GP Advisor to Greater Midlands Cancer Network
Dr Antony Feltbower  GP, Coventry
Ms Gillian Godsell OBE  Skin Cancer Clinical Nurse Specialist, Nottingham University Hospital NHS Trust
Dr Stephen Keohane  Consultant Dermatologist, Portsmouth Hospital
Dr David Marshall  GP, Reading
Mr Barry Powell  Consultant Plastic Surgeon, St George’s Hospital, London
Dr Julia Schofield  Principal Lecturer, University of Hertfordshire, Consultant Dermatologist, United Lincolnshire Hospital NHS Trust
Mrs Sylvia Toresen  Patient/carer member
Mrs Pippa Tostevin  Patient/carer member
Declarations of interest

GDG members were asked to declare any possible conflicts of interest that could interfere with their work on the guidance.

<table>
<thead>
<tr>
<th>GDG member</th>
<th>Interest declared</th>
<th>Type of interest</th>
<th>Decision taken</th>
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<tr>
<td>Julia Schofield (JS)</td>
<td>Received an honorarium from Leo Pharm Lecture to give a lecture on GPwSI</td>
<td>Personal pecuniary specific</td>
<td>Declare and must withdraw from discussions on topics that focus on GPwSI accreditation until Jan 2010. Chairperson’s decision taken that JS can be asked specific technical questions about GPwSI accreditation.</td>
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<td></td>
<td>accreditation and community cancer services</td>
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<td></td>
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<td>Chairperson’s action taken that JS can be asked specific technical questions about GPwSI accreditation.</td>
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<tr>
<td></td>
<td>Received an honorarium from Schering Plough to give a lecture on</td>
<td>Personal pecuniary non-specific</td>
<td>Declare can participate in discussions as the meeting was not specific to skin cancer.</td>
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<td>commissioning dermatology services</td>
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## Appendix 1.2: Organisations invited to comment on guidance development

The following stakeholders registered with NICE and were invited to comment on the draft version of this guidance:

<table>
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<th>Organisation</th>
<th>Organisation</th>
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<tr>
<td>Association of British Insurers (ABI)</td>
<td>Cancer Research UK</td>
</tr>
<tr>
<td>Association of Chartered Physiotherapists in Oncology and Palliative Care</td>
<td>Care Quality Commission (CQC)</td>
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<tr>
<td>Association of Surgeons in Primary Care</td>
<td>Central South Coast Cancer Network</td>
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<tr>
<td>Associazione Infermieristica per lo Studio delle Lesioni Cutanee (AISLeC)</td>
<td>College of Occupational Therapists</td>
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<td>AstraZeneca UK Ltd</td>
<td>Commission for Social Care Inspection</td>
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<td>Brighton and Sussex University Hospitals Trust</td>
<td>ConvaTec</td>
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<tr>
<td>British Association of Dermatologists, The</td>
<td>Cornwall &amp; Isles of Scilly PCT</td>
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<td>British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)</td>
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<td>British Dietetic Association</td>
<td>Department of Health</td>
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<td>Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)</td>
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<td>British Society for Dermatopathology</td>
<td>East and North Herts NHS Trust</td>
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<td>East Midlands Cancer Network</td>
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<td>Gorlin Syndrome Group</td>
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<table>
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<tr>
<th>Greater Midlands Cancer Network</th>
<th>NHS Clinical Knowledge Summaries Service (SCHIN)</th>
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<td>Guy's and St Thomas NHS Foundation Trust</td>
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<td>Huntingdon Community Dermatology Service</td>
<td>NHS Improvement</td>
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<tr>
<td>Institute of Biomedical Science</td>
<td>NHS Northamptonshire</td>
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<td>Johnson &amp; Johnson Medical</td>
<td>NHS Plus</td>
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<td>Juvenile Diabetes Research Foundation</td>
<td>NHS Quality Improvement Scotland</td>
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<td>NHS Sheffield</td>
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<td>North East Lancashire NHS Trust</td>
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<td>Liverpool PCT Provider Services</td>
<td>North East Lincolnshire Care Trust Plus</td>
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<td>Luton &amp; Dunstable Hospital NHS Foundation Trust</td>
<td>North East London Cancer Network</td>
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<td>Macmillan Cancer Support</td>
<td>North London Cancer Network</td>
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<td>Medicines and Healthcare Products Regulatory Agency (MHRA)</td>
<td>North Trent Cancer Network</td>
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<td>Met Office</td>
<td>North West London Cancer Network</td>
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<td>Ministry of Defence (MoD)</td>
<td>Northwick Park and St Mark's Hospitals NHS Trust</td>
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<td>National Patient Safety Agency (NPSA)</td>
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<td>Primary Care Dermatology Society</td>
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Appendix 1.3: Individuals carrying out literature reviews and complementary work

<table>
<thead>
<tr>
<th><strong>Overall Coordinators</strong></th>
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<tbody>
<tr>
<td>Dr John Graham</td>
<td>Director, National Collaborating Centre for Cancer, Cardiff</td>
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<td>Dr Andrew Champion</td>
<td>Centre Manager, National Collaborating Centre for Cancer, Cardiff</td>
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<th><strong>Project Manager</strong></th>
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<tr>
<td>Lianne Black</td>
<td>National Collaborating Centre for Cancer, Cardiff</td>
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<tr>
<th><strong>Senior Researcher</strong></th>
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<tr>
<td>Angela Melder</td>
<td>National Collaborating Centre for Cancer, Cardiff</td>
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<tr>
<th><strong>Researcher</strong></th>
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<tr>
<td>Karen Francis</td>
<td>National Collaborating Centre for Cancer, Cardiff</td>
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<th><strong>Information Specialist</strong></th>
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<tr>
<td>Stephanie Arnold</td>
<td>National Collaborating Centre for Cancer, Cardiff</td>
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<th><strong>Health Economist</strong></th>
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<tr>
<td>Sarah Willis</td>
<td>London School of Hygiene and Tropical Medicine</td>
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</table>
Appendix 1.4: Members of the Guideline Review Panel

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring its quality. The members of the Guideline Review Panel are:

**Dr John Hyslop – Chair**
Consultant Radiologist, Royal Cornwall Hospital NHS Trust

**Dr Ash Paul**
Deputy Medical Director, Health Commission Wales

**Professor Liam Smeeth**
Professor of Clinical Epidemiology, London School of Hygiene and Tropical Medicine

**Mr Peter Gosling**
Lay member

**Mr Johnathan Hopper**
Medical Director (Northern Europe), ConvaTec Ltd
Appendix 2.0: Glossary of terms

**Basal cell carcinoma (see table 1)**
A type of cancer that arises from the basal cells, small round cells found in the lower part (or base) of the epidermis, the outer layer of skin.

**Biopsy**
Removal of a sample of tissue from the body to assist in diagnosis of disease.

**Cancer**
Growth of altered body cells that keep on growing, which is able to spread from where it started to another part of the body.

**Carcinoma**
Cancer of the lining tissue that covers all the body organs.

**Cautery**
The application of a hot instrument, an electrical current, a caustic substance or other substance to kill certain types of small tumours or seal-off blood vessels to stop bleeding.

**Clinician**
A healthcare professional providing patient care, for example, a doctor, nurse or physiotherapist

**Cosmetic result**
Outcome of appearance after treatment.

**Cryosurgery**
A procedure performed with an instrument that freezes and destroys abnormal tissue.

**Cryotherapy**
A treatment that uses cold temperature to remove cells or tissue by freezing.

**Curettage**
Removal of tissue with a curette, a spoon-shaped instrument with a sharp edge.

**Dermis**
The sensitive connective tissue layer of the skin located below the epidermis, containing nerve endings, sweat and sebaceous glands, and blood and lymph vessels. Also called corium, cutis vera or derma.

**Epidemiology**
The study of populations in order to determine the frequency and distribution of disease and to measure risks.

**Excision**
The act of surgically removing or ‘cutting out’ tissue from the body.

**Gorlin’s syndrome**

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An inherited condition that can increase an individual’s chance of developing basal cell carcinoma. Also called basal cell nevus syndrome.

**Health Service Epidemiology**
The framework for the facts that enable health officials to identify important health problems and to define their dimensions. Epidemiologic methods are used to define these health problems; to classify, identify and explain their causes.

**Healthcare professional**
Any individual, institution or agency that provides health services.

**Histological**
Relating to the study of cells and tissue on the microscopic level.

**Immunosuppression**
Suppression of the body’s immune system and its ability to fight infections or disease. Immunosuppression may be deliberately induced with drugs. It may also result from certain diseases such as lymphoma or from anticancer drugs.

**Incidence**
The number of new cases of a disease in a given time period.

**Incidence rates**
The number of new cases per 100,000 population. This may also be age standardised to account for differences in the age structure of populations or age specific for specific age groups.

**Lesion**
An area of abnormal tissue.

**Local Health Board**
The group of people responsible for all healthcare services for a geographical area within Wales.

**Management**
Assessment of a lesion and patient, and recommendation of treatment or monitoring options.

**Margins**
The edge of the tissue removed.

**Medical treatment**
Care of a patient and management of their condition.

**Minimum dataset**
A widely agreed upon and generally accepted set of terms and definitions making up a core of data required for medical records and used for developing statistics for different types of analyses and users.

**Mohs micrographic surgery**
A surgical technique used to treat skin cancer. Individual layers of cancerous tissue are removed and examined under a microscope one at a time until all cancerous tissue has been removed.

**Multidisciplinary team**
The management of low-risk basal cell carcinomas in the community:
A team with members from different healthcare professions (for example, surgery, oncology, pathology, radiology, nursing)

**Patient**
A person who requires medical care.

**Perineural**
Around a nerve or group of nerves.

**Photodynamic therapy**
Treatment with drugs that become active when exposed to light. These drugs kill cancer cells.

**Practitioner**
A person qualified and registered to practice a learned profession.

**Primary Care Trust**
A type of NHS trust that is responsible for all healthcare services for a geographical area within England.

**Radiotherapy**
The use of radiation, usually X-rays or gamma rays, to kill cancer cells and treat tumours.

**Secondary care**
Services provided by a multidisciplinary team in a hospital, as opposed to a GP and a primary care team.

**Superficial BCC (see table 1)**
A subtype of basal cell carcinoma that occurs most commonly on the trunk.

**Squamous cell carcinoma**
Cancer that begins in squamous cells. Squamous cells are found in the tissue that forms the surface of the skin, the lining of the hollow organs of the body, and the passages of the respiratory and digestive tracts. Also called epidermoid carcinoma.

**Topical treatment**
Treatment with drugs in a lotion, ointment or cream applied to the skin.
Appendix 3.0: Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<td>BCC</td>
<td>basal cell carcinoma</td>
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<tr>
<td>CPD</td>
<td>continuing professional development</td>
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<td>DES</td>
<td>direct enhanced service</td>
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<td>DH</td>
<td>Department of Health</td>
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<td>DOPs</td>
<td>direct observation of procedural skills</td>
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<td>GDG</td>
<td>guidance development group</td>
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<tr>
<td>GP</td>
<td>general practitioner</td>
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<tr>
<td>GPwSI</td>
<td>general practitioner with special interest</td>
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<td>LES</td>
<td>local enhanced service</td>
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<td>LHB</td>
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<td>LSMDT</td>
<td>local hospital skin cancer multidisciplinary team</td>
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<td>MDT</td>
<td>multidisciplinary team</td>
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<td>MM</td>
<td>malignant melanoma</td>
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<td>National Institute for Health and Clinical Excellence</td>
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<td>Primary Care Trust</td>
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<td>PDT</td>
<td>photodynamic therapy</td>
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<td>SAS</td>
<td>specialist and associate specialist</td>
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<td>SCC</td>
<td>squamous cell carcinoma</td>
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<td>SS1</td>
<td>GPwSIs offering basic skin surgery</td>
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<td>SS2</td>
<td>GPwSIs offering basic skin surgery and more advanced surgery</td>
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<td>SSMDT</td>
<td>specialist skin cancer multidisciplinary team</td>
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<td>SWPHO</td>
<td>South West Public Health Observatory</td>
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<td>UKACR</td>
<td>United Kingdom Association of Cancer Registries</td>
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