NICE National Institute for Health and Care Excellence

2019 surveillance of melanoma: assessment and management (NICE guideline NG14) and improving outcomes for people with skin tumours including melanoma (NICE guideline CSG8)

Surveillance report

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Contents

Surveillance decision

In May 2019 we decided to update the following guidelines:

- Melanoma: assessment and management (NICE guideline NG14)
- Improving outcomes for people with skin tumours including melanoma (NICE guideline CSG8)

In December 2020, we decided to retain but not update the guideline on improving outcomes for people with skin tumours including melanoma. For information on progress of the melanoma guideline update, see the guideline in development page.

Reasons for the decision

Melanoma: assessment and management

Topic experts, stakeholders and external correspondents highlighted the introduction of a revised 8th edition of the American Joint Committee on Cancer (AJCC) staging system for melanoma. Development of the 8th edition involved an evidence-based revision of stage I-III melanoma, and the introduction of a new category of stage IV disease. Nomenclature for stage III disease also changed, so that microscopic nodal disease should now be termed 'clinically occult' and macroscopic nodal disease should be termed 'clinically detected'. A comparison between the 7th and 8th editions of the AJCC staging systems indicated that stage 0 and stages IIA-IIC melanoma should be unaffected by the introduction of the 8th AJCC edition. All other stages of melanoma are likely to be affected by the revision in staging.

The stages of melanoma referred to in the NICE guideline are from the previous 7th edition of the AJCC staging system. Therefore, this revision has the potential to impact on multiple recommendations in the NICE guideline that refer to specific stages of melanoma that have been redefined under the new system. These include recommendations under the following sections:

- 1.2 Assessing melanoma (recommendations on genetic testing in early stage melanoma).

- 1.5 Staging investigations (recommendations on sentinel lymph node biopsy [SLNB] and the use of imaging in staging).
- 1.6 Managing stages 0-II melanoma (1 recommendation on excision for stage I melanoma).
- 1.7 Managing stage III melanoma (recommendations on completion lymphadenectomy, lymph node dissection, and adjuvant radiotherapy).
- 1.8 Managing stage IV melanoma (as a new subcategory has been introduced under stage IV disease to denote central nervous system disease).
- 1.9 Follow-up after treatment for melanoma (potential impact on several recommendations).

We consulted on a proposal to withdraw recommendations 1.1.1, 1.1.2, 1.1.4 and 1.1.5 on communication and support and replace them with a cross reference to the NICE guideline on patient experience in adult NHS services, and also to retain recommendation 1.1.3 on the provision of advice on skin protection and avoidance of vitamin D depletion, but to move it to section 1.3 on managing suboptimal vitamin D levels. However, comments received at consultation described the value of specific communication, information and support to people with melanoma and so recommendations 1.1.1 to 1.1.5 will be retained.

For further details and a summary of all evidence identified in surveillance, see appendix A1.

Improving outcomes for people with skin tumours including melanoma

Topic expert feedback received during surveillance indicated that this NICE guideline is considered outdated, does not reflect current service structures, and is no longer fit for purpose. Key issues include changes in cancer infrastructure and strategy, and developments in assessment, staging and management of skin cancer since the publication of the guideline.

The 2010 partial update refers to service structures that are no longer in operation, including cancer networks and primary care trusts.

We consulted on the surveillance proposal to withdraw this guideline. Stakeholders emphasised the continuing usefulness of it to clinical practice. However, as service

structures have changed since it was published, it is proposed that we update it.

In December 2020, we decided to retain but not update this guideline. For information on progress of the melanoma guideline update, see the guideline in development page.

Overview of 2019 surveillance methods

NICE's surveillance team checked whether recommendations in the following guidelines remain up to date:

- Melanoma: assessment and management (NICE guideline NG14)
- Improving outcomes for people with skin tumours including melanoma (NICE guideline CSG8)

The surveillance process consisted of:

- Feedback from topic experts via a questionnaire.
- A search for new or updated Cochrane reviews.
- Examining related NICE guidance and quality standards and NIHR signals.
- A search for ongoing research.
- Examining the NICE event tracker for relevant ongoing and published events.
- Literature searches to identify relevant evidence.
- Assessing the new evidence against current recommendations to determine whether or not to update sections of the guideline, or the whole guideline.
- Consulting on the decision with stakeholders, except if we propose to update and replace the whole guideline.
- Considering comments received during consultation and making any necessary changes to the proposal.

For further details about the process and the possible update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence considered in surveillance

Search and selection strategy for melanoma: assessment and management

We searched for new evidence related to specific parts of the guideline suggested as priorities of interest for surveillance by topic experts.

Focused searches included:

The role of genetic testing of the tumour at diagnosis for a person with early stage I-III melanoma

Studies were eligible if they compared the genetic testing of tumour at diagnosis with no genetic testing at diagnosis on outcomes in people with early stage I-III melanoma. No restriction was placed on study design.

We found 0 studies in a search for studies published between 1 January 2014 and 17 December 2018.

The use of completion lymph node dissection in patients diagnosed with stage III melanoma

Eligible studies examined lymph node dissection in patients diagnosed with stage III melanoma. For patients with micro-metastatic nodal disease as detected by sentinel lymph node biopsy (SLNB), completion lymphadenectomy was compared with clinical observation or clinical follow-up using ultrasound. For patients with palpable nodal disease, standard (local) lymphadenectomy was compared with extended lymphadenectomy. No restriction was placed on study design.

We found 9 studies in a search for studies published between 9 June 2014 and 11 December 2018.

The use of imaging in patients with clinicopathological stage IA, IB–IIC, stage III or stage IV melanoma

Eligible studies compared different imaging modalities with each other in terms of

diagnostic performance, recurrence, survival, health-related quality of life and adverse events. No restriction was placed on study design.

We found 19 studies in a search for studies published between 1 January 2014 and 12 December 2018.

Regular surveillance imaging compared with routine clinical follow-up in people treated for high risk stage II and III melanoma

Studies were eligible if they compared the effects of regular surveillance imaging with routine clinical follow-up on outcomes in people treated for high risk stage II and III melanoma. Only randomised controlled trials (RCTs) were eligible.

We found 0 studies in a search for RCTs published between 1 January 2014 and 12 December 2018.

We also included:

- 17 relevant studies from a total of 100 identified by topic experts
- 7 eligible Cochrane systematic reviews identified in a search of the Cochrane Database of Systematic Reviews and the 2018 Cochrane special collection on diagnosing skin cancer.

From all sources, we considered 52 studies to be relevant to the guideline.

See appendix A1 for details of all evidence considered, and references.

Search and selection strategy for improving outcomes for people with skin tumours including melanoma

We searched for new evidence related to the role and structure of the multidisciplinary team (MDT) in the management of skin cancer. This area was highlighted in topic expert feedback as being a priority of interest for surveillance. Eligible studies compared impact on outcomes of the MDT with MDT team care of a different composition, or no MDT. No restriction was placed on study design.

We found 7 studies in a search for studies published between 1 January 2005 and 4

December 2018.

We also included:

- 21 relevant studies from a total of 22 identified by topic experts
- 13 studies identified by a search in a previous evidence update in 2011
- 13 eligible Cochrane systematic reviews identified in a search of the Cochrane Database of Systematic Reviews and the 2018 Cochrane special collection on diagnosing skin cancer.

From all sources, we considered 54 studies to be relevant to the guideline.

See appendix A2 for details of all evidence considered, and references.

Selecting relevant studies

In order to manage the number of potentially eligible studies resulting from these focused searches, pragmatic limits were placed on inclusion:

- studies with narrative description of results and limited numerical data were considered to have inadequate reporting of data and were not included
- observational studies were required to have a minimum sample size of 50 for inclusion.

Ongoing research

We checked for relevant ongoing research; of the ongoing studies identified, none were assessed as having the potential to change recommendations.

Intelligence gathered during surveillance

Views of topic experts

We considered the views of topic experts who were recruited to the NICE Centre for Guidelines Expert Advisers Panel to represent their specialty. For this surveillance review, topic experts completed a questionnaire about developments in evidence, policy and

services related to the guidelines.

We sent questionnaires to 15 topic experts and received 8 responses.

Melanoma: assessment and management

Seven of the 8 topic experts stated that recommendations need to be updated in the guideline (with no comment received from 1 topic expert).

Topic experts indicated several areas where clinical practice had developed since the guideline published (with focused searches undertaken in some of these areas):

- Changes to the American Joint Committee on Cancer (AJCC) staging system (revision from the 7th to the 8th edition).
- Genetic testing in early stage melanoma.
- SLNB.
- Use of imaging in staging of disease.
- Completion lymphadenectomy.
- Increased availability of systemic treatments for stage III and stage IV melanoma.
- Follow-up after treatment, including the use of imaging.
- New evidence on communication and support. We originally proposed to withdraw recommendations 1.1.1, 1.1.2, 1.1.4 and 1.1.5 on communication and support and replace them with a cross reference to the NICE guideline on patient experience in adult NHS services and retain recommendation 1.1.3 on the provision of advice on skin protection and avoidance of vitamin D depletion but move it to section 1.3 on managing suboptimal vitamin D levels. However, comments received at consultation indicated the value of specific communication, information and support to people with melanoma. Therefore, recommendations 1.1.1 to 1.1.5 on communication and support will be retained.
- Managing suboptimal vitamin D levels. No evidence in this area was identified in the current surveillance review.

- Use of antibiotics during immunotherapy. No evidence in this area was identified in the current surveillance review.

Improving outcomes for people with skin tumours including melanoma

Key issues identified in topic expert feedback included:

- Views that the guideline is now outdated.
- Changes in organisation of cancer services and provision of care (for example referrals to cancer networks in the guideline).
- Changes in staging systems for skin cancer (that is AJCC and Union for International Cancer Control [UICC]) affecting management of melanoma and non-melanoma skin cancer.
- Developments in management of skin cancers since the guideline published (for example systemic treatments).

Implementation

The NICEimpact cancer report (2018) presents data relevant to the NICE guideline on melanoma: assessment and management in the area of prescribing cancer medicines for melanoma. These medicines include immunotherapy and targeted treatments covered by several NICE technology appraisals, some of which are covered by recommendations in section 1.8 on managing stage IV melanoma. No other information was available on implementation of other aspects of either of the NICE guidelines.

Other sources of information

We considered all other correspondence received since the 2 NICE guidelines were published. These included external communications from healthcare professionals and external organisations received before and during this surveillance review.

Two external queries relating to the omission of excision biopsy and pathology and excision depth from the scope were received since the publication of the guideline on melanoma: assessment and management. No focused searches were performed relating to excision. Search results from the Cochrane Database of Systematic Reviews and studies suggested by topic experts were examined for any studies relating to excision. No

evidence was identified. A systematic review (Mocellin et al. 2011) on excision margins was identified in the evidence update considered as part of the surveillance review for the NICE guideline on improving outcomes for people with skin tumours including melanoma. However, the publication date of this study pre-dated the date cut-off for the surveillance review for the NICE guideline on melanoma: assessment and management.

External correspondence was received highlighting the publication of the MSLT-II study and changes in the AJCC melanoma staging system since the publication of both NICE guidelines.

We also considered changes from the 7th to the 8th edition of the AJCC staging system in order to assess the potential impact of these changes in staging on recommendations in both guidelines.

Views of stakeholders

Stakeholders are consulted on all surveillance reviews except if the whole guideline will be updated and replaced. Because this surveillance proposal was to update the NICE guideline on melanoma: assessment and management (with withdrawal of recommendations 1.1.1, 1.1.2, 1.1.4 and 1.1.5 on communication and support), and the withdrawal of the NICE guideline on improving outcomes for people with skin tumours including melanoma (including withdrawal of the 2010 partial update), we consulted with stakeholders.

Melanoma: assessment and management

Overall, 13 stakeholders commented on the consultation for this NICE guideline. Responding stakeholders included professional bodies, royal colleges, a charitable organisation, and commercial organisations. Eleven stakeholders agreed with the proposal to update it (with 2 stakeholders not providing a response).

Issues raised during this consultation included:

- The importance of using the melanoma staging system with most relevance to current clinical practice (that is AJCC 8th edition or UICC 8th edition) in the proposed update. We will pass on these comments to the developers for consideration during the guideline update.

- The need for the guideline to be updated following the AJCC 8th edition. After consideration of the changes in the AJCC 8th edition, we agree that this revision has the potential to impact on multiple recommendations in the guideline. This change in staging system is a key factor in the proposal to update this guideline.
- The SLNB section is considered out of date and factually incorrect. This point was also raised in topic expert feedback and external correspondence. While no evidence was identified in surveillance with potential impact on current recommendations, this feedback will be forwarded to developers for their consideration during scoping of the proposed update.
- The need for positron emission tomography-computed tomography (PET/CT) to be considered for imaging of melanoma. This guideline does not include recommendations on the use of PET/CT imaging in staging and several primary studies are now available.
- Consideration of new evidence on completion lymph node dissection in the update. New evidence was considered in this surveillance review (including 2 RCTs and additional observational studies). We concluded that this evidence has potential to impact on recommendations on completion lymphadenectomy.
- Need for the guideline to consider survivorship. No evidence or intelligence on survivorship was identified in the surveillance review.
- The importance of communication and support for people with melanoma and that recommendations on communication and support should be retained in the guideline rather than withdrawn. Following consultation, these recommendations will be retained and will not be withdrawn.
- The value of the skin cancer clinical nurse specialist in care and support of people with melanoma. Following consultation, recommendations 1.1.1 to 1.1.5 on communication and support will be retained and will not be withdrawn.
- Timing of BRAF gene testing. Topic expert feedback during surveillance noted that recommendations on genetic testing should be reviewed considering the increased availability of treatments for later stage melanoma since the guideline published. However, we did not identify any eligible evidence on early genetic testing in focused searches performed in this surveillance review to justify inclusion in the planned update.

- Comments on the inclusion of systemic therapies in the NICE Pathway on melanoma, with cross-referral to the pathway from the guideline. It is proposed that the planned update will link to the pathway in order to provide a cross-referral to the existing NICE-recommended systemic treatments.
- The omission of assessment of equivocal lesions in the scope. No evidence or intelligence on this area was identified in the surveillance review.

Improving outcomes for people with skin tumours including melanoma

Overall, 9 stakeholders commented on the consultation for this guideline. Responding stakeholders included professional bodies, royal colleges, and a charitable organisation.

- Two agreed with the proposal to withdraw the guideline.
- An additional stakeholder agreed with the proposal to withdraw the guideline but with an urgent replacement.
- Five stakeholders did not agree with the proposal to withdraw the guideline with one indicating an update is needed.
- One did not provide a response.

Issues raised during consultation included:

- The continuing value of this guidance to delivery of skin cancer services (for example, MDT structure and function, community dermatology, non-melanoma skin cancer and rare skin tumours). As a result, we propose to update this guideline.
- Need for guidance on MDTs (including structure and function). We will pass these comments to developers for their consideration during scoping of the planned update.
- Impact of the introduction of AJCC 8th edition of staging. We acknowledge that the change in skin cancer staging since this guideline published may have potential impact on it. We will pass these comments to the developers for their consideration during scoping of the planned update.

- Need for guidance on use of teledermatology in skin cancer. Evidence from a Cochrane systematic review was included in the surveillance review. Topic expert feedback also supported the need to reconsider the use of teledermatology. The Cochrane review authors concluded that the evidence base was limited. Therefore, this surveillance review concluded that additional well-conducted primary research on clinical accuracy and cost-effectiveness, patient confidentiality and patient acceptability would be beneficial.

Following consideration of these stakeholder responses, we propose to update this guideline.

See appendix B1 and appendix B2 for full details of stakeholders' comments and our responses.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

Equalities

No equalities issues were identified during the surveillance process for the NICE guideline on melanoma: assessment and management. For the NICE guideline on improving outcomes for people with skin tumours including melanoma, it was noted that the withdrawal of this guideline would risk inequity of services and patient care and would result in people with non-melanoma skin cancer, not being treated equally to melanoma. An update of this guideline is now planned.

Editorial amendments

During surveillance, we identified the following points that should be amended.

Melanoma: assessment and management

Section 1.7 on managing stage III melanoma should be revised to include a cross-referral to the NICE Pathway on melanoma describing NICE technology appraisal guidance of systemic treatments for stage III melanoma. We propose the following text be added: Following the development of this guideline, new technology appraisals are available that are relevant to this section. Please see the NICE Pathway on melanoma for further information.

Section 1.8 on managing stage IV melanoma should be revised to include a cross-referral to the NICE Pathway on melanoma describing NICE technology appraisal guidance of systemic treatments for stage IV melanoma. We propose that recommendations 1.8.5, 1.8.6 (targeted treatments), and 1.8.7 (immunotherapy) be replaced with the following text: Following the development of this guideline, new technology appraisals are available that are relevant to this recommendation. Please see the NICE Pathway on melanoma for further information.

Overall decision

After considering all evidence and other intelligence and the impact on current recommendations, we decided that updates of both guidelines are necessary.

In December 2020, we decided to retain but not update the guideline on improving outcomes for people with skin tumours including melanoma. For information on progress of the melanoma guideline update, see the guideline in development page.

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