Complete Summary

GUIDELINE TITLE

Guideline for blood grouping and antibody testing in pregnancy.

BIBLIOGRAPHIC SOURCE(S)

Gooch A, Parker J, Wray J, Qureshi H. Guideline for blood grouping and antibody testing in pregnancy. London (UK): British Committee for Standards in Haematology (BCSH); 2006. 22 p. [48 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Pregnancy
- Fetal anaemia
- Hemolytic disease of the newborn (HDN) and fetus
- Hydrops fetalis

GUIDELINE CATEGORY

Evaluation
Management

CLINICAL SPECIALTY

Family Practice
Hematology
Internal Medicine
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Clinical Laboratory Personnel
Physicians

GUIDELINE OBJECTIVE(S)

To define the red cell immunohaematology tests which should be applied in pregnancy to prevent haemolytic disease of the fetus and newborn

TARGET POPULATION

Pregnant women in the United Kingdom

INTERVENTIONS AND PRACTICES CONSIDERED

1. Sample handling
2. ABO and Rh D blood typing
3. Issuing of blood group cards to women who are D negative
4. Maternal screening by indirect antiglobulin test [IAT] and processing (column agglutination, liquid-phase tube, solid-phase methods; reagent cells)
5. Additional antibody testing (Anti-A and anti-B testing (not recommended), anti-c, anti-K or other Kell antibodies, anti-G, other antibodies associated with haemolytic disease of the newborn [HDN])
6. Antenatal and postnatal maternal testing protocols (timing of tests)
7. Routine antenatal anti-D prophylaxis (RAADP)
8. Identification of sensitising events
9. Antibody testing after administration of prophylactic anti-D
10. Paternal testing
11. Fetal testing

MAJOR OUTCOMES CONSIDERED

- Fetal mortality
- Feto-maternal haemorrhage
- Spontaneous miscarriage

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
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A search of published literature was undertaken using PubMed, Cochrane Library and Ingenta databases. The National Institute for Health and Clinical Excellence (NICE) guidance and Health Technology Assessment underpinned the evidence base to support the review work. A comprehensive literature search was undertaken to capture information applicable to the review aims. The search was undertaken in 2004 using Medline, for the past 20 years and the key words were anti D, prophylaxis, antibodies in pregnancy, haemolytic disease of the newborn. In addition, broad termed searches were made of the Cochrane Library and Medscape. Appropriate non-published literature, published policy documents and knowledge from experts in the field were incorporated and utilised.

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

Level 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 randomization

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

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

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

A writing group was formed to synthesise and collate the information. This covered the period 1999-2004. The papers included were subjected to critical reading by the authors using the Critical Appraisal Skills Programme (CASP) appraisal tool and were also ranked according to the hierarchy of evidence. This approach took account of the National Institute for Health and Clinical Excellence (NICE) systematic review undertaken in 2000 so as to be contemporary in locating and including the relevant literature.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline group was selected to be representative of UK based medical experts and patients' representatives.

The writing group produced the draft guideline which was subsequently revised by consensus by members of the Transfusion Task Force of the British Committee for Standards in Haematology.

Appropriate non-published literature, published policy documents and knowledge from experts in the field were incorporated and utilised.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade of Recommendation

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

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

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

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

The guideline was reviewed by a sounding board of United Kingdom (UK) haematologists, the British Committee for Standards in Haematology (BCSH) and the British Society for Haematology (BSH) Committee and comments incorporated where appropriate.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Recommendation grades (**A-C**) and levels of evidence (**Ia-IV**) are defined at the end of the "Major Recommendations" field.

Recommendations for Samples and Request Forms

1. Samples for antenatal screening are identified to the same standard as pre-transfusion samples. (**Good Practice Point [GPP]**)
2. Samples should be dated, labelled and signed by the person taking them, in the presence of the patient who should be asked to confirm demographic details. Any labels pre-printed away from the phlebotomy procedure, e.g., Addressograph labels, should not be accepted on the specimen [Chapman et al., 2004]. **(Level IV, Grade C**)

Recommendations for Laboratory Testing

3. ABO and D grouping must be performed in accordance with the guidelines for compatibility procedures in blood transfusion laboratories [Chapman et al., 2004].(**Level IV, Grade C**)
4. All pregnant women found to be D negative should be issued with blood group cards to inform them, and those responsible for their care, of the D negative status and the need for prophylactic anti-D. (**Level IV, Grade C**)
5. The screening cells and methods used for red cell antibody screening should comply with the guidelines for compatibility procedures in blood transfusion laboratories [Chapman et al., 2004]. (**Level IV, Grade C**)

Antenatal Testing Protocols

See also the clinical algorithm in the original guideline document.

6. All pregnant women should be ABO and D typed and screened for the presence of red cell antibodies early in pregnancy and at 28 weeks gestation [National Collaborating Centre for Women's and Children's Health, 2003]. (**Level III, Grade B**)
7. Blood transfusion laboratories should keep a record of anti-D administration to provide a basis for distinguishing between immune and prophylactic anti-D. (**Level IV, Grade C**)
8. Cases of anti-D, anti-c and anti-K [unless the father is confirmed K negative] should be assessed at monthly intervals to 28 weeks gestation and at fortnightly intervals thereafter. Such cases must be referred to a specialist

fetal medicine unit if the antibody reaches the critical level and/or the level is rising significantly. (**Grade B**)

9. Clinically significant antibodies, other than anti-D, -c or -K, should be assessed, and other antibodies excluded, at 'first appointment' and at 28 weeks gestation. (**Level IIb Grade B**)
10. All women who have previously had an infant affected by haemolytic disease of the newborn (HDN) should be referred before 20 weeks to a specialist unit for advice and for assessment of fetal haemolysis, irrespective of antibody level. (**Level IIa Grade B**)

Reports of Laboratory Investigation

11. Women with clinical significant red cell antibodies should be issued with a card giving details of the antibody. (**GPP**)

Action at Time of Birth

12. All infants born to women who have clinically significant antibodies should be closely observed for evidence of HDN. A direct antiglobulin test (DAT) should be performed and if positive, haemoglobin and bilirubin levels should be measured. (**Level IV, Grade C**)

Definitions:

Level of Evidence

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CLINICAL ALGORITHM(S)

The original guideline document contains the clinical algorithm "Samples and Testing Required in a Viable Pregnancy."

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

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

Reduction in fetal morbidity and mortality

POTENTIAL HARMS

- The risks associated with the misinterpretation of passive and immune anti-D are clear: if passive anti-D is misinterpreted as immune, anti-D prophylaxis may be omitted leaving the women unprotected from sensitisation. If immune anti-D is misinterpreted as passive, appropriate follow-up of the antibody level during pregnancy may be curtailed putting the fetus at risk.
- The fetus can be K typed from an amniocentesis sample, but this sampling involves physical intervention with associated risks to the fetus and of stimulating the antibody level. These invasive techniques carry a small risk of spontaneous miscarriage and may boost maternal antibody levels.

QUALIFYING STATEMENTS

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While the advice and information in these guidelines is believed to be true and accurate at the time of going to press, neither the authors, the British Society for Haematology nor the publishers accept any legal responsibility for the content of these guidelines.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Audits of practice should be undertaken on a continuing basis to ensure compliance with these guidelines and, where identified, variance or concerns in relation to compliance, should be addressed.

IMPLEMENTATION TOOLS

Clinical Algorithm

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

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

British Committee for Standards in Haematology - Professional Association

SOURCE(S) OF FUNDING

British Committee for Standards in Haematology

GUIDELINE COMMITTEE

Writing Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Writing Group: Gooch A, National Blood Service, Manchester; Parker J, Department of Haematology, Derby City Hospital, Derby; Wray J, University of Salford, Salford, Greater Manchester; Qureshi H, Department of Haematology, University Hospitals of Leicester, Leicester, UK

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

None of the authors have declared a conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the British Committee for Standards in Haematology Web site.

Print copies: Available from the British Committee for Standards in Haematology; Email: bcsh@b-s-h.org.uk.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on May 27, 2008. The information was verified by the guideline developer on June 30, 2008.

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Date Modified: 10/6/2008