NICE GUIDELINE ON MELANOMA (NG14): A NURSE PERSPECTIVE

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ABSTRACT

This article will look at the melanoma guideline published in 2015, focusing on the areas that may impact nursing practice. This article only provides an overview of the guideline, with subsequent articles analysing the implications for practice.

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KEY WORDS

- NICE
- Guideline
- Melanoma
- Vitamin D
- Management

Since 2010, reflecting contemporary health and social care provision, NICE has been instrumental, in developing quality standards, statements and performance metrics for those providing and commissioning health, public health and social care services.[1] The Melanoma Guideline (NG14)[2] was commissioned by NICE from the National Collaborating Centre for Cancer (NCC-C) in Cardiff.

Following consultation with key stakeholders, a scope of the proposed guideline is agreed. The Guideline Development Group (GDG) is enlisted following a formal recruitment process, of professionals and lay/patient members, representing the subject of interest and the skin cancer multidisciplinary team (MDT).

The GDG has to work within certain limitations, such as the fact that the "scoping document" – which reflects the key issues pertaining to areas of complexity or controversy posed by stakeholders – cannot be modified at GDG stage. Therefore, if an issue is not raised during the scoping consultation, it cannot be included in the guideline. The GDG is also unable to consider topics that are previously appraised or undergoing appraisal, but is able to link to these.

In the context of the melanoma guideline, this posed issues in respect of Vitamin D. Here, this consultation document was published by the Scientific Advisory Committee on Nutrition,[3] and included a discussion of anticancer treatments such as (Dabrafenib/ Vemurafenib) and immunotherapy (Ipilimumab).

The scope of the guideline required the GDG to consider the evidence provided for the various topics and make recommendations for clinical practice, some of which were relatively straightforward, some of which were controversial and required "expert witnesses" to present evidence to help the GDG in the decision-making process. Additionally, where evidence was not conclusive a consensus was required of the group.

The author will share some insights into some of the key recommendations/priorities and the changes they may pose in clinical practice. The guideline in full can be found on the NICE website and describes methods and evidence used to develop the guidance.[2]

Communication and Support

The recommendations for communication and support reflected those that were published in 2006 in "Improving outcomes for people with skin tumours including melanoma".[4] This was because the GDG felt most of these recommendations were still relevant today. The recommendations include the following:

- Improved, preferably nationally standardised, written information should be made available to all patients. Information should be appropriate to the patients' needs at that point in their diagnosis and treatment, and should be repeated over time. The information given must be specific to the histopathological type of lesion, type of treatment, local services and any choice within them, and should cover both physical and psychosocial issues
- Those who are directly involved in treating patients should receive specific training in communication and breaking bad news
- Patients should be invited to bring a companion with them to consultations
- Each LSMDT [local hospital skin cancer multidisciplinary team] and SSMDT [specialist skin cancer multidisciplinary team] should have at least one skin cancer

BOX 1.

Key Recommendations NG14

- Communication and support
- Assessing melanoma
- Managing suboptimal vitamin D levels
- Managing concurrent drug treatment
- Staging investigations
- Managing stage III melanoma
- Follow-up after treatment for melanoma

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clinical nurse specialist (CNS) who will play a leading role in supporting patients and carers. There should be equity of access to information and support regardless of where the care is delivered
- All LSMDTs and SSMDTs should have access to psychological support services for skin cancer patients
- Give people with melanoma and their families or carers advice about protecting against skin damage caused by exposure to the sun while avoiding vitamin D depletion
- Carry out a holistic needs assessment (HNA) to identify the psychosocial needs of people with melanoma and their needs for support and education about the likelihood of recurrence, metastatic spread, new primary lesions and the risk of melanoma in their family members
- Follow the recommendations on communication and patient-centred care in NICE's guideline on patient experience in adult NHS services.

One of the main questions posed related to the specific information and support needs in melanoma patients and how these could be met. Extensive research on these subjects was unavailable and poor, with most of the evidence derived from the National Cancer Patient Experience Survey (CPES) 2012/2013.[5] Unfortunately, this survey targets in patients or those admitted as day cases. Therefore, few melanoma patients are generally included. Additionally, 15% stated they had not received written information.

A recent systemic review looking at psychosocial outcomes for patients with stage III/IV melanoma, found that those with advanced disease had more needs relating to stage-specific high quality melanoma information, [6] confirming findings by Molassiotis et al (2014)[7] and Stamataki et al (2015).[8] Both of these studies provided evidence that melanoma patients have significant unmet needs, irrespective of melanoma stage, mainly in the psychosocial support, information/education, and physical health domains. This unmet need was a contributor to anxiety and depression. These findings pose challenges for healthcare professionals working with this patient group and different ways of providing support and information may need to be considered.

The GDG did agree to recommend "holistic needs assessment" (HNA) as a tool, which is currently used to measure patient needs and subsequent care/ treatment planning, at the various stages of the patient pathway and as a means to open up communication between the patient, their carers /relatives and healthcare professionals.[9,10] It is thought that this can help healthcare professionals, when appropriately trained, to recognise depression and other symptoms of distress and to treat or to refer patients to additional sources of help, such as psychosocial support. The HNA forms part of the recovery package[11] which also includes:
- End of treatment summary
- Health and well-being events.
- Cancer care review (CCR- by GPs within 6/12 weeks of diagnosis).

The HNA assessment is completed at various stages of the patient pathway, and specifically where treatment modalities may change, the Skin Cancer CNS will also complete with the patient a HNA on discharge, this may change management i.e., discharge may be delayed due to anxiety, physical or psychosocial issues.

In 2015, NHS England committed to ensure that every person with cancer has access to the elements of the Recovery Package by 2020.[12]

Assessing melanoma

All pigmented skin lesions that are referred for assessment or identified during follow up in secondary or tertiary care should be assessed using dermoscopy carried out by trained healthcare professionals.

This has some implications for practice with respect to training and competency and purchase of dermatoscopes. Most skin cancer nurses, who are involved in two week wait or skin cancer follow up clinics, will be assessing for possible skin cancers on a daily basis. Dermoscopy helps to recognise pigmented lesions and can help improve accuracy of diagnosis, and a number of dermoscopy courses are available nationally, ranging from a study day to MSc modules. Competency can also be determined in the dermatology department, workplace-based learning and using assessment tools published with the BDNG Skin Cancer Competencies.[13]

Photography

For a clinically atypical melanocytic lesion that does not need excision at first presentation in secondary or tertiary care:
- Use baseline photography (preferably dermoscopic) **and**
- Review the clinical appearance of the lesion, and compare it with the baseline photographic images, 3 months after first presentation to identify early signs of melanoma.

Assessing and managing atypical spitzoid lesions

Discuss all suspected atypical spitzoid lesions at the specialist skin cancer multidisciplinary team meeting (SSMDT).

Make the diagnosis of a spitzoid lesion of uncertain malignant potential on the basis of the histology, clinical features and behaviour.

Manage a spitzoid lesion of uncertain malignant potential as melanoma.

As Spitzoid lesions can be challenging, the GDG felt that the above was the most appropriate way to manage these lesions. As a result, some patients may be overtreated and referrals to SSMDT may increase, however this was in the interest of patient safety.

Managing suboptimal vitamin D levels

All people with melanoma should have vitamin D levels measured at diagnosis in secondary care.

People who are thought to have suboptimal vitamin D levels should be given supplementation and monitored in line with local policies and NICE's guideline on vitamin D.

Further advice on vitamin D levels was published in 2016 by the Scientific Advisory Committee on Nutrition (SACN).[3] Following a long consultation period, SACN recognises that most of the UK population (four years and older) will need 400IU/10µg of Vitamin D daily to avoid deficiency during the winter months. They state: "It is not possible to make a recommendation regarding the amount of sunlight exposure that would be required during the summer to maintain vitamin D levels of at least 25nmol/L in winter in 97.5% of the population because of variation in endogenous factors governing vitamin D production."

A podcast and further advice are available through the tools and resources section of the melanoma guideline. A patient information leaflet can be found on

www.genomel.org although the recommendation states for vitamin D3 to be measured at diagnosis, secondary care is not responsible for prescribing supplementation. Therefore, in practice, many patients will purchase supplements from health food shops or pharmacies, over the counter.

Managing concurrent drug treatment

Drug treatments for other conditions should not be withheld on the basis of a melanoma diagnosis, except for immunosuppressants. Therefore, consider minimising or avoiding immunosuppressants for people with melanoma.

In practice, this can be a difficult discussion to have with a patient suffering with Crohn's, psoriasis or rheumatoid/psoriatic arthritis, who has been stable on biologic therapy (anti -TNF-α, IL 12/23 or IL17-A) with significant improvement in quality of life. Encourage discussion with treating physician and recognise the support needs of these patients.

Staging investigations

Taking tumour samples for genetic testing

- If targeted systemic therapy is a treatment option, offer genetic testing
- Do not offer genetic testing of stage IA–IIB primary melanoma at presentation except as part of a clinical trial
- Consider genetic testing of stage IIC primary melanoma or the nodal deposits or in transit metastases for people with stage III melanoma
- If insufficient tissue is available from nodal deposits or in transit metastases, consider genetic testing of the primary tumour for people with stage III melanoma.

Sentinel lymph node biopsy

- Consider sentinel lymph node biopsy as a staging rather than a therapeutic procedure for people with stage IB–IIC melanoma with a Breslow thickness of more than 1mm, and give them detailed verbal and written information about the possible advantages and disadvantages, using *Table 1*.

The role of sentinel lymph node biopsy (SNLB) is controversial, with its routine use being very variable across the country. However, it is "standard of care" in many countries, part of the American Joint Committee on Cancer's (AJCC) staging system,[14] and utilised for stratification in clinical trials.

Expert presentations were sought by the GDG on the subject. It is clearly very important to have an open discussion about SLNB and its lack of therapeutic value with the patient, especially as this staging procedure requires a general anaesthetic (NHS Choices).[15] However, as a staging procedure SLNB is accurate and can help inform further treatment choices. In the resources part an "option grid" on SLNB is available, developed in collaboration with The Dartmouth Institute for Health Policy and Clinical Practice.[16] SLNB is not available in certain parts of England and Wales, posing an inequity of care, patients can still opt to have the procedure but would have to travel significant distances and may experience delays in treatment by referral out of area.

Imaging

- Offer CT staging to people with stage IIC melanoma who have not had sentinel lymph node biopsy, and to people with stage III or suspected stage IV melanoma
- Include the brain as part of imaging for people with suspected stage IV melanoma
- Consider whole-body MRI for children and young people (from birth to 24 years) with stage III or suspected stage IV melanoma.

Managing stage III melanoma

Completion lymphadenectomy (CLND)

- Consider completion lymphadenectomy for people whose sentinel lymph node biopsy shows micro metastases, and give them detailed verbal and written information about the possible advantages and disadvantages, using the *Table 2*.

Although CLND is still standard of care in the UK, management of lymph nodes following positive SNLB is changing with the alternative of physical examination and ultrasound follow up (Liu & Bilimoria).[17] In view of the fact that only 8%-25% of patients undergoing CLND will have further microscopically positive nodes (Murali et al),[18] it is important to discuss all possible options with the patient, including the not insignificant potential post-operative side effects.[19] To ensure an informed decision can be made, an "Option Grid"[20] has been devised to enable patient decision making.

Adjuvant radiotherapy

Do not offer adjuvant radiotherapy to people with stage IIIB or IIIC melanoma unless a reduction in the risk of local recurrence is estimated to outweigh the risk of significant adverse effects.

Follow-up after treatment for melanoma

Follow-up for all people who have had melanoma

- Consider personalised follow up for people who are at increased risk of further primary melanomas, for example

Table 1.

Advantages and disadvantages of sentinel lymph node biopsy

Possible advantages of sentinel lymph node biopsy	Possible disadvantages of sentinel lymph node biopsy
The operation helps to find out whether the cancer has spread to the lymph nodes. It is better than ultrasound scans at finding very small cancers in the lymph nodes.	The purpose of the operation is not to cure the cancer. There is no good evidence that people who have the operation live longer than people who do not have it.
The operation can help predict what might happen in the future. For example, in people with a primary melanoma that is between 1 and 4mm thick: • around 1 out of 10 die within 10 years if the sentinel lymph node biopsy is negative • around 3 out of 10 die within 10 years if the sentinel lymph node biopsy is positive.	The result needs to be interpreted with caution. Of every 100 people who have a negative sentinel lymph node biopsy, around 3 will subsequently develop a recurrence in the same group of lymph nodes.
People who have had the operation may be able to take part in clinical trials of new treatments for melanoma. These trials often cannot accept people who haven't had this operation.	A general anaesthetic is needed for the operation.
	The operation results in complications in between 4 and 10 out of every 100 people who have it.

Table 2.

Advantages and disadvantages of completion lymphadenectomy

Possible advantages of completion lymphadenectomy	Possible disadvantages of completion lymphadenectomy
Removing the rest of the lymph nodes before cancer develops in them reduces the chance of the cancer returning in the same part of the body.	Lymphoedema (long term swelling) may develop, and is most likely if the operation is in the groin and least likely in the head and neck.
The operation is less complicated and safer than waiting until cancer develops in the remaining lymph nodes and then removing them.	In 4 out of 5 people, cancer will not develop in the remaining lymph nodes, so there is a chance that the operation will have been done unnecessarily.
People who have had the operation may be able to take part in clinical trials of new treatments to prevent future melanoma. These trials often cannot accept people who have not had this operation.	There is no evidence that people who have this operation live longer than people who do not have it.
	Having any operation can cause complications.

people with atypical mole syndrome, previous melanoma, or a history of melanoma in first degree relatives or other relevant familial cancer syndromes

- Perform a full examination of the skin and regional lymph nodes at all follow up appointments
- Provide psychosocial support for the person with melanoma and their family or carers at all follow up appointments
- All local follow-up policies should include reinforcing advice about self-examination and health promotion for people with melanoma and their families, including sun awareness, avoiding vitamin D depletion and NICE guidance on smoking cessation.

Stage 0 melanoma

Discharge people who have completed treatment for Stage 0 melanoma with advice as above.

Stage IA Melanoma

For people who have had stage IA melanoma, consider follow-up two-four times during the first year after completion of treatment and discharging them at the end of that year.

Do not routinely offer screening investigations (including imaging and blood tests) as part of follow-up to people who have had stage IA melanoma.

Stages IB-IIB melanoma or stage IIC melanoma (fully staged using sentinel lymph node biopsy)

For people who have had stages IB–IIB melanoma or stage IIC melanoma with a negative sentinel lymph node biopsy, consider follow-up every three months for the first three years after completion of treatment, then every six months for the next two years, and discharging them at the end of five years.

Do not routinely offer screening investigations (including imaging and blood tests) as part of follow-up to people who have had stages IB-IIB melanoma or stage IIC melanoma with a negative sentinel lymph node biopsy.

Follow-up after stage IIC melanoma with no sentinel lymph node biopsy or stage III melanoma

Consider surveillance imaging as part of follow up for people who have had stage IIC melanoma with no sentinel lymph node biopsy or stage III melanoma and who would become eligible for systemic therapy as a result of early detection of metastatic disease if:

- There is a clinical trial of the value of regular imaging or
- The specialist skin cancer multidisciplinary team agrees to a local policy and specific funding for imaging six monthly for three years is identified.

Take into account the possible advantages and disadvantages of surveillance imaging and discuss these with the person, using *Table 3.*

The above is available as an "Option Grid"[21] to help patient decision making on follow up with CT scans.

Stage IV Melanoma

Offer personalised follow-up to people who have had stage IV melanoma.

Conclusion

These are dynamic times in melanoma cancer management, especially considering the many breakthroughs in immunotherapy, ongoing drug trials and monotherapy or combinations. Therefore, it is likely that this guideline will need to be reviewed in the not too distant future. Although a comprehensive document, implementation of this guideline may pose some challenges and there may be a variation in care provision across England and Wales.[22] The HNA is an useful tool to measure patient needs in all domains and is commonly used today for melanoma patients.

As identified by numerous studies, significant distress is still experienced by melanoma patients, and identifying how to manage these psychological/social care needs,[23] poses a further challenge for skin cancer nurses.

The effect of the NICE recommendations on the CNS/key worker – particularly in relation to the patients' cancer journey – is significant. Many CNS's are directly involved in the clinical management of melanoma patients, and may deliver diagnosis and discuss treatments options, review patients post treatment and share the management of melanoma patients' follow up in clinical settings, with consultant colleagues.

As a key worker, the CNS is the patients' first point of contact when there is concern or evidence of recurring disease and thus provides access to continuing specialist service management, either in original hospital setting or specialist/ melanoma oncology services. The CNS is also key in managing and supporting patients while receiving targeted treatments and immunotherapies, or if the patient is included in clinical trials, ensuring best supportive care is provided and appropriate health care professionals are involved throughout the process. With more patients benefitting from these innovative treatments, CNSs working in the melanoma oncology centres have become experienced in recognising and managing side effects that are unique to the immunotherapies which, if not treated quickly, can have devastating effects. Combined with the difficulties some may experience in accessing specialist treatment centres, patients may find themselves admitted into local hospitals. In these instances, the role of the CNS is pivotal in liaising with local

Table 3.

Advantages and disadvantages of surveillance imaging

Possible advantages of surveillance imaging (having regular scans)	Possible disadvantages of surveillance imaging (having regular scans)
If the melanoma comes back (recurrent melanoma), it is more likely to be detected sooner. It is possible that this could lead to a better outcome by allowing treatment with drugs (such as immunotherapy drugs) to start earlier.	Although early drug treatment of recurrent melanoma might improve survival, there is currently no evidence showing this.
Some people find it reassuring to have regular scans.	Some people find that having regular scans increases their anxiety.
	Scans expose the body to radiation, which can increase the risk of cancer in the future.
	Scans of the brain and neck increase the risk of developing cataracts.
	Scans of the chest cause a very small increase in the risk of thyroid cancer.
	Scans may show abnormalities that are later found to be harmless, causing unnecessary investigations and anxiety.

skin cancer CNSs and admitting teams to ensure appropriate side effect algorithms are followed.

The CNS continues to play an important role in ensuring referral to palliative care, when appropriate, and is involved in the terminal phase of a patient's life.

More and more patients are surviving melanoma, with their care being transferred back to their GP at completion of treatment and follow up. The recovery (survivorship in Scotland) package is designed to empower patients to live beyond their cancer diagnosis and provides supportive tools, health and psychosocial advice and sign posting in case of cancer recurrence.

Further articles will look in more detail at the following:

- Part 2: Role of the keyworker; HNA and care planning in practice; Recovery package
- Part 3: Implications for practice; Implementing the guidelines; Local centres and their experiences of the guidelines; Quality Surveillance Team and Peer review
- Part 4: NICE Skin Cancer Quality Standards; Implementation in practice. DN

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