# **Complete Summary**

#### **GUIDELINE TITLE**

Management of cervical cancer.

## **BIBLIOGRAPHIC SOURCE(S)**

Scottish Intercollegiate Guidelines Network (SIGN). Management of cervical cancer. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2008 Jan. 73 p. (SIGN publication; no. 99). [254 references]

## **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.

## \*\* 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.

- July 31, 2008, Erythropoiesis Stimulating Agents (ESAs): Amgen and the U.S. Food and Drug Administration (FDA) informed healthcare professionals of modifications to certain sections of the Boxed Warnings, Indications and Usage, and Dosage and Administration sections of prescribing information for Erythropoiesis Stimulating Agents (ESAs). The changes clarify the FDA-approved conditions for use of ESAs in patients with cancer and revise directions for dosing to state the hemoglobin level at which treatment with an ESA should be initiated.
- November 8, 2007 and January 3, 2008 Update, Erythropoiesis Stimulating
   Agents (ESAs): The U.S. Food and Drug Administration (FDA) notified
   healthcare professionals of revised boxed warnings and other safety-related
   product labeling changes for erythropoiesis-stimulating agents (ESAs) stating
   serious adverse events, such as tumor growth and shortened survival in
   patients with advanced cancer and chronic kidney failure.

# **COMPLETE SUMMARY CONTENT**

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## SCOPE

# **DISEASE/CONDITION(S)**

Cervical cancer

**Note**: The management of small cell and large cell neuroendocrine carcinomas is not covered.

#### **GUIDELINE CATEGORY**

Counseling
Diagnosis
Evaluation
Management
Risk Assessment
Treatment

## **CLINICAL SPECIALTY**

Family Practice
Internal Medicine
Obstetrics and Gynecology
Oncology
Pathology
Physical Medicine and Rehabilitation
Radiation Oncology
Radiology
Surgery

## **INTENDED USERS**

Advanced Practice Nurses Allied Health Personnel Nurses Physical Therapists Physician Assistants Physicians

# **GUIDELINE OBJECTIVE(S)**

To ensure that optimal management by a multidisciplinary team minimises the huge social, economic and emotional burden experienced by women with the disease and their families

## **TARGET POPULATION**

Women with cervical cancer

## INTERVENTIONS AND PRACTICES CONSIDERED

# **Diagnosis/Assessment**

- 1. Assessment of signs and symptoms in pre-menopausal and post-menopausal women with abnormal vaginal bleeding
- 2. Testing for *Chlamydia trachomatis* infection
- 3. Histopathological features and reporting of cervical tumors
- 4. Radiological assessment of pelvic or para-aortic lymph nodes
  - Magnetic resonance imaging (MRI) scan
  - Computed tomography (CT) scan (post contrast spiral slice CT for advanced disease)
  - Positron emission tomography (PET) scan with fluorodeoxy glucose
  - Cystoscopy
  - Sigmoidoscopy

# **Treatment/Management**

- 1. Surgery
  - Radical hysterectomy
  - Laparoscopic-vaginal radical hysterectomy
  - Surgical management in women with subtotal hysterectomy
  - Removal of pelvic lymph nodes
  - Fertility conservation surgery
    - Radical trachelectomy and pelvic lymph node dissection
    - Cold knife conisation or large loop excision of the transformation zone combined with pelvic lymph node dissection
- 2. Non-surgical treatment
  - Concurrent chemoradiotherapy
  - Adjuvant chemoradiotherapy/radiotherapy
  - Brachytherapy
- 3. Management of anemia
  - Monitoring of hemoglobin levels
  - Blood transfusion, erythropoietin and iron products
- 4. Treatment of radiation induced complications of the rectum
- 5. Hormone replacement therapy
- 6. Treatment during pregnancy
- 7. Physical and psychosocial interventions for sexual morbidity
  - Vaginal stent or dilator
  - Provision of patient information and support sessions
- 8. Management of lymphoedema
  - Diagnosis

- Decongestive lymphatic therapy with a designated lymphoedema practitioner
- Antibiotic therapy for cellulitis
- Self management
- 9. Follow-up
  - Post-surveillance treatment
  - Detection of relapsed disease (MRI, CT, PET, PET-CT)
- 10. Management of relapsed disease
  - Total pelvic exenteration
  - Chemotherapy
- 11. Management of complications in advanced disease
  - Renal failure (retrograde ureteric stents, percutaneous nephrostomy, antegrade stent, urinary diversion)
  - Thrombotic and bleeding problems (low molecular weight heparin for deep vein thrombosis, compression garments, walking exercises)
- 12. Psychosocial care and support
  - Support services
  - Provision of information to patients and carers
  - Communication methods (written, audiotape)

### **MAJOR OUTCOMES CONSIDERED**

- Sensitivity and specificity of radiologic tests
- Incidence of cervical cancer
- Complications of cervical cancer
- Complications of treatment
- Mortality and morbidity rates
- Prevalence of cervical cancer in women with post coital bleeding
- Relapse rate based on treatment

## **METHODOLOGY**

## METHODS USED TO COLLECT/SELECT 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**

The evidence base for this guideline 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 Information Officer. Databases searched include Medline, Embase, Cinahl, and the Cochrane Library. The year range covered was 1999-2005, although searches for certain questions went back to 1990. Internet searches were carried out on various websites including the New Zealand Guidelines Programme, the Canadian Medical Association, National Electronic Library for Health (NELH) Guidelines Finder, and the US National Guidelines Clearinghouse. The main searches were supplemented by material identified by individual members of the development group.

## **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**

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. 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 judgement. 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 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 <u>SIGN Web</u> 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 judgement is made on the basis of an (objective) assessment of the design and quality of each study and a (perhaps more subjective) judgement 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 judgement.

Under the heading of considered judgement, guideline development groups 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
- Directness of application to the target population for the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources needed to treat them)
- Implementability (i.e., how practical it would be for the NHS in Scotland to implement the recommendation)

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 group is asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive 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 <u>SIGN Web site</u>.

## RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

#### **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 of randomized 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+

**Good Practice Points**: Recommended best practice based on the clinical experience of the guideline development group

## **COST ANALYSIS**

Analyses of resource implications (the likely impact of implementing the recommendations) were made for human papillomavirus (HPV) vaccination, cross-sectional imaging, magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), chest x-ray, squamous cell carcinoma antigen, surgery, chemotherapy, brachytherapy, and screening for distress (see the original guideline document for details of the cost analyses).

#### 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 a lay reviewer in order to obtain comments from the patient's perspective. The comments received from peer reviewers and others are carefully tabulated and discussed with the chairman 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 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.

# **Presentation and Referral**

# Signs and Symptoms

- **D** Pre-menopausal women presenting with abnormal vaginal bleeding should be tested for *Chlamydia trachomatis*.
- **D** Post-menopausal women presenting with abnormal vaginal bleeding should be referred for gynaecological investigation.
- **D** Chlamydia trachomatis testing should be done if appropriate.

## **Diagnosis and Staging**

## **Diagnosis and Prognosis**

Histopathological Reporting

- **D** Pathology reports of cervical tumours should include the following histological features:
- Tumour type
- Tumour size
- Extent of tumour (e.g., involvement of the vaginal wall or parametrium)
- Depth of invasion
- Pattern of invasion (infiltrative or cohesive invasive front)
- Lymphovascular space invasion (LVSI)

- Status of resection margins (presence of tumour and distance from margin)
- Status of lymph nodes (including site and number of nodes involved)
- Presence of pre-invasive disease

## **Radiological Staging**

Pelvic or Para-aortic Lymph Nodes

- **B** All patients with visible, biopsy proven cervical carcinoma (except those with International Federation of Gynecology and Obstetrics [FIGO] IV disease) should have an magnetic resonance imaging (MRI) scan.
- C The MRI scan should include:
- Thin section T2 weighted images perpendicular to the cervix
- Sequences to include urinary tract and para-aortic nodal areas
- **B** Post contrast spiral computed tomography (CT) should be considered as an alternative to MRI in patients who cannot have MRI.
- **B** Women who have clinically apparent FIGO stage IV disease should have post contrast spiral or multislice CT scans of chest abdomen and pelvis.

Positron Emission Tomography (PET)

C - Patients not suitable for surgery should be considered for a PET scan.

The Relative Benefit of Imaging Over Other Options in Pre-treatment Staging

- **C** Cystoscopy and sigmoidoscopy should not be routinely performed for staging purposes.
- **C** If imaging cannot exclude bladder or bowel involvement, cystoscopy and sigmoidoscopy should be used for staging.
- $\boldsymbol{\mathsf{C}}$  Ultrasound, intravenous urography (IVU) and lymphangiography are not recommended for staging.

## Surgery

## **Radical Hysterectomy**

 ${\bf B}$  - Radical surgery is recommended for FIGO IB1 disease if there are no contraindications to surgery.

#### **Treatment of Cervical Cancer After Subtotal Hysterectomy**

**C** - Cancer of the cervical stump should be managed in the same way as cervical cancer arising in an intact uterus.

# Treatment of Early Stage Disease (FIGO IA1 and IA2)

Pelvic Node Metastases

- **D** Removal of pelvic lymph nodes is not recommended during treatment for FIGO IA1 disease.
- **D** Pelvic lymph nodes should be removed if FIGO IA2 disease is present.

Fertility Conservation Surgery

- **C** Women requesting fertility conservation should be offered radical trachelectomy and pelvic lymph node dissection, providing the tumour diameter is less than 2 cm and no lymphatic-vascular space invasion is present.
- **D** Women with early stage disease and no lymphovascular space invasion (LVSI) (FIGO IA2 and microscopic IB1) requesting fertility conservation may be offered cold knife conisation or large loop excision of the transformation zone (LLETZ) combined with pelvic lymph node dissection.

## **Laparoscopic-Vaginal Radical Hysterectomy**

- **D** Laparoscopic-vaginal radical hysterectomy should not be offered to patients with tumour diameter greater than 2 cm.
- **D** Surgeons wishing to offer laparoscopic-vaginal radical hysterectomy should have appropriate training.

## **Non-surgical Treatment**

# **Concurrent Chemoradiotherapy**

**A** - Any patient with cervical cancer considered suitable for radical radiotherapy treatment should have concurrent chemoradiotherapy with a platinum based chemotherapy, if fit enough.

## Adjuvant Chemoradiotherapy/Radiotherapy

Positive Lymph Nodes

**B** - Patients who have undergone surgery for cervical carcinoma and have positive nodes should be considered for adjuvant treatment with concurrent chemoradiotherapy with platinum based chemotherapy.

Negative Lymph Nodes

**B** - Patients who have undergone surgery for cervical carcinoma, have negative nodes and any two of the following risk factors should be considered for adjuvant treatment with radiotherapy, if fit enough:

- Greater than a third stromal invasion
- Lymphovascular space invasion
- Tumour diameter of >4 cm
- **D** Concurrent chemoradiation should be considered in preference to radiation alone.

# **Brachytherapy**

**D** - Brachytherapy should be considered an essential component of radical radiotherapy or chemoradiotherapy.

## **Treatment of Anemia**

- **C** Patients with cervical carcinoma undergoing radiotherapy or chemoradiotherapy should have their haemoglobin level monitored and corrected if it falls below 12 g/dL.
- **B** Anaemia should be corrected with either blood transfusion or erythropoietin and iron products after consideration of the attendant costs, risks and benefits.

# **Treatment of Radiation Induced Complications**

#### Rectum

- **B** Rectal or oral sucralfate is not recommended to reduce acute radiation induced proctitis.
- **D** Rectal sucralfate may be considered to reduce late radiation induced proctitis.

Hormone Replacement Therapy (HRT)

**C** - HRT is recommended for women who have lost ovarian function as a result of treatment for cervical cancer.

## **Treatment During Pregnancy**

- **C** For pregnant women with cervical cancer, the choice of therapeutic modality should be decided in the same manner as for non-pregnant patients.
- **C** For pregnant women diagnosed with cervical cancer before 16 weeks of gestation, immediate treatment is recommended.
- **C** For pregnant women with early stage disease (FIGO IA1, IA2, IB) diagnosed after 16 weeks of gestation, treatment may be delayed to allow fetal maturity to occur.
- **C** For pregnant women with advanced disease (FIGO 1B2 or greater) diagnosed after 16 weeks of gestation, consideration for delay must be based on gestational age at time of diagnosis.

## **Sexual Morbidity**

# **Physical Interventions**

**C** - Women should be offered a vaginal stent or dilator to prevent post-radiotherapy vaginal complications.

## **Psychoeducational Interventions**

- **B** Information about female sexual function should be offered to patients by a relevantly-trained healthcare professional using a model of care that involves addressing motivational issues and teaching behavioural skills.
- **C** Patients should be offered support sessions by a designated member of their care team, as soon as possible after treatment, which may include one or more of the following:
- Relaxation
- Personalised information about their disease and treatment
- Emotional support and care

# **Lymphoedema**

#### **Risk Factors**

**D** - Patients with lymphoedema, or at risk of lymphoedema, should have access to appropriate information.

# Diagnosis

- **D** Patient review should include identification and recording of lower limb lymphoedema.
- **D** Patients with symptoms suggestive of lymphoedema should be referred early for assessment by a designated lymphoedema practitioner.

#### **Treatment**

- **D** Patients with severe or poorly controlled lymphoedema should be offered decongestive lymphatic therapy (DLT) with a specialist lymphoedema practitioner.
- **D** Early and appropriate use of antibiotic therapy is recommended for patients with cellulitis.

# **Patient Self Management**

**D** - Patients with lymphoedema should be supported to self manage by a practitioner qualified in lymphoedema management.

## Follow Up

## **Post-treatment Surveillance**

- **D** History taking and clinical examination should be carried out during follow up of patients with cervical cancer to detect symptomatic and asymptomatic recurrence.
- **D** Cervical cytology or vault smears are not indicated to detect asymptomatic recurrence of cervical cancer.

## **Detection of Relapsed Disease**

- **C** MRI or CT should be considered initially to assess potential clinical recurrence in symptomatic patients.
- **B** A whole body PET scan or PET-CT should be performed on all patients in whom recurrent or persistent disease has been demonstrated on MRI or CT and in whom salvage therapy (either pelvic exenteration or radiotherapy) is being considered.

## **Management of Recurrent Disease**

## **Total Pelvic Exenteration**

- **D** Pelvic exenteration should be reserved as salvage surgery for women with recurrent cervical cancer in the central pelvis whose chemoradiotherapy has failed.
- $\boldsymbol{\mathsf{C}}$  MRI or CT should be considered initially to assess potential clinical recurrence in symptomatic patients.
- **B** A whole body PET scan or PET-CT should be performed on all patients in whom recurrent or persistent disease has been demonstrated on MRI or CT and in whom salvage therapy (either pelvic exenteration or radiotherapy) is being considered.

## Chemotherapy

- **B** Palliative chemotherapy should be offered to women with FIGO stage IVB or recurrent cervical carcinoma, after discussion of the relative benefits and risks, with either:
- Cisplatin 50 mg/m² on day 1 plus topotecan 0.75 mg/m² on days 1 to 3 every 3 weeks, or
- Cisplatin 50 mg/m<sup>2</sup> on day 1 plus paclitaxel 135 mg/m<sup>2</sup> every 3 weeks

## **Management of Complications in Advanced Disease**

## **Renal Failure**

- **D** Retrograde ureteric stents should be changed according to the level of ureteric obstruction (*ranging from 3 to 12 months*).
- **D** If a retrograde stent is unsuccessful:
- The stent should be changed more frequently
- An alternative stent should be tried
- Patients should be offered percutaneous nephrostomy (PCN) and/or antegrade stent.
- **D** Urinary diversion may be considered in suitable patients.
- **D** Patients should have careful follow up and access to counselling.

# **Thrombotic and Bleeding Problems**

Deep Venous Thrombosis

- **C** Low molecular weight heparin should be considered for treatment of deep venous thrombosis (DVT) and prevention of recurrent thromboembolism.
- **D** Compression garments, in conjunction with low molecular weight heparin (LMWH) and early walking exercises should be considered in patients with DVT.

Treatment of Minor Haemorrhage

- **D** Treatment for minor haemorrhage may include:
- · Oral tranexamic acid or aminocaproic acid
- Tranexamic acid applied topically to superficial fungating wound
- Tranexamic acid by rectal or bladder instillation
- A single fraction of radiotherapy

## **Psychosocial Care and Support for Patients and Carers**

## **Support Needs**

- **D** Patients with cervical cancer should be offered psychological support at the time of diagnosis and at intervals throughout their management.
- **D** Information about local support services should be made available to patients.
- **D** Carers, families and dependants should be made aware of support available including local and national organisations.

#### **Information Needs**

C - Patients should be offered information throughout their journey of care.

## **Communication Methods**

- **B** Healthcare professionals in cancer care should be trained in listening and communication skills.
- **B** Healthcare professionals in cancer care should consider giving either written summaries or audiotapes of consultations to people who have expressed a preference for them.

# **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 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

#### **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 of randomized 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+

**Good Practice Points**: Recommended best practice based on the clinical experience of the guideline development group

# **CLINICAL ALGORITHM(S)**

Algorithms are available in the original guideline document for:

- Investigation of Post-Coital Bleeding
- Imaging to Detect Relapsed Disease
- Management of Renal Failure in Patients with Cervical Cancer

## **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**

Appropriate management and treatment of women with cervical cancer

#### **POTENTIAL HARMS**

Risks involved in treatment, including adverse effects of radiation and chemotherapy and surgical complications

## **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.

## **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 Board 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.

#### **IMPLEMENTATION TOOLS**

Chart Documentation/Checklists/Forms Clinical Algorithm 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**

End of Life Care Getting Better Living with Illness

## **IOM DOMAIN**

Effectiveness Patient-centeredness

## **IDENTIFYING INFORMATION AND AVAILABILITY**

## **BIBLIOGRAPHIC SOURCE(S)**

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#### **ADAPTATION**

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

#### **DATE RELEASED**

2008 Jan

## **GUIDELINE DEVELOPER(S)**

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

# **SOURCE(S) OF FUNDING**

Scottish Government Health Department

## **GUIDELINE COMMITTEE**

Not stated

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

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

## **GUIDELINE AVAILABILITY**

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

### **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- Quick reference guide: Management of cervical cancer. Scottish
   Intercollegiate Guidelines Network, 2008. 2 pages. 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 <u>SIGN Web site</u>.
- 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>.

Additional tools, including a minimum dataset proforma and a screening tool for measuring distress are available in the Annexes of the <u>original guideline</u> <u>document</u>.

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This summary was completed by ECRI Institute on April 10, 2008. The information was verified by the guideline developer on May 21, 2008. This summary was updated by ECRI Institute on August 15, 2008 following the U.S. Food and Drug Administration advisory on Erythropoiesis Stimulating Agents (ESAs).

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