Complete Summary

GUIDELINE TITLE

Prevention of early onset neonatal group B streptococcal disease.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Prevention of early onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Nov. 10 p. (Guideline; no. 36). [39 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Early onset neonatal group B streptococcal disease

GUIDELINE CATEGORY

Prevention
Risk Assessment
Screening
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physicians

GUIDELINE OBJECTIVE(S)

To provide guidance for obstetricians, midwives, and neonatologists on the prevention of early-onset neonatal group B streptococcal (GBS) disease

TARGET POPULATION

Pregnant women and newborn infants

INTERVENTIONS AND PRACTICES CONSIDERED

Prophylactic Antibiotic Therapy in Pregnant Women

1. Intrapartum antibiotic prophylaxis (to women with a previous baby with neonatal group B streptococcal (GBS) disease or with GBS bacteriuria or in whom GBS is detected incidentally)
    - Penicillin
    - Clindamycin
2. Broad spectrum antibiotic therapy for chorioamnionitis

Management of Newborn Infants with Clinical Signs of GBS Disease

1. Broad spectrum antibiotic therapy
2. Blood cultures
3. Cerebrospinal fluid (CSF) cultures

The following interventions were considered but not recommended: antenatal screening (bacteriological or risk based) for antenatal GBS carriage, antenatal treatment with penicillin, intrapartum antibiotic prophylaxis for women in whom GBS was detected in a previous pregnancy, postnatal antibiotic prophylaxis for newborn infants, antibiotic prophylaxis for women undergoing planned caesarean section in the absence of labour and with intact membranes, and for women with preterm rupture of membranes unless they are in established labour.

MAJOR OUTCOMES CONSIDERED

- Incidence of early onset group B streptococcal (GBS) disease
- Side effects of pharmacological therapy
- Mortality of early onset GBS disease

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 Medline were searched using the terms "group B streptococcus," "*Streptococcus agalactiae*," "pregnancy," and "neonate."

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

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
Internal 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) website 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.

Antenatal Screening

C - Routine screening (either bacteriological or risk based) for antenatal group B streptococcal (GBS) carriage is not recommended.

Prophylaxis

Should Women Be Treated Antenatally, if GBS is Detected Incidentally?

B - Antenatal treatment with penicillin is not recommended.

Should Women Receive Intrapartum Antibiotic Prophylaxis, if GBS Detected Incidentally?

C - Intrapartum antibiotic prophylaxis should be considered if GBS is detected incidentally.

Should Women Receive Intrapartum Antibiotic Prophylaxis if GBS Was Detected in a Previous Pregnancy?

C - There is no good evidence to support the administration of intrapartum antibiotic prophylaxis to women in whom GBS carriage was detected in a previous pregnancy. [Evidence level IV]

Should Women with a Previous Baby with Neonatal GBS Disease Be Offered Intrapartum Antibiotic Prophylaxis?

C - Intrapartum antibiotic prophylaxis should be offered to women with a previous baby with neonatal GBS disease.

Vaginal or rectal swabs are not helpful, as intrapartum antibiotic prophylaxis would be recommended even if these swabs were negative for GBS. [Evidence level IV]

Intrapartum Antibiotic Prophylaxis for Other Groups

C - Clinicians should use Table 1 in the original guideline document to inform discussions with women regarding the use of intrapartum antibiotic prophylaxis in the presence of known risk factors including incidental carriage. The argument for prophylaxis becomes stronger in the presence of two or more risk factors. [Evidence level IV]

A - If chorioamnionitis is suspected, broad-spectrum antibiotic therapy including an agent active against GBS should replace GBS-specific antibiotic prophylaxis. [Evidence level Ib]

B - Intrapartum antibiotic prophylaxis (IAP) should be offered to women with GBS bacteriuria in the current pregnancy after discussion.

GBS bacteriuria is associated with a higher risk of neonatal disease. Again, it is not possible to quantify this increased risk. These women should be offered antibiotic prophylaxis after appropriate discussion. Women with GBS urinary tract infection during pregnancy should receive appropriate treatment at the time of diagnosis as well as antibiotic prophylaxis. [Evidence level III]

C - Antibiotic prophylaxis is not required for women undergoing planned caesarean section in the absence of labour and with intact membranes.

Women undergoing planned caesarean delivery in the absence of labour or membrane rupture do not require antibiotic prophylaxis for GBS, regardless of GBS colonisation status. The risk of neonatal GBS disease is extremely low in this circumstance. [Evidence level IV]

C - Antibiotic prophylaxis for GBS is unnecessary for women with preterm rupture of membranes unless they are in established labour.

Antibiotic administration specifically for GBS colonisation is not necessary prior to labour. If these women are known to be colonised with GBS, antibiotic prophylaxis should be considered, especially if labour occurs prior to 37 weeks (see Table 1 in original guideline document). [Evidence level IV]

Which Antibiotics Should be Given?

B - Penicillin should be administered as soon as possible after the onset of labour. Clindamycin should be administered to those women allergic to penicillin.

It is recommended that intravenous penicillin 3 g be given as soon as possible after the onset of labour and 1.5 g four-hourly until delivery. Clindamycin 900 mg should be given intravenously eight-hourly to those allergic to penicillin. It should be noted that these doses are based on tradition rather than good evidence. Broad-spectrum antibiotics such as ampicillin should be avoided if possible, as concerns have been raised regarding increased rates of neonatal Gram negative sepsis. To optimise the efficacy of antibiotic prophylaxis, the first dose should be given at least two hours prior to delivery. [Evidence level III]

Management of the Newborn Infant

Sick Infants

C - Newborn infants with clinical signs of early-onset GBS disease should be treated promptly with the necessary antibiotics.

Whether they received intrapartum antibiotics or not, any newborn infant with clinical signs compatible with infection should be treated promptly with broad-spectrum antibiotics, which provide cover against early-onset GBS disease and other common pathogens. Blood cultures should always be obtained before antibiotic treatment is commenced, and cerebrospinal fluid (CSF) cultures should be considered. [Evidence level IV]

Low-Risk Term Infants

B - Postnatal antibiotic prophylaxis is not recommended for low-risk term infants.

Well Infant with Risk Factor, Including Incidental Finding of Maternal GBS Carriage, With or Without Intrapartum Antibiotics

C - Randomised controlled trials (RCTs) have not provided a sufficient evidence base for clear treatment recommendations in well newborn infants.

Previous Infant with GBS Disease

C - For an infant whose mother had a previous infant with GBS disease, either clinical evaluation after birth and observation for at least twelve hours are necessary, or blood cultures should be obtained and the infant treated with penicillin until the culture results are available.

Breastfeeding

C - Breastfeeding does not increase the risk of neonatal GBS disease, and women concerned about late-onset disease should be given the usual advice about breastfeeding. [Evidence level IV]

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

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

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" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening and management for the prevention of early onset group B streptococcal disease

POTENTIAL HARMS

- The incidence of severe anaphylaxis associated with the use of penicillin in labour has been estimated at 1/10,000 women treated. Fatal anaphylaxis has been estimated to occur in as many as 1/100,000 women treated.
- The widespread use of antibiotics is known to contribute to the development of resistance organisms. This is a particular risk when broad-spectrum antibiotics are used but should not be ignored as a possibility with using penicillin.
- Exposure to antibiotics in the neonatal perinatal period may affect neonatal faecal flora, with a subsequent impact on immune development and later allergy.

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*.
- 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

Pocket Guide/Reference Cards

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

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). Prevention of early onset neonatal group B streptococcal disease. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2003 Nov. 10 p. (Guideline; no. 36). [39 references]

ADAPTATION

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

DATE RELEASED

2003 Nov

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

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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

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:

- Prevention of early onset neonatal group B streptococcal disease. Recommendations from Green-Top Guideline No. 36. 2003 Nov. 1 p. Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.
- 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.

PATIENT RESOURCES

None available

NGC STATUS

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