Melanoma

Consultation on draft guideline - stakeholder comments

Comments to be submitted
before 5pm on Friday 13 March 2015

Please note:	Please fill in both the 'stakeholder organisation' and 'name of commentator' fields. We cannot accept forms with attachments such as research articles, letters or leaflets. Forms that are not correctly submitted as requested may be returned to you. NICE has developed a list of possible areas for comment on the draft guideline for your information.
Stakeholder organisation(s) (if you are responding as an individual rather than a registered stakeholder please state name here):	**British Association of Dermatologists (BAD)**
Name of commentator (if you are responding as an individual rather than a registered stakeholder please leave blank):	**Drs Pamela McHenry and Steve Keohane, on behalf of the BAD's Officers, Therapy & Guidelines, Skin Cancer and Health Informatics sub-committees**

Comment number	Document Indicate if you are referring to the **Full** version, **NICE** version or the **Appendices**	Page number Indicate **number** or **'General'** if your comment relates to the whole document	Line number Indicate **number** or **'General'** if your comment relates to the whole document	Comments Please insert each comment in a new row. Please do not paste other tables into this table, because your comments could get lost – type directly into this table.

Please add extra rows as needed

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	Full	6		Vitamin D: Please see the “Comments on implementation” below.
	Full	6		Dermoscopy – diagnosis and follow-up: Please see the “Comments on implementation” below.
	Full	7		Sentinel lymph node biopsy: Please see the “Comments on implementation” below.
	Full	7		Lentigo maligna: What evidence is there that Mohs surgery is going to offer a better alternative than simple excision ensuring complete excision irrespective of clinical margin? Why should Mohs be carried out for lentigo maligna rather than any other type of *in-situ* melanoma?
	Full	21		Algorithm on diagnosing melanoma: 1. Guidance is unclear regarding subsequent follow up/discharge in patients assessed with photographs after 3 months who do not need excision. There should be a mechanism for discharging patients with these lesions back to the GP. If they are kept under follow-up until the lesion is excised, it would lead to increased burden on clinics and would lead to increase in benign lesions being excised. Also, the algorithm gives no guidance regarding follow-up for multiple atypical naevi. 2. The statement “Do not routinely use confocal microscopy or computer assisted diagnostic tools to assess pigmented lesions” is very negative and suggests these may be harmful. This could be rephrased to “Confocal microscopy or computer assisted diagnostic tools are not routinely required”. 3. Suspected atypical spitzoid lesion – it is unclear from the algorithm whether this is based on a clinical suspicion/dermoscopic diagnosis or histological diagnosis before referral to the SSMDT.

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				4. Discharge: should include advice regarding changes to look for in future and sensible sun protection.
	Full	24		Stage 2: Breslow thickness 2 mm or more' but this does not include stage 2A with Breslow 1.01-2 mm with ulceration. Where does it fall in the algorithm?
	Full	26		Follow-up of Stage 1B: Not all pathology laboratories report on mitotic rate for melanomas with Breslow of 1 mm or below, in order to classify as pT1a or pT1b – it should be stressed that this is required as it is part of the Royal College of Pathologists' NICE-accredited minimum dataset for reporting melanoma.
	Full	26		Imaging: The role of CT-PET should be discussed
	Full	26		"Personalised follow-up": We are not sure what "personalised follow-up" means. There should be a clear definition for this and it would be good to define it in the algorithm as well.
	Full	34		Projected incidence of melanoma: *"The age-standardised rates of melanoma are projected to increase by > 1% per year from 14.6 per 100,000 for men and 15.4 per 100,000 for women in 2007 to 22.3 and 23.4, respectively, in 2030 (Mistry et al. 2011)."* This statement seems redundant due to the sentence *"..in 2012 was higher for men (25.0 melanomas per 100,000 men) than for women (22.1 melanomas per 100,000 women)"*.
	Full	56		Patient Information: It is much more important for patients to have information that is stage-appropriate than the histopathological subtype.
	Full	84		The role of ulceration and mitosis in staging should be addressed.
	Full	107		Staging recommendations:

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				In the follow-up, the recommendations are to *consider* surveillance imaging for stage 2C patients who did not have SLNB. But the staging recommendations say to *offer* staging imaging only to stage 3 or suspected stage 4 melanoma patients. Hence there is a disparity between the recommendation not to offer staging imaging for stage 2C patients (without SLNB) but to consider surveillance imaging for stage 2c patients.
	Full	119		Stage 0 melanoma: It is well known that clinical margins and histological margins in lentigo maligna are very discordant. Hence suggesting 0.5 cm margin may not be valid. Practically it might be better to advise to aim to achieve clear margins ideally of at least 0.5 cm.
	Full	126		Imiquimod and lentigo maligna: Evidence for all non-surgical forms of treatment of lentigo maligna is weak and it is surprising that imiquimod should be given clear preference over, for instance, cryotherapy when there is very little evidence available (Stage 0-2 melanoma).
	Full	226		Advice on vitamin D: The management of patients with normal vitamin D levels at diagnosis of melanoma requires more specific guidance. Normal vitamin D levels at diagnosis do not rule out development of vitamin D deficiency in the future due to sun protection advice that would have been given at the time of diagnosis. If the GDG recommendation wishes to avoid development of vitamin D deficiency and possibly the treatment leading to benefits in overall survival, it would be advisable to repeat the tests intermittently in order to identify patients who develop vitamin D deficiency after diagnosis.
	Full	General		Management of melanoma in special situations such as pregnancy, and recommendations for genetic screening in patients with family history of melanoma seems to have been missed.

Please add extra rows as needed

Comments on implementation (please see chapter 2 in NICE version)
Do you agree with the areas that have been identified as having a big impact on practice or challenging to implement? Let us know if you would give priority to other areas and why.

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What would help users overcome these challenges? (For example, you could signpost us to examples of good practice or provide details of educational materials or other relevant resources that you have found useful). Please note that we will not formally respond to your comments on this section as we view these as an information gathering exercise.				
Comment Number	**Document** There is no need to indicate this as the implementation section is only featured in the NICE version	**Page Number** Not applicable	**Line Number** Not applicable	**Comments**
1				The recommendation about use of dermoscopy in diagnosis and follow-up should be qualified by a caveat about the risks of this technique giving false reassurance when practitioners are not thoroughly trained in its application. The studies supporting its use are subject to the limitation that they are generally performed on groups of typical rather than difficult pigmented lesions. The recommendation of imaging for follow-up was left for local policies to decide without any precise guidelines on how frequent it should be. We think that it would be very useful to suggest a range period to arrange for such a test. Plus, such surveillance imaging as “agreed by local policy/funding” appears to be a recipe for postcode variation in care – is this appropriate for a national guideline? Not sure if baseline photographs especially for dermoscopic features of “atypical melanocytic lesion not requiring excision” is practical in terms of service implications or even required as a national guideline recommendation. Not clear that the benefits of this are proven on the scale proposed, whether cost-effective, and to what extent such a recommendation would drive us towards even more surgery. Appreciate the aspiration, but is this suitable for a national guideline? We would prefer to have this as an option rather than a recommendation. For all the clinical images of moles that are taken, there are very limited cases where melanoma was picked up purely from a change relative to photographic image; dermoscopy imaging would be similar. Standardising the colour in photos is very difficult as lighting can vary in clinics. Dermoscopic follow-up would require recorded and reproducible photo-documentation.

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				There should be a further emphasis on a self-monitoring element which is to define the naevus for the patient in terms that they can recognise, e.g. shape, size, colour and symptoms and then document this in a letter and ask them to monitor and ask again if there are changes. It may be good practice to monitor with repeated dermoscopy images, but it is not something that is going to improve the chance of patients monitoring themselves effectively and is not practical for many clinicians with limited resources.
2				Evidence of a critical role for vitamin D deficiency in melanoma is limited and it is surprising that measurement of vitamin D levels in all melanoma patients is given as a key implementation priority on the basis of the existing evidence. The measurement of vitamin D levels would appear to need more evidence before wider recommendation.
3				The recommendation to consider sentinel node biopsy routinely in stage 1B melanoma patients is not well supported by the study of cost-effectiveness, making it difficult to support its use out with the context of clinical trials.

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