



Complete Summary

GUIDELINE TITLE

Amniocentesis and chorionic villus sampling.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Amniocentesis and chorionic villus sampling. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2005 Jan. 11 p. (Guideline; no. 8). [48 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Foetal chromosomal abnormalities, rhesus disease, infection, preterm labour, fetal lung immaturity

GUIDELINE CATEGORY

Diagnosis
Prevention
Risk Assessment
Screening

CLINICAL SPECIALTY

Family Practice
Medical Genetics
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To ensure that the timing and techniques for invasive prenatal diagnostic tests (amniocentesis or chorionic villus sampling) procedures do not vary significantly between practitioners and healthcare settings, thereby minimising associated risks
- To provide up-to-date information, based on clinical evidence, rates of miscarriage associated with the procedures, optimal techniques and timing, training and competence, and clinical governance issues

TARGET POPULATION

Pregnant women

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Procedures

1. Amniocentesis
2. Chorionic villus sampling (CVS)
 - Transcervical
 - Transabdominal
3. Ultrasound guidance for amniocentesis and CVS
4. Timing of procedures
5. Obtaining informed consent

Management of Specific Patient Populations

1. Multiple pregnancies
2. Hepatitis B positive patients
3. Hepatitis C positive patients
4. Human immunodeficiency virus (HIV)-positive patients (note that testing in this population is generally to be avoided)
5. Rhesus prophylaxis with anti-D immunoglobulin based on Rhesus status

MAJOR OUTCOMES CONSIDERED

- Miscarriage rate
- Complication rate

- Presence of fetal anomaly or abnormal karyotype
- Risks to fetus

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Cochrane Database of Systematic Reviews and the Cochrane Register of Controlled Trials were searched for relevant randomised controlled trials (RCTs), systematic reviews, and meta-analyses. A search of Medline and PubMed from 1966 to 2003 was also carried out.

The databases were searched using the relevant Medical Subject Heading (MeSH) terms, including all subheadings. This was combined with a keyword search using "amniocentesis," "chorionic villi sampling," "standards," and "adverse effects."

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

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

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

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading scheme used was based on a scheme formulated by the Clinical Outcomes Group of the National Health Service (NHS) Executive.

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Following discussion in the Guidelines and Audit Committee, each green-top guideline is formally peer reviewed. At the same time the draft guideline is

published on the Royal College of Obstetricians and Gynaecologists (RCOG) Web site for further peer discussion before final publication.

The names of author(s) and nominated peer reviewers are included in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (**Ia-IV**) and grading of recommendations (**A-C**) are defined at the end of the "Major Recommendations" field.

Timing of Amniocentesis and Chorionic Villus Sampling (CVS)

A - Early amniocentesis performed before 14 completed weeks of gestation (14+0) is not a safe alternative to second-trimester amniocentesis or CVS.

It is recommended that an early amniocentesis is undertaken only in exceptional circumstances after the mother has been made fully aware of the potential complications. [Evidence level Ia/Ib]

B - It is recommended that CVS should not be performed before 10 completed weeks of gestation (10+0).

Consent

It is good clinical practice to obtain formal consent for amniocentesis or CVS before the procedure. Practice should conform to recommendations on consent from the General Medical Council and the Royal College of Obstetricians & Gynaecologists (RCOG). Use of the Department of Health consent form 3 is recommended.

Written or oral information should include what results are possible from the procedure; how, when, and by whom it is performed; and how their practice is monitored. Information should also be given on:

- National and local risks of the procedures
- Analysis (and subsequent storage) of the sample in the local cytogenetics laboratory
- Accuracy of the particular laboratory test being performed
- Culture failure rates
- Reporting time
- Method of communication of results
- Indications for seeking medical advice following the test

Where written material is not used, the counselling process, including verbal consent, needs to be clearly recorded in the patient's notes.

Method

B - Amniocentesis is associated with higher rates of successful taps and lower rates of "bloody" taps when performed under direct ultrasound control with continuous needle tip visualization.

The current recommendation for 'continuous ultrasound control' rests on the need to avoid 'bloody taps,' because the presence of blood interferes with amniocyte culture. [Evidence level III]

Best practice is that ultrasound scanning during the procedure should be performed by the person inserting the needle. An alternative technique involves ultrasound scanning being performed by a separate practitioner. Whatever the individual's views, there is no objective evidence favouring one technique over the other.

B - A transplacental approach may be appropriate if it provides easy access to a pool of amniotic fluid, but care should be taken to avoid the cord insertion.

In fact, if a clear pool of amniotic fluid can be reached **only** by passage through the placenta then this is the approach of choice [Evidence level IIb].

B - The outer needle diameter should not be wider than 20-gauge (0.9 mm).

B - CVS should always be performed under direct ultrasound control.

Skill of the Operator

B - Very experienced operators performing amniocentesis may have a higher success rate and a lower procedure-related loss rate. Occasional operators who perform amniocentesis less than ten times per annum may have increased rates of procedure-related loss.

B - Independent performance of amniocentesis and CVS should only occur following adequate training, which should include the use of a clinical skills model, assessment of interaction with patients, and supervised procedures.

Before undertaking procedures on women, consideration should be given to initial training using a clinical skills model. [Evidence level III]

As there are no data to guide practice, individual centres should agree a training and assessment process that is open and transparent, and with a clearly responsible trainer. Local deaneries and NHS trust clinical governance systems should have a role in ensuring quality training. It is suggested that trainers should be performing at least 50 ultrasound-guided invasive procedures per annum.

Third Trimester Amniocentesis

B - Third-trimester amniocentesis does not appear to be associated with significant risk of emergency delivery. Compared with mid-trimester procedures, complications including multiple attempts and bloodstained fluid are more common.

Control of Infection

B - Invasive prenatal testing in the first or second trimester can be carried out in women who carry hepatitis B or C. The limitations of the available data should be explained. Testing in women with human immunodeficiency virus (HIV) should be avoided, particularly in the third trimester.

Rhesus status should be available or obtained in every case. Rhesus prophylaxis with anti-D immunoglobulin must be offered following each procedure in line with national recommendations. [Evidence level Ia]

Organisation of Care

Trusts and organisations should ensure that the equipment, environment, staff training, arrangements for follow up, and links with related services carrying out pregnancy termination or support for women with diagnosed chromosomal or genetic disease are of sufficient standard and that these aspects of care are continuously reviewed.

Definitions:

Grading of Recommendations

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of recommendations (evidence levels IIa, IIb, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well-designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasi-experimental study

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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 selected recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prenatal diagnosis of fetal chromosomal abnormalities

POTENTIAL HARMS

Complications of procedures, including miscarriage, "bloody" tap, and amniotic fluid leakage

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Clinical guidelines are "systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions." Each guideline is systematically developed using a standardised methodology. Exact details of this process can be found in Clinical Governance Advice No. 1: *Guidance for the Development of Royal College of Obstetricians & Gynaecologists (RCOG) Green-top Guidelines*. (See "Availability of Companion Documents" field.)
- These recommendations are not intended to dictate an exclusive course of management or treatment. They must be evaluated with reference to individual patient needs, resources and limitations unique to the institution, and variations in local populations. It is hoped that this process of local ownership will help to incorporate these guidelines into routine practice. Attention is drawn to areas of clinical uncertainty where further research may be indicated.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

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

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Amniocentesis and chorionic villus sampling. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2005 Jan. 11 p. (Guideline; no. 8). [48 references]

ADAPTATION

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

DATE RELEASED

1996 Oct (revised 2005 Jan)

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

Royal College of Obstetricians and Gynaecologists

GUIDELINE COMMITTEE

Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Deirdre J Murphy, MRCOG (Chair); Lizzy Dijeh (Secretary); Ms Toni Belfield, Consumers' Representative; Professor P R Braude, FRCOG, Chairman, Scientific Advisory Committee; Mrs C Dhillon, Head of Clinical Governance and Standards Dept.; Dr Martin Dougherty, A. Director NCC-WCH; Miss L M M Duley, FRCOG, Chairman, Patient Information Subgroup; Mr Alan S Evans, FRCOG; Dr Mehmet R Gazvani, MRCOG; Dr Rhona G Hughes, FRCOG; Mr Anthony J Kelly MRCOG; Dr Gwyneth Lewis, FRCOG, Department of Health; Dr Mary A C Macintosh, MRCOG, CEMACH; Dr Tahir A Mahmood, FRCOG; Mrs Caroline E Overton, MRCOG, Reproductive medicine; Dr David Parkin, FRCOG; Oncology; Ms Wendy Riches, NICE; Mr Mark C Slack, MRCOG, Urogynaecology; Mr Stephen A Walkinshaw, FRCOG, Maternal and Fetal Medicine; Dr Eleni Mavrides, Trainees Representative

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Guideline authors are required to complete a "declaration of interests" form.

No conflicts of interest were declared.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#).

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the [RCOG Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guidance for the development of RCOG green-top guidelines. Clinical Governance Advice No 1. 2000 Jan. Available from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#).
- Searching for evidence. Clinical Governance Advice No 3. 2001 Oct. Available from the [Royal College of Obstetricians and Gynaecologists \(RCOG\) Web site](#).

Additionally, auditable standards can be found in section 13 of the [original guideline document](#).

PATIENT RESOURCES

None available

NGC STATUS

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