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# BMJ Open

## High Risk Basal Cell Carcinoma Excision in Primary Care – Compliance with NICE Guidance

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## High Risk Basal Cell Carcinoma Excision in Primary Care – Compliance with NICE Guidance

**Keywords:** Primary Care; Dermatological tumours; Protocols and guidelines; Histopathology; Surgical Pathology; Plastic and Reconstructive Surgery

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46 Data Sharing statement:

47 All data is included in article and will be published in an open journal making it freely  
48 accessible. There is no unpublished data.  
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## ABSTRACT Article Summary

### Objectives

To assess compliance with the 2010 National Institute for Health and Care Excellence (NICE) guidance on cancer services relating to the management of Basal Cell Carcinomas (BCC) in the community, where it is recommended that only low risk BCCs should be excised routinely except in specific circumstances.

### Design and setting

A comparative retrospective study of the histopathology reports of BCC excisions received from Primary Care in the histopathology laboratories of two district general hospitals in the south of England. One hundred consecutive BCC excisions were analysed from each hospital.

### Outcome measures

The numbers of high risk BCCs excised in Primary Care according to histological sub-type, patient age, anatomical site and if these excisions were compliant with NICE 2010 guidance. Completeness of BCC excision was measured as a secondary outcome.

### Results

Histologically high risk subtypes were present in 32 percent (64/200) of BCCs excised in the community. Only 17 of these 64 were excised by GPs who were accredited to do so. Noncompliance regarding anatomical site occurred in 16 percent of samples; only one sample was noncompliant regarding patient age. There was a high overall rate of complete excision (94.5%) of all types of BCC.

### Conclusions

The NICE 2010 guidance relating to BCC excision in Primary Care was not followed in a considerable number of cases. Compliance with NICE 2010 guidance depends on the ability to recognise high risk BCCs clinically and manage appropriately. This study shows that despite close supervision by Secondary Care there are currently failures of compliance.

In view of the increasing age of the population and the rising incidence of all BCCs sub-types, it would be desirable for GP training in identification of sub-types of BCC to be improved and also to increase the number of GPs accredited to carry out high risk BCC excisions.

**Strengths and Limitations:**

- The introduction of Model 2 practitioner status means that the conclusions of previous studies on primary care adherence to NICE guidance are less relevant now. There is relatively little published on high risk BCC excision according the categories of GP that are appropriate to carry out the surgery.
- Comparison between two different geographical areas allowed assessment of compliance with NICE guidance according to different status of GPs. Some GPs (Model 2 practitioners) are trained and accredited to excise certain high risk subtypes of BCC.
- Presence or absence of high risk features of BCCs is a binary measure and therefore simplifies data analysis. Two hundred BCCs represent a relatively small sample but it is likely that a larger study would confirm the overall findings.
- It was not possible to comment on overall diagnostic accuracy of GPs because no information was obtained relating to other lesions that had been referred in directly for excision to be done within Secondary Care and were subsequently diagnosed histologically as BCCs.
- It was assumed that any high risk histological subtype excisions performed in the area with a Model 2 GP were approved for excision by an MDT member, consistent with NICE guidance.

## INTRODUCTION

Basal cell carcinoma is the commonest type of cancer in the UK and, although it rarely metastasises, inadequate treatment or late diagnosis can result in the BCC invading important anatomical structures, making them difficult to treat or resulting in the lesion becoming advanced or inoperable<sup>1</sup>.

The 2010 NICE guidance primarily addresses the excision of low risk BCCs in the community. It has been shown<sup>2</sup> that patients are generally more satisfied if their procedure can be performed in Primary Care because of convenience.

However, NICE 2010 also addressed the importance of high risk BCCs being treated appropriately. "High risk" BCCs include those in difficult anatomical sites including the face and lower leg, in young patients under 24 years of age, those which have previously been incompletely excised or are recurrent, and those of a high risk histological sub-type. In a study of 1039 consecutive BCC excisions in secondary care<sup>3</sup> only 38.4% were low risk histologically (nodular or superficial) and all the remaining BCCs had high risk features such as micro-nodular, infiltrative or morphoeic sub-types.

The NICE guidance aims to provide the best care for patients with BCCs whether these are excised in Primary Care or Secondary Care. As a GP who is part of a Direct Enhanced Service (DES) or Local Enhanced Service (LES), an Enhanced services GP (ESGP) is eligible to excise low risk BCCs below the clavicle if less than 1cm in diameter and not in the pre-tibial region. If a GP with a Special Interest (GPwSI, which since 2015 is included under the new term GP with Extended Role) sees a lesion that is a possible BCC but is unable to confirm this clinically as a low risk lesion then they are expected to refer the case to the local specialist MDT. If it is pre-diagnosed by the local specialist MDT, a Model 2 Practitioner can excise a high risk BCC.

Initial working diagnosis of a lesion as a BCC precedes classification into low or high risk subtypes. In a study in the Grampian region<sup>4</sup>, the accuracy of clinical diagnosis of BCC based on 1087 histology reports was 67.1% for the GPs, 82.1% for the dermatologists and 83.3% for plastic surgeons. GPs were more likely to state "no diagnosis" than secondary care specialists.

In a self-reported study from volunteer GPs doing local anaesthetic skin lesion excisions<sup>5</sup> 6138 procedures were analysed, of which 926 were confirmed as malignancies, including 722 BCCs. Model 2 GPs and GPwSIs had statistically significantly higher rates of complete excision than ESGPs. Only 37% of Model 2 GPs took written consent. In a review of 1743 BCCs excised over a 32 month period by GPs<sup>6</sup> only 3% were considered to be "low risk" according to NICE 2010 criteria. The authors concluded that low risk BCCs are of low prevalence which therefore leads to difficulties for GPs to maintain competencies. NICE guidance includes clinical governance recommendations. However, in a small study whereby questionnaires were sent out to 13 GPs with a Special Interest in Dermatology or skin surgery, only eight replies were received and it was confirmed that none of them were following the Department of Health guidelines for MDT attendance and annual appraisal<sup>7</sup>.

Other studies have reported on the variability of suitability for case selection for primary care treatment. Two audits in 2008 and 2009 from Liverpool<sup>8</sup> reported that in 2008, out of 117 BCCs excised in Primary Care, 46% were high risk (clinically and/or histologically) and in 2009, out of 251

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3 BCCs excisions in Primary Care, 35% were high risk. In a further study of skin cancer excisions in  
4 Primary Care prior to the 2010 NICE guidance<sup>9</sup> reporting on the treatment of 71 lesions, there were  
5 50 excisions and 21 other procedures. Of these 71, 64 were reported as high risk, 27 were at high  
6 risk sites, and 37 of 44 lesions at low risk sites were actually high risk histologically. Of the 71 skin  
7 cancers 24 (34%) required further excision. Further evidence of high risk BCC excisions in primary  
8 care was reported in a 2010 study in Lothian, Fife and Tayside<sup>10</sup> where GPs excised 380 skin cancers  
9 in one year compared to 385 excised by dermatologists in one month and 179 by plastic surgeons  
10 also in one month. There were high risk features (recurrent BCC, infiltrative BCC or located on the  
11 head and neck regions) in 63% of the BCCs excised by GPs.  
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14 Compliance with NICE 2010 guidance is compromised by the difficulties recognising and diagnosing  
15 basal cell carcinoma, and the clinical recognition of the morphological subtypes. The aim of this  
16 study is to assess compliance with NICE 2010 guidance and also the reasons why this fails and how  
17 compliance could be improved.  
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## 20 METHODS

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22 The outcome of 200 BCC excisions carried out in Primary Care received at the histopathology  
23 laboratories of two district general hospitals in the south of England was studied. GPs were  
24 categorised as GPs, GPwSI or Model 2 Practitioners so that appropriateness of BCC different sub-  
25 type excisions according to type of GP could be assessed.  
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28 A total of 100 consecutive cases of lesion excisions confirmed on histology as BCC from each hospital  
29 were analysed according to the NICE criteria and also the level of GP performing the surgery. Data  
30 was collected from 2014, giving time for the update guidance from NICE in 2010 to be included in  
31 the practice of both areas.  
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33 “High risk” BCCs are defined by the NICE 2010 guidance including those at specific anatomical sites  
34 (including face and pre-tibial region), those with high risk histological sub-types, and in patients  
35 under 24 years of age.  
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38 As secondary outcomes, completeness of BCC excision was assessed and whether the possibility of  
39 BCC as a clinical diagnosis was included on the histology request form.  
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## 43 RESULTS

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45 Out of the total of 200 BCC excisions shown in Table 1, there was noncompliance in one case on the  
46 grounds of the age of the patient. There was noncompliance in 31 excisions on the anatomical site  
47 criterion. There were 47 incidents of noncompliance on the histological sub-type criterion. Some  
48 excisions were non-compliant on more than one criterion.  
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51 For the lesions received from the Area associated with a Model 2 Practitioner (Area 1), there were  
52 19 excisions of high risk histological subtype BCCs but 17 of those were carried out by the Model 2  
53 Practitioner. In the area with GPwSI and GPs only (Area 2), there were 45 BCCs with high risk  
54 histological features, none of which were excised by a Model 2 Practitioner.  
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The overall completeness of excision rate was 189 out of 200 (94.5%). The term “basal cell carcinoma” was not on the request forms accompanying 28 specimens.

Table 1. Results of BCC excisions and compliance with NICE 2010.

	Not stated as “BCC” on request	Incomplete excision	High Risk Histology	Fail Histology criterion	Fail Age criterion	Fail Site Criterion	Total BCCs
<u>Area 1</u>							
GP	5	3	2	2	0	1	14
Model 2 Practitioner	3	4	17	0	0	15	86
Total	8	7	19	2	0	16	100
<u>Area 2</u>							
GP	14	2	26	26	0	15	54
GPwSI	5	2	19	19	1	0	46
Total	20	4	45	45	1	15	100
<u>Area 1 &amp; 2</u> Total	28	11	64	47	1	31	200

## DISCUSSION

### Principle findings

The principle finding of this study is low compliance NICE 2010 guidance, particularly regarding high risk histological sub-types of BCC and anatomical site of the lesion (Table 1). Histologically high risk BCCs have an increased risk of incomplete removal. A study examining the association between histological pattern and adequacy of excision<sup>3</sup> showed that completeness of excision was worse for high risk micronodular, infiltrative and mixed types of BCC. From a study of 16,066 BCC excisions<sup>11</sup> it was concluded that, for a non-morpheiform type of BCC of less than 2cm in diameter, a 3mm margin

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3 is sufficient to obtain a 95% cure rate. The importance of an involved margin was also shown in this  
4 study which was a review of 89 articles published on the subject and confirmed that a positive  
5 pathological margin would lead to an average recurrence rate of 27%. A BCC of 2cm diameter  
6 requires a surgical margin of at least 13mm for relative certainty of removal of the tumour in 95% of  
7 cases<sup>12</sup>. Surgical margins of this width create large defects closure of which may be challenging in a  
8 primary care setting.  
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11 Various studies have reported on inadequacy of completeness of excision of BCCs in primary care. In  
12 a review of 366 BCC excisions in Aberdeen<sup>13</sup> those excised by GPs had a 34.1% incomplete excision  
13 rate. In a review from the Netherlands in 2009<sup>14</sup> of 1898 pathological specimens of skin tumours  
14 excised by GPs, 35% were incomplete and 65.4% were incomplete from the face and neck region. A  
15 study of 2586 BCC excisions in 1717 patients<sup>15</sup> quoted a recurrence rate of incompletely excised  
16 BCCs at 5 year follow-up of 30-41%. Of 184 incompletely excised BCCs, 62 were re-excised and 39 of  
17 these showed residual tumour so complete excision is essential and is therefore of importance as an  
18 outcome measure. The majority of publications report a high incomplete excision rate in primary  
19 care but in a review of 124 BCC excisions in primary care<sup>16</sup> there was an incomplete excision rate of  
20 only 1.6%. In the present study the incomplete excision rate was 5.5 per cent.  
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24 The strength of this study is that the NICE guidance is clear on sub-types of BCC that are considered  
25 "high risk" and also which anatomical sites and age of patient represent high risk cases. These  
26 binary parameters make it relatively easy to assess compliance.  
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29 A further strength of this study is that there is relatively little published on high risk BCC excision  
30 according the new categories of GP that can carry out the surgery. The introduction of Model 2  
31 practitioner status means that the conclusions of previous studies on adherence to NICE guidance  
32 are of less relevance.  
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35 A potential weakness of this study is that the sample is small but a clear pattern still emerged. This  
36 confirmed a high complete excision rate by all of the GPs involved, but no information was obtained  
37 about any suboptimal healing or complications which could lead to scarring or less than satisfactory  
38 cosmetic results. Delayed healing or scarring is of particular relevance to the higher risk sites such as  
39 the face and lower leg. There was also no information on BCCs that were referred into secondary  
40 care for treatment by specialists and whether or not those were originally diagnosed correctly  
41 clinically as BCCs.  
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### 45 **Explanation and Implications**

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47 Some high risk features are easy to ascertain, such as age of patient and anatomical site, but it can  
48 be difficult to differentiate clinically between histological sub-types, and a significant proportion of  
49 BCCs are of mixed sub-type which include high risk morphology. Further training in primary care in  
50 the recognition of sub-types of BCC, possibly assisted by more widespread use of dermoscopy, could  
51 improve compliance with regard to recognition of histological sub-type. Greater numbers of these  
52 operations carried out by Model 2 Practitioners with a link to the Local Specialist MDTs would also  
53 improve compliance with NICE 2010 guidance.  
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Future research in this area could involve a comparison of the performance in terms of diagnosis of skin cancers by GP with Extended Roles (GPwERs) and Model 2 Practitioners compared to Secondary Care; a larger study could examine GP referrals that were subsequently confirmed as being BCCs and what was stated in the referral letter. Accuracy of clinical diagnosis of pigmented lesions referred for excision would be of interest and also consideration of squamous cell carcinoma excisions inadvertently carried out in Primary Care.

In conclusion, compliance with NICE 2010 BCC excision guidance could be improved with further GP education, closer involvement with the local skin MDTs and greater progression to accreditation as Model 2 practitioner status. Consideration might be given to revising the NICE guidance taking into account the difficulty of diagnosing high risk histological sub-types of BCC preoperatively which makes compliance with this parameter difficult.

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## High Risk Basal Cell Carcinoma Excision in Primary Care – A retrospective observational study of compliance with NICE Guidance

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8 **observational study of compliance with NICE Guidance**  
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46 Data Sharing statement:

47 All data is included in article and will be published in an open journal making it freely  
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### Objectives

To assess compliance with 2010 National Institute for Health and Care Excellence (NICE) guidance on cancer services relating to the management of Basal Cell Carcinomas (BCC) in the community, where except in specific circumstances it is recommended that only low risk BCCs should be excised routinely.

### Design and setting

A retrospective observational study of the histopathology reports of BCC excisions received from Primary Care in two district general hospitals in the south of England. One hundred consecutive BCC excisions were analysed from each hospital.

### Outcome measures

The numbers of high risk BCCs excised in Primary Care according to histological sub-type, anatomical site, and age and if these excisions were compliant with NICE 2010 guidance. Completeness of excision and mention of BCC on histology request were secondary outcomes.

### Results

Histologically high risk subtypes were present in 32% (64/200) of BCCs excised in the community. Only 17/64 were excised by General Practitioners (GPs) who were accredited to do so. Noncompliance regarding anatomical site occurred in 16% of samples; only one was noncompliant regarding patient age. There was a high overall rate of complete excision (94.5%) with variation in presence of the term BCC on histology request forms.

### Conclusions

NICE 2010 guidance relating to BCC excision in Primary Care was not followed in a considerable number of cases. Compliance with NICE 2010 guidance depends on the ability to recognise high risk BCCs clinically and manage appropriately. It also shows that despite close supervision by Secondary Care there are still failures of compliance.

GP training in identification of sub-types of BCC might be improved, as well as an increase in numbers of GPs accredited to carry out high risk BCC excisions. Difficulty in diagnosing high risk histological sub-types of BCC preoperatively should be considered in any future revision of NICE guidance.

### Strengths and Limitations:

- The introduction of Model 2 practitioner status means that the conclusions of previous studies on Primary care adherence to NICE guidance are less relevant now and there is relatively little published on high risk BCC excision according the categories of GP that are appropriate to carry out the surgery.
- Presence or absence of high risk features of BCCs is a binary measure and therefore simplifies data analysis.



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- Two hundred BCCs represent a relatively modest sample but it is likely that a larger study would confirm the overall findings.
  - It was not the aim to comment on overall diagnostic accuracy of GPs so no information was obtained relating to other lesions that had been referred directly for excision to be done within Secondary Care, and were subsequently diagnosed histologically as BCCs or lesions which were excised as possible BCCs but were revealed to be other skin cancers on histology.
  - It was assumed that any high risk histological subtype excisions performed in the Area with a Model 2 GP were approved for excision by a Multidisciplinary team (MDT) member, consistent with NICE guidance; this process means that Model 2 GPs will have a different case mix with more high risk BCCs which could affect secondary outcome measures.

## INTRODUCTION

Basal cell carcinoma (BCC) is the commonest type of cancer in the UK and, although it rarely metastasises, inadequate treatment or late diagnosis can result in the BCC invading important anatomical structures, making them difficult to treat or resulting in the lesion becoming advanced or inoperable<sup>1</sup>.

The 2010 National Institute for Health and Care Excellence (NICE) guidance primarily addresses the excision of low risk BCCs in the community. It has been shown<sup>2</sup> that patients are generally more satisfied if their procedure can be performed in Primary Care because of convenience.

However, NICE 2010 also addressed the importance of high risk BCCs being treated appropriately. "High risk" BCCs include those of a high risk histological sub-type, those in difficult anatomical sites including the face and lower leg, in young patients under 24 years of age and those which have previously been incompletely excised or are recurrent. In a study of 1039 consecutive BCC excisions in secondary care<sup>3</sup> only 38.4% were low risk histologically (nodular or superficial) and all the remaining BCCs had high risk features such as micro-nodular, infiltrative or morpheic sub-types.

The NICE guidance aims to provide the best care for patients with BCCs whether these are excised in Primary Care or Secondary Care. As a General Practitioner (GP) who is part of a Direct Enhanced Service (DES) or Local Enhanced Service (LES), an Enhanced services GP (ESGP) is eligible to excise low risk BCCs below the clavicle if less than 1cm in diameter and not in the pre-tibial region. If a GP with a Special Interest (GPwSI, which since 2015 is included under the new term GP with Extended Role) sees a lesion that is a possible BCC but is unable to confirm this clinically as a low risk lesion then they are expected to refer the case to the local specialist Multidisciplinary team (MDT). If it is pre-diagnosed by the local specialist MDT, a Model 2 Practitioner can excise a high risk BCC.

Prior to classification as a high or low risk sub-type, clinicians must first have suspected the lesion to be a BCC. In a study in the Grampian region<sup>4</sup>, the accuracy of clinical diagnosis of BCC based on 1087 histology reports was 67.1% for the GPs, 82.1% for the dermatologists and 83.3% for plastic surgeons. GPs were more likely to state "no diagnosis" than secondary care specialists.

In a self-reported study from volunteer GPs doing local anaesthetic skin lesion excisions<sup>5</sup> 6138 procedures were analysed, of which 926 were confirmed as malignancies, including 722 BCCs. Model 2 GPs and GPwSIs had statistically significantly higher rates of complete excision than ESGPs. Only 37% of Model 2 GPs took written consent. In a review of 1743 BCCs excised over a 32 month period by GPs<sup>6</sup> only 3% were considered to be "low risk" according to NICE 2010 criteria. The authors concluded that low risk BCCs are of low prevalence which therefore leads to difficulties for GPs to maintain competencies. NICE guidance includes clinical governance recommendations. However, in a small study whereby questionnaires were sent out to 13 GPs with a Special Interest in Dermatology or skin surgery, only eight replies were received and it was confirmed that none of them were following the Department of Health guidelines for MDT attendance and annual appraisal<sup>7</sup>.

Other studies have reported on the variability of suitability for case selection for Primary care treatment. Two audits in 2008 and 2009 from Liverpool<sup>8</sup> reported that in 2008, out of 117 BCCs excised in Primary Care, 46% were high risk (clinically and/or histologically) and in 2009, out of 251

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3 BCC excisions in Primary Care, 35% were high risk. In a further study of skin cancer excisions in  
4 Primary Care prior to the 2010 NICE guidance<sup>9</sup> reporting on the treatment of 71 lesions, there were  
5 50 excisions and 21 other procedures. Of these 71, 64 were reported as high risk, 27 were at high  
6 risk sites, and 37 of 44 lesions at low risk sites were actually high risk histologically. Of the 71 skin  
7 cancers, 24 (34%) required further excision. Further evidence of high risk BCC excisions in Primary  
8 care was reported in a 2010 study in Lothian, Fife and Tayside<sup>10</sup> where GPs excised 380 skin cancers  
9 in one year compared to 385 excised by dermatologists in one month and 179 by plastic surgeons  
10 also in one month. There were high risk features (recurrent BCC, infiltrative BCC or located on the  
11 head and neck regions) in 63% of the BCCs excised by GPs.  
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13

14 Compliance with NICE 2010 guidance is compromised by the difficulties recognising and diagnosing  
15 basal cell carcinoma, and the clinical recognition of the morphological subtypes. The aim of this  
16 study is to assess compliance with NICE 2010 guidance and also the reasons for non-compliance and  
17 how it could be improved.  
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19

## 20 METHODS

21  
22 The outcome of 200 BCC excisions carried out in Primary Care received at the histopathology  
23 laboratories of two district general hospitals in the south of England was studied.  
24

25 Using the same start date a total of 100 consecutive cases of lesion excisions confirmed on histology  
26 as BCC from each hospital were analysed according to the NICE criteria and also the category of GP  
27 performing the surgery.  
28  
29

30 Full pathology reports were studied by two independent researchers (SC and RH) who were blinded  
31 to operator's identity and category. Re-excisions, shaves, punch biopsies and other diagnostic  
32 samples were excluded as were all Secondary Care excisions. Presence or absence of each of the  
33 high risk criteria was recorded for every excision. Where required, clarifications were provided by  
34 the Pathology department. The category of each operator whose excisions were studied was  
35 revealed by the Pathology department at the end of data collection. Operators were categorised as  
36 GPs, GPwSI or Model 2 Practitioners so that appropriateness of different BCC risk group according to  
37 type of GP could be assessed.  
38  
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40 Data was collected from September 4<sup>th</sup> 2014, giving time for the update guidance from NICE in 2010  
41 to be included in the practice of both Areas.  
42

43 "High risk" BCCs are defined by the NICE 2010 guidance including those with high risk histological  
44 sub-types, those at specific anatomical sites (including face and pre-tibial region), and in patients  
45 under 24 years of age.  
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48 As secondary outcomes, completeness of BCC excision was assessed and whether the possibility of  
49 BCC as a clinical diagnosis was included on the histology request form.  
50  
51

## 52 RESULTS

Out of the total of 200 BCC excisions shown in Table 1, histologically high risk subtypes were present in 32% (64/200). For the lesions received from the Area associated with a Model 2 Practitioner (Area 1), there were 19 excisions of high risk histological subtype BCCs but 17 of those were carried out by the Model 2 Practitioner which is in line with guidance. In the Area with GPwSI and GPs only (Area 2), there were 45 BCCs with high risk histological features, none of which were excised by a Model 2 Practitioner. Across both Areas there were 47 incidents of non-compliance on the histological subtype criterion (23.5%).

There was non-compliance in 31 excisions on the anatomical site criterion (15.5%). There was non-compliance in one case on the grounds of the age of the patient (0.5%). Some excisions were non-compliant on more than one criterion.

Secondary outcome measures are shown in table 2. The overall completeness of excision rate was 189 out of 200 (94.5%) with GPs across both Areas achieving 92.65%, GPwSIs 95.65% and Model 2 95.4%. The terms "basal cell carcinoma" or "BCC" were not on the request forms accompanying 28 specimens. Model 2 Practitioners were most likely to mention BCC on their request form (96.6%), followed by GPwSI (88.2%) then GPs (72.1%).

**Table 1.** Results of BCC excisions and compliance with NICE 2010.

	High Risk Histology	Fail Histology criterion	Fail Site criterion	Fail Age criterion	Total BCCs
<u>Area 1</u>					
GP	2	2	1	0	14
Model 2 Practitioner	17	0	15	0	86
Total	19	2	16	0	100
<u>Area 2</u>					
GP	26	26	15	0	54
GPwSI	19	19	0	1	46
Total	45	45	15	1	100
<u>Area 1 &amp; 2</u>					
Total	64	47	31	1	200

**Table 2.** Secondary outcome measures

	Incomplete excision	Not stated as "BCC" on request form	Total BCCs
<u>Area 1</u>			
GP	3	5	14
Model 2 Practitioner	4	3	86
Total	7	8	100
<u>Area 2</u>			
GP	2	14	54
GPwSI	2	5	46
Total	4	20	100
<u>Area 1 &amp; 2 Total</u>	11	28	200

## DISCUSSION

### Principle findings

The principle finding of this study is low compliance NICE 2010 guidance, particularly regarding high risk histological sub-types of BCC and anatomical site of the lesion (Table 1). Histologically high risk BCCs have an increased risk of incomplete removal. A study examining the association between histological pattern and adequacy of excision<sup>3</sup> showed that completeness of excision was worse for high risk micronodular, infiltrative and mixed types of BCC. From a study of 16,066 BCC excisions<sup>11</sup> it was concluded that, for a non-morpheiform type of BCC of less than 2cm in diameter, a 3mm margin is sufficient to obtain a 95% cure rate. The importance of an involved margin was also shown in this study which was a review of 89 articles published on the subject and confirmed that a positive pathological margin would lead to an average recurrence rate of 27%. A BCC of 2cm diameter requires a surgical margin of at least 13mm for relative certainty of removal of the tumour in 95% of cases<sup>12</sup>. Surgical margins of this width create large defects closure of which may be challenging in a Primary care setting.

Various studies have reported on inadequacy of completeness of excision of BCCs in Primary care. In a review of 366 BCC excisions in Aberdeen<sup>13</sup> those excised by GPs had a 34.1% incomplete excision rate. In a review from the Netherlands in 2009<sup>14</sup> of 1898 pathological specimens of skin tumours excised by GPs, 35% were incomplete and 65.4% were incomplete from the face and neck region. A

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3 study of 2586 BCC excisions in 1717 patients<sup>15</sup> quoted a recurrence rate of incompletely excised  
4 BCCs at 5 year follow-up of 30-41%. Of 184 incompletely excised BCCs, 62 were re-excised and 39 of  
5 these showed residual tumour so complete excision is essential and is therefore of importance as an  
6 outcome measure. The majority of publications report a high incomplete excision rate in Primary  
7 care but in a review of 124 BCC excisions in Primary care<sup>16</sup> there was an incomplete excision rate of  
8 only 1.6%. In the present study the incomplete excision rate was also low at only 5.5 per cent.  
9

10 Model 2 Practitioners and GPwSI performed better in secondary outcome measures compared to GPs  
11 which may reflect their increased training and experience in the field or closer supervision from  
12 secondary care.  
13

14  
15 The strength of this study is that the NICE guidance is clear on sub-types of BCC that are considered  
16 "high risk", and also which anatomical sites and age of patient represent high risk cases. These  
17 binary parameters make it relatively easy to assess compliance.  
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19  
20 A further strength of this study is that there is relatively little published on high risk BCC excision  
21 according to the new categories of GP that can carry out the surgery. The introduction of Model 2  
22 practitioner status means that the conclusions of previous studies on adherence to NICE guidance  
23 are of less relevance.  
24

25 A potential weakness of this study is that the sample is modest but a clear pattern still emerged.  
26 This confirmed a high complete excision rate by all of the GPs involved, but no information was  
27 obtained about any suboptimal healing or complications which could lead to scarring or less than  
28 satisfactory cosmetic results. Delayed healing or scarring is of particular relevance to the higher risk  
29 sites such as the face and pre-tibial region. There was also no information on BCCs that were  
30 referred into secondary care for treatment and whether or not those were originally diagnosed  
31 correctly clinically as BCCs.  
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### 34 35 36 **Explanation and Implications** 37

38 Some high risk features are easy to ascertain once aware of the guidance, such as age of patient and  
39 anatomical site, but it can be difficult to differentiate clinically between histological sub-types, and a  
40 significant proportion of BCCs are of mixed sub-type which include high risk morphology. Further  
41 training in Primary care in the recognition of sub-types of BCC, possibly assisted by more widespread  
42 use of dermoscopy, could improve compliance with regard to recognition of histological sub-type.  
43 Greater numbers of these operations carried out by Model 2 Practitioners with a link to the Local  
44 Specialist MDTs would also improve compliance with NICE 2010 guidance. We believe that our  
45 suggestions for improving compliance will be relevant to any other units with similar outcomes and  
46 that these results are likely to be representative of the UK as a whole in terms of variations in  
47 adherence to guidance.  
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51 Future research in this area could involve a comparison of the performance in terms of diagnosis of  
52 skin cancers by GP with Extended Roles (GPwERs) and Model 2 Practitioners compared to Secondary  
53 Care; a larger study could examine GP referrals that were subsequently confirmed as being BCCs and  
54 what was stated in the referral letter. Accuracy of clinical diagnosis of pigmented lesions referred  
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for excision would be of interest and also consideration of squamous cell carcinoma excisions inadvertently carried out in Primary Care because they did not look clinically suspicious.

In conclusion, compliance with NICE 2010 BCC excision guidance could be improved with further GP education, closer involvement with the local skin MDTs and a more straightforward progression to accreditation as Model 2 practitioner status. Consideration might be given to revising the NICE guidance taking into account the difficulty of diagnosing high risk histological sub-types of BCC preoperatively which makes compliance with this parameter difficult. Although operating on a high risk site or younger aged patient is avoidable, operating on a high risk histological BCC is not. A revision of NICE guidance to allow for this could help to negate any perceived criticism of GPs who excise skin lesions in Primary care, which is more convenient for patients and also reduces the pressure on Secondary Care.

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# Reporting checklist for quality improvement study.

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	Reporting Item	Page Number
	#1 Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
	#02a Provide adequate information to aid in searching and indexing	1
	#02b Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	3
Problem description	#3 Nature and significance of the local problem	5
Available knowledge	#4 Summary of what is currently known about the problem, including relevant previous studies	5
Rationale	#5 Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or	5

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1			assumptions that were used to develop the intervention(s), and	
2			reasons why the intervention(s) was expected to work	
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4	Specific aims	#6	Purpose of the project and of this report	3
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6	Context	#7	Contextual elements considered important at the outset of	6
7			introducing the intervention(s)	
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10	Intervention(s)	#08a	Description of the intervention(s) in sufficient detail that others	6
11			could reproduce it	
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14		#08b	Specifics of the team involved in the work	6
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16	Study of the	#09a	Approach chosen for assessing the impact of the intervention(s)	6
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20		#09b	Approach used to establish whether the observed outcomes	6
21			were due to the intervention(s)	
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24	Measures	#10a	Measures chosen for studying processes and outcomes of the	6
25			intervention(s), including rationale for choosing them, their	
26			operational definitions, and their validity and reliability	
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29		#10b	Description of the approach to the ongoing assessment of	6
30			contextual elements that contributed to the success, failure,	
31			efficiency, and cost	
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34		#10c	Methods employed for assessing completeness and accuracy	6
35			of data	
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38	Analysis	#11a	Qualitative and quantitative methods used to draw inferences	6
39			from the data	
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42		#11b	Methods for understanding variation within the data, including	6
43			the effects of time as a variable	
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46	Ethical	#12	Ethical aspects of implementing and studying the intervention(s)	NA
47	considerations		and how they were addressed, including, but not limited to,	
48			formal ethics review and potential conflict(s) of interest	
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51		#13a	Initial steps of the intervention(s) and their evolution over time	NA
52			(e.g., time-line diagram, flow chart, or table), including	
53			modifications made to the intervention during the project	
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56		#13b	Details of the process measures and outcome	6
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1		#13c	Contextual elements that interacted with the intervention(s)	NA
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3		#13d	Observed associations between outcomes, interventions, and	6
4			relevant contextual elements	
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7		#13e	Unintended consequences such as unexpected benefits,	NA
8			problems, failures, or costs associated with the intervention(s).	
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11		#13f	Details about missing data	NA
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13	Summary	#14a	Key findings, including relevance to the rationale and specific	7
14			aims	
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16		#14b	Particular strengths of the project	7
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19	Interpretation	#15a	Nature of the association between the intervention(s) and the	7
20			outcomes	
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23		#15b	Comparison of results with findings from other publications	8
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25		#15c	Impact of the project on people and systems	8
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28		#15d	Reasons for any differences between observed and anticipated	8
29			outcomes, including the influence of context	
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32		#15e	Costs and strategic trade-offs, including opportunity costs	NA
33				
34	Limitations	#16a	Limits to the generalizability of the work	8
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36		#16b	Factors that might have limited internal validity such as	8
37			confounding, bias, or imprecision in the design, methods,	
38			measurement, or analysis	
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42		#16c	Efforts made to minimize and adjust for limitations	8
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44	Conclusion	#17a	Usefulness of the work	9
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46		#17b	Sustainability	9
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48		#17c	Potential for spread to other contexts	9
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51		#17d	Implications for practice and for further study in the field	9
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53		#17e	Suggested next steps	9
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56	Funding	#18	Sources of funding that supported this work. Role, if any, of the	2
57			funding organization in the design, implementation,	
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interpretation, and reporting

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# BMJ Open

## High Risk Basal Cell Carcinoma Excision in Primary Care – A retrospective observational study of compliance with NICE Guidance

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Secondary Subject Heading:	Dermatology, Pathology, Surgery
Keywords:	PRIMARY CARE, Dermatological tumours < ONCOLOGY, Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HISTOPATHOLOGY, Surgical pathology < PATHOLOGY, Plastic & reconstructive surgery < SURGERY

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8 **High Risk Basal Cell Carcinoma Excision in Primary Care – A retrospective**  
9 **observational study of compliance with NICE Guidance**  
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32 Ethical appraisal:  
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34 As a retrospective audit of practice against National Clinical Excellence guidance using  
35 histology data for which patients have given consent for use in audit and research formal ethical  
36 approval was not required.  
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41 Data Sharing statement:  
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43 All data is included in article and will be published in an open journal making it freely accessible.  
44 There is no unpublished data.  
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## Article Summary

### Abstract

#### Objectives

To assess compliance with 2010 National Institute for Health and Care Excellence (NICE) guidance on cancer services relating to the management of Basal Cell Carcinomas (BCC) in the community, where except in specific circumstances it is recommended that only low risk BCCs should be excised routinely.

#### Design and setting

A retrospective observational study of the histopathology reports of BCC excisions received from Primary Care in two district general hospitals in the south of England. One hundred consecutive BCC excisions were analysed from each hospital.

#### Outcome measures

The numbers of high risk BCCs excised in Primary Care according to histological sub-type, anatomical site, and age and if these excisions were compliant with NICE 2010 guidance. Completeness of excision and mention of BCC on histology request were secondary outcomes.

#### Results

Histologically high risk subtypes were present in 32% (64/200) of BCCs excised in the community. Only 17/64 were excised by General Practitioners (GPs) who were accredited to do so. Non-compliance regarding anatomical site occurred in 16% of samples; only one was non-compliant regarding patient age. There was a high overall rate of complete excision (94.5%) with variation in presence of the term BCC on histology request forms.

#### Conclusions

NICE 2010 guidance relating to BCC excision in Primary Care was not followed in a considerable number of cases. Compliance with NICE 2010 guidance depends on the ability to recognise high risk BCCs clinically and manage appropriately. It also shows that despite close supervision by Secondary Care there are still failures of compliance.

GP training in identification of sub-types of BCC might be improved, as well as an increase in numbers of GPs accredited to carry out high risk BCC excisions. Difficulty in diagnosing high risk histological sub-types of BCC pre-operatively should be considered in any future revision of NICE guidance.

#### Strengths and Limitations:



- The introduction of Model 2 practitioner status means that the conclusions of previous studies on Primary care adherence to NICE guidance are less relevant now and there is relatively little published on high risk BCC excision according the categories of GP that are appropriate to carry out the surgery.
- Presence or absence of high risk features of BCCs is a binary measure and therefore simplifies data analysis.
- Two hundred BCCs represented a sufficient sample size to demonstrate a large percentage discrepancy in compliance with guidance between the two groups, and the short time frame limited the opportunity for changes in potentially confounding variables.
- It was not the aim to comment on overall diagnostic accuracy of GPs so no information was obtained relating to other lesions that had been referred directly for excision to be done within Secondary Care, and were subsequently diagnosed histologically as BCCs or lesions which were excised as possible BCCs but were revealed to be other skin cancers on histology.
- It was assumed that any high risk histological subtype excisions performed in the Area with a Model 2 GP were approved for excision by a Multidisciplinary team (MDT) member, consistent with NICE guidance; this process means that Model 2 GPs will have a different case mix with more high risk BCCs which could affect secondary outcome measures.

## INTRODUCTION

Basal cell carcinoma (BCC) is the commonest type of cancer in the UK and, although it rarely metastasises, inadequate treatment or late diagnosis can result in the BCC invading important anatomical structures, making them difficult to treat or resulting in the lesion becoming advanced or inoperable<sup>1</sup>.

The 2010 National Institute for Health and Care Excellence (NICE) guidance primarily addresses the excision of low risk BCCs in the community. It has been shown<sup>2</sup> that patients are generally more satisfied if their procedure can be performed in Primary Care because of convenience.

However, NICE 2010 also addressed the importance of high risk BCCs being treated appropriately. “High risk” BCCs include those of a high risk histological sub-type, those in difficult anatomical sites including the face and lower leg, in young patients under 24 years of age and those which have previously been incompletely excised or are recurrent. In a study of 1039 consecutive BCC excisions in secondary care<sup>3</sup> only 38.4% were low risk histologically (nodular or superficial) and all the remaining BCCs had high risk features such as micro-nodular, infiltrative or morpheic sub-types.

The NICE guidance aims to provide the best care for patients with BCCs whether these are excised in Primary or Secondary Care. This guidance is based on best available evidence from observational studies, a randomised controlled trial and expert opinion including from primary care, patients and carers. To quote from the guidance: “the retrospective studies, although flawed, do indicate a consistent trend of current practices and outcomes in favour of specialist care in this setting”. As a General Practitioner (GP) who is part of a Direct Enhanced Service (DES) or Local Enhanced Service (LES), an Enhanced services GP (ESGP) is eligible to excise low risk BCCs below the clavicle if less than 1cm in diameter and not in the pre-tibial region. If a GP with a Special Interest (GPwSI, which since 2015 is included under the new term GP with Extended Role) sees a lesion that is a possible BCC but is unable to confirm this clinically as a low risk lesion then they are expected to refer the case to the local specialist Multidisciplinary team (MDT). If it is pre-diagnosed by the local specialist MDT, a Model 2 Practitioner can excise a high risk BCC.

Prior to classification as a high or low risk sub-type, clinicians must first have suspected the lesion to be a BCC. In a study in the Grampian region<sup>4</sup>, the accuracy of clinical diagnosis of BCC based on 1087 histology reports was 67.1% for the GPs, 82.1% for the dermatologists and 83.3% for plastic surgeons. GPs were more likely to state “no diagnosis” than secondary care specialists.

In a self-reported study from volunteer GPs doing local anaesthetic skin lesion excisions<sup>5</sup> 6138 procedures were analysed, of which 926 were confirmed as malignancies, including 722 BCCs. Model 2 GPs and GPwSIs had statistically significantly higher rates of complete excision than ESGPs. Only 37% of Model 2 GPs took written consent. In a review of 1743 BCCs excised over a 32 month period by GPs<sup>6</sup> only 3% were considered to be “low risk” according to NICE 2010 criteria. The authors concluded that low risk BCCs are of low prevalence which therefore leads to difficulties for GPs to maintain competencies. NICE guidance includes clinical governance recommendations. However, in a small study whereby questionnaires were sent out to 13 GPs with a Special Interest in Dermatology or skin surgery,

only eight replies were received and it was confirmed that none of them were following the Department of Health guidelines for MDT attendance and annual appraisal<sup>7</sup>.

Other studies have reported on the variability of suitability for case selection for Primary care treatment. Two audits in 2008 and 2009 from Liverpool<sup>8</sup> reported that in 2008, out of 117 BCCs excised in Primary Care, 46% were high risk (clinically and/or histologically) and in 2009, out of 251 BCC excisions in Primary Care, 35% were high risk. In a further study of skin cancer excisions in Primary Care prior to the 2010 NICE guidance<sup>9</sup> reporting on the treatment of 71 lesions, there were 50 excisions and 21 other procedures. Of these 71, 64 were reported as high risk, 27 were at high risk sites, and 37 of 44 lesions at low risk sites were actually high risk histologically. Of the 71 skin cancers, 24 (34%) required further excision. Further evidence of high risk BCC excisions in Primary care was reported in a 2010 study in Lothian, Fife and Tayside<sup>10</sup> where GPs excised 380 skin cancers in one year compared to 385 excised by dermatologists in one month and 179 by plastic surgeons also in one month. There were high risk features (recurrent BCC, infiltrative BCC or located on the head and neck regions) in 63% of the BCCs excised by GPs.

Compliance with NICE 2010 guidance is compromised by the difficulties recognising and diagnosing basal cell carcinoma, and the clinical recognition of the morphological subtypes. The aim of this study is to assess compliance with NICE 2010 guidance and also the reasons for non-compliance and how it could be improved.

## METHODS

The outcome of 200 BCC excisions carried out in Primary Care received at the histopathology laboratories of two district general hospitals in the south of England was studied.

Using the same start date a total of 100 consecutive cases of lesion excisions confirmed on histology as BCC from each hospital were analysed according to the NICE criteria and also the category of GP performing the surgery.

Full pathology reports were studied by two independent researchers (SC and RH) who were blinded to operator's identity and category. Re-excisions, shaves, punch biopsies and other diagnostic samples were excluded as were all Secondary Care excisions. Presence or absence of each of the high risk criteria was recorded for every excision. Where required, clarifications were provided by the Pathology department. The category of each operator whose excisions were studied was revealed by the Pathology department at the end of data collection. Operators were categorised as GPs, GPwSI or Model 2 Practitioners so that appropriateness of different BCC risk group according to type of GP could be assessed.

Data was collected from September 4<sup>th</sup> 2014, giving time for the update guidance from NICE in 2010 to be included in the practice of both Areas.

“High risk” BCCs are defined by the NICE 2010 guidance including those with high risk histological subtypes, those at specific anatomical sites (including face and pre-tibial region), and in patients under 24 years of age.

As secondary outcomes, completeness of BCC excision was assessed and whether the possibility of BCC as a clinical diagnosis was included on the histology request form.

#### Patient involvement

Consideration of patient preference for excision in Primary care was key factor in study conception, balanced against the need for effective and safe procedures. Patients were not directly involved in the design or conduct of the study.

## RESULTS

Out of the total of 200 BCC excisions shown in Table 1, histologically high risk subtypes were present in 32% (64/200). For the lesions received from the Area associated with a Model 2 Practitioner (Area 1), there were 19 excisions of high risk histological subtype BCCs but 17 of those were carried out by the Model 2 Practitioner which is in line with guidance. In the Area with GPwSI and GPs exclusively (Area 2), there were 45 BCCs with high risk histological features, none of which were excised by a Model 2 Practitioner. Across both Areas there were 47 incidents of non-compliance on the histological sub-type criterion (23.5%).

There was non-compliance in 31 excisions on the anatomical site criterion (15.5%). There was non-compliance in one case on the grounds of the age of the patient (0.5%). Some excisions were non-compliant on more than one criterion.

Secondary outcome measures are shown in table 2. The overall completeness of excision rate was 189 out of 200 (94.5%) with GPs across both Areas achieving 92.65%, GPwSIs 95.65% and Model 2 95.4%. The terms “basal cell carcinoma” or “BCC” were not on the request forms accompanying 28 specimens. Model 2 Practitioners were most likely to mention BCC on their request form (96.6%), followed by GPwSI (88.2%) then GPs (72.1%).

**Table 1.** Results of BCC excisions and compliance with NICE 2010.

	High Risk Histology	Fail Histology criterion	Fail Site criterion	Fail Age criterion	Total BCCs

<u>Area 1</u>					
GP	2	2	1	0	14
Model 2 Practitioner	17	0	15	0	86
Total	19	2	16	0	100
<u>Area 2</u>					
GP	26	26	15	0	54
GPwSI	19	19	0	1	46
Total	45	45	15	1	100
<u>Area 1 &amp; 2</u> Total	64	47	31	1	200

**Table 2.** Secondary outcome measures

	Incomplete excision	Not stated as "BCC" on request form	Total BCCs
<u>Area 1</u>			
GP	3	5	14
Model 2 Practitioner	4	3	86
Total	7	8	100
<u>Area 2</u>			
GP	2	14	54
GPwSI	2	5	46
Total	4	20	100
<u>Area 1 &amp; 2 Total</u>	11	28	200

## DISCUSSION

### Principle findings

The principle finding of this study is low compliance with NICE 2010 guidance, particularly regarding high risk histological sub-types of BCC and anatomical site of the lesion (Table 1). Histologically high risk BCCs have an increased risk of incomplete removal. A study examining the association between histological pattern and adequacy of excision<sup>3</sup> showed that completeness of excision was worse for high risk micronodular, infiltrative and mixed types of BCC. From a study of 16,066 BCC excisions<sup>11</sup> it was concluded that, for a non-morpheiform type of BCC of less than 2cm in diameter, a 3mm margin is sufficient to obtain a 95% cure rate. The importance of an involved margin was also shown in this study which was a review of 89 articles published on the subject and confirmed that a positive pathological margin would lead to an average recurrence rate of 27%. A BCC of 2cm diameter requires a surgical margin of at least 13mm for relative certainty of removal of the tumour in 95% of cases<sup>12</sup>. Surgical margins of this width create large defects closure of which may be challenging in a Primary care setting.

Various studies have reported on inadequacy of completeness of excision of BCCs in Primary care. In a review of 366 BCC excisions in Aberdeen<sup>13</sup> those excised by GPs had a 34.1% incomplete excision rate. In a review from the Netherlands in 2009<sup>14</sup> of 1898 pathological specimens of skin tumours excised by GPs, 35% were incomplete and 65.4% were incomplete from the face and neck region. A study of 2586 BCC excisions in 1717 patients<sup>15</sup> quoted a recurrence rate of incompletely excised BCCs at 5 year follow-up of 30-41%. Of 184 incompletely excised BCCs, 62 were re-excised and 39 of these showed residual tumour so complete excision is essential and is therefore of importance as an outcome measure. The majority of publications report a high incomplete excision rate in Primary care but in a review of 124 BCC excisions in Primary care<sup>16</sup> there was an incomplete excision rate of only 1.6%. In the present study the incomplete excision rate was also low at only 5.5 per cent.

Model 2 Practitioners and GPwSI performed better in secondary outcome measures compared to GPs which may reflect their increased training and experience in the field or closer supervision from secondary care.

The strength of this study is that the NICE guidance is clear on sub-types of BCC that are considered "high risk", and also which anatomical sites and age of patient represent high risk cases. These binary parameters make it relatively easy to assess compliance.

A further strength of this study is that there is relatively little published on high risk BCC excision according the new categories of GP that can carry out the surgery. The introduction of Model 2

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3 practitioner status means that the conclusions of previous studies on adherence to NICE guidance are of  
4 less relevance.  
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7 A potential weakness of this study is the sample size. The main requirement for the samples was that  
8 they were consistent across the two geographically similar areas. By using the same start date for  
9 sampling, the only difference was the category of operators. The study was designed to be able to show  
10 a difference between the two areas, and by avoiding a long data collection period, changes in staffing  
11 structure or training and other confounding variables could also be minimised. The sample size and  
12 findings were comparable to those in the literature, suggesting generalisability and a clear pattern  
13 emerged within the data.  
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17 The present study confirmed a high complete excision rate by all of the GPs involved, but no information  
18 was obtained about any suboptimal healing or complications which could lead to scarring or less than  
19 satisfactory cosmetic results. Delayed healing or scarring is of particular relevance to the higher risk sites  
20 such as the face and pre-tibial region. There was also no information on BCCs that were referred into  
21 secondary care for treatment and whether or not those were originally diagnosed correctly clinically as  
22 BCCs.  
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### 25 26 27 **Explanation and Implications** 28

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30 Some high risk features are easy to ascertain once aware of the guidance, such as age of patient and  
31 anatomical site, but it can be difficult to differentiate clinically between histological sub-types, and a  
32 significant proportion of BCCs are of mixed sub-type which include high risk morphology. Further  
33 training in Primary care in the recognition of sub-types of BCC, possibly assisted by more widespread use  
34 of dermoscopy, could improve compliance with regard to recognition of histological sub-type. Greater  
35 numbers of these operations carried out by Model 2 Practitioners with a link to the Local Specialist  
36 MDTs would also improve compliance with NICE 2010 guidance. The authors believe that these  
37 suggestions for improving compliance will be relevant to any other units with similar outcomes and that  
38 these results are likely to be representative of the UK as a whole in terms of variations in adherence to  
39 guidance.  
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44 NICE guidance should put patients at the forefront and also make the most of opportunities to deliver  
45 care in the most convenient location for them; the present study has demonstrated a high complete  
46 excision rate for BCCs treated in Primary Care. However, several other studies have shown that the  
47 recognition of BCC was poor and there were high incomplete excision rates which can lead to poor  
48 patient outcomes. NICE guidance is specifically intended to improve the outcomes for people with skin  
49 tumours. In its Patient perspective section the 2010 NICE guidance reports that patients want their BCC  
50 to be accurately diagnosed and treated effectively first time, with minimal risk of recurrence and the  
51 best cosmetic result possible by adequately trained professionals who have met prescribed standards.  
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55 There is the potential to increase the numbers of Model 2 practitioners as a bridge between Primary and  
56 Secondary Care for skin cancer surgery. Murchie et al<sup>4</sup> also comment on the scope for improving training  
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for GPwSIs. To quote from the 2010 NICE guidance: “only doctors and nurses who have received locally approved training and who are active members of a skin cancer MDT should carry out surgery for skin cancers”. Increased provision in both Primary and Secondary care is likely to be necessary to give the best outcomes for people with skin tumours.

Future research in this area could involve a comparison of the performance in terms of diagnosis of skin cancers by GP with Extended Roles (GPwERs) and Model 2 Practitioners compared to Secondary Care; a larger study could examine GP referrals that were subsequently confirmed as being BCCs and what was stated in the referral letter. Accuracy of clinical diagnosis of pigmented lesions referred for excision would be of interest and also consideration of squamous cell carcinoma excisions inadvertently carried out in Primary Care because they did not look clinically suspicious.

In conclusion, this study of the management of BCCs in adjacent areas in the South of England demonstrated that compliance with NICE 2010 BCC excision guidance could be improved with further GP education, closer involvement with the local skin MDTs and a more straightforward progression to accreditation as Model 2 practitioner status. Consideration might be given to revising the NICE guidance taking into account the difficulty of diagnosing high risk histological sub-types of BCC pre-operatively which makes compliance with this parameter difficult. Although operating on a high risk site or younger aged patient is avoidable, operating on a high risk histological BCC is not. A revision of NICE guidance to allow for this could help to negate any perceived criticism of GPs who excise skin lesions in Primary care, which is more convenient for patients and also reduces the pressure on Secondary Care.

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# Reporting checklist for quality improvement study.

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	Reporting Item	Page Number
	#1 Indicate that the manuscript concerns an initiative to improve healthcare (broadly defined to include the quality, safety, effectiveness, patientcenteredness, timeliness, cost, efficiency, and equity of healthcare)	1
	#02a Provide adequate information to aid in searching and indexing	1
	#02b Summarize all key information from various sections of the text using the abstract format of the intended publication or a structured summary such as: background, local problem, methods, interventions, results, conclusions	3
Problem description	#3 Nature and significance of the local problem	5
Available knowledge	#4 Summary of what is currently known about the problem, including relevant previous studies	5
Rationale	#5 Informal or formal frameworks, models, concepts, and / or theories used to explain the problem, any reasons or	5

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		assumptions that were used to develop the intervention(s), and reasons why the intervention(s) was expected to work	
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4	Specific aims	#6 Purpose of the project and of this report	3
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6	Context	#7 Contextual elements considered important at the outset of introducing the intervention(s)	6
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10	Intervention(s)	#08a Description of the intervention(s) in sufficient detail that others could reproduce it	6
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14		#08b Specifics of the team involved in the work	6
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16	Study of the Intervention(s)	#09a Approach chosen for assessing the impact of the intervention(s)	6
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20		#09b Approach used to establish whether the observed outcomes were due to the intervention(s)	6
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24	Measures	#10a Measures chosen for studying processes and outcomes of the intervention(s), including rationale for choosing them, their operational definitions, and their validity and reliability	6
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29		#10b Description of the approach to the ongoing assessment of contextual elements that contributed to the success, failure, efficiency, and cost	6
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34		#10c Methods employed for assessing completeness and accuracy of data	6
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38	Analysis	#11a Qualitative and quantitative methods used to draw inferences from the data	6
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42		#11b Methods for understanding variation within the data, including the effects of time as a variable	6
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46	Ethical considerations	#12 Ethical aspects of implementing and studying the intervention(s) and how they were addressed, including, but not limited to, formal ethics review and potential conflict(s) of interest	NA
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51		#13a Initial steps of the intervention(s) and their evolution over time (e.g., time-line diagram, flow chart, or table), including modifications made to the intervention during the project	NA
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56		#13b Details of the process measures and outcome	6
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1		#13c	Contextual elements that interacted with the intervention(s)	NA
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3		#13d	Observed associations between outcomes, interventions, and	6
4			relevant contextual elements	
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7		#13e	Unintended consequences such as unexpected benefits,	NA
8			problems, failures, or costs associated with the intervention(s).	
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11		#13f	Details about missing data	NA
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13	Summary	#14a	Key findings, including relevance to the rationale and specific	7
14			aims	
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28		#15d	Reasons for any differences between observed and anticipated	8
29			outcomes, including the influence of context	
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32		#15e	Costs and strategic trade-offs, including opportunity costs	NA
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36		#16b	Factors that might have limited internal validity such as	8
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38			measurement, or analysis	
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44	Conclusion	#17a	Usefulness of the work	9
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51		#17d	Implications for practice and for further study in the field	9
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56	Funding	#18	Sources of funding that supported this work. Role, if any, of the	2
57			funding organization in the design, implementation,	
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interpretation, and reporting

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