General

Guideline Title

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

Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


Any updates to the guideline that result from the availability of new evidence will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- October 25, 2016 – Testosterone and Other Anabolic Androgenic Steroids (AAS): The U.S. Food and Drug Administration (FDA) approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS.

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.

**Subsequent Primary Cancers**

**Overall Risk**

C - Healthcare professionals should be aware that survivors of childhood cancer are at particular and lifelong increased risk of developing a subsequent primary cancer and that this may occur at any site on the body.

**Risks Associated with Particular Treatment Modalities**

**Risk Associated with Radiotherapy**

C - Healthcare professionals should be aware that all survivors of childhood cancer who were treated with radiotherapy are at risk of subsequent primary cancer and should adopt a high index of suspicion when assessing health concerns.

**Risk Associated with Chemotherapy**

C - Healthcare professionals should be aware that chemotherapy exposure is associated with increased risk of subsequent primary cancers in patients treated for childhood cancer. The effect is most consistently seen with alkylating agents and epipodophyllotoxins.

**Fertility Issues**

**Risk to Fertility Associated with Treatment for Childhood Cancer in Males**

**Fertility**

D - The potential impact of cytotoxic treatment in young male patients with cancer should be considered in discussion with the patient and their parents in order to offer appropriate fertility preservation options.

D - Men who have received cytotoxic treatment or gonadal radiotherapy should be offered access to fertility testing.

**Testosterone Production**

D - Pubertal onset should be closely monitored in boys who have received radiotherapy to the testes, with early testosterone supplementation considered.

**Risk to Fertility Associated with Treatment for Childhood Cancer in Females**

**Fertility**

D - Pubertal onset should be closely monitored in girls who have received abdominopelvic radiotherapy or cytotoxic therapy.

D - Assessment of adult ovarian function should be offered to women who have received abdominopelvic radiotherapy or cytotoxic therapy.

**Pregnancy and Birth**

C - Women who have had radiotherapy treatment to a field which included the uterus are at increased risk of adverse pregnancy outcome. Preconception counselling may be appropriate and women should be advised that pregnancy should be supervised in a high risk obstetric unit.

**Protecting Fertility**

**Protecting Fertility in Boys Undergoing Treatment for Childhood Cancer**

D - Teenage boys should be referred for semen cryopreservation if their fertility is considered to be at risk.

**Protecting Fertility in Girls Undergoing Treatment for Childhood Cancer**

D - Cryopreservation of ovarian tissue (within the context of a clinical trial) should be considered in girls at high risk of premature ovarian insufficiency.
Risks of Congenital Abnormalities in Offspring of Survivors of Childhood Cancer Treatment

C - Healthcare professionals should provide reassurance to survivors of childhood cancer that their offspring are not at increased risk of congenital abnormality.

Cardiac Effects

Treatment-related Effects

Association with Radiotherapy

C - Survivors of childhood cancer who received either anthracyclines or radiation to a field that included the heart should be assessed with respect to cardiac muscle function.

D - Healthcare professionals should reassure survivors of childhood cancer who did not receive anthracyclines or radiation to a field that included the heart that the lifelong risk of treatment related cardiac problems is very low.

Assessment for Cardiac Problems

D - Survivors of childhood cancer who have had anthracyclines or radiation to a field that includes the heart should have long term monitoring for cardiac dysfunction using echocardiography to determine fractional shortening and ejection fraction.

Bone Health

Assessment of Bone Health

D - Survivors of childhood cancer who have had the following interventions are at increased risk of bone mineral density (BMD) deficits and should have a baseline evaluation of BMD at around two years after completion of treatment:

- High cumulative doses of steroids
- High cumulative doses of methotrexate
- Cranial irradiation
- Bone marrow transplantation

D - Evaluation of bone mineral density should also be undertaken in survivors whose treatment puts them at risk of endocrine dysfunction.

Metabolic Syndrome

Factors Associated with Metabolic Syndrome

D - Survivors of childhood cancer (particularly those who have been treated for acute lymphoblastic leukaemia or brain tumours) should be advised that they may be at higher risk of developing metabolic syndrome than the general population.

Cognitive and Psychosocial Outcomes

Brain 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.

D - Regular review of neurological function should be part of normal follow up.

D - If a problem is suspected, the patient should be referred to a psychologist for a neuropsychological assessment.

Psychosocial Issues

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.

D - Regular review for possible educational and psychosocial dysfunction or morbidity should take place.

D - If a problem is suspected, the patient should be referred appropriately.

Growth Problems
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.

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

Problems with Orofacial and Dental Growth

D - Children undergoing cancer treatment, and their parents/careers, 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.

Thyroid Dysfunction

Special Groups at Risk of Thyroid Dysfunction

Cranial Radiotherapy

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

Definitions:

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, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews, 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

Grades of Recommendation

Note: 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, 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+

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Late effects related to treatment for cancer

Guideline Category

Counseling
Evaluation
Management
Treatment

Clinical Specialty

Cardiology
Dentistry
Endocrinology
Intended Users
Advanced Practice Nurses
Dentists
Dietitians
Nurses
Patients
Physician Assistants
Physicians
Psychologists/Non-physician Behavioral Health Clinicians
Social Workers

Guideline Objective(s)
To provide recommendations based on current evidence for best practice in identification, assessment and management of late effects in survivors of childhood cancer

Target Population
Everyone who has been treated for cancer as a child or teenager, who may be at risk of developing late effects that are largely, but not exclusively, related to the treatment they received for their cancer

Note: Survivors of childhood cancer are defined by age at cancer diagnosis and treatment. Across studies this varies from age less than 15 to age less than 24 years. Survival is commonly defined in studies as from two or five or more years post-treatment.

Interventions and Practices Considered
Evaluation
1. Fertility testing
2. Assessment of adult ovarian function
3. Assessment of cardiac muscle function
4. Assessment of bone health (baseline evaluation of bone mineral density [BMD])
5. Measurement of height and body mass index (BMI)
6. Testing for growth or pituitary deficiencies
7. Evaluation of thyroid function

Management/Treatment

1. Consideration of fertility preservation options (cryopreservation of semen, ovarian tissue)
2. Monitoring of pubertal onset, including precocious puberty in girls
3. Testosterone supplementation
4. Pre-conception counseling
5. Long-term monitoring of cardiac dysfunction (echocardiography)
6. Review of neurological, educational, and social function
7. Referral to paediatric specialist as necessary (psychologist, endocrinologist, dentist)
8. Treatment of growth or pituitary hormone deficiencies or other problems related to early or delayed puberty (growth hormone replacement therapy)
9. Discussion of possible effects on facial and dental development with patients and parents/carers

Major Outcomes Considered

- Subsequent primary cancers
- Fertility
- Cardiac effects
- Bone health
- Metabolic syndrome
- Cognitive and psychosocial issues
- Growth problems
- Dental and facial problems
- Thyroid dysfunction

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Systematic Literature Review

The evidence base for the original guideline document was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised by a SIGN Evidence and Information Scientist. Databases searched include Medline, EMBASE, CINAHL, PsycINFO and the Cochrane Library. The year range covered was 2002-2011. Internet searches were carried out on various websites including the US National Guideline Clearinghouse. The main searches were supplemented by material identified by individual members of the development group.

Literature Search for Patient Issues

At the start of the guideline development process, a SIGN Evidence and Information Scientist conducted a literature search for qualitative and quantitative studies that addressed patient issues of relevance to early management of patients who are survivors of childhood cancer. Databases searched include Medline, EMBASE, CINAHL and PsycINFO, and the results were summarised and presented to the guideline development group.
Number of Source Documents
Not stated

Methods Used to Assess the Quality and Strength of the Evidence

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, or RCTs with a low risk of bias
1-: Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++: High quality systematic reviews of case control or cohort studies
2+: 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 with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. The result of this assessment will affect the level of evidence allocated to the paper, which will in turn influence the grade of recommendation that it supports.

The methodological assessment is based on a number of key questions that focus on those aspects of the study design that research has shown to have a significant influence on the validity of the results reported and conclusions drawn. These key questions differ between study types, and a range of checklists is used to bring a degree of consistency to the assessment process. The Scottish Intercollegiate Guidelines Network (SIGN) has based its assessments on the MERGE (Method for Evaluating Research and Guideline Evidence) checklists developed by the New South Wales Department of Health, which have been subjected to wide consultation and evaluation. These checklists were subjected to detailed evaluation and adaptation to meet SIGN's requirements for a balance between methodological rigour and practicality of use.

The assessment process inevitably involves a degree of subjective judgment. The extent to which a study meets a particular criterion - e.g., an acceptable level of loss to follow up - and, more importantly, the likely impact of this on the reported results from the study will depend on the clinical context. To minimise any potential bias resulting from this, each study must be evaluated independently by at least two group members. Any differences in assessment should then be discussed by the full group. Where differences cannot be resolved, an independent reviewer or an experienced member of SIGN Executive staff will arbitrate to reach an agreed quality assessment.

Evidence Tables

Evidence tables are compiled by the SIGN executive staff based on the quality assessments of individual studies provided by guideline
development group members. The tables summarise all the validated studies identified from the systematic literature review relating to each key question. They are presented in a standard format to make it easier to compare results across studies, and will present separately the evidence for each outcome measure used in the published studies. These evidence tables form an essential part of the guideline development record and ensure that the basis of the guideline development group’s recommendations is transparent.

Additional details can be found in the companion document titled “SIGN 50: A Guideline Developers’ Handbook.” (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [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

Synthesising the Evidence

Guideline recommendations are graded to differentiate between those based on strong evidence and those based on weak evidence. This judgment is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgment on the consistency, clinical relevance and external validity of the whole body of evidence. The aim is to produce a recommendation that is evidence-based, but which is relevant to the way in which health care is delivered in Scotland and is therefore implementable.

It is important to emphasise that the grading does not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data was obtained. Thus, the grading assigned to a recommendation indicates to users the likelihood that, if that recommendation is implemented, the predicted outcome will be achieved.

Considered Judgement

It is rare for the evidence to show clearly and unambiguously what course of action should be recommended for any given question. Consequently, it is not always clear to those who were not involved in the decision making process how guideline developers were able to arrive at their recommendations, given the evidence they had to base them on. In order to address this problem, SIGN has introduced the concept of considered judgment.

Under the heading of considered judgement, guideline development groups summarise their view of the total body of evidence covered by each evidence table.

Each guideline group considers the following factors:

- Quantity, quality, and consistency of evidence
- External validity (generalisability) of studies
- Directness of application to the target population for the guideline
- Any evidence of potential harms associated with implementation of a recommendation
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them in accordance with the recommendation)
- Whether, and to what extent, any equality groups may be particularly advantaged or disadvantaged by the recommendations made
- Implementability (i.e., how practical it would be for the National Health Service [NHS] Scotland to implement the recommendation)

Then the group is asked to summarise its view on all of these issues, both the quality of the evidence and its potential impact, before making a graded recommendation. This summary should be succinct, and taken together with its views of the level of evidence represent the first draft of the text that will appear in the guideline immediately before a graded recommendation.

Additional detail about SIGN’s process for formulating guideline recommendations is provided in Section 6 of the companion document titled “SIGN 50: A Guideline Developers’ Handbook.” (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]), available from the SIGN Web site.

Rating Scheme for the Strength of the Recommendations
Grades of Recommendation

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A: At least one meta-analysis, systematic review, or randomised controlled trial (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 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

The national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development.

Peer Review

All SIGN guidelines are reviewed in draft form by independent expert referees, who are asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline. A number of general practitioners (GPs) and other primary care practitioners also provide comments on the guideline from the primary care perspective, concentrating particularly on the clarity of the recommendations and their assessment of the usefulness of the guideline as a working tool for the primary care team. The draft is also sent to at least two lay reviewers in order to obtain comments from the patient's perspective.

It should be noted that all reviewers are invited to comment as individuals, not as representatives of any particular organisation or group. Corporate interests, whether commercial, professional, or societal, have an opportunity to make representations at the national meeting stage where they can send representatives to the meeting or provide comment on the draft produced for that meeting. Peer reviewers are asked to complete a declaration of interests form.

The comments received from peer reviewers and others are carefully tabulated and discussed with the Chair and with the guideline development group. Each point must be addressed and any changes to the guideline as a result noted or, if no change is made, the reasons for this recorded.

As a final quality control check prior to publication, the guideline and the summary of peer reviewers' comments are reviewed by the SIGN Editorial Group for that guideline to ensure that each point has 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 is then asked formally to approve the final guideline for
Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

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

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate long term follow up of survivors of childhood cancers

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

- This guideline is not intended to be construed or to serve as a standard of 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. Adherence to guideline recommendations 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 must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is, however, 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.

- Recommendations within this guideline are based on the best clinical evidence. Some recommendations may be for medicines prescribed outwith the MA also known as product licence. This is known as "off label" use.

Medicines may be prescribed off label in the following circumstances:

- For an indication not specified within the marketing authorization
- For administration via a different route
- For administration of a different dose
- For a different patient population

An unlicensed medicine is a medicine which does not have MA for medicinal use in humans.

Generally the off label use of medicines becomes necessary if the clinical need cannot be met by licensed medicines within the MA. Such use should be supported by appropriate evidence and experience.

"Prescribing medicines outside the conditions of their MA alters (and probably increases) the prescribers' professional responsibility and potential liability."

The General Medical Council (GMC) recommends that when prescribing a medicine off label, doctors should:

- Be satisfied that such use would better serve the patient's needs than an authorised alternative (if one exists)
- Be satisfied that there is sufficient evidence/experience of using the medicines to show its safety and efficacy, seeking the necessary
information from appropriate sources

- Record in the patient's clinical notes the medicine prescribed and, when not following common practice, the reasons for the choice
- Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring the effects of the medicine

Non-medical prescribers should ensure that they are familiar with the legislative framework and their own professional prescribing standards.

Prior to any prescribing, the licensing status of a medication should be checked in the current version of the British National Formulary (BNF). The prescriber must be competent, operate within the professional code of ethics of their statutory body and the prescribing practices of their employer.

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. The Managed Service Network for Children and Young People with Cancer in Scotland, which is committed to developing evidence based practice and risk-based long term follow up, will facilitate the implementation of this guideline across all Health Boards.

Refer to Section 13 of the original guideline document for advice on the resource implications associated with implementing the key clinical recommendations and advice on audit as a tool to aid implementation.

Implementation Tools

Audit Criteria/Indicators
Mobile Device 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
- Staying Healthy

IOM Domain
- Effectiveness
- Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)
Adaptation

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

Date Released

2004 Jan (revised 2013 Mar)

Guideline Developer(s)

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

Source(s) of Funding

Scottish Executive Health Department

Guideline Committee

Guideline Development Group

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Financial Disclosures/Conflicts of Interest

Declarations of interests were made by all members of the guideline development group. Further details are available from the Scottish Intercollegiate Guidelines Network (SIGN) Executive.

Guideline Status

This is the current release of the guideline.

Any updates to the guideline that result from the availability of new evidence will be noted on the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

Guideline Availability


Availability of Companion Documents

The following are available:


In addition, Section 13 of the original guideline document contains key points to audit.

Executive summaries of SIGN guidelines are available for mobile devices through the guidelines app on the SIGN Web site.

Patient Resources

None available

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. This NGC summary was updated by ECRI Institute on June 19, 2013. The updated information was verified by the guideline developer on June 26, 2013. This summary was updated by ECRI Institute on April 3, 2015 following the U.S. Food and Drug Administration advisory on Testosterone Products. This summary was updated by ECRI Institute on November 17, 2016 following the U.S. Food and Drug Administration advisory on Testosterone and Other Anabolic Androgenic Steroids (AAS).

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