

The MoleMate Trial: outcomes and impact

Fiona Walter

**GP & NIHR Clinician Scientist
Primary Care Cancer Research
University of Cambridge**



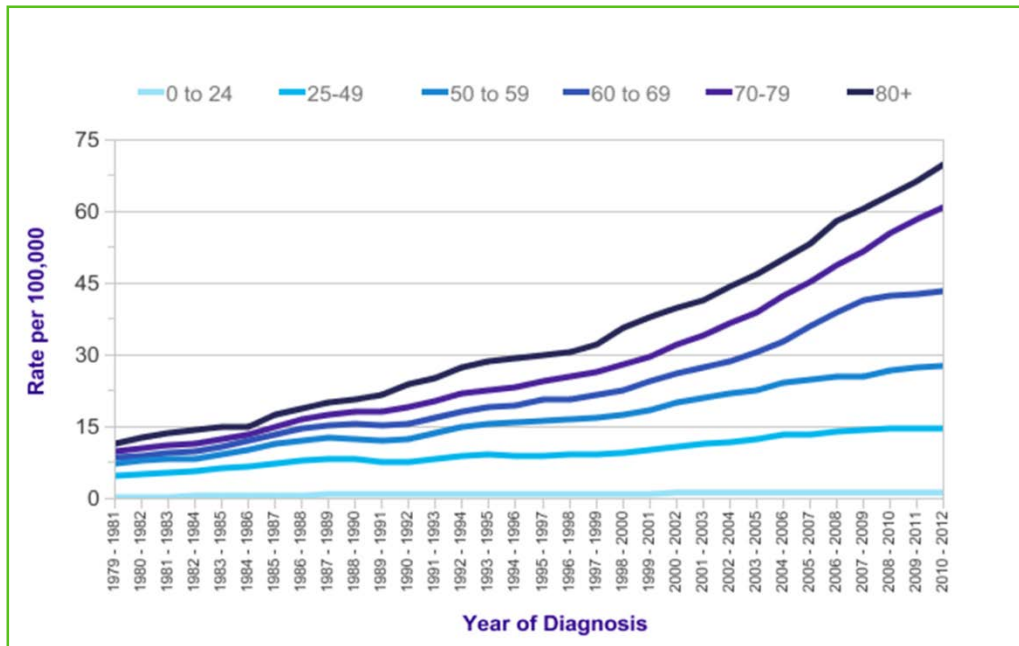
**School for
Primary Care
Research**

The National Institute for Health
Research School for Primary Care
Research (NIHR SPCR) is a
partnership between the
Universities of Bristol, Cambridge,
Keele, Manchester, Newcastle,
Nottingham, Oxford, Southampton
and University College London.



Malignant cutaneous melanoma

- 5th commonest cancer
- >85% due to UV exposure
- Incidence rising rapidly
 - men, higher SES



- Increasing evidence that early detection leads to:
 - early stage at diagnosis
 - improved outcomes

Detecting melanoma in primary care can be challenging

In primary care

- pigmented lesions present commonly
- 2005 NICE guidelines: refer all suspicious lesions

For every 20 referred

- 10-15 excised
- 1 will be melanoma

Approaches to improve detection/management

- educational
- guidelines, checklists
- technical, diagnostic aids



Glasgow 7 point checklist:

MAJOR FEATURES:

- Change in size
- Irregular shape
- Irregular colour

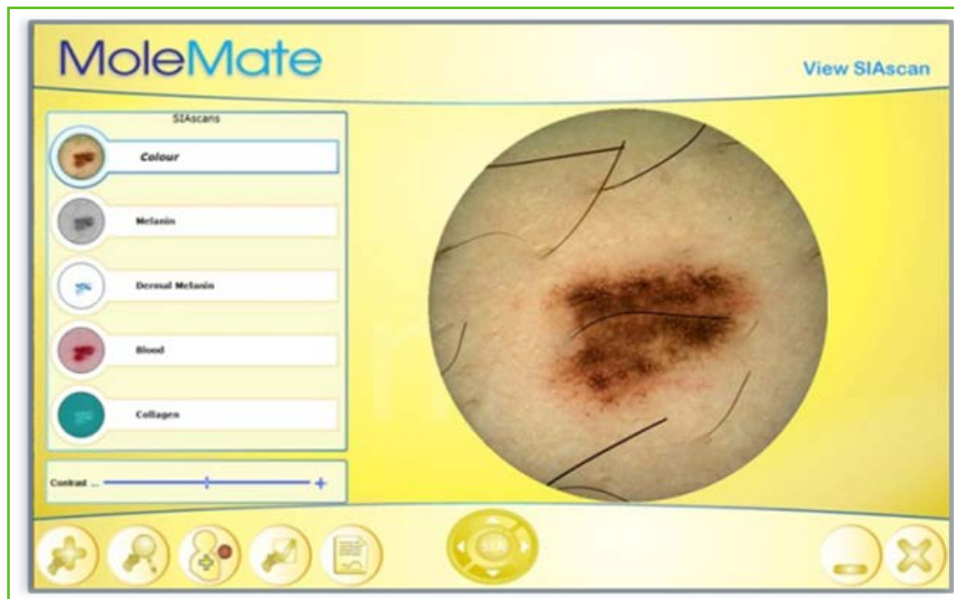
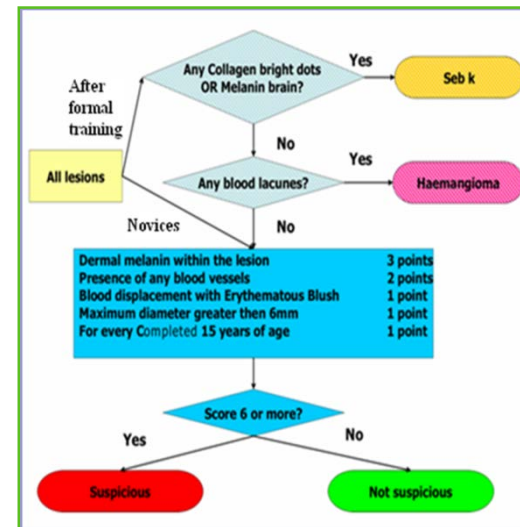
MINOR FEATURES:

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



SIAscopy and the MoleMate system

- SIAscopy = Spectrophotometric Intracutaneous Analysis
- patterns highly predictive of melanoma
- SIAscopy + primary care algorithm = the MoleMate system



The MoleMate Trial

2008-10, prospective RCT, set in 15 general practices in East England

Participants:

- Suspicious pigmented lesion: 'could not immediately be diagnosed as benign and the patient reassured'

Randomised at patient level:

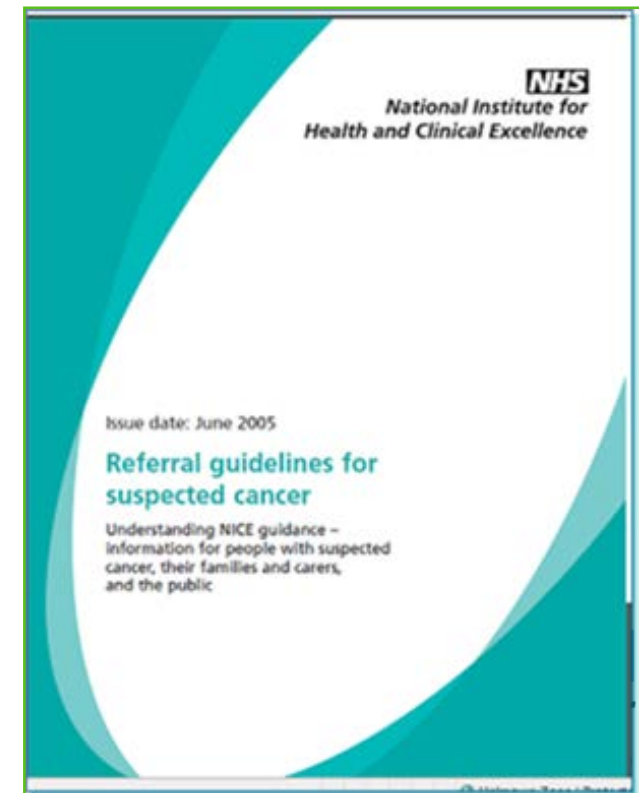
- Comparison- 'Best Practice'
- Intervention- 'Best Practice' + MoleMate

Reference standard diagnosis:

- Histology, dermatology expert opinion

Primary outcome:

- Proportion of referred lesions biopsied/monitored by the experts
'Clinically significant'



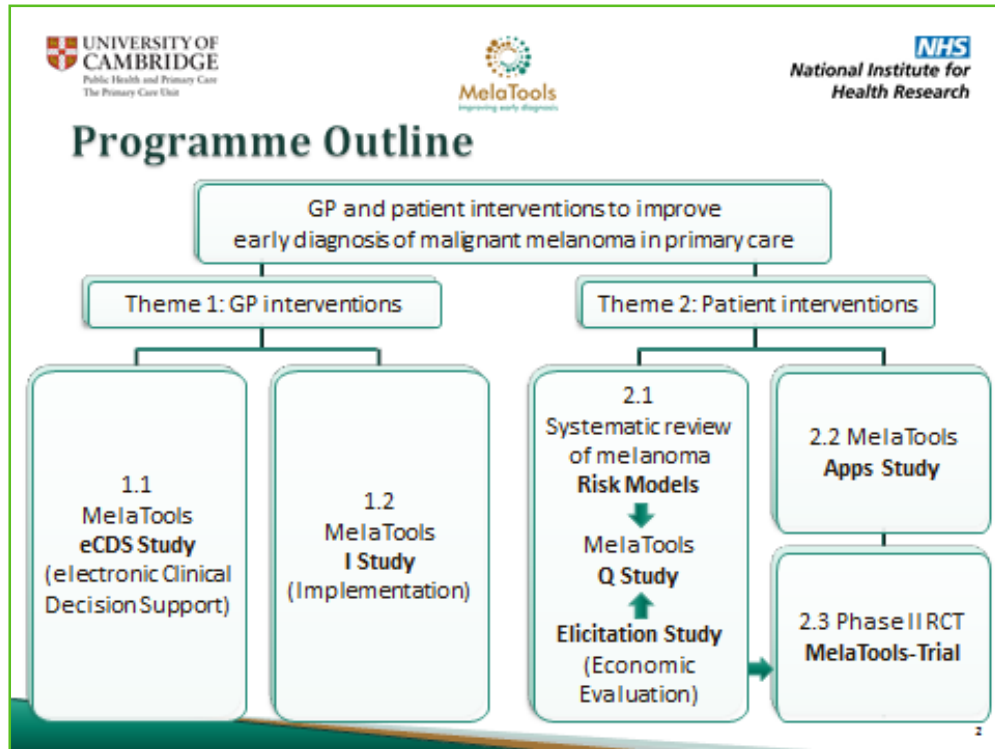


Effect of adding a diagnostic aid to best practice to manage suspicious pigmented lesions

- 1,297 participants with 1,580 lesions
- Randomised 643 (788 lesions) to intervention and 654 (792 lesions) to control groups
- Both groups performed much better than reported current practice
- No difference in appropriateness of referral
- Lower specificity of MoleMate led to increased referrals
- Clinicians: simple, cost-effective, easy, fast, unlikely to worry
- Patients: not anxious; diagnostic aid users more thorough, better communication, reassuring care

Early Outcomes

- 2012 Main findings
- 2013 RCGP Cancer Paper of the Year
- 2013-18 NIHR Clinician Scientist award



BMJ

BMJ 2012;344:e4110 doi: 10.1136/bmj.e4110 (Published 4 July 2012) Page 1 of 14

RESEARCH

Effect of adding a diagnostic aid to best practice to manage suspicious pigmented lesions in primary care: randomised controlled trial

OPEN ACCESS

Fiona M Walter *clinical lecturer in general practice*¹⁹, Helen C Morris *trial coordinator*¹, Elka Humphrys *research assistant*², Per N Hall *consultant plastic surgeon*³, A Toby Prevost *reader in medical statistics*^{4,1}, Nigel Burrows *consultant dermatologist*², Lucy Bradshaw *statistician*⁵, Edward C F Wilson *lecturer in health economics*⁶, Paul Norris *consultant dermatologist*⁷, Joe Walls *plastic surgeon*⁷, Margaret Johnson *lay member of trial steering committee*⁸, Ann Louise Kinmonth *foundation professor of general practice*¹, Jon D Emery *Winthrop professor of general practice*^{9,1}

¹The Primary Care Unit, Department of Public Health and Primary Care, University of Cambridge, Cambridge CB2 0SR, UK; ²Cancer Research UK and UCL Cancer Trials Centre, London, UK; ³Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Hospital, Cambridge, UK; ⁴Department of Primary Care and Public Health Sciences, King's College London, London, UK; ⁵Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK; ⁶Health Economics Group, Faculty of Health, University of East Anglia, Norwich, UK; ⁷Norfolk and Norwich University Hospital NHS Trust, Norwich, UK; ⁸Cambridge; ⁹School of Primary Aboriginal and Rural Health Care, University of Western Australia, Crawley, WA, Australia

'Best Practice'

- Systematic use of 7 point checklist
- Collaborated with Macmillan Cancer Support and BMJ Informatica
- Tool embedded in GP software

Studies


- Can electronic clinical decision support (eCDS) impact cancer outcomes using cancer registry data?
- How does eCDS implementation effect GPs, patients, the consultation?

The screenshot shows a software window titled "Melanoma Risk Tool (NICE guidance) - Mr Isobell Calpee". The window has two tabs: "Details" (selected) and "Acknowledgements". The main content area is titled "Melanoma Risk Tool (NICE guidance)" and includes the "WE ARE MACMILLAN. CANCER SUPPORT" logo. Below the title, there is a "Mole Position:" dropdown menu set to "Other" and an "Additional Info:" text input field. A section titled "Please tick any of the following you have noticed:" contains a list of seven symptoms, each with an unchecked checkbox: "Change in size of lesion", "Irregular shape and/or border", "Irregular colour and/or pigmentation", "Inflammation", "Oozing and/or crusting of lesion", "Itch and/or altered sensation", and "Larger than other lesions (diameter ≥7mm)". Below this list is a "Recommendation" text input field. At the bottom of the window, there is a note: "If there are strong concerns about cancer, any one feature is adequate to prompt urgent referral." and two buttons: "OK" and "Cancel".


Technology and diagnostic aids

Follow-up, using cancer registry

- After one year
 - **Control:** 2 new early melanomas, same sites; 1 in different site
 - **Intervention:** none
- After five years- none in same sites
- Spectroscopy based techniques
- Dermoscopy
- Teledermatology
- Mobile phone apps
- Computer-assisted diagnosis
- Reflectance confocal microscopy



Available online at www.sciencedirect.com
SciVerse ScienceDirect
journal homepage: www.elsevier.com/locate/jval




The Cost-Effectiveness of a Novel SIAscopic Diagnostic Aid for the Management of Pigmented Skin Lesions in Primary Care: A Decision-Analytic Model

Edward C.F. Wilson^{1,*}, Jon D. Emery^{2,3}, Ann Louise Kinmonth², A. Toby Prevost^{2,4}, Helen C. Morris², Elka Humphrys⁵, Per N. Hall⁶, Nigel Burrows⁶, Lucy Bradshaw⁷, Joe Walls⁸, Paul Norris⁶, Margaret Johnson⁹, Fiona M. Walter^{2,3}

¹Health Economics Group, University of East Anglia, Norwich, UK; ²The Primary Care Unit, Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK; ³School of Primary, Aboriginal and Rural Health Care, University of Western Australia, Crawley, Australia; ⁴Department of Primary Care and Public Health Sciences, King's College London, Capital House, London, UK; ⁵Cancer Research UK & UCL Cancer Trials Centre, London, UK; ⁶Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge, UK; ⁷Division of Epidemiology and Public Health, University of Nottingham, Nottingham, UK; ⁸Department of Plastic Surgery, Norfolk & Norwich University Hospital, Norwich, UK; ⁹Lay member

Tests to assist in the diagnosis of cutaneous melanoma in adults: a generic protocol (Protocol)

Díaz J, Matin RN, Morreu JF, Patel L, Chan SA, Chucho N, Beylis SE, Grainge M, Takwoingi Y, Daveyport C, Walter FM, Fleming C, Schofield J, Shroff N, Godfrey K, O'Sullivan C, Deeks JJ, Williams HC



THE COCHRANE COLLABORATION®

This is a reprint of a Cochrane protocol, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library 2015, Issue 10
<http://www.thecochranelibrary.com>

WILEY

Policy and Practice

- Validation of 7 point checklist in primary care using MoleMate data
- Influenced national and international clinical guidelines
 - **UK**- 2015 revised NICE guidelines for suspected cancer
 - **Australia**- 2016 RACGP Guidelines for preventive activities in general practice 9th edition (Red Book)

Research

Fiona M Walter, A Toby Prevost, Joana Vasconcelos, Per N Hall, Nigel P Burrows, Helen C Morris, Ann Louise Kinmonth and Jon D Emery

Using the 7-point checklist as a diagnostic aid for pigmented skin lesions in general practice:

a diagnostic validation study

National Collaborating Centre for Cancer

Suspected cancer

Suspected cancer: recognition and referral

NICE Guideline
Full guideline
June 2015

Final version
Commissioned by the National Institute for
Health and Care Excellence

NHS

**National Institute for
Health Research**

Acknowledgements

Our thanks to all the patients, GPs and practice staff who contributed to this work

- Helen Morris *Trial coordinator*
- Elka Humphrys *Research assistant*
- Per Hall *Consultant plastic surgeon*
- Toby Prevost *Statistics lead*
- Nigel Burrows *Consultant dermatologist*
- Lucy Bradshaw *Statistician*
- Edward Wilson *Health economics*
- Paul Norris *Consultant dermatologist*
- Joe Walls *Plastic surgeon*
- Margaret Johnson *Lay member of trial steering committee*
- Ann Louise Kinmonth *Professor of general practice*
- Jon Emery *Professor of primary care cancer research*

School for
Primary Care
Research

The MoleMate Trial was funded by the National Institute for Health Research School for Primary Care Research (NIHR SPCR). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health


**National Institute for
Health Research**