NICE guidance on cancer services update

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

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

Draft for consultation

Contents

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

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. 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. Following a meeting at NICE in April 2009, an update to the 2006 NICE guidance was commissioned to address the management of low-risk BCCs in the community.

The epidemiology of basal cell carcinoma

The importance of BCC is underestimated, probably because it is rarely fatal. BCC is the commonest type of cancer in the UK, with at least 49,815 cases registered in England in 2006[3] – although this is likely to be a significant underestimation. Even with this underestimate, the incidence of BCC in England is still 1.8 times higher than that of lung cancer[3,4]. It not only affects many individuals but also places a significant burden on NHS resources.

Accurate data on the true prevalence and incidence of BCC in the UK is difficult to obtain because some cancer registries do not register BCCs or do not register multiple BCCs in the same individual, so the total number of BCCs is probably much higher than stated in the published literature. Data from Northern Ireland, where the cancer registry does capture information, documented age-adjusted incidence rates of 104 and 71 per 100,000 population for males and females respectively[5]. One study, based on a UK primary care database cohort study, estimates about 53,000 new cases of BCC per year in the UK[6].

Furthermore, not all 'low-risk' BCCs are subject to histology before medical treatment; 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 (National Cancer Action Team: personal communication 2009). This contravenes the NICE guidance on skin

[1] National Institute for Health and Clinical Excellence (2006) Improving outcomes for people with skin tumours including melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM
[2] National Cancer Action Team (2008) National Cancer Peer Review Programme. Manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources
[3] Available from the United Kingdom Association of Cancer Registries (UKACR): http://82.110.76.19/
[4] Available from the National Cancer Intelligence Network (NCIN): http://www.ncin.org.uk/index.shtml
[5] Hoey et al (2007) British Journal of Dermatology 156, 1301-1307
[6] Bath-Hextall et al (2007) International Journal of Cancer 121 (9), 2105-2108

cancer services[7] and the NICE 'Referral guidelines for suspected cancer'[8] 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 multiplicity of tumours that patients develop and the predominance of tumours in sun-exposed areas, for example the head, neck, forearms, hands, lower legs and feet, and trunk. Superficial BCCs are seen on the trunk, especially in men. Individuals with fair skin are more at risk. Age-standardised rates of BCC in the south west of England are much higher than in England overall (121.3 per 100,000 population compared with 93.72 per 100,000 population)[9].

BCCs also arise in patients with a genetic predisposition, for example Gorlin's syndrome or xeroderma pigmentosum. These patients have large numbers of BCCs, should be referred to and managed by the local skin cancer multidisciplinary team (LSMDT) or the specialist skin cancer multidisciplinary team (SSMDT) and should not have their BCCs treated with radiotherapy (as recommended in the NICE guidance on skin cancer services[10]).

The incidence of BCC increases with age and it is more common in men[11]. Using 2002–06 age-standardised rates, at ages up to 50 years, men have lower incidence rates ($p < 0.01$) than women, or there is no significant difference. In those aged 50 years and over the incidence rate is higher for men ($p < 0.01$). The largest difference is for the 80–84 age group, where the incidence rate for men is 66% higher than that for women[12].

Patients diagnosed with one BCC are at increased risk of having further BCCs diagnosed at the same time, or of developing them subsequently[13]. Studies suggest that the risk of developing a second BCC within 3 years of the first presentation is approximately 44%[14].

Where epidemiological studies have been undertaken, it has been shown that the incidence of BCC is rising, with evidence suggesting a 3% year-on-year increase[15]. The largest reported increase in incidence was seen in the 30–39 age group[16]. Unless population attitudes to sun exposure and skin protection change, the numbers of BCCs will continue 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[17]. Thus numbers would rise even if incidence rates stayed static.

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[7] National Institute for Health and Clinical Excellence (2006) Improving outcomes for people with skin tumours including melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM
[8] National Institute for Health and Clinical Excellence (2005) Referral guidelines for suspected cancer. Available from: www.nice.org.uk/CG27
[9] Available from the United Kingdom Association of Cancer Registries (UKACR): http://82.110.76.19/
[10] National Institute for Health and Clinical Excellence (2006) Improving outcomes for people with skin tumours including melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM
[11] Hoey et al (2007) British Journal of Dermatology 156, 1301-1307
[12] Available from the United Kingdom Association of Cancer Registries (UKACR): http://82.110.76.19/
[13] Cantwell et al (2009) British Journal of Cancer 100, 174-177
[14] Marcil and Stern (2000) Archives of Dermatology 136, 1524
[15] Brewster et al (2007) British Journal of Dermatology 156, 1295-1300
[16] Bath-Hextall et al (2007) International Journal of Cancer 121 (9), 2105-2108
[17] Møller et al (2007) British Journal of Cancer 96, 1484-1488

BCC is rarely fatal. Moreover, 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 erode important anatomical structures. Such tumours are very challenging to treat, making it difficult to obtain a good cosmetic result. The number of in-patient bed days devoted to managing BCCs is roughly comparable to those devoted to in-patient management of malignant melanoma[18]. 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 (NAEDI) programme[19] could reduce the proportion of patients presenting with advanced disease.

Burden of disease

The epidemiology and health services epidemiology of BCC, described above, demonstrates that the number of cases is rising significantly. These cases of BCC impose a significant workload on both primary and secondary care services and their management (if they are of a high-risk type) and require expertise to ensure curative resection is combined with a good cosmetic result and low risk of complications.

It is estimated that 24% of primary care workload is related to the diagnosis and management of skin conditions, including skin lesions[20]. 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[21]. This figure is as high as 60% in some areas[22]. Furthermore, approximately 88% of two-week wait urgent referrals for suspected skin cancer turn out to be non-malignant[23], 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.

Patient perspective

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

- have been fully and adequately trained
- have met prescribed standards
- participate in audit
- undertake continuous professional development (CPD) in this clinical area.

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[18] South West Public Health Observatory (www.swpho.nhs.uk/)
[19] The National Awareness and Early Diagnosis Initiative. Available from: http://www.ncin.org.uk/outcomes/naedi.shtml
[20] 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
[21] 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
[22] Joseph et al (2008) British Journal of Dermatology, 159 (Suppl. 1), 52.
[23] Cox N (2004) British Journal of Dermatology 150, 291-8.

Patients want their BCC(s) to be treated effectively the first time, with minimal risk of recurrence. They want to have the best cosmetic result achievable and surgery that, if undertaken, minimises the risk of damaging important, proximate anatomical features, such as nerves, where possible. Most importantly, they want to be clearly informed of their diagnosis and involved in the decision on choice of treatment and where this is delivered. The healthcare professional's advice and choice of treatment should not be influenced by a patient's age, gender or other disabilities unless the latter has a direct clinical relationship with the success of certain forms of treatment.

Patients are also keen to have their care provided close to home, which should not mean a compromise on the quality of care they receive[24]. This emphasis on equity of access to high quality care is reinforced in the recent Darzi review[25].

Training and accreditation

It is recognised that the training of healthcare professionals in dermatology is limited[26,27]. This includes undergraduate and postgraduate medical, nurse and pharmacy training. In particular, undergraduate medical training may be as little as 2 weeks, with no formal training or assessment of skin surgery. There is also no mandatory postgraduate training in dermatology or skin surgery for GPs, with no further requirement currently for formal assessment in these skills, or a mandatory system of accreditation including ongoing 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[28], the Department of Health 'Guidance and competencies for the provision of services using GPs with a special interest (GPwSIs)'[29] and the 'Manual for cancer services: skin measures'[30]. Early results from the peer review of skin cancer services in England (National Cancer Action Team: personal communication 2009) show generally poor levels of compliance to the standards, especially with respect to the primary care component and commissioning, although there are many notable exceptions across the country.

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[24] Department of Health (2006) Our health, our care, our say: a new direction for community services. Cm 6737. Norwich: The Stationery Office.
[25] Department of Health (2008) High quality care for all: NHS next stage review final report. Cm 7432. Norwich: The Stationery Office.
[26] All Party Parliamentary Group on Skin (1998) Enquiry into the training of healthcare professionals who come into contact with skin diseases. London
[27] All Party Parliamentary Group on Skin (2004) Dermatological training for health professionals. London
[28] National Institute for Health and Clinical Excellence (2006) Improving Outcomes for People with Skin Tumours including Melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM
[29] Department of Health (2007) Guidance and competencies for the provision of services using GPs with a Special Interest (GPwSIs). Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074665
[30] National Cancer Action Team (2008) National Cancer Peer Review Programme. manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources

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

- weak commissioning
- 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, 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 showed that some incorporate histological features that would only be available after biopsy or excision. However, for the purposes of the clinical recognition of high-risk BCCs, criteria were defined for the 'Manual for cancer services 2008: skin measures'[31]. There is a need for a clear clinical triage definition for high- and low-risk BCCs to ensure simple and efficient referral to appropriate healthcare professionals for management.

To aid clinical assessment of patients in the community with suspected BCC, and for clinical triage to the appropriate level of expertise for intervention, a range of definitions and criteria for defining high- and low-risk BCC were reviewed by the Guideline Development Group (GDG). These definitions had been summarised in a review paper prepared by Dr Dafydd Roberts and presented to the meeting at NICE in April 2009. The GDG concluded that the clinical triage definitions for the face and scalp (head) 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 the recommended 4 mm margins would lead to tissue removal of at least 18 mm diameter, which even on the cheek would result in a poor cosmetic result and make primary closure challenging
- proximity to facial structures presents a challenge to achieving 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 that new criteria be adopted for the definition of high- and low-risk BCC presenting in the community that take into account:

- risk of recurrence (incomplete excision)
- the skill and experience required by the healthcare professional to achieve a good cosmetic result
- risk caused by underlying anatomical structures

[31] National Cancer Action Team (2008) National Cancer Peer Review Programme. Manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources

- other management risks (for example, recurrent BCC, Gorlin's syndrome, immunosuppression).

Recommendations

The following definition of high-risk BCC should be used for clinical triage in primary care:

- recurrent BCCs
- BCCs on the head (face and scalp)
- BCCs greater that 2 cm in diameter, unless they are superficial BCCs that can be managed non-surgically
- lesions that have a clinical appearance of morphoeic, infiltrative or basosquamous
- lesions with poorly defined margins
- BCCs in patients who are immunosuppressed or have Gorlin's syndrome
- BCCs located over important underlying anatomical structures (for example, major vessels or nerves) or where primary surgical closure may be difficult (for example, digits or front of shin).

Patients with superficial BCCs (not usually classified as high risk) should be appropriately referred in order that they are offered a full range of medical treatments, including photodynamic therapy.

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

Patients with clinically suspected or histologically confirmed high-risk BCCs should continue to be referred to approved specialists as recommended in 'Improving outcomes for people with skin tumours including melanoma' (NICE guidance on cancer services)[32].

Training and education

All healthcare professionals dealing with skin lesions in the community should have access to specialist training in the diagnosis and management of skin lesions.

All healthcare professionals wishing to excise skin lesions in the community should be fully accredited to do so and undergo continuous professional development in the diagnosis and management of skin lesions to maintain their accreditation status.

Quality assurance

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

[32] National Institute for Health and Clinical Excellence (2006) Improving outcomes for people with skin tumours including melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM

cancer'[33]. Where multiple lesions exist, they should be sent in separate specimen pots with individual referral forms.

Histology request and reporting forms, and the electronic recording of these data items, should be improved to capture the minimum dataset requirements (National Cancer Intelligence Network dataset project [in development][34] and the Royal College of Pathology dataset[35]).

Healthcare professionals in the community sending skin lesion samples for histological assessment should have a mechanism in place to ensure that they receive histology results and should take appropriate action.

Healthcare professionals dealing with low-risk BCCs in the community should maintain a log book or spreadsheet of the suspected and actual skin cancer lesions they have managed.

All healthcare professionals performing skin surgery in the community should provide quarterly feedback to their primary care trusts (PCTs) on histology reported in the minimum dataset.

As required by the 'Manual for cancer services 2008: skin measures'[36] there should be an audit of all BCCs excised by healthcare professionals in the community. The PCT should make these audit results available to the multidisciplinary team (MDT) on a quarterly basis and it should be included in the cancer network annual audit (cancer standards 08-6A-103J[36]).

All healthcare professionals dealing with low-risk BCCs in the community should attend an educational meeting (organised by the Cancer Network Site Specific Group) where the annual BCC network results are presented along with a breakdown of individual healthcare professional data. This meeting should also include one CPD session (a total of 4 hours) on the diagnosis and management of low-risk BCCs. These meetings should be run at least twice a year and healthcare professionals should attend on at least one occasion.

The MDT should facilitate the development of a patient reported outcome measure (PROM) for the treatment of BCCs.

[33] National Institute for Health and Clinical Excellence (2005) Referral guidelines for suspected cancer. Available from: www.nice.org.uk/CG27
[34] Available from the National Cancer Intelligence Network (NCIN): http://www.ncin.org.uk/index.shtml
[35] Available from the Royal College of Pathologists: http://www.rcpath.org/index.asp?PageID=154
[36] National Cancer Action Team (2008) National Cancer Peer Review Programme. Manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources

Clinical governance

PCTs commissioning 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 dealing with skin lesions in the community should obtain informed consent before any treatment is undertaken[37,38,39].

This updated guidance and other national clinical guidelines should be used in the development of local protocols and guidelines at the cancer network level.

PCTs should ensure that all primary care healthcare professionals excising skin lesions are appropriately accredited.

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

Commissioning

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 use the commissioning cycle[40] and follow the process outlined in the NHS primary care contracting guidance[41].

The commissioning process should plan for a significant increase in the number of patients with low-risk BCC, especially in an older population.

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[37] Department of Health Guidance on informed consent. Available at: http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf
[38] General Medical Council (GMC) guidance on informed consent. Available at: http://www.gmc-uk.org/static/documents/content/Consent_2008.pdf
[39] Welsh Assembly Government Guidance on informed consent. Available at: www.wales.nhs.uk/consent
[40] Department of Health (2007) World class commissioning: vision. London: Department of Health.
[41] NHS Primary Care Contracting (2008) Providing care for patients with skin conditions: guidance and resources for commissioners. Leeds: NHS Primary Care Contracting.

Commissioners should ensure that the management of low-risk BCCs by healthcare professionals in the community is subject to the quality standards and requirements outlined in this guidance.

All providers of community cancer services for low-risk BCC should demonstrate that they are competent in the diagnosis and management of skin lesions, including skin cancer surgery (SS1 and SS2 competencies[42]). This should be assessed by direct observation of procedural skills (DOPS).

Commissioners should consider innovative approaches to the diagnosis of low-risk BCCs so that patients are not inconvenienced with unnecessary travel/access arrangements.

Commissioners should consider quality of care and value for money in commissioning services for low-risk BCCs.

Provided quality standards can be ensured, commissioners should commission services from different providers. The options are:

- Group 3 community cancer GPwSIs[43,44].
- Outreach specialist services provided by secondary care (including consultants, staff grade and associate specialist [SAS] doctors, specialist nurses and new model 2 practitioners[45]).
- A new GP expert in skin lesions (a framework should be developed based on SS1/SS2[42] that will enable commissioners to commission skin services and low-risk BCCs from suitably trained individuals).
- GPs already performing minor surgery within the Directed Enhanced Services (DES)[46] (minor surgery) arrangements under General Medical Services (GMS) or Personal Medical Services (PMS). Such GPs may undertake low-risk BCC surgery if the following additional criteria are met:
  - GPs should satisfy their contracting PCT that they are competent in the diagnosis of BCCs and carry out the appropriate surgical procedures; this should be reviewed annually as part of the contracting arrangements for the DES.
  - GPs already excising BCCs should provide evidence that they have been excising low-risk BCCs appropriately with adequate skin margins. If the GP cannot provide such evidence, they should undergo a direct observation of procedural skills (DOPS).

[42] Department of Health (2007) Guidance and competencies for the provision of services using GPs with special interests (GPwSIs). Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074665
[43] Department of Health (2007) Guidance and competencies for the provision of services using GPs with special interests (GPwSIs). Available from: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074665
[44] Department of Health (2007) Implementing care closer to home: convenient quality care for patients. Part 3: the accreditation of GPs and pharmacists with special interests. London: Department of Health.
[45] National Cancer Action Team (2008) National Cancer Peer Review Programme. Manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources
[46] Department of Health (2006) The primary medical services (Directed Enhanced Services) (England) Directions.

- GPs wishing to start providing this service should undergo a DOPS to demonstrate competency.
- GPs should keep a log book or spreadsheet of all suspected low-risk BCCs to be excised.
- All skin specimens removed should be sent to histology for analysis.
- GPs should provide information about the site of excision and provisional diagnosis on the histology request form.
- Practices should have a robust process to ensure that patients are informed of the final diagnosis, and whether any further treatment or follow-up is required.
- GPs should provide quarterly feedback to their PCT on the histology reported in the minimum dataset. This should include details of all proven BCCs clinically diagnosed before surgery. GPs should also provide details of any type of skin cancer removed in their practice, as it is acknowledged that GPs will occasionally excise a skin cancer unknowingly.
- GPs should attend an educational meeting (organised by the Skin Cancer Network Site Specific Group) where the annual BCC network results are presented, including a breakdown of individual GP performance. This meeting should also include one CPD session (a total of 4 hours) on the diagnosis and management of low-risk BCCs. These meetings should be run at least twice a year and GPs should attend on at least one occasion.

Models of care

PCTs should ensure that services procured/commissioned (by practice-based commissioning) for low-risk BCCs for their population adhere to national standards.

Data collection

Improved quality of data collection for BCC should be implemented by cancer peer review following the publication of the skin cancer minimum dataset now in development[47].

BCCs should be comprehensively registered by cancer registries to allow national and sub-national epidemiology and health service epidemiological studies to take place.

Communication

All healthcare professionals managing BCCs in the community should be responsible for the provision of information, advice and support for patients and their carers.

[47] Available from the National Cancer Intelligence Network (NCIN): http://www.ncin.org.uk/index.shtml

Research recommendations

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

- Research on the epidemiology and health service epidemiology of BCCs should be increased.
- Further research should be undertaken on predictive factors in recurrence and other outcome measures.

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[48] 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'[49]
- 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?'.

[48] National Institute for Health and Clinical Excellence (2006) Improving outcomes for people with skin tumours including melanoma. Available from: http://guidance.nice.org.uk/CSGSTIM
[49] National Cancer Action Team (2008) National Cancer Peer Review Programme. Manual for cancer services: skin measures. Available from: http://www.ncpr.nhs.uk/index.php?menu=resources

Evidence summary

[*References for this evidence review 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 evidence is limited in the UK setting.

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 high levels of 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 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%: 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 superior in the detection of BCCs and malignant melanomas but not squamous cell carcinomas. 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 (Wylie *et al*. 2009). Wylie *et al*. (2009) reported a study that 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 basal cell carcinoma 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. Similar wide variations in practice were found with examples for high-/low-risk squamous cell carcinoma and also for initial primary melanoma excision. Grade of operator and frequency of surgery were linked with the use of 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 to be conducted and, along with more well-conducted studies using reliable audit data, the outcomes of excisional surgery will be more adequately reported.

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

References for evidence summary

Carter, E. J., L. R. Whittam, and D. A. Buckley. 2009. Failure of adherence to NICE guidelines for skin cancer surgery in general practice. *British Journal of Dermatology* 161: 63.

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 secondary care in a county over 1 year. *British Journal of Dermatology* 159: 111-112.

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.

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Appendices

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

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1.1 Members of the Guideline 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 Guideline 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	North West London Cancer Network Director
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	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 guideline.

GDG member	Interest declared	Type of interest	Decision taken
Julia Schofield	Received an honorarium from Leo Pharm Lecture to give a lecture on GPwSI accreditation and community cancer services	Personal pecuniary specific	Declare and must withdraw from discussions on topics that focus on GPwSI accreditation until Jan 2010. Chairperson's action taken that JS can be asked specific technical questions about GPwSI accreditation.
	Received an honorarium from Schering Plough to give a lecture on commissioning dermatology services	Personal pecuniary non-specific	Declare can participate in discussions as the meeting was not specific to skin cancer.

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

Association of British Insurers (ABI)

Associazione Infermieristica per lo Studio delle Lesioni Cutanee (AISLeC)

Antimicrobial Resistance and Healthcare Associated Infection

Association of Chartered Physiotherapists in Oncology and Palliative Care

Association for Clinical Biochemistry

Association of Surgeons in Primary Care

AstraZeneca UK Ltd

British Association of Dermatologists

British Medical Association

British National Formulary

British Nuclear Medicine Society

Care Quality Commission

Central South Coast Cancer Network

College of Occupational Therapists

Commission for Social Care Inspection

Connecting for Health

ConvaTec

County Durham PCT

Criminal Justice Women's Strategy Unit

Department of Health

Dudley Group of Hospitals NHS Trust

Gloucestershire Hospitals NHS Trust

Gorlin Syndrome Group

Institute of Biomedical Science

Johnson & Johnson Medical

Juvenile Diabetes Research Foundation

Kent County Council Children and Families Directorate

Liverpool PCT Provider Services

Luton & Dunstable Hospital NHS Foundation Trust

Macmillan Cancer Support

Medicines and Healthcare Products Regulatory Agency

Met Office

Ministry of Defence

National Patient Safety Agency

National Public Health Service – Wales

National Treatment Agency for Substance Misuse

NHS Clinical Knowledge Summaries Service (SCHIN)

NHS Plus

NHS Quality Improvement Scotland

NHS Sheffield

Patients Council

PERIGON Healthcare Ltd

Plymouth PCT

Primary Care Dermatology Society

Royal College of Anaesthetists

Royal College of General Practitioners

Royal College of General Practitioners - Wales

Royal College of Midwives

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Royal College of Paediatrics and Child Health

Royal College of Pathologists

Royal College of Physicians of London

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Surgeons of England

Royal Pharmaceutical Society of Great Britain

Sandwell PCT

Scottish Intercollegiate Guidelines Network (SIGN)

Sheffield Teaching Hospitals NHS Foundation Trust

Skin Care Campaign

Social Care Institute for Excellence (SCIE)

Social Exclusion Task Force

The Teenage Cancer Trust

Thames Valley Cancer Network

University College London Hospitals (UCLH) Acute Trust

Welsh Assembly Government

Welsh Scientific Advisory Committee (WSAC)

Western Health and Social Care Trust

York NHS Foundation Trust

Appendix 1.3: Individuals carrying out literature reviews and complementary work

Overall Coordinators	
Dr John Graham	Director, National Collaborating Centre for Cancer, Cardiff
Dr Andrew Champion	Centre Manager, National Collaborating Centre for Cancer, Cardiff
Project Manager	
Lianne Black	National Collaborating Centre for Cancer, Cardiff
Senior Researcher	
Angela Melder	National Collaborating Centre for Cancer, Cardiff
Researcher	
Karen Francis	National Collaborating Centre for Cancer, Cardiff
Information Specialist	
Stephanie Arnold	National Collaborating Centre for Cancer, Cardiff
Health Economist	
Sarah Willis	London School of Hygiene and Tropical Medicine

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