Complete Summary

GUIDELINE TITLE

Immunization of preterm and low birth weight infants.

BIBLIOGRAPHIC SOURCE(S)

Saari TN. Immunization of preterm and low birth weight infants. Pediatrics 2003 Jul;112(1 Pt 1):193-8. [45 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Vaccine-preventable diseases:

- Hepatitis B
- Diphtheria
- Tetanus
- Pertussis
- *Haemophilus influenzae* b infection
- Poliomyelitis

- Pneumococcal disease
- Influenza

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide updated information on the immunogenicity, durability, and safety of routinely recommended childhood vaccines given to preterm and low birth weight infants

TARGET POPULATION

Preterm and low birth weight infants

INTERVENTIONS AND PRACTICES CONSIDERED

Routine immunization using:

1. Hepatitis B vaccine
2. Diphtheria and tetanus toxoids with acellular pertussis (DTaP) vaccine
3. Inactivated poliovirus (IPV) vaccine
4. *Haemophilus influenzae* type b (Hib) vaccine
5. Heptavalent pneumococcal conjugate vaccine (PCV7)
6. Influenza vaccine

MAJOR OUTCOMES CONSIDERED

- Seroconversion rates
- Antibody concentrations
- Vaccine-associated adverse events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

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

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

General

Timing

Medically stable preterm (PT) and low birth weight (LBW) infants should receive all routinely recommended childhood vaccines at the same chronologic age as recommended for full-term (FT) infants. Under most circumstances, gestational age at birth and birth weight should not be limiting factors when deciding whether a PT or LBW infant is to be immunized on schedule. Infants with birth weight less than 2,000 g, however, may require modification of the timing of hepatitis B immunoprophylaxis depending on maternal hepatitis B surface antigen (HbsAg) status.

Dosing

Vaccine dosages normally given to FT infants should not be reduced or divided when given to PT and LBW infants. Although studies have shown decreased immune responses to some vaccines given to very low birth weight (VLBW), extremely low birth weight (ELBW), and very early gestational age (<29 weeks) neonates, most PT infants produce sufficient vaccine-induced immunity to prevent disease when full doses are given. The severity of vaccine-preventable diseases in PT and LBW infants precludes any delay in initiating the administration of these vaccines.

Vaccine Administration

The anterolateral thigh is the site of choice when administering intramuscular vaccines to PT infants. The choice of needle length used for intramuscular vaccine administration is made on the basis of the available muscle mass of the PT infant and may be less than the standard 7/8-inch to 1-inch length used for FT infants (Atkinson et al., 2002).

Hepatitis B

Infants Born to HBsAg-Negative Mothers

Medically stable PT infants and infants weighing greater than 2,000 g at birth should be treated like FT infants and preferentially receive the first dose of monovalent hepatitis B vaccine shortly after birth and no later than hospital discharge. Practitioners who are certain of the mother's negative HBsAg status and wish to use a hepatitis B-containing combination vaccine for PT and LBW infants with birth weight greater than 2,000 g must delay the first dose of the combination vaccine until the infant is at least 6 weeks of age. There is no contraindication to giving a birth dose of hepatitis B vaccine as the first of 4 doses when a combination vaccine containing hepatitis B vaccine subsequently is used. The final dose of hepatitis B vaccine should not be given earlier than 6 months chronologic age.

Medically stable PT and LBW infants with birth weight less than 2,000 g should receive the first dose of hepatitis B vaccine as early as 30 days of chronologic age regardless of gestational age or birth weight. Alternatively, PT and LBW infants weighing less than 2,000 g showing consistent weight gain leading to discharge home from the hospital before attaining 30 days of age should receive the first dose of hepatitis B vaccine at the time of hospital discharge.

Infants Born to HBsAg-Positive Mothers

PT and LBW infants born to mothers who are HBsAg positive must receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours after birth, regardless of gestational age or birth weight. Infants weighing less than 2,000 g and born to HBsAg-positive mothers should not have the birth dose of hepatitis B vaccine counted as part of the hepatitis B virus (HBV) immunization series, and 3 additional doses of hepatitis B vaccine should be given starting at 1 month of age. Combination vaccines containing a hepatitis B component have not been assessed for efficacy when given to infants born to HBsAg-positive mothers. All infants of HBsAg-positive mothers should be tested for the presence of antibody to hepatitis B surface antigen (anti-HBs) and HBsAg at 9 to 15 months of age, after completion of the HBV immunization series. Some experts prefer to perform serologic testing 1 to 3 months after completion of the primary series.

Infants Born to Mothers Whose HBsAg Status Is Unknown

All PT and LBW infants born to mothers whose HBsAg status is unknown at the time of delivery should receive monovalent hepatitis B vaccine within 12 hours of birth. Because infants weighing less than 2,000 g have less predictable responses to hepatitis B vaccine given at birth, they should be given hepatitis B immune globulin by 12 hours of life if the mother's HBsAg status cannot be determined within that time period. Hepatitis B immune globulin may be delayed up to 7 days for PT and LBW infants weighing more than 2,000 g at birth while awaiting the mother's HBsAg test results.

Table 1 in the original guideline provides a schematic outline for hepatitis B immunoprophylaxis given to PT and LBW infants.

Diphtheria and Tetanus Toxoid and Acellular Pertussis (DTaP), *Haemophilus influenzae* Type b (Hib), and Inactivated Poliovirus (IPV) Vaccines

All medically stable PT and LBW infants should begin routine childhood immunization with full doses of any DTaP, Hib, and IPV vaccines licensed by the Food and Drug Administration at 2 months of chronologic age regardless of gestational age or birth weight. Although apnea has not been reported in ELBW infants born at less than 31 weeks' gestation after the use of DTaP vaccine alone, in conjunction with other routinely recommended childhood vaccines, or in combination with other vaccine antigens, it is deemed prudent to closely observe hospitalized ELBW infants for significant adverse events for up to 72 hours after immunization until such a time that sufficient data have been collected to firmly establish a pattern of safety.

Pneumococcal Conjugate Vaccine (PCV7)

All PT and LBW infants are considered at increased risk of invasive pneumococcal disease, and medically stable PT patients should receive full doses of PCV7 beginning at 2 months of chronologic age.

Influenza

All PT infants are considered at high risk of complications of influenza virus infection and should be offered influenza vaccine beginning at 6 months of age and as soon as possible before the beginning and during influenza season. PT and LBW infants receiving influenza vaccine for the first time will require 2 doses of vaccine administered 1 month apart.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The conclusions in the guideline are based on current knowledge of the immune response of preterm infants to specific antigens contained in various vaccines. These data, however, are limited by the relatively small number of preterm infants studied to date.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Benefit

- Routine immunization of preterm (PT) and low birth weight (LBW) infants with vaccines universally given to full-term infants
- Although the immunogenicity of some childhood vaccines may be decreased in the smallest PT infants, antibody concentrations achieved usually are protective.

Specific Benefit

- Earlier initiation of hepatitis B virus (HBV) immunization provides timely protection of vulnerable PT infants who are more likely to receive multiple blood products and undergo surgical interventions. The theoretic risk of horizontal transmission from household members and other hospital visitors with chronic hepatitis B infection also would be minimized. Finally, hepatitis B vaccine given closer to the time of birth increases the likelihood that the

hepatitis B vaccine series and other recommended childhood vaccines will be completed on time.

POTENTIAL HARMS

Adverse Events

In a study of 1,756 low birth weight (LBW) infants and 4,340 preterm (PT) infants assessed for pneumococcal conjugate vaccine (PCV7) immunogenicity, efficacy, and safety, the following results were published: Most local and systemic adverse events from PCV7 were similar in PT and full-term (FT) vaccine recipients. PT and LBW recipients of PCV7 had more fever, emesis, irritability, and tenderness or swelling at the injection site than did infants in a control group. Urticarial reactions within 48 hours of PCV7 administration were more common in FT and PT infants compared with controls. PT infants receiving PCV7 concomitantly with diphtheria and tetanus toxoids with whole-cell pertussis (DTwP) and *Haemophilus influenzae* type b (Hib) vaccines experienced more febrile seizures compared with FT infants, but this may be reflective of the increased propensity for febrile convulsions of PT infants, immunizations notwithstanding.

QUALIFYING STATEMENTS

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The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

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

DATE RELEASED

2003 Jul

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee on Infectious Diseases, 2002-2003: Jon S. Abramson, MD, *Chairperson*; Carol J. Baker, MD; Robert S. Baltimore, MD; Joseph A. Bocchini, Jr, MD; Sarah S. Long, MD; Julia A. McMillan, MD; H. Cody Meissner, MD; Keith R. Powell, MD; Charles G. Prober, MD; Margaret B. Rennels, MD; Thomas N. Saari, MD; Leonard B. Weiner, MD

Liaisons: Jack Swanson, MD, AAP Practice Action Group; Joanne Embree, MD, Canadian Paediatric Society; Marc A. Fischer, MD, Centers for Disease Control and Prevention; Martin C. Mahoney, MD, American Academy of Family Physicians; Mamodikoe Makhene, MD, National Institutes of Health; Bruce G. Gellin, MD, MPH, National Vaccine Program Office; Walter A. Orenstein, MD, Centers for Disease Control and Prevention; Douglas R. Pratt, MD, Food and Drug Administration; Jeffrey R. Starke, MD, American Thoracic Society

Red Book Editor: Larry K. Pickering, MD

Consultant: Edgar O. Ledbetter, MD

Staff: Martha Cook, MS

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Pediatrics (AAP) Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 20, 2004. The information was verified by the guideline developer on May 27, 2004.

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