NICE Guidelines and Access to Clinical Trials

Dr Pippa Corrie, NCRI Skin Cancer CSG Chair, pippa.corrie@addenbrookes.nhs.uk
Consultant and Associate Lecture in Medical Oncology, Cambridge University Hospitals NHS Foundation Trust and University of Cambridge
What are NICE Guidelines?

- The National Institute for Health and Care Excellence (NICE) provides national guidance and advice to improve health and social care.
- NICE Guidance applies to NHS England:
  - Scotland has an independent Scottish Medicines Agency.
  - Wales Assembly Government accepts NICE Guidance.
Different Types of NICE Guidance

- NICE Technology Appraisal Guidance
  - Recommendations on the use of new and existing medicines and treatments within the NHS

- These can be:
  - Medicines
  - Medical Devices
  - Diagnostic techniques
  - Surgical procedures
  - Health promotion activities
Different Types of NICE Guidance

- Clinical Guidelines
  - Care for people with specific conditions
  - Prevention, Diagnosis, Treatment, Longer term management

- Public Health Guidelines
  - Interventions to prevent disease and improve health

- Social Care Guidelines

- Medicines Practice Guidelines

- Safe Staffing Guidelines

- NICE Interventional Procedure Guidance
Different Types of NICE Guidance

- Clinical Guidelines
  - Melanoma assessment and management guidelines
  - 29 July 2015

- Single Technology Appraisals
  - Melanoma drug treatments
NICE Melanoma Assessment and Management Guidelines, July 2015

+ British Association of Dermatology
  + Revised Guidelines for the Management of Cutaneous Melanoma 2010
  + Predate new systemic therapies

+ No pre-existing NICE Melanoma Management Guidelines
  + Aim to reduce variation in practice and improve survival
  + Intended for healthcare professionals & patients
  + Not mandatory, but are used to develop national Quality Standards, which offer guidance for commissioning of services
NICE Melanoma Assessment and Management Guidelines, July 2015

- Addresses areas where there is uncertainty or variation in practice
  - Assessing and staging melanoma, including use of SLNB
  - Treating stages 0-4 melanoma
  - Treating in-transit melanoma metastases
  - Follow-up after treatment for melanoma

- Advice on managing Vitamin D levels and drug therapy for intercurrent conditions in people diagnosed with melanoma
NICE Melanoma Guidelines: Practice Change – Vitamin D

+ Measure vitamin D levels at diagnosis in all people with melanoma

+ Give people with suboptimal vitamin D levels supplementation
Consider sentinel lymph node biopsy (SLNB) as a staging procedure in people with stage IB – IIC melanoma with a Breslow thickness of >1mm.

Consider completion lymphadenectomy for people whose sentinel lymph node biopsy shows micro-metastases.
Consider surveillance imaging as part of follow-up for people who have had stage IIC melanoma with SLNB or stage III melanoma and who become eligible for systemic therapy as a result of early detection of metastatic disease:
+ imaging 6 monthly for 3 years
NICE Melanoma Guidelines: Practice change – gene mutation testing

+ If targeted systemic therapy is an option, **offer** genetic testing

+ NICE Guidelines did not evaluate new immunotherapy and targeted therapies, as they are subject to NICE Technology Appraisals
NICE Melanoma Guidelines: Practice Change – inclusion of ECT

Consider the following options as non-surgical treatment for in-transit metastases
- Systemic therapy
- Isolated limb infusion
- Isolated limb perfusion
- Radiotherapy
- Electrochemotherapy (ECT)
- CO2 laser
- Imiquimod
Quality Standards - What are They?

- Quality Standards are generated following NICE Guidance.
- They set out the priority areas for quality improvement in health and social care.
- Quality Standards are not mandatory, but they can be used to plan and deliver services to provide the best possible care.
- Each standard provides:
  - A set of statements to help improve quality.
  - 3 dimensions of quality: safety, patient experience and clinical effectiveness.
  - Information on how to measure progress.
Management Guidelines for Non-cutaneous Melanoma

- NICE Melanoma Guidelines covered cutaneous melanoma only
- Uveal Melanoma National Guidelines, January 2015
  - Supported by Melanoma Focus
  - Endorsed by NICE
- Mucosal Melanoma Guidelines in Development
  - Supported by Melanoma Focus
Different Types of NICE Guidance

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  - 29 July 2015

- Single Technology Appraisals
  - Melanoma drug treatments
Single Technology Appraisal (STA)
- Usually new pharmaceutical products or new indications of existing licensed products
- Aim to produce guidance soon after the technology is introduced in the UK

Multiple Technology Appraisal (MTA)
- Assesses several drugs or treatments used for 1 condition

Fast Track Appraisal (FTA) – new since 1 April 2017
- For technologies that offer exceptional value for money
- NHS England/commissioners will provide funding within 30 days of guidance publication (compared with standard 90 days)
NICE Technology Appraisals

- Recommendations are based on:
  - Clinical Evidence
    - How well the medicine works
  - Economic Evidence
    - How well the medicine works in relation to how much it costs the NHS
    - Does it represent value for money?
NICE Technology Appraisal Process

- Scoping Workshop
- Appraisal Consultation
- Appraisal Committee Meeting
- Appraisal Consultation Document (ACD)
- Final Appraisal Determination (FAD)
NICE Technology Appraisal Process

- Scoping Workshop
- Appraisal Consultation
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Patient representatives, Clinical Experts, Manufacturer, Evidence Review Group (ERG)
New Drug Treatments for Advanced Melanoma

**Immunotherapeutics**
- Ipilimumab
- Pembrolizumab and Nivolumab
- NIVO + IPI

**MAP kinase inhibitors**
- Vemurafenib
- Dabrafenib
- Dabrafenib + Trametinib
Translating NICE Guidance into Clinical Practice

+ NICE approvals are based on the Manufacturer Licensed Indication (‘Marketing Authorisation’)

+ Commissioners are required to provide funding for a positive STA within 90 days of publication

+ Since December 2016, clinicians must apply to prescribe all new high cost drugs via the national BlueTeq on-line registration system which was previously confined to CDF-listed drugs

+ Health Warning: BlueTeq criteria may well restrict patient access
  + Melanoma Working Group established to negotiate access criteria with NHS England
Why Clinical Trials?

- Clinical trials provide the evidence that justifies change in practice.
- A drug treatment found to be effective in clinical trials will be given a license for use.
- NICE will only review licensed drugs and the clinical trial evidence will inform NICE guidance.
- Clinical trials offer patients a route to early access of state-of-the-art treatments.
- Not everyone taking part in a clinical trial directly benefits from doing so, but everyone taking part in a clinical trial directly contributes to helping future patients.
Vemurafenib: the first effective treatment for BRAF mutant metastatic melanoma showed activity in the very first patients treated.
Immune checkpoint inhibitors tested in clinical trials have improved survival of metastatic melanoma patients.
New Drug Treatments for Advanced Melanoma

Immunotherapeutics
- Ipilimumab
- Pembrolizumab and Nivolumab
- NIVO + IPI

2010                   2012                     2015                                       2016

MAP kinase inhibitors
- Vemurafenib
- Dabrafenib
- Dabrafenib + Trametinib

MAP kinase inhibitors
New Drug Treatments for Advanced Melanoma

Immunotherapeutics

- Ipilimumab
- Pembrolizumab and Nivolumab
- NIVO + IPI

Life expectancy:
- 2010: 6-12 months
- 2012: 3 years
- 2015: 30% long term remissions
- 2016: Average 3 years

MAP kinase inhibitors

- Vemurafenib
- Dabrafenib
- Dabrafenib + Trametinib
Year 2000:

for every 100 patients diagnosed with cancer in the UK, 4 entered a well-designed peer-reviewed clinical study
Year 2014:

for every 100 patients diagnosed with cancer in the UK, 20 entered a well-designed peer-reviewed clinical study
National Infrastructure for Development and Delivery of Cancer Clinical Trials

construct a national portfolio
write the studies
launch the studies
recruit the patients
deliver reliable data
have an impact

NCRI CSGs
NIHR CRN Cancer
NCRI Skin Cancer Clinical Studies Group

Membership:
- Oncologists
- Dermatologists
- Surgeon
- Pathologist
- Statistitician
- GP
- Patient reps x 2

Types of Trials:
- Commercial sponsored
- Non-commercial/academic/IIT
- Interventional
  - Drugs, radiotherapy, surgery
  - Non-interventional
- Phase 1, 2, 3
- Screening
- Prevention
- Early Diagnosis
- Treatment
How Can YOU Get Involved?

- Access to clinical trials
  - Clinical Trials Gateway
  - https://www.ukctg.nihr.ac.uk
Try searching for a clinical trial  You can search by condition or relevant keywords

melanoma in Cambridge, United Kingdom

Can’t find the trial you were looking for? Sign up to create a volunteer profile so that researchers can find you in the future

Your search for melanoma in Cambridge, United Kingdom returned 93 trials

Sorted by Relevance

Melanoma Image Analysis Algorithm (MIAA) Validation Study
Prospective, single-arm, cross-sectional, study to establish the effectiveness of MIAA to detect melanoma in pigmented lesions, compared to gold standard histological determination...

46.7 miles away

MelmarT Melanoma Margins Trial Investigating 1cm v 2cm Wide Excision Margins for Primary Cutaneous Melanoma

33.2 miles away
How Can YOU Get Involved?

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  - [https://www.ukctg.nihr.ac.uk](https://www.ukctg.nihr.ac.uk)

- NCRI Portfolio Maps
  - [https://csg.ncri.org.uk/homepage/portfolio-maps/](https://csg.ncri.org.uk/homepage/portfolio-maps/)
## Skin Cancer

### Map A - Melanoma

**Click square below to reset map**

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<th>All melanomas</th>
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<th>Non - cutaneous</th>
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- **Open Single CSG**
- **Open Multi CSG**
- **In Setup, Waiting NHS Permission Single CSG**
- **In Setup, Waiting NHS Permission Multi CSG**
- **In Setup, Waiting HRA Approval Single CSG**
How Can YOU Get Involved?

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- **Patient representatives needed**
  - NCRI Clinical Studies Groups
  - Local Research Networks
THANK YOU
VERY MUCH!

YOU Make a Difference