



## Complete Summary

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### GUIDELINE TITLE

Guideline for the evaluation of cholestatic jaundice in infants: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition.

### BIBLIOGRAPHIC SOURCE(S)

Moyer V, Freese DK, Whittington PF, Olson AD, Brewer F, Colletti RB, Heyman MB. Guideline for the evaluation of cholestatic jaundice in infants: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. *J Pediatr Gastroenterol Nutr* 2004 Aug;39(2):115-28. [135 references]  
[PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

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## SCOPE

### DISEASE/CONDITION(S)

Cholestatic jaundice

### GUIDELINE CATEGORY

Diagnosis  
Evaluation

### CLINICAL SPECIALTY

Family Practice  
Gastroenterology  
Pediatrics

## **INTENDED USERS**

Advanced Practice Nurses  
Nurses  
Physician Assistants  
Physicians

## **GUIDELINE OBJECTIVE(S)**

To provide a guideline for the diagnostic evaluation of cholestatic jaundice in infants

## **TARGET POPULATION**

Two- to 8-week-old infants with cholestatic jaundice in primary care outpatient settings and specialty referral facilities

**Note:** This guideline is not intended for the care of the ill premature infant in the intensive care setting.

## **INTERVENTIONS AND PRACTICES CONSIDERED**

1. Measurement of total and direct serum bilirubin
2. Medical history (cholestasis of pregnancy, consanguinity, urine color, stool color)
3. Physical examination (vital signs, assessment of general health, skin condition)
4. Consultation with a pediatric gastroenterologist
5. Laboratory tests: complete blood count, platelet count, prothrombin time, albumin, alanine transaminase, aspartate transaminase, alkaline phosphatase, alpha-1 antitrypsin, urine reducing substances
6. Abdominal ultrasound
7. Percutaneous liver biopsy

**Note:** The following diagnostic tests were considered but not routinely recommended: gamma-glutamyl transpeptidase (GGTP), lipoprotein X, scintigraphy, duodenal aspirate, magnetic resonance cholangiopancreatography (MRCP), and endoscopic retrograde cholangiopancreatography (ERCP).

## **MAJOR OUTCOMES CONSIDERED**

Sensitivity, specificity, accuracy, and safety of diagnostic procedures used to diagnose cholestatic jaundice in infants

## **METHODOLOGY**

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

## **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

To develop evidence-based estimates of the sensitivity, specificity, and accuracy of the diagnostic tests under consideration, Medline (1966--2002) was searched without language restriction using the terms listed in Table 2 of the original guideline document. Unpublished literature was not sought.

Abstracts for articles found in each search were reviewed for relevance. After editorials, letters, and review articles were eliminated, original studies that appeared to address the accuracy and reliability of the tests in question for the diagnosis of biliary atresia were retrieved in full and independently reviewed by two committee members.

## **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**

### **Coding Scheme for Quality of Evidence**

#### **Level A**

Recommendation based on 2 or more studies that compared the test to a criterion standard in an independent, blind manner in an unselected population of infants similar to those addressed in the guideline.

#### **Level B**

Recommendation based on a single study that compared the test to a criterion standard in an independent, blind manner in an unselected population of infants similar to those addressed in the guideline.

#### **Level C**

Recommendation based on lower quality studies or studies for which inadequate information is provided to assess quality, together with expert opinion and consensus of the committee.

#### **Level D**

No studies available; recommendations based on expert opinion and consensus of the committee.

## **METHODS USED TO ANALYZE THE EVIDENCE**

Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Two guideline committee members independently reviewed studies using previously published criteria for the validity of studies of diagnostic tests (refer to Table 3 in the original guideline document). The key criteria include an independent, blind comparison of the diagnostic test to a criterion standard, performed in nonselected, consecutive patients at risk for the condition of interest. Studies were considered to meet minimum criteria for validity if the test was performed in consecutive patients and did not appear to influence the determination of the final diagnosis. Each article was assigned a score based on these criteria, and the quality of evidence underlying each of the recommendations made by the Cholestasis Guideline Committee was determined.

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus (Nominal Group Technique)

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

The Cholestasis Guideline Committee based its recommendations on a comprehensive and systematic review of the medical literature integrated with expert opinion. Consensus was achieved through the Nominal Group Technique, a structured quantitative method.

## **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**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

The guidelines were reviewed by primary care physicians in community and academic practices. In addition, the guidelines were distributed to the North

American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) membership for review and comment and were officially endorsed by the NASPGHAN Executive Council.

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

*Note from the National Guideline Clearinghouse (NGC):* The following key points summarize the content of the guideline recommendations. Refer to the full text for additional information, including detailed information about the initial evaluation of the jaundiced infant, the initial evaluation of the infant with conjugated hyperbilirubinemia, and diagnostic tests used for further evaluation of the infant with cholestasis.

Levels of evidence (A-D) are defined at the end of "Major Recommendations" field.

It is recommended that any infant noted to be jaundiced at 2 weeks of age be clinically evaluated for cholestasis with measurement of total and direct serum bilirubin. However, breast-fed infants who can be reliably monitored and who have an otherwise normal history (no dark urine or light stools) and physical examination may be asked to return at 3 weeks of age and, if jaundice persists, have measurement of total and direct serum bilirubin at that time. **(C)**

Retest any infant with an acute condition or other explanation for jaundice whose jaundice does not resolve with appropriate management of the diagnosed condition. **(D)**

Ultrasound is recommended for infants with cholestasis of unknown etiology. **(A)**

Liver biopsy is recommended for most infants with cholestasis of unknown etiology. **(A)**

Gamma-glutamyl transpeptidase (GGTP) and lipoprotein X are not routinely recommended in the evaluation of cholestasis in young infants. **(C)**

Scintigraphy and duodenal aspirate are not routinely recommended but may be useful in situations in which other tests are not readily available. **(A)**

Magnetic resonance cholangiopancreatography (MRCP) and endoscopic retrograde cholangiopancreatography (ERCP) are not routinely recommended, although ERCP may be useful in experienced hands. **(C)**

#### **Definitions:**

#### **Coding Scheme for Quality of Evidence**

##### **Level A**

Recommendation based on 2 or more studies that compared the test to a criterion standard in an independent, blind manner in an unselected population of infants similar to those addressed in the guideline.

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#### **Level D**

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### **CLINICAL ALGORITHM(S)**

An algorithm is provided in the original guideline document for diagnostic evaluation of cholestatic jaundice for a 2- to 8-week-old infant.

## **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**

Early detection of cholestatic jaundice by the primary care provider and timely, accurate diagnosis by the pediatric gastroenterologist are important for successful treatment and a favorable prognosis.

### **POTENTIAL HARMS**

Not stated

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

These recommendations are a general guideline and are not intended as a substitute for clinical judgment or as a protocol for the care of all patients with this problem.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### 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

Getting Better

### IOM DOMAIN

Effectiveness  
Timeliness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Moyer V, Freese DK, Whittington PF, Olson AD, Brewer F, Colletti RB, Heyman MB. Guideline for the evaluation of cholestatic jaundice in infants: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr 2004 Aug;39(2):115-28. [135 references] [PubMed](#)

### ADAPTATION

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

### DATE RELEASED

2004 Aug

### GUIDELINE DEVELOPER(S)

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition  
- Professional Association

#### **SOURCE(S) OF FUNDING**

North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

#### **GUIDELINE COMMITTEE**

Cholestasis Guideline Committee

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

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#### **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

Not stated

#### **ENDORSER(S)**

American Academy of Pediatrics - Medical Specialty Society

#### **GUIDELINE STATUS**

This is the current release of the guideline.

#### **GUIDELINE AVAILABILITY**

Electronic copies: Available in Portable Document Format (PDF) from the [North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition \(NASPGHAN\) Web site](#).

Print copies: Available from NASPGHAN, PO Box 6, Flourtown, PA 19031; Telephone (215) 233-0808; Fax (215) 233-3939; E-mail: [naspghan@naspghan.org](mailto:naspghan@naspghan.org).

#### **AVAILABILITY OF COMPANION DOCUMENTS**

None available

#### **PATIENT RESOURCES**

None available

#### **NGC STATUS**

This NGC summary was completed by ECRI on May 19, 2005.

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