Complete Summary

GUIDELINE TITLE

Long term follow up of survivors of childhood cancer. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Long term follow up of survivors of childhood cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jan. 33 p. (SIGN publication; no. 76). [273 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

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SCOPE

DISEASE/CONDITION(S)

Childhood cancer treatment-related late effects, including:

- Growth problems
- Problems with puberty and reproduction
- Cardiac problems
- Thyroid dysfunction
- Cognitive and psychosocial outcomes

Note: The guideline does not systematically address other important areas, including second malignancy, or renal, respiratory, and liver dysfunction. Late effects involving vision and hearing have also not been addressed.

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Cardiology
Dentistry
Family Practice
Internal Medicine
Nursing
Oncology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Dentists
Nurses
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

GUIDELINE OBJECTIVE(S)

To present evidence-based recommendations for the long term follow up of survivors of childhood cancer

TARGET POPULATION

All young people who have survived cancer and who may experience expected and unexpected late effects that are related to the treatment received, rather than the specific cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Growth assessment plotted on growth charts including:
    - height measurement
    - bone age
    - puberty staging
    - Body Mass Index (BMI)

2. Testing for growth and other pituitary hormone deficiencies in children with craniopharyngioma
3. Assessment of male pubertal development and fertility, including testicular volume using the Prader orchidometer, Tanner staging, serum follicle stimulating hormone (FSH), luteinising hormone (LH), testosterone, inhibin B, and semen analysis
4. Detailed cardiologic assessment for those who are pregnant, are planning to get pregnant, or take part in competitive sports

Management

1. Patient/parent education including:
    - Healthy lifestyle (e.g., diet, exercise, and smoking avoidance/cessation)
    - Risks of cancer recurrence
    - Medication side effects
2. Specialist referral as appropriate:
    - Pediatric endocrinologist
    - Pediatric dentist
3. Fertility counseling
4. Echocardiogram surveillance as appropriate
5. Thyroid dysfunction monitoring for those treated with radiotherapy
6. Regular review of neurological, educational, and social function and referral for cognitive assessment as appropriate

Treatment

1. Growth hormone replacement therapy, when applicable
2. Assisted reproductive technology for patients with impaired fertility
3. Cryopreservation of semen
4. Thyroid replacement therapy

MAJOR OUTCOMES CONSIDERED

Incidence and severity of treatment-induced late effects

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Systematic searches were carried out on the Cochrane Library, Embase, Medline, and Psychlit and covered the period from 1993 to 2000. The main searches were supplemented by material identified by individual members of the development group. This allowed the inclusion of older seminal publications and of material published during the guideline development process, although not systematically.

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

Systematic Review with Evidence Tables

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: SIGN 50: A guideline developer's handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001 Feb. (SIGN publication; no. 50). Available from the SIGN Web site.

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 "SIGN 50: A Guideline Developer's Handbook." (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 on

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 not 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

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of the 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 on 27 March 2002 and was attended by around 80 representatives of all the key specialties relevant to the guideline. The draft guideline was also 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 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.

The guideline was then reviewed by an Editorial Group comprising relevant specialty representatives on SIGN Council, to ensure that the peer reviewers' comments had been addressed adequately and that any risk of bias in the guideline development process as a whole had 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 full-text guideline document.

The grades of recommendations (A-D) and levels of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Monitoring for Growth Problems

B - All children who have survived childhood cancer should have their height measured regularly until they reach final adult height. Sitting height should also be measured in children who have received craniospinal irradiation.

C - Children with impaired growth velocity should be referred to a paediatric endocrinologist for growth hormone level measurement.

B - Causes of poor growth, other than growth hormone deficiency, including potential deficiencies of other pituitary hormones or problems related to early or delayed puberty, should be considered and treated as necessary.

B - Children with craniopharyngioma should be tested at presentation for growth and other pituitary hormone deficiencies and at regular intervals thereafter.

B - Prepubertal girls receiving cranial radiotherapy should be closely monitored for clinical signs of precocious puberty (*see section 4 of the original guideline document*).

Obesity

C - Regular growth monitoring should include evaluation of body mass index and be related to growth charts.

Treatment with Growth Hormone

Effectiveness

B - On confirmation of growth hormone deficiency, growth hormone replacement therapy is indicated. For children with craniopharyngioma, the need for growth hormone replacement may be from presentation.

C - If the cause of growth impairment is unclear, a trial of growth hormone treatment may be appropriate.

Safety

B - Survivors of childhood cancer should be informed that current evidence indicates that there is no increased risk of cancer recurrence from growth hormone replacement therapy.

Dental and Facial Problems

D - Children undergoing cancer treatment and their parents/carers should be advised about the possible effects on orofacial and dental development. Specialist paediatric dentists should have a role in the care of these children.

Female Puberty and Fertility

C - Girls treated with cranial irradiation should have their pubertal status assessed three to four times a year from the end of treatment as part of a routine clinical assessment.

C - Women who have evidence of impaired fertility should be referred for specialist assessment as they could benefit from assisted reproductive technology.

Cardiac Problems

C - Healthcare professionals should be aware that effective doses of anthracyclines for the treatment of childhood cancer may cause congestive cardiac failure later in life. These problems should be assessed during regular review.

C - Healthcare professionals should be aware that mediastinal irradiation over 30 Gy is a risk factor for cardiac disease in later life and monitoring is necessary.

Thyroid Dysfunction

B - Survivors of childhood cancer who received radiotherapy to the neck, spine, or brain should have thyroid function checked after completion of treatment and regularly thereafter. Survivors are likely to require lifetime surveillance.

Cognitive Structure and Neurological Function

D - Healthcare and education professionals should be aware that the treatment of childhood cancer may have an impact on neurological function in later life, particularly if irradiation of the brain occurs at a young age.

- Regular review of neurological function should be part of normal follow up.
- If a problem is suspected, the patient should be referred to a psychologist for a cognitive assessment.

D: Healthcare and education professionals should be aware that the treatment of childhood cancer may have an impact on educational and social function in later life.

- Regular review for possible educational and psychosocial dysfunction or morbidity should take place.
- If a problem is suspected, the patient should be referred appropriately.

Definitions:

Grades of Recommendations

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

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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)

None provided

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

With follow up and early detection and treatment, many potential problems related to the late effects of cancer treatment may be ameliorated, allowing cancer survivors to enjoy full and active lives.

POTENTIAL HARMS

Doubts have been expressed about the safety of recombinant growth hormone replacement therapy for childhood cancer survivors, based on the theoretical possibility that it may cause unwanted effects on any remaining cancer cells after treatment. Patients on growth hormone therapy in the USA, Canada, and Europe are registered and closely monitored, allowing large studies to address the rate of cancer recurrence. The evidence supports the view that there is no increased risk of cancer recurrence. Other adverse effects in survivors of craniopharyngioma are common and include headache, seizures, and water retention. These effects are likely to be due to the tumour and/or surgery, rather than the growth hormone.

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 judgment 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. However, it is advised, 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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health Service (NHS) Board and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

Key points for audit are identified in the original guideline document.

IMPLEMENTATION TOOLS

Patient Resources
Quick Reference Guides/Physician Guides

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

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Long term follow up of survivors of childhood cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jan. 33 p. (SIGN publication; no. 76). [273 references]

ADAPTATION

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

DATE RELEASED

2004 Jan

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 Hamish Wallace (*Chair*), Consultant Paediatric Oncologist, Royal Hospital for Sick Children, Edinburgh; Dr Chris Kelnar (*Methodologist*), Reader in Child Health and Consultant Paediatric Endocrinologist, University of Edinburgh; Professor Ann Barrett, Professor of Oncology, University of East Anglia; Mrs Jane Belmore, Paediatric Macmillan Nurse, Royal Hospital for Sick Children, Glasgow; Dr Jan Clarkson, Honorary Consultant in Paediatric Dentistry and Senior Lecturer, Dundee Dental Hospital and School; Dr Alison Cozens, Scottish Intercollegiate Guidelines Network (SIGN) Fellow and Specialist Registrar in Paediatrics, Tayside University Hospitals National Health Services (NHS) Trust, Dundee; Dr Ali El-Ghorr, Programme Manager, SIGN; Dr Brenda Gibson, Consultant Haematologist, Royal Hospital for Sick Children, Glasgow; Dr Robert Grant, Macmillan General Practitioner Facilitator, Kirkcaldy; Mr Robin Harbour, Information and Quality Director, SIGN; Dr Peter Hoare, Honorary Consultant Child and Adolescent Psychiatrist, Royal Hospital for Sick Children, Edinburgh; Dr Stewart Irvine, Consultant in Obstetrics and Gynaecology, Centre for Reproductive Biology, Edinburgh; Dr Paul Lim, General Practitioner, Falkirk; Mr Gordon MacKinlay, Consultant in Paediatric Surgery, Royal Hospital for Sick Children, Edinburgh; Mrs Ethel McNeill, Endocrine Nurse Specialist, Royal Hospital for Sick Children, Glasgow; Ms Lynn Myles, Honorary Consultant Neurosurgeon, Western General Hospital, Edinburgh; Dr Robert Simpson, Consultant Paediatrician, Dumfries and Galloway Royal Infirmary; Ms Anne Thomson, Patient Representative, Kirkcaldy; Dr Brenda Wilson, Associate Professor, Department of Epidemiology and Community Medicine, University of Ottawa, Canada; Dr John Wilson, General Practitioner, Selkirk

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 SIGN executive.

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.

GUIDELINE AVAILABILITY

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

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Quick reference guide: Long term follow up of survivors of childhood cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jan. 1 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (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 SIGN Web site.

PATIENT RESOURCES

The following is available:

- Patient issues. In: Long term follow up of survivors of childhood cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2004 Jan. 33 p. (SIGN publication; no. 76).

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

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on May 3, 2004. The information was verified by the guideline developer on July 15, 2004.

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