Complete Summary

GUIDELINE TITLE

Cutaneous melanoma. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Cutaneous melanoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jul. 50 p. (SIGN publication; no. 72). [277 references]

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on **Scottish** Intercollegiate Guidelines Network (SIGN) Web site

COMPLETE SUMMARY CONTENT

SCOPE

DISCLAIMER

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Cutaneous melanoma

Note: The guideline does not address melanomas of non-cutaneous origin such as melanomas arising from mucosae, ocular melanomas, and other rare non-cutaneous sites.

GUIDELINE CATEGORY

Diagnosis Management Prevention Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Pathology
Radiation Oncology
Surgery

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Nurses Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

To provide advice at all stages of the patient's pathway of care, from primary prevention to early recognition, treatment, and follow up

TARGET POPULATION

Individuals at risk for and/or diagnosed with cutaneous melanoma

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention

- 1. Public education on the use of sun protective measures (e.g., sunscreen and clothing) and identification of risk factors
 - Non-alarmist brochures and leaflets
 - Interactive computer programmes (considered but not recommended)

Screening (considered but not recommended)

Diagnosis

- 1. Assessment with or without magnification according to the 7 point checklist or ABCDE system
- 2. Hand held dermatoscopy
- 3. Biopsy
- 4. Pathological diagnosis and microscopic staging
 - Essential features:

- Breslow thickness
- Clark level (if Breslow thickness <1mm)
- Ulceration
- Growth phase characteristics
- Regression
- Lymphovascular space invasion
- Microscopic satellites
- Microscopic clearance (mm)
- Desirable features:
 - Histogenetic type
 - Cell type
 - Host inflammatory response
 - Mitotic rate

Management

Surgical management and staging

- 1. Surgical excision with recommended tumour clearance
- 2. Radical lymph node dissection
- 3. Elective lymph node dissection
- 4. Sentinel lymph node biopsy (SLNB)
- 5. Surgical management considered but not routinely recommended:
 - Examination of the regional lymph node basin and fine needle aspiration cytology (FNAC), if palpable
 - Isolated limb perfusion (ILP) with melphalan and/or Tissue Necrosis Factor
 - Carbon dioxide laser ablation
 - Other methods such as cryotherapy, intralesional bacilli Calmette-Guerin (BCG) and radiotherapy

Further investigations and non-surgical staging

- 1. Assessment of metastatic spread (discussed but not specifically recommended) including:
 - Surgery (SLNB)
 - Imaging (conventional radiotherapy, ultrasound scanning (US), computerized tomography (CT), magnetic resonance imaging (MRI), and positron emission tomography (PET)
 - Blood tests (routine haematology, tumour markers, liver function tests and lactic dehydrogenase (LDH)

Treatment

Adjuvant treatment (stage II and III) & follow-up (stage I, II and III)

- 1. Treatments (stage II and III) considered but not routinely recommended include:
 - Radiotherapy
 - Adjuvant interferon
 - Vaccines
- 2. Follow up considered but not routinely recommended:

- Frequency and duration of follow up
- Psychological and emotional support
- Laboratory tests
- Imaging
- 3. Patient education regarding sun protection, features of melanoma and skin self examination

Management/Treatment (stage IV)

- 1. Metastasectomy (considered but not recommended)
- 2. Surgical resection of central nervous system disease, as appropriate
- 3. Chemotherapy, chemoimmunotherapy and immunotherapy
 - Single agent therapy (Dacarbazine)
 - Combination therapy is not recommended
- 4. Radiotherapy
 - Single dose
 - Whole brain radiotherapy combined with corticosteroids for central nervous system disease
- 5. Specialist palliative care team
- 6. Provision of information to patients with melanoma

MAJOR OUTCOMES CONSIDERED

- Incidence of melanoma
- Sensitivity and specificity of diagnostic tests and techniques
- Accuracy of staging tools/techniques
- Pathological features (e.g., lesion size, thickness, ulceration)
- Patient outcomes including:
 - Morbidity and mortality
 - Survival rate
 - Recurrence rate and time
 - Side effects of treatment
 - Symptom relief
 - Quality of life
- Outcomes for women who are pregnant or using oral contraceptives or hormone replacement therapy

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature searches were initially conducted in Medline, Embase, Cinahl, Cancerlit, and the Cochrane Library using the year range 1993 to 2001. The literature search was updated with new material during the course of the guideline development process. A final update literature search was performed in March 2003. Key Web sites on the Internet were also used, such as the National Guidelines Clearinghouse. The searches were extended back to 1970 in areas

where evidence was scarce. These searches were supplemented by the reference lists of relevant papers and group members' own files. The Medline version of the main search strategies can be found on the Scottish Intercollegiate Guidelines Network (SIGN) website.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

- **1++**: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
- **1+**: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
- 1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- **2++**: High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
- **2+**: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- **2-**: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- 3: Non-analytic studies, e.g. case reports, case series
- 4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative

process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance, and after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the <u>SIGN Web site</u>.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesizing the evidence base to form graded guideline recommendations is illustrated in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

Evidence tables should be compiled, summarising all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation and to emphasise that the body of evidence should be considered as a whole and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are <u>not</u> an alternative to evidence-based recommendations and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

COST ANALYSIS

Screening for cutaneous melanomas

A well conducted cost-effectiveness analysis using a hypothetical cohort of 50-year-old Australians suggested that screening for melanoma by primary care physicians may be relatively cost effective. Comparing an organised programme of screening to the existing opportunistic regime, the model predicted that the cost per life-year saved for men was Aus\$6,853 to \$12,137 for five-yearly and two-yearly screening respectively. The programme was less cost effective in women principally due to lower mortality from melanoma. The cost effectiveness of screening in high-risk populations has also been addressed in two American studies. The findings suggested that such programmes were cost effective compared to other screening programmes used in the USA. The cost-effectiveness ratios were however sensitive to changes in the cost of the screening test and the prevalence of disease and hence the economic efficiency of screening high-risk individuals in Scotland may differ. *No economics evidence was found which would support mass screening programmes*.

Sentinel lymph node biopsy (SLNB)

The key interest here is how the information obtained from the SLNB changes patient management, subsequent outcomes and associated costs. Only one study was identified, a cost analysis of 73 patients in the USA undergoing SLNB or an elective lymph node dissection (ELND). The results indicate that significant cost savings could be made by using SLNB rather than elective lymph node dissection. The study was non-randomised and hence subject to potential bias in the distribution of cost drivers between the groups, making the conclusion unreliable. Information on final patient outcomes was also lacking, making it hard to be certain of the cost effectiveness of the intervention, particularly when applied to the UK setting.

Adjuvant interferon therapy

Five economic evaluations or cost studies relating to adjuvant interferon therapy were reviewed. Three studies used the trial results from the E1684 trial and hence investigated the cost effectiveness of adjuvant high-dose interferon therapy versus observation alone. These studies all found cost per life year gained and cost per QALY (Quality Adjusted Life Years) figures that would be considered broadly acceptable by current conventions. The UK meta-analysis and economic analysis however found insufficient evidence of benefit and thus, given its considerable incremental cost, concluded that it could not be recommended for

routine use in the UK. The remaining economic evaluation was a French study examining the cost effectiveness and cost utility of low-dose interferon in patients with surgical resection of American Joint Committee on Cancer (AJCC) stage II melanoma versus observation alone. The cost effectiveness ratios in this study represent reasonable value for money. The majority of economic evaluations were based on the E1684 trial, however, that had the most positive findings; therefore cost effectiveness will tend to have been overstated. Further, if no significant difference exists in overall survival (as was found in the E1684 and French studies), the use of life years gained as an outcome is not tenable (since obviously no life years have been gained) rendering the cost-effectiveness results invalid. The robustness of the findings of the economic evaluations must be questioned.

Follow up of patients with stage I and II disease

A German study used retrospective case note review to examine the relative cost effectiveness of various tests used in the follow-up of patients with stage I-III disease. The study did not assess the value of surveillance *per se* or the cost effectiveness of various frequencies of contact. The results indicated that at any stage of melanoma and follow-up the most cost-effective test was physical examination and that lymph node sonography was the best performing imaging procedure, albeit less cost effective than physical examination. Similar conclusions were reached in a French study of patients with stage I melanoma. Both studies suffered from methodological weaknesses, but they tend to support the recommendations made in section 7 of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held in March 2002 and was attended by all of the key specialties relevant to the guideline. The draft guideline was available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline.

The guideline was also reviewed in draft form by a panel of independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline is reviewed by an Editorial Group comprising the relevant specialty representatives on SIGN Council to ensure that the specialist reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

Each member of the guideline development group then approved the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-D) and level of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Prevention, Surveillance, and Genetics

D - Brochures and leaflets should be used to deliver preventive information on melanoma to the general public.

Diagnosis and Prognostic Indicators

- **D** Clinicians should be familiar with the 7 point or the ABCDE checklist for assessing lesions (see Tables 3 and 4 in the original guideline document).
- **D** Clinicians using hand held dermatoscopy should be appropriately trained.
- **D** Health professionals should be encouraged to examine patients' skin during other clinical examinations.
- **D** A suspected melanoma should be excised with a 2-mm margin and a cuff of fat.
- **C** If complete excision cannot be performed as a primary procedure, a full thickness incisional or punch biopsy of the most suspicious area is advised.
- **C** A superficial shave biopsy is inappropriate for suspicious pigmented lesions.
- **D** The macroscopic description of a suspected melanoma should:
- state the biopsy type, whether excision, incision, or punch
- describe and measure the biopsy (in mm)
- state the size of the lesion in mm and describe the lesion in detail (shape, pattern of pigment distribution, presence or absence of a nodular component, and presence or absence of ulceration)
- state the clearance of the lesion (in mm) from the nearest lateral margin and the deep margin.
- **D** Selection of tissue blocks:

- the entire lesion should be submitted for histopathological examination
- the lesion should be sectioned transversely at 3 mm intervals and the blocks loaded into labeled cassettes
- cruciate blocks should not be selected (they limit the assessment of low power architectural features such as symmetry).

Note: a photograph of the macroscopic specimen may be of great value, especially if the precise origins of labeled blocks are drawn onto the photograph to permit exact orientation.

- **B** The histogenetic type should be included in the pathology report.
- **B** The growth phase characteristics should be stated in the pathology report of all melanomas except nodular melanomas which, by the time of diagnosis, show only vertical growth phase characteristics.
- **B** An accurate (to within 0.1 mm) measurement of the Breslow thickness should be included in the pathology report for any melanoma that has an invasive component.
- **B** The Clark level of invasion should be provided when the lesion has a Breslow thickness <1 mm.
- **B** The presence or absence of histological evidence of epidermal ulceration should be noted in the pathology report.
- **C** If late regression is apparent, it should be included in the pathology report.
- **B** Identification of lymphatic space invasion and/or microscopic satellites should be included in the pathology report.
- **B** If the likelihood of survival is calculated using the Cochran model, the breadth of any epidermal ulcer should be measured by micrometer and stated in the pathology report.

Surgical Management and Staging

- ${f D}$ In pTis (melanoma in situ) a surgical excision margin of 2 to 5 mm is recommended to achieve complete histological excision. (p = pathological; T = tumour)
- **B** In pT1 (melanoma 0- to 1-mm thickness) a surgical excision margin of 1 cm is recommended.
- **B** In pT2 (melanoma 1- to 2-mm thickness) a surgical excision margin of 1 to 2 cm is recommended.
- **B** In pT3 (melanoma 2- to 4-mm thickness) a surgical excision margin of 2 cm is recommended.
- **D** In pT4 (melanoma >4-mm thickness) a surgical excision margin of 2 cm is recommended.

- **D** The microscopic clearance of the tumour from the nearest lateral margin and from the deep margin should be stated (in mm) for all excision biopsies.
- **B** Radical lymph node dissection requires complete and radical removal of all draining lymph nodes to allow full pathological examination.
- **B** Elective lymph node dissection should not be routinely performed in patients with primary melanoma.
- **B** Sentinel lymph node biopsy (SLNB) should be considered as a staging technique in patients with a primary melanoma ≥ 1 mm thick or a primary melanoma < 1 mm thick of Clark level 4 (see section 3.8.5 of the original guideline document).

Further Investigations and Non-surgical Staging

- **C** Chest x-ray, ultrasound scanning, and computerised tomography scanning are not indicated in the initial assessment of primary melanoma unless indicated for investigation of clinical symptoms and signs.
- **D** Routine blood tests are not indicated in staging asymptomatic melanoma patients.

Adjuvant Treatment of Stage II and III Disease

- **D** The routine use of adjuvant radiotherapy is not recommended for patients who have had therapeutic lymph node dissections.
- **A** Adjuvant interferon should not be used for American Joint Committee on Cancer (AJCC) stage II and III melanoma patients other than in a trial setting.

Patient Follow-Up in Stage I, II and III Disease

- **D** Patients who have had melanoma in situ do not require follow-up.
- **D** Routine full blood counts, liver function tests, tumour markers, chest x-rays, ultrasound scans, computed tomography, and lactate dehydrogenase are not recommended as part of a follow-up schedule in the asymptomatic patient.
- **B** Healthcare professionals and members of the public should be aware of the risk factors for melanoma.
- **C** Individuals identified as being at higher risk should be
- advised about appropriate methods of sun protection
- educated about the diagnostic features of cutaneous melanoma
- encouraged to perform self examination of the skin

D - Genetic testing in familial or sporadic melanoma is not appropriate in a routine clinical setting and should only be undertaken in the context of appropriate research studies.

Management of Stage IV Disease

- A Dacarbazine (DTIC) is the standard single agent of choice in stage IV melanoma.
- **A** Multiple drug regimens including those with tamoxifen and interferon alpha do not improve survival compared to single agent DTIC and are not recommended outside of clinical trials.
- **D** Single dose radiotherapy of a least 8 Gy is an effective treatment for bone metastases.
- **D** Patients with good performance status, favourable response to corticosteroid treatment, and the absence of systemic disease and who harbour favourable central nervous system (CNS) disease should be considered for surgical resection of their CNS disease.
- **D** If surgery is not possible, whole brain radiotherapy combined with corticosteroids may help palliate neurological symptoms.
- **B** Patients with advanced melanoma require a coordinated multiprofessional approach with input from a specialist palliative care team.
- **D** Patients with poorly controlled symptoms should be referred to specialist palliative care at any point in the cancer journey.

Information for Patients

C - Patients should receive targeted information throughout their journey of care.

Definitions:

Grades of Recommendation

A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; *or*

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Levels of Evidence

- **1++**: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
- **1+**: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
- 1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
- **2++**: High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
- **2+**: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
- **2-**: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
- **3**: Non-analytic studies, e.g. case reports, case series
- 4: Expert opinion

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the management of patients with melanoma.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved prevention and early detection of melanoma
- Improved response to treatment
- Improved survival
- Improved patient quality of life, including:
 - Better symptom control
 - Reduced number of inpatient hospital days
 - Reduced overall costs
 - Increased patient satisfaction with treatment and outcomes

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results.
- The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor, following discussion of the options with the patient, in light of the diagnostic and treatment choices available. It is advised however that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken.
- Clinical diagnosis of melanoma is difficult and the accuracy of diagnosis may vary according to a clinician's level of experience, with reports of considerable variation in sensitivity from 50 to 86% and an inverse relationship between sensitivity and experience.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Managed Clinical Networks (MCN)

For a definition of Managed Clinical Networks refer to the original guideline document.

Resources Implications

• It is hard to ascertain whether the implementation of this guideline can be met within existing resources. This is because the guideline contains both recommendations that may require new funds for implementation and

- recommendations that may halt certain existing practices, thereby freeing up resources. The net effect of this is hard to quantify and will depend on current standards, practices and resources in each Health Board area.
- By recommending that all health professionals should be encouraged to
 examine patients for potential melanomas, there is likely to be a potential
 impact on all areas of clinical practice in the National Health System (NHS)
 Scotland. Resources for staff training and education may be required to
 implement this recommendation. Many of the recommendations made in
 section 2 of the original guideline document will have an impact on pathology
 departments. Similarly, the need for appropriate palliation services
 recommended in section 8.4 of the guideline may require investment if
 adequate services are not already available.
- Palliative care services provided by charitable organisations may experience resource effects through the implementation of the guideline. Such organisations may also be involved in the provision of patient/carer information and support groups.
- The costs of appropriate primary preventative products recommended in the guideline (sunscreens, hats, and clothing) will result in costs to patients.
- Implementation of the guideline is unlikely to affect other groups.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Cutaneous melanoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jul. 50 p. (SIGN publication; no. 72). [277 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jul

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Group: Dr Valerie Doherty (Chairman), Consultant Dermatologist, Royal Infirmary, Edinburgh; Mr Taimur Shoaib (Secretary), Specialist Registrar in Plastic Surgery, Canniesburn Hospital, Glasgow; Ms Moira Black, Health Visitor, Perth; Dr David Brewster, Director of Cancer Registration in Scotland, Information and Statistics Division, Edinburgh; Dr Graham Duncan, General Practitioner, Kirkcaldy; Dr Alan T Evans, Consultant Histopathologist, Ninewells Hospital, Dundee; Dr Marie Fallon, Senior Lecturer in Palliative Medicine, Western General Hospital, Edinburgh; Mrs Carol Horne, Manager, TakTent Cancer Support, Glasgow; Professor Rona MacKie, Consultant Dermatologist, Glasgow University; Mrs Lesley Marley, Senior Health Promotion Officer, National Health System (NHS) Tayside, Dundee; Mr Alan J McKay, Consultant Vascular Surgeon, Gartnavel General Hospital, Glasgow; Dr Kathryn McLaren, Senior Lecturer, Pathology, University of Edinburgh; Dr Iain McLellan, General Practitioner, Kilmalcolm Renfrewshire; Dr Nigel McMillan, Consultant Radiologist, Western Infirmary, Glasgow; Mr Jack Miller, Consultant Surgeon, Dr Gray's Hospital, Elgin; Dr Marianne Nicolson, Consultant in Medical Oncology, Aberdeen Royal Infirmary; Dr Jonathan Norris, Consultant Dermatologist, Dumfries and Galloway Royal Infirmary; Dr Gerry Robertson, Consultant Clinical Oncologist, Beatson Oncology Centre, Glasgow; Mr Duncan Service, Information Services Officer, Scottish Intercollegiate Guidelines Network (SIGN); Mrs Karen Smith, Specialist Nurse, Plastic Surgery, Ninewells Hospital, Dundee; Mr David Soutar, Consultant Plastic Surgeon, Canniesburn Hospital, Glasgow; Ms Joanne Topalian, Programme Manager, SIGN

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both

personal and non-personal. A personal interest involves payment to the individual concerned (e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry); a non-personal interest involves payment which benefits any group, unit, or department for which the individual is responsible (e.g., endowed fellowships or other pharmaceutical industry support). Details of the declarations of interest of any guideline development group member(s) are available from the Scottish Intercollegiate Guidelines Network executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on <u>Scottish</u> Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Scottish</u> <u>Intercollegiate Guidelines Network (SIGN) Web site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Cutaneous melanoma. A national clinical guideline. Scottish Intercollegiate Guidelines Network, 2003. 2 p. Available in Portable Document Format (PDF) from the <u>Scottish Intercollegiate Guidelines Network</u> (SIGN) Web site.
- SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the <u>SIGN Web site</u>.

PATIENT RESOURCES

The following is available:

- Information for patients. In: Cutaneous melanoma. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 50 p. (SIGN publication; no. 72). Electronic copies: Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- Advice to patients cutaneous melanoma. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2 p. Electronic copies: Available in Portable Document Format (PDF) from the <u>SIGN Web site</u>.

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