**National audit of Non-Melanoma Skin Cancer excisions by Plastic Surgery in the United Kingdom (NMSC: PlastUK)**

**Protocol version 2.3**

***NMSC: PlastUK* working group**

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# Background

Non-melanoma skin cancer includes basal cell carcinoma (BCC) and squamous cell carcinoma (SCC). They are the commonest cancers in the United Kingdom (UK) accounting for 20% of all new malignancies1. The UK incidence is 124-148 per 100 000 person years2. Annually skin cancer (including melanoma) is estimated to cost the NHS over £180 million in 20203. The reported incidence is rising (30% in the last decade), likely due to increased reporting and historic exposure to ultraviolet radiation.

The mainstay of treatment for non-melanoma skin cancer is surgical excision with a ‘cuff’ of normal tissue, which allows examination of the histological subtype and accurate assessment of margins: excision confirms the tumours complete removal. The outcome is highly dependent upon achieving clear margins; just 1%4, 5 of lesions recur with clear margins compared to 31-41%6, 7 with involved margins. Recurrent lesions are more difficult to treat and often require a more extensive reconstruction to cover the defect.

Radiotherapy is another treatment modality which offers an alternative to surgery for the treatment of non-melanoma skin cancer. It may be used for primary lesions8, 9. It also has a role in the treatment of incompletely excised BCC and high-risk SCC as an adjunct to excision10. In practice however, radiotherapy is rarely utilised for primary lesions as it does not allow examination of the margins to confirm clearance.

In the UK, surgical excision of skin cancer is mainly performed in secondary care11 where it is more cost effective12 and consequently makes up a significant proportion of the workload for Dermatology and Plastic Surgery. There is joint guidance from the National Institute for Health and Care Excellence (NICE) and the British Association of Dermatologists (BAD) on the treatment of skin cancer which includes the planned surgical margins8, 9.

**Previous Dermatology national audits**

Two UK national audits have been undertaken by Dermatology to establish the incomplete excision rate and complications from non-melanoma skin cancer. UK Dermatology consultants submitted 10 consecutive cases of non-micrographic excision from 135 centres. The first cycle in 2014 of 2739 lesions had an incomplete excision rate of 2.3% 13. A second cycle in 2016 of 3290 reported an incomplete rate of 3.0% 14. There were no audit changes instigated following the original audit. In the subsequent audit cycle, they recommended histopathologists include all core data items in their reports but no changes to Dermatologists practice. This data gave an insight into the ‘typical’ lesion a dermatologist might encounter and their approach; a suspected BCC on the head and neck (58%), of mean diameter of 11mm which is excised and closed directly (88%) and not followed up in secondary care 13, 14.

**Other published audits**

In contrast there is a paucity of large-scale multi-centre data from Plastic Surgery units on their typical lesion or outcomes. Often Dermatology refer patients to Plastic Surgery (27-52% of referrals15-17) when they are unable to excise the lesion, which may be for a multitude of reasons; larger/invasive tumour; higher grade; cosmetically sensitive area; recurrent lesion; requiring a more complex reconstruction of the defect. All these factors may influence outcomes in terms of clear margins and complications. Multiple single centre and regional studies from Plastic Surgery units in the UK and abroad support this hypothesis.

At least 28 published studies worldwide have reported the incomplete excision rate of non-melanoma skin cancer (or solely BCC/SCC) since 2000. While it is very easy to compare the final incomplete excision rate, this fundamentally misses the huge amount of variation in these studies which confound the results to the point that comparison is in some ways meaningless. See table 1.

Plastic Surgeons more commonly operate on the head and neck which comprises between 74-86.4%18-20 of the lesions they excise. Dermatologists operated on the head and neck less often at between 50-58.3%13, 14, 20, 21 in all bar one study where it was 100%22 and GPs the least at between 30-50%21, 23. Specific anatomical locations were noted to be higher risk for incomplete excision by multiple studies, all of which are on the head. Specifically the temple 15, 16, 24, 25, medial canthus15, 24, 26, nose15, 25-28 and ears25, 27, 28.

The size of the lesions affects the incomplete excision rate. One study on scalp BCC showed larger tumours were more often higher grade and more commonly had perineural invasion29. These factors increased their incomplete excision rate to 26% from 16%29. Larger tumours were more likely to be incompletely excised in another study19 however not correlated in two others20, 28. Larger tumours required more complex reconstructions (mean diameter 10.2mm in direct closure compared to 17mm with skin grafts and 12.5mm with flaps30). Dermatologists excised the largest tumours in one study21 and Plastic Surgeons excised the largest in another20.

Conflicting results were found in terms of whether surgeon experience was correlated with incomplete excisions. Three studies found no correlation18, 20, 31, two studies found junior surgeons had more incomplete excision24, 32 and two studies found consultant surgeons had more incomplete excisions15, 27. All three observations can simultaneously be true if the case mix is sufficiently different, with units where juniors are excising incompletely more may be working on cases beyond their capabilities and in units where the rate is lower may be because they are not being challenged or trusted enough with cases they are well capable of.

Specific histological types of BCC (infiltrative and morphoeic) are known to be higher risk for incomplete excision8, 15, 33. Data from the UK and abroad showed between 26-31% of the BCC excised in Plastic Surgery units had a high-risk histological element19, 33. This was not reported in any of the studies by Dermatologists.

Plastic Surgeons would be expected to be performing more skin grafts and flaps than Dermatologists who have a more medical background. In Plastic Surgery units skin grafts were used in 19-34%15, 19 and flaps in 12-13.2%15, 19. In contrast UK Dermatologists used skin grafts 2.5-4.2%13, 14 and flaps in 6-6.8%13, 14. The complication rates were rarely reported, however was 4.4%15 in one Plastic Surgery unit and 3.0-3.4%13, 14 in UK Dermatologists.

Finally, three studies have directly compared incomplete excision rates between different practitioners who excised skin cancer. These all reported Dermatology (0-14.2%20, 21, 34) had the lowest rate compared to Plastic Surgeons (17-27.6%20, 21, 34) and GPs (23-30%21, 34). Studies often concluded this difference was due to increased amount of training time of Dermatologists spend on skin cancer. Pre-operative selection may play a role in reducing Dermatologists incomplete margin rate. They generally have the greatest access to Moh’s micrographic surgery, removing the most challenging and highest risk tumours from their caseload. Indeed in one study where Moh’s micrographic surgery was being used by dermatology, they unsurprisingly reported a 0% incomplete margin21.

There is a potential for a conflict of interest in terms of reporting one’s own incomplete excision rate which may affect funding from national bodies or cause patients to seek a different specialist in a private system. While there is nothing to doubt the integrity of the above published data, there may be a publication or selection bias, where authors consciously or subconsciously wish to publish data which places their own unit in the best light and are less forthcoming on a ‘bad’ audit cycle.

**Role of antibiotics in ulcerated lesions**

Little is known about the use of prophylactic antibiotics in the surgical excision of non-melanoma skin cancer. Certain lesion characteristics, such as ulceration, have previously been reported as independent risk factors for post-operative wound infection35. Despite this, a recent review of 4 RCTs on the use of prophylactic antibiotics in ulcerated BCC/SCC found a lack of high-quality evidence for their benefit36.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Author,**  **Year,**  **Country** | **Type of study,**  **Years of data collection** | **Operators** | **Number of lesions** | **Incomplete excision rate (%)** |
| *Kumar et al.*  *2000, UK31* | Single centre  2 years | Plastics | 879 BCC | 4.7% |
| *Fleischer et al.*  *2001, USA20* | Multi centre  Between 1 year and 5.5 years depending on centre | Plastics | 1 459 BCC | 27.6% |
| ENT | 46.9% |
| Dermatology | 14.2% |
| General surgery | 17.9% |
| *Hallock et al.*  *2001, USA37* | Single centre  7.5 years | Plastics | 309 BCC | 16.2% |
| 106 SCC | 14.2% |
| *Dieu et al.*  *2002, Australia25* | Single centre  3.5 years | Plastics | 3 558 BCC | 6.3% |
| *Kumar et al.*  *2002, UK32* | Regional  1 year | Plastics | 757 BCC | 4.5% |
| *Timmons et al.*  *2002, UK18* | Single centre  1 year | Plastics | 557 BCC | 3.8% |
| *Hussain et al.*  *2003, Ireland38* | Single centre  1 year | Plastics | 126 BCC | 7.9% |
| *Bogdanov-Berzovsky et al.*  *2004, Israel28* | Single centre  4 years | Plastics | 1 478 BCC | 10.8% |
| *Talbot et al.*  *2004,*  *New Zealand27* | Regional  0.5 years | Plastics | 818 NMSC | 11.3% |
| General Practice | 1003 NMSC | 16% |
| *Wilson et al.*  *2004, UK26* | Regional  10 years | Maxillofacial | 3 795 BCC | 6.2% |
| *Deo et al.*  *2005, India39* | Single centre  7 years | Surgical oncology | 14 BCC | 0% |
| 43 SCC | 0% |
| *Griffiths et al.*  *2007, UK16* | Single centre  5 years | Plastics | 1 539 BCC | 8.4% |
| *Dhepnorrarat et al.*  *2009, Australia40* | Regional  7 years | Plastics | 21 677 BCC | 4.0% |
| 8 355 SCC | 3.7% |
| *Haque Hussain et al.*  *2009, UK41* | Single centre  0.5 years | Dermatology | 80 SCC | 7.5% |
| Plastics | 8.3% |
| General Practice | 15 SCC | 43% |
| *Macbeth et al.*  *2009, UK22* | 4 regions  Between 1 month - 1 year per region. Totalling 3.25 years | Dermatology | 955 BCC | 10% |
| General Practice | 254 BCC | 33% |
| *Twist.*  *2009, UK23* | Single centre  3 years | General Practice (special interest) | 124 BCC | 1.6% |
| *Malik et al.*  *2010, Ireland15* | Single centre  5 years | Plastics | 1 832 BCC | 14% |
| *Salmon et al.*  *2010,*  *New Zealand21* | Regional  0.3 years | Dermatology | 743 BCC  181 SCC | 0% (included Moh’s)\* |
| ENT, Ophthalmology, Gen. surgeons | 20%\* |
| General Practice | 23%\* |
| General Practice (special interest) | 21.5%\* |
| *Seretis et al.*  *2010, Greece42* | Single centre  2 years | Maxillofacial | 125 BCC | 3.3% |
| 54 SCC | 5.8% |
| *Delaney et al.*  *2012, UK43* | Regional  1 year | Dermatology | 72 SCC | 13.9% |
| Plastics | 443 SCC | 12.9% |
| General Practice | 207 SCC | 14.5% |
| *Stolle et al.*  *2013, Denmark19* | Single centre  1 year | Plastics | 616 BCC | 9.6% |
| 179 SCC |
| *Robinson et al.*  *2015, UK24* | Single centre  1 year | Plastics | 392 BCC | 4.8% |
| *Cho et al.*  *2016, Australia29* | Regional  5 years | Dermatology | 2 202 scalp BCC | 16% |
| *Luz et al.*  *2016, Brazil44* | Single team  1.2 years | Dermatology | 881 BCC | 4.1% |
| *Keith et al.*  *2017, UK13* | National  0.4 years | Dermatology | 2 167 BCC | 2.3% |
| 491 SCC |
| *Stathopoulos et al.*  *2017, UK30* | Single team  4.8 years | Maxillofacial | 178 SCC | 5.6% |
| *Cole et al.*  *2018, UK45* | Two hospitals  Unclear time period | General Practice (including special interest) | 200 BCC | 5.5% |
| *Ramdas et al.*  *2018, Netherlands34* | Regional  6 years | Plastics | 1 040 BCC | 17% |
| Dermatology | 1 015 BCC | 7% |
| General Practice | 931 BCC | 30% |
| *Keith et al.*  *2019, UK14* | National  0.4 years | Dermatology | 2162 BCC | 3.0% |
| 882 SCC |
| *Kiely et al.*  *2019, UK33* | Single centre  1.3 years | Plastics | 694 BCC | 6.4% |
|  |  |  |  |  |
| **Totals** |  |  | **Mean** | **Median** |
| *BCC - Dermatology* | |  | 7.1% | 5.6% |
| *BCC - Plastics* | |  | 9.7% | 7.9% |
| *BCC - General Practice* | |  | 17.5% | 17.8% |
| *BCC - total* | |  | 11.1% | 7% |
|  | |  |  |  |
| *SCC - Dermatology* | |  | 6.7% | 5.3% |
| *SCC - Plastics* | |  | 9.7% | 9.6% |
| *SCC - General Practice* | |  | 25.5% | 22.3% |
| *SCC - total* | |  | 11.8% | 9.0% |

Table 1: Published studies of non-melanoma skin cancer since 2000 and their incomplete excision rate. Abbreviations used are NMSC = non-melanoma skin cancer, BCC = basal cell carcinoma, SCC= squamous cell carcinoma, UK = United Kingdom, USA = United States of America. \* represents incomplete excision margin for all malignant lesions including melanoma

# Aims, objectives, rationale and hypothesis

To conduct a national audit of the treatment of non-melanoma skin cancer by Plastic Surgery units within the UK. This will establish the incomplete excision rate, early complications (bleeding, infection, graft/flap failure) and further management of incomplete excisions (re-excision, referral for radiotherapy) on a national scale.

We hypothesize that Plastic Surgeons are treating a different subset of patients to Dermatology in the UK in terms of 1) lesion size, 2) histological subtype, 3) cosmetically sensitive areas 4) and utilising different reconstructions. We hypothesize that these will affect the incomplete excision rate causing it to be higher than that observed by UK Dermatologists.

This study will allow patients to be better streamed to appropriate services and would enable more accurate information during counselling about the risks of incomplete excision or other complications.

# Methods

**Achieving nation-wide data collection**

In order to recruit all Plastic Surgery units in the UK, a trainee collaborative approach will be used. The *NMSC: PlastUK* Collaborative is a group of trainees recruited from the Reconstructive Surgery Trials Network. The Reconstructive Surgery Trials Network is the UK clinical trials network for plastic and hand surgery. Collaborators will be asked to collect prospective data on non-melanoma skin cancer excisions during a 2.5 month period (16th March to 31st May 2020). Patients will be followed up to their first clinic appointment (up to 3 months later). Each patient’s data will be input to a secure database, hosted by REDCap system. In total, 50 Plastic Surgery units have been identified, and collaborators are expected to be recruited from >95% of these units. Units will additionally be contacted through other means such as via the British Association of Plastic Aesthetic and Reconstructive Surgeons (BAPRAS) and directly through email.

**Audit design**

This audit will compare the incomplete excision rate in UK Plastic Surgery units to the world-wide published data already discussed (BCC 7% median or 11% mean, SCC 9% median or 12% mean) and to a systematic review of this which is currently underway. To allow direct comparison of between Plastic Surgery units and Dermatology, the data collection will be based primarily on the two previous national Dermatology audits13, 14 with only minor alterations. The alterations will be 1) not record risk for bleeding, risk for infection, cardiac devices or other risks, as this data was not published in the previous national Dermatology audits 2) record actual measurements of margins (rather than a range) which will allow more detailed analysis 3) additional data will be collected on the presence of lesion ulceration, the use of prophylactic antibiotics and if patients are referred on for further treatment (re-excision or radiotherapy). See table 1 and Data collection sheet v2.3 for details.

**Inclusion and exclusion criteria**

All adult patients who had a pre-operative diagnosis of non-melanoma skin cancer and undergo surgical excision will be included. Those undergoing excision via Moh’s micrographic surgery or with intra-operative frozen section will be excluded, as will incision, shave or punch biopsies.

**Ethics**

Ethics approval is not required, as the project will be classified as audit and will not involve access to sensitive or identifiable information. This was confirmed using the HRA decision tool46.

**Statistical analysis**

Statistical analysis will be performed comparing the novel data to the previous Dermatology audits. Group differences in continuous variables will be evaluated using the Mann-Whitney U test and Students t-test depending on data distribution. Group differences in nominal data will be analysed using Fisher’s exact test or Pearson’s chi-square test. Significance will be set at the level of p≤0.05. Statistical analysis will be carried out in SPSS version 25 (IBM, USA).

**Definitions**

A lesion will be considered incompletely excised if residual tumour is found at either the peripheral or deep margin. ‘Closely’ or ‘near to’ excised lesions will be considered as fully excised in line with previous studies and recorded as such20.

In terms of complications, ‘bleeding’ will be defined as requiring return to theatre or consultation with healthcare professional due to this (includes GP/A&E who may apply direct pressure only). ‘Infection’ will be defined as requiring antibiotics, causing wound dehiscence or graft/flap failure.

**Table 2:** Data collection fields used to collect data by trainees in Plastic Surgery units in the UK. Primarily based on the previous UK national Dermatology audits.

* Patient demographics
  + Demographics
    - Age, gender
  + Number of lesions being excised
* Pre-operative details
  + Clinical diagnosis (BCC vs SCC)
    - Biopsy proven?
  + Presence of ulceration
  + Body site
  + If < 10mm from previous treatment scar (for recurrence)
  + Primary or re-excision
* Operation details
  + Date of surgery
  + Prophylactic antibiotic use
  + Planned clinical margin
    - Peripheral, deep, not stated
  + Type of immediate reconstruction
    - Left open (or delayed reconstruction), direct closure, full-thickness skin graft, split-thickness skin graft, flap
* Histological details
  + BCC, SCC, Bowens, Actinic Keratosis, Melanoma, Benign, Other
    - Subtype of BCC
  + Largest tumour diameter (mm)
  + Margins
    - Peripheral margin (mm)
    - Deep margin (mm)
    - Involved? At which margin?
* Complications
  + Bleeding
  + Infection
  + Graft/flap failure for other reason
* Further treatment
  + No further treatment planned
  + Clinical surveillance
  + Listed for re-excision
  + Referral for radiotherapy
  + Discharged from Plastic Surgery

‘Listed for re-excision’ will only be those patients who after discussion were formally re-listed. If patients will be monitored then they will not be included, also those who declined further surgery will not be included, but in both instances the numbers will be recorded.

# Data collection sheet v2.3

|  |  |
| --- | --- |
| **Question** | **Responses** |
| Demographics | * *Age* * *Gender* |
| How many suspected non-melanoma skin cancer lesions are being excised? | * *1, 2, 3, 4, 5*   + *If 2 or more is selected, then all questions below will be repeated for the 2nd, 3rd lesions etc* |
| Pre-op diagnosis (from Plastic Surgery) | * *BCC* * *SCC* * *Unknown or biopsy proven* |
| Is the lesion ulcerated? | * *Yes, No, Unknown* |
| Body site | * *Head and neck*   + *Scalp*   + *Periocular, temple, forehead or eyebrow*   + *Cheek or chin*   + *Ear (or within 2cm)*   + *Nose (or within 1cm) or lips*   + *Neck* * *Trunk* * *Limb* * *Hand or foot* * *Genitalia, perineum or perianal area* * *Unknown* |
| Is this area within 10mm of a previous treatment scar? | * *Yes, No, Unknown* |
| Type of excision | * *Date of surgery* * *Primary* * *Re-excision* * *Unknown* |
| Planned clinical margin from op note | * *Peripheral (mm or unknown)* * *Deep (mm, tissue layer or unknown)* |
| Type of immediate reconstruction | * *Left open (or delayed reconstruction)* * *Direct closure* * *Skin graft*   + *Full thickness skin graft*   + *Split thickness skin graft*   + *Unknown* * *Flap* * *Unknown* |
| Did the patient receive prophylactic antibiotics? | * *At induction*   + *Yes, No, Unknown* * *Post-op*   + *Yes, No, Unknown* |
| Histological diagnosis | * *BCC*   + *Subtypes – can select more than one if mixed*     - *Nodular*     - *Infiltrative*     - *Superficial*     - *Micronodular*     - *Morpheaform*     - *Sclerosing*     - *Adenoid*     - *Fibroepithliomatous*     - *Other*     - *Unknown* * *SCC* * *Actinic keratosis* * *Bowen’s Disease* * *Melanoma* * *Benign – therefore skip next 2 questions* * *Other* |
| Largest tumour diameter | * *Size in mm (or unknown)* |
| Margins (from histology report) | * *Peripheral (mm or involved)* * *Deep margin (mm or involved)* |
| Complications   * *Definitions above* | * *None* * *Bleeding* * *Infection* * *Graft/flap failure for other reasons* * *Other* * *Unknown / patient not followed up* |
| Further treatment | * *Listed for re-excision*    + *Yes, No, Unknown* * *Referral for radiotherapy*   + *Yes, No, Unknown* * *Discharged from Plastic Surgery?* |

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