Document Type:	Policy	
Reference Number : **1851**	Version Number: **4**	Next Review Date: **18 December 2023**
Title:	**Clinical Guidelines For Management Of Suspected Melanoma Of The Foot**	
Document Author:	Podiatry Team Leader	
Applicability:	All patients as indicated	

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1 Introduction

Melanoma is a life threatening but potentially treatable form of cancer if diagnosed and managed at early stages. It is therefore prudent to identify evidence based approaches to the assessment and management of patients presenting with this condition by Podiatrists within Torbay and South Devon NHS Foundation Trust (TSDFT).

2 Purpose

This document has been produced to support the clinical practice of Podiatrists within Torbay and South Devon NHS Foundation Trust to improve the quality of referrals and recognition of melanoma on the foot and lower limb.

The information and standards should support and promote the following principles:

- Evidence based clinical practice
- Continuity of assessment and patient management across the Service and betweenindividual practitioners
- Individual clinical decisions/discretion

3 Responsibilities

3.1 The Head of Podiatry Services will be responsible for the implementation and monitoring of this guideline. It will be presented at staff meeting and an audit of compliance will be carried out.

3.2 This guideline applies to all podiatrists, podiatry assistant practitioners and podiatry clinical support workers employed by the Podiatry Service of Torbay and South Devon NHS Foundation Trust.

3.3 Podiatry students of the University of Plymouth's Podiatry Programme , working under honorary contracts within the Trust, are also governed by this and allied documents.

3.4 Health Care Professions Council Registered podiatrists, will retain responsibility and accountability for the actions of clinical support workers and students under in their supervision.

3.5 The terms "staff" and "podiatrist(s)" are used in this document to encompass all those individuals detailed in paragraphs 3.2 and 3.3. All such persons are responsible for engaging with and implementing the content of this document in their clinical practice.

4. Classification of pigmented lesions

4.1 Pre-malignant and malignant pigmented lesions

- Melanoma in situ
- Lentigo Maligna
- Invasive Melanoma
- Superficial Spreading Melanoma
- Nodular Melanoma
- Acral and Subungual Melanomna
- Mucosal Melanoma
- Lentigo Maligna Melanoma

4.2 Benign pigmented naevi

- Congenital
- Acquired

Acquired may be junctional, compound or intradermal naevi.
Specials can be classified as Atypical, Blue, Spitz, Reed or Naevus Spilus.

5. Making a differential diagnosis and clinical examination

5.1 At the initial appointment details and a description of any pigmented or solitary lesion arising on the feet should be recorded in the patient's notes.

5.2 It is essential to have good room lighting to enable a full examination of the patient to include the feet. Palpation of the lesion might also be part of the examination. If onward referrals are required correct terminology is an essential part of the referral process.

5.3 Important observations include:

- Size
- Elevation
- Shape
- Colour (main colour, number of other colours, symmetry of colour distribution)
- Surface (e.g. crusty, warty)
- Ulceration,
- Definition (can you see exactly where it stops and starts?)

5.4 It is important to use the correct terminology for describing lesions.

Papule -Palpable circumscribed lesion <0.5cm.
Macule- Flat circumscribed non palpable lesion.
Pustule- Yellowish or white pus filled lesion <1cm.
Plaque- Large flat topped, elevated palpable lesions, often disc shaped and >2cm in size (may be formed by coalescence of several papules or nodules).
Patch- large macule, flat, non-palpable with altered skin colour or texture.
Mole- Localised collection of melanocytes, extremely common and usually occur during childhood. Most people have 5-20 melanocytic naevi. Some moles have potential for malignant change so should be examined if there is change of size, pigmentation, asymmetry, irregularity of shape, changes at the edges, inflammation, bleeding, itching or nodularity.

5.5 **Skin cancers** All cases of suspected malignant melanoma, high risk basal cell carcinomas (BCC) and squamous cell carcinoma should be referred urgently for dermatological opinion via the GP. Actinic keratoses and pre-cancerous lesions should be referred to the GP.

Glasgow 7-point checklist

Major features:

- Change in size
- Irregular shape
- Irregular colour

Minor features:

- Diameter >7mm
- Inflammation
- Oozing
- Change in sensation

Any of Glasgow 7 point major features noted or 3 or 4 minor features without major features noticed by podiatrist then patient to be referred immediately to GP for urgent referral to dermatology.

The following is guidance on recognising high risk BCC

- Location (face, scalp, ears)
- Size>2cm
- Immuno-compromised patients
- Previously treated lesions
- Flat lesions with hard thickened skin (morphoeic BCCs)
- Genetically predisposed patients

(Low risk BCCs are considered to be any BCC not fulfilling above criteria)

5.6 **Risk factors** for the development of melanoma

- Fair skin
- A history of sunburn
- Excessive ultraviolet (UV) light exposure
- Living closer to the equator or at a higher elevation
- Having many moles or unusual moles
- A family history of melanoma
- Weakened immune system

5.7 The use of the simple acronym ABCDE- Area, Border, Colour, Diameter, Evolution (Appendix 1) is a useful aid memory to help identify the main clinical signs of a potential melanoma (but may miss amelanotic or smaller lesions). Any mole or solitary vascular lesion, whether new or pre-existing ,which is growing or changing shape or colour should be referred for a specialist dermatology opinion via their GP.

Data has highlighted how melanoma on the foot holds a poorer prognosis than melanoma elsewhere due to delays in presentation and misdiagnosis of the condition, particularly so when located in the periungual areas, beneath or around the nails. Lack of pigmentation in suspect pedal lesions can compound the problem.

Differential diagnosis can include:

- Ingrowing toe nail
- Foot ulcer
- Wart/verrucae
- Tinea Pedis/Onychomycosis
- Bruising
- Foreign body
- Sub-ungual haematoma
- Pyogenic granuloma
- Poroma (benign tumour of the sweat gland)
- Hyperkeratosis-corns/callus
- Necrosis
- Paronychia
- Ganglion

5.8 As many of the benign conditions are very common, identifying a rare occurrence of melanoma amongst them can be challenging. In view of this, an alternative acronym can be used to highlight potential melanoma on the foot using the acronym "CUBED" (**C**oloured lesion, **U**ncertain diagnosis, **B**leeding, **E**nlargement, **D**elay in healing). (Appendix 2).

5.9 **Causes of melanonychia compared with those of subungual bleeding.**

Melanonychia is characterised by a brown to black discolouration of the nail.
See Table 1

Table 1

Melanonychia	**Subungual Bleeding**
Benign racial melanonychia	Direct trauma
Laugier Hunziker Syndrome	Indirect micro-trauma-end on repetitive trauma
Inflammation • Lichen planus • Chronic paronychia • Trauma/friction	Haemorrhagic tendency lowering threshold for effects of trauma • Warfarin • Leukaemia • Thrombocytopenia
Radiation	Subungual tumour • Squamous cell carcinoma • Wart • Exostosis • Melanoma • Pyogenic granuloma
Medication • Minocycline • Chemotherapy • HIV disease or medication	

Addison's Disease	
Peutz Jeghers	
Subungual naevus	
Benign melanocyte	
Melanoma	
Bowen's Disease (in situ squamous cell carcinoma)	
Onychomycosis	

5.10 Amelanotic melanoma arises in the nail unit at a higher rate than other body sites. The lack of overt pigment can delay diagnosis, which in turn affects prognosis. There may sometimes be small pigmented tints to an otherwise pink or granulomatous mass. The differential diagnosis of amelanotic melanoma is considered for all pyogenic granuloma. Pyogenic granuloma are usually found on fingers or toes, bleed easily and do not easily remit. Pyogenic granulomas have much in common with the granulation tissue of ingrowing toe nails. Amelanotic melanoma presenting as a granulating mass of the nail fold can be misinterpreted as an ingrowing nail. Squamous cell carcinoma can also present in the same way. There is value in asking for histological examination for any bleeding, oozing lesion of unclear diagnosis, which does not resolve in 2 months. Concern should be greatest when the tumour causes disturbance of nail integrity as it arises in the nail matrix epithelium such that it cannot produce nail. Avoid long periods of conservative treatment regarding change in the nail or peri-ungual tissues that are limited to one digit and do not respond promptly to treatment.

5.11 **Features of longitudinal melanonychia compared with those of subungual bleeding**.

All features are generally true, but there can be individual exceptions. See table 2

Table 2

Melanoncyhia	**Subungual bleeding**
The duration of history is from 3-6 months upwards to 20 years or more	The duration of history is rarely more than 6 months and is typically shorter
A history of trauma is quite common	A history of trauma or precipitating activity is quite common

Lateral margins within the nail are mainly straight and longitudinally oriented	Lateral margins may be irregular
Where margins merges with the nail fold, pigment may spread onto nail fold (Hutchinson's sign)	Pigment rarely extends from beneath the nail plate
There are rarely any detectable transverse features	There may be a proximal transverse groove and/or transverse white mark within the nail
In the absence of clinical tumour, nail plate pigmentation is in continuity with a single zone.	Haemorrhage may be broken up into a number of zones.
Dermoscopy reveals • Continuous pigment between proximal nail fold and distal free edge • In the transverse axis, pigment may vary-whereas in the longitudinal axis it remains largely constant • There may be longitudinal flecks of darker pigment within the background pigment of the nail • Pigment is mainly brown black	**Dermoscopy reveals** • Pigment may not be continuous in the longitudinal axis, with clear nail at either the proximal or distal margin • Pigment may vary in any axis • Droplets of blood may be seen separated from the main zone of pigmentation • Blood may be seen as a discrete layer of material on the lower aspect of the nail plate at the free margin • Pigment may be purple black, with increasing red hues at margins. It is rarely brown

5.12 If X-ray arranged, ensure follow up of results by putting clinic session message on the computer clinic list for the patient's next appointment and record in swab folder.

5.13 Levit modified the ABCDE rule developed for detection of suspicious skin lesions and applied it to the nail. The ABCDEF **A**ge range, **B**and of pigment, **C**hange, **D**igit involved, **E**xtension to nail fold, **F**amily history of nail melanoma was developed by Levit **(**Appendix 3). All these points are reasonable and may guide the podiatrist to seek advice. A final diagnosis of melanoma will always depend on the histology.

6. Referral

6.1 This document is a guide in deciding whether a presenting lesion should be referred on to the GP to consider referral to dermatology. Confirmation of diagnosis can only be secured through appropriate biopsy, histological examination and specialist interpretation. Malignant melanoma is not the only malignant skin tumour arising on the foot. However, these guidelines should alert the practitioner to any skin lesions exhibiting unusual features. If there is any doubt, second opinion should be sought from the GP. Record all findings in the notes, including photographs, with patient's written consent.

6.2 If a melanoma is suspected, local policy is that immediate contact should be made with the GP to request an urgent referral to Dermatology. Under current NICE guidelines in the UK, patients with suspected melanoma should be seen by a specialist within two weeks of presentation. As a diagnosis of melanoma is relatively uncommon, and can only be made after a full professional assessment and biopsy, practitioners should be cautious and not speculative when giving any advice to the patient about potential diagnoses. This will prevent any unnecessary alarm and concern.

6.3 When making a referral for a skin lesion:-

- Describe the size, colour, where it is on the foot, any bleeding, asymmetry, border (regular / irregular), how long it's been there and whether patient has noticed any changes in terms of size, shape or colour.
- Refer to Glasgow 7 point checklist.
- Photograph (obtaining patient consent and labelling photograph with name and date)
- Refer to ABCDE/F
- Check for risk factors (high total naevi count, pre-existing naevi on soles of foot, exposure to agricultural chemicals, history of penetrating injury, family history of skin cancer).
- Patient to be made aware of lesion and told to check for any changes in size, shape colour
- Any concerns at initial assessment patient to be immediately referred to GP for urgent referral to dermatology.

6.4 When making a referral for a nail lesion:-

- Describe the size, colour, which toe nail, whether asymmetrical, border (regular / irregular), how long it's been there, any history of trauma and nail fold / nail bed involvement, any oozing and whether patient has noticed any changes in terms of size, shape or colour (in line with Glasgow 7 point checklist)
- Photograph (obtaining patient consent and labelling photograph with name and date)

- Take sample for microscopy and culture if fungal infection suspected.
- If possible cut a little nail off distal edge, flip it over and see if the black is on the nail. Is it possible to scape some black off with a scalpel? If so, this is likely to be dried blood / haematoma.
- Patient to be made aware of lesion and told to check for any changes in size, shape colour.
- If suspects that it could be a malignancy, then patient to be referred immediately to GP for urgent referral to dermatology

7. Monitoring Compliance and Effectiveness

7.1 The Head of Podiatry Services will retain overall accountability and responsibility for the content, monitoring and implementation of this guideline.

7.2 Periodic clinical audit, patient satisfaction surveys and an annual peer review of staff compliance and competency will be included in the on-going process to monitor quality, compliance and effectiveness.

7.3 Responsibility for undertaking the various review processes will be devolved by the Head of Podiatry Services to appropriate and capable members of staff as required.

7.4 Audits and patient satisfaction surveys will be registered, published and actioned in line with current Trust policy whilst peer reviews will be subject to internal scrutiny and a part of annual appraisal processes.

8. Training and staff support

Training and CPD should be provided and should include all podiatrists, Clinical support workers and assistant practitioners

9. Associated documentation

N/A

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Appendix 1

PODIATRY ASSESSMENT OF PIGMENTED AND AMELANOTIC SKIN LESIONS ON THE FOOT- ABCDE	
A	Shape of lesion - asymmetry
B	Border (irregular)
C	Colour/s of lesion (more than one colour?)
D	Diameter of lesion *(greater than 6mm?)*
E	Evolution *(change in lesion - size/shape/colour)*
Any mole or solitary vascular lesion whether new or pre-existing which is growing or changing shape or colour should be referred for a specialist dermatology opinion via their GP.	

Appendix 2

CUBED acronym to highlight potential melanoma on the foot

"CUBED"
Coloured lesions where any part is not skin colour
Uncertain diagnosis. Any lesion that does not have a definite diagnosis
Bleeding lesions on the foot or under the nail, whether the bleeding is direct bleeding or oozing of fluid. This includes chronic "granulation tissue".
Enlargement or deterioration of a lesion or ulcer despite therapy
Delay in healing of any lesion beyond 2 months.

Any mole or solitary vascular lesion whether new or pre-existing which is growing or changing shape or colour should be referred for a specialist dermatology opinion via their GP.

Appendix 3

Podiatry assessment of pigmented and melanotic nail lesions on the foot.

Refer to GP when any 2 features apply

The ABCDEF of nail melanoma Use these features to guide referral for specialist advice in case biopsy is necessary. Suspicion of fungus should always be explored by microscopy and culture	
A	Age Range 20-90, peak 5th -7th decades.
B	Band (nail band): Pigment (brown-black). Breadth > 3 mm. Border (irregular/blurred).
C	Change: rapid increase in size/growth rate of nail band. Lack of change: failure of nail dystrophy to improve despite adequate treatment.
D	Digit Involved: Thumb > hallux > index finger > single digit > multiple digits
E	Extension: Extension of pigment to involve proximal or lateral nail fold (Hutchinson's sign) or free edge of nail plate.
F	Family or personal history: Of previous melanoma or dysplastic nevus

Document Control Information

This is a controlled document and should not be altered in any way without the express permission of the author or their representative.

Please note this document is only valid from the date approved below, and checks should be made that it is the most up to date version available.

If printed, this document is only valid for the day of printing.

This guidance has been registered with the Trust. The interpretation and application of guidance will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using clinical guidance after the review date, or outside of the Trust.

Ref No:	1851		
Document title:	Clinical Guidelines For Management Of Suspected Melanoma Of The Foot		
Purpose of document:			
Date of issue:	18 December 2020	**Next review date:**	18 December 2023
Version:	4	**Last review date:**	
Author:	Podiatry Team Leader		
Directorate:	Podiatry		
Equality Impact:	The guidance contained in this document is intended to be inclusive for all patients within the clinical group specified, regardless of age, disability, gender, gender identity, sexual orientation, race and ethnicity & religion or belief		
Committee(s) approving the document:	Care and Clinical Policies Group		
Date approved:	16 October 2019		
Links or overlaps with other policies:			

Have you identified any issues on the Rapid (E)quality Impact Assessment. If so please detail on Rapid (E)QIA form.	Yes ☐	
	Please select *Yes*	*No*
Does this document have implications regarding the Care Act? *If yes please state:*	☐	☐
Does this document have training implications? *If yes please state:*	☐	☐
Does this document have financial implications? *If yes please state:*	☐	☐

Is this document a direct replacement for another? *If yes please state which documents are being replaced:*	☐	☐

Document Amendment History

Date	Version no.	Amendment summary	Ratified by:
September 2014	2	Updating process in line with practice	Care and Clinicals Policies Group
4 November 2016	3	Revised	Care and Clinicals Policies Group
18 December 2020	4	Revised	Care and Clinical Policies Group

The Mental Capacity Act 2005

The Mental Capacity Act provides a statutory framework for people who lack capacity to make decisions for themselves, or who have capacity and want to make preparations for a time when they lack capacity in the future. It sets out who can take decisions, in which situations, and how they should go about this. It covers a wide range of decision making from health and welfare decisions to finance and property decisions

Enshrined in the Mental Capacity Act is the principle that people must be assumed to have capacity unless it is established that they do not. This is an important aspect of law that all health and social care practitioners must implement when proposing to undertake any act in connection with care and treatment that requires consent. In circumstances where there is an element of doubt about a person's ability to make a decision due to 'an impairment of or disturbance in the functioning of the mind or brain' the practitioner must implement the Mental Capacity Act.

The legal framework provided by the Mental Capacity Act 2005 is supported by a Code of Practice, which provides guidance and information about how the Act works in practice. The Code of Practice has statutory force which means that health and social care practitioners have a legal duty to have regard to it when working with or caring for adults who may lack capacity to make decisions for themselves.

"The Act is intended to assist and support people who may lack capacity and to discourage anyone who is involved in caring for someone who lacks capacity from being overly restrictive or controlling. It aims to balance an individual's right to make decisions for themselves with their right to be protected from harm if they lack the capacity to make decisions to protect themselves". (3)

All Trust workers can access the Code of Practice, Mental Capacity Act 2005 Policy, Mental Capacity Act 2005 Practice Guidance, information booklets and all assessment, checklists and Independent Mental Capacity Advocate referral forms on ICON.

https://icon.torbayandsouthdevon.nhs.uk/areas/mental-capacity-act/Pages/default.aspx

Infection Control

All staff will have access to Infection Control Policies and comply with the standards within them in the work place. All staff will attend Infection Control Training annually as part of their mandatory training programme.

NHS
Devon
Clinical Commissioning Group

NHS
Torbay and South Devon
NHS Foundation Trust

Rapid (E)quality Impact Assessment (EqIA) *(for use when writing policies)*

Policy Title (and number)				Version and Date	
Policy Author					
An (e)quality impact assessment is a process designed to ensure that policies do not discriminate or disadvantage people whilst advancing equality. Consider the nature and extent of the impact, not the number of people affected.					
Who may be affected by this document?					
Patients/ Service Users ☐	Staff ☐	Other, please state…		☐	
Could the policy treat people from protected groups less favourably than the general population? PLEASE NOTE: Any 'Yes' answers may trigger a full EIA and must be referred to the equality leads below					
Age	Yes ☐ No☐	Gender Reassignment	Yes ☐ No☐	Sexual Orientation	Yes ☐ No☐
Race	Yes ☐ No☐	Disability	Yes ☐ No☐	Religion/Belief (non)	Yes ☐ No☐
Gender	Yes ☐ No☐	Pregnancy/Maternity	Yes ☐ No☐	Marriage/ Civil Partnership	Yes ☐ No☐
Is it likely that the policy could affect particular 'Inclusion Health' groups less favourably than the general population? (substance misuse; teenage mums; carers[1]; travellers[2]; homeless[3]; convictions; social isolation[4]; refugees)					Yes ☐ No☐
Please provide details for each protected group where you have indicated 'Yes'.					
VISION AND VALUES: Policies must aim to remove unintentional barriers and promote inclusion					
Is inclusive language[5] used throughout?					Yes ☐ No☐ NA ☐
Are the services outlined in the policy fully accessible[6]?					Yes ☐ No☐ NA ☐
Does the policy encourage individualised and person-centred care?					Yes ☐ No☐ NA ☐
Could there be an adverse impact on an individual's independence or autonomy[7]?					Yes ☐ No☐ NA ☐
EXTERNAL FACTORS					
Is the policy a result of national legislation which cannot be modified in any way?					Yes ☐ No☐
What is the reason for writing this policy? (Is it a result in a change of legislation/ national research?)					
Who was consulted when drafting this policy?					
Patients/ Service Users ☐	Trade Unions ☐	Protected Groups (including Trust Equality Groups)		☐	
Staff ☐	General Public ☐	Other, please state…		☐	
What were the recommendations/suggestions?					
Does this document require a service redesign or substantial amendments to an existing process? PLEASE NOTE: 'Yes' may trigger a full EIA, please refer to the equality leads below					Yes ☐ No☐
ACTION PLAN: Please list all actions identified to address any impacts					
Action			Person responsible		Completion date
AUTHORISATION: By signing below, I confirm that the named person responsible above is aware of the actions assigned to them					
Name of person completing the form			Signature		
Validated by (line manager)			Signature		

Please contact the Equalities team for guidance:
For Devon CCG, please email d-ccg.equalityanddiversity@nhs.net & d-ccg.QEIA@nhs.net
For Torbay and South Devon NHS Trusts, please call 01803 656676 or email pfd.sdhct@nhs.net
This form should be published with the policy and a signed copy sent to your relevant organisation

Consider any additional needs of carers/ parents/ advocates etc, in addition to the service user
[2] Travelers may not be registered with a GP - consider how they may access/ be aware of services available to them
[3] Consider any provisions for those with no fixed abode, particularly relating to impact on discharge
[4] Consider how someone will be aware of (or access) a service if socially or geographically isolated
[5] Language must be relevant and appropriate, for example referring to partners, not husbands or wives
[6] Consider both physical access to services and how information/ communication in available in an accessible format
[7] Example: a telephone-based service may discriminate against people who are d/Deaf. Whilst someone may be able to act on their behalf, this does not promote independence or autonomy

Clinical and Non-Clinical Policies – Data Protection

Torbay and South Devon NHS Foundation Trust (TSDFT) has a commitment to ensure that all policies and procedures developed act in accordance with all relevant data protection regulations and guidance. This policy has been designed with the EU General Data Protection Regulation (GDPR) and Data Protection Act 2018 (DPA 18) in mind, and therefore provides the reader with assurance of effective information governance practice.

The UK data protection regime intends to strengthen and unify data protection for all persons; consequently, the rights of individuals have changed. It is assured that these rights have been considered throughout the development of this policy. Furthermore, data protection legislation requires that the Trust is open and transparent with its personal identifiable processing activities and this has a considerable effect on the way TSDFT holds, uses, and shares personal identifiable data.

Does this policy impact on how personal data is used, stored, shared or processed in your department? Yes ☐ No ☐

If yes has been ticked above it is assured that you must complete a data mapping exercise and possibly a Data Protection Impact Assessment (DPIA). You can find more information on our GDPR page on ICON (intranet)

For more information:

- Contact the Data Access and Disclosure Office on dataprotection.tsdft@nhs.net,
- See TSDFT's Data Protection & Access Policy,
- Visit our Data Protection site on the public internet.