



## Complete Summary

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### GUIDELINE TITLE

Cord blood banking for potential future transplantation.

### BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Section on Hematology/Oncology, American Academy of Pediatrics Section on Allergy/Immunology, Lubin BH, Shearer WT. Cord blood banking for potential future transplantation. Pediatrics 2007 Jan;119(1):165-70. [62 references] [PubMed](#)

### GUIDELINE STATUS

This is the current release of the guideline.

All clinical reports and policy statements from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

## COMPLETE SUMMARY CONTENT

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## SCOPE

### DISEASE/CONDITION(S)

Diseases or conditions that are treatable with umbilical cord blood transplantation, including:

- Malignancies
- Bone marrow failure
- Hemoglobinopathies
- Immunodeficiencies
- Inborn errors of metabolism

**GUIDELINE CATEGORY**

Counseling  
Management

**CLINICAL SPECIALTY**

Allergy and Immunology  
Family Practice  
Hematology  
Obstetrics and Gynecology  
Oncology  
Pediatrics

**INTENDED USERS**

Physicians

**GUIDELINE OBJECTIVE(S)**

- To provide information to guide physicians in responding to parents' questions about cord blood donation and banking and the types and quality of cord blood banks
- To provide recommendations about appropriate ethical and operational standards, including informed consent policies, financial disclosures, and conflict-of-interest policies for physicians, institutions, and organizations that operate or have a relationship with cord blood-banking programs

**TARGET POPULATION**

Prospective parents seeking information on cord blood banking

**INTERVENTIONS AND PRACTICES CONSIDERED**

1. Counseling of prospective parents about benefits and risks of cord blood banking and transplantation
2. Obtaining informed and written consent for cord blood donation
3. Cord blood banking (when there is knowledge of a full sibling in the family with a medical condition that could potentially benefit from cord blood transplantation)
4. Cord blood donation
5. Genetic and infectious disease testing of donated cord blood
6. Appropriate policies and procedures for cord blood collection, processing, and storage
7. Appropriate ethical and legal standards for cord blood banking, including financial disclosures and conflict-of-interest policies for physicians and institutions

**MAJOR OUTCOMES CONSIDERED**

Not stated

## 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**

Not stated

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

Not applicable

## RECOMMENDATIONS

### MAJOR RECOMMENDATIONS

Cord blood transplantation has been shown to be curative in patients with a variety of serious diseases. Physicians should be familiar with the rationale for cord blood banking and with the types of cord blood-banking programs available. Physicians consulted by prospective parents about cord blood banking can provide the following information:

1. Cord blood donation should be discouraged when cord blood stored in a bank is to be directed for later personal or family use, because most conditions that might be helped by cord blood stem cells already exist in the infant's cord blood (i.e., premalignant changes in stem cells). Physicians should be aware of the unsubstantiated claims of private cord blood banks made to future parents that promise to insure infants or family members against serious illnesses in the future by use of the stem cells contained in cord blood. Although not standard of care, directed cord blood banking should be encouraged when there is knowledge of a full sibling in the family with a medical condition (malignant or genetic) that could potentially benefit from cord blood transplantation.
2. Cord blood donation should be encouraged when the cord blood is stored in a bank for public use. Parents should recognize that genetic (e.g., chromosomal abnormalities) and infectious disease testing is performed on the cord blood and that if abnormalities are identified, they will be notified. Parents should also be informed that the cord blood banked in a public program may not be accessible for future private use.
3. Because there are no scientific data at the present time to support autologous cord blood banking and given the difficulty of making an accurate estimate of the need for autologous transplantation and the ready availability of allogeneic transplantation, private storage of cord blood as "biological insurance" should be discouraged. Cord blood banks should comply with national accreditation standards developed by the Foundation for the Accreditation of Cellular Therapy (FACT), the US Food and Drug Administration (FDA), the Federal Trade Commission, and similar state agencies. At a minimum, physicians involved in procurement of cord blood should be aware of cord blood collection, processing, and storage procedures as shown in the table below.

#### **Table. Recommended Procedures for Related and Unrelated Cord Blood Banking**

- Cord blood should be collected in a bag containing citrate-phosphate-dextrose anticoagulant.
- Cord blood should be processed and frozen within 48 hours of collection.
- Standardized freezing and storage conditions should be followed (FACT).
- Segments should be attached to the cord blood for testing and confirmation of identity.
- Extra cells and plasma should be stored for potential additional testing.

- FDA regulations regarding infectious disease testing should be followed.
- Banks should be accredited by FACT and follow FACT cord blood banking standards.
- Cord blood units should be stored under liquid nitrogen or at equivalent temperatures.

Institutions or organizations (private or public) involved in cord blood banking should consider the following recommendations:

1. Cord blood-banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women and their families and friends. Efforts should be made to minimize the effect of this vulnerability on cord blood banking decisions.
2. Accurate information about the potential benefits and limitations of allogeneic and autologous cord blood banking and transplantation should be provided. Parents should be informed that autologous cord blood would not be used as a stem cell source if the donor developed leukemia later in life. Parents should recognize that there are no scientific data to support the claim that autologous cord blood is a tissue source proven to be of value for regenerative medical purposes. The current standard uses of cord blood transplantation are listed in the table below:

**Table: Disease Treatable with Umbilical Cord Blood Transplantation**

•	Malignancies
•	Bone marrow failure
•	Hemoglobinopathies
•	Immunodeficiencies
•	Inborn errors of metabolism

3. A policy should be developed by cord blood banks regarding disclosing to the parents any abnormal findings in the harvested blood.
4. Specific permission for maintaining demographic medical information should be obtained, and the potential risks of breaches of confidentiality should be disclosed.
5. Written permission for obtaining cord blood should be obtained before onset of active labor.
6. If the cord blood bank is conducting research, an institutional review board must review and approve recruitment strategies and consent forms.
7. Cord blood collection should not be performed in complicated deliveries. The cord blood stem cell-collection program should not alter routine practice for the timing of umbilical cord clamping.
8. Regulatory agencies (e.g., FDA, Federal Trade Commission, and state equivalents of these federal agencies) are encouraged to have an active role in providing oversight of the cord blood program. All cord blood-banking programs should comply with FACT or equivalent accreditation standards.
9. Physicians or other professionals who recruit pregnant women and their families for for-profit placental cord blood stem cell banking should disclose

- any financial interest or other potential conflict of interest they have in the procedure to their patients.
10. Professionals affiliated with institutions or organizations that promote for-profit placental blood stem cell banking should make annual financial-disclosure and potential-conflicts-of-interest statements to an appropriate institutional review committee that possesses oversight authority.
  11. Targeted efforts should be made to recruit underserved minorities (black, Hispanic, American Indian/Alaska Native individuals) in public cord blood-banking programs to extend to them potential treatments afforded other segments of society.

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

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of evidence supporting the recommendations is not specifically stated.

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

- Appropriate counseling for parents seeking information about cord blood donation and banking
- Appropriate ethical and operational standards for cord blood-banking programs

### **POTENTIAL HARMS**

Not stated

## **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  
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**

2007 Jan

### **GUIDELINE DEVELOPER(S)**

American Academy of Pediatrics - Medical Specialty Society

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

American Academy of Pediatrics

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

Not stated

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## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American Academy of Pediatrics \(AAP\) Policy 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 April 20, 2007. The information was verified by the guideline developer on April 23, 2007.

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