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Committee on Genetics Committee on Obstetric Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Genetics in collaboration with committee member Britton Rink, MD, MS; and the Committee on Obstetric Practice in collaboration with committee member Russell S. Miller, MD.

Umbilical Cord Blood Banking

ABSTRACT: Since the first successful umbilical cord blood transplant in 1988, it has been estimated that more than 35,000 transplants have been performed in children and adults for the correction of inborn errors of metabolism, hematopoietic malignancies, and genetic disorders of the blood and immune system. Two types of banks have emerged for the collection and storage of umbilical cord blood: 1) public banks and 2) private banks. The benefits and limitations of public versus private umbilical cord blood banking should be reviewed with the patient because they serve different purposes. This patient discussion also should include the concept of autologous and allogeneic use of umbilical cord blood. Umbilical cord blood collected from a neonate cannot be used to treat a genetic disease or malignancy in that same individual (autologous transplant) because stored cord blood contains the same genetic variant or premalignant cells that led to the condition being treated. There is no current evidence to support the use of an autologous umbilical cord blood sample in regenerative medicine. Patients should be made aware of the quality control and regulatory organizations that provide oversight for the process of umbilical cord collection and storage. Umbilical cord blood collection should not compromise obstetric or neonatal care or alter routine practice of delayed umbilical cord clamping with the rare exception of medical indications for directed donation. Therefore, it is important to inform patients that the medical condition of the woman or neonate may prevent adequate umbilical cord blood collection. This document is updated with a statement that the routine use of private cord blood banking is not supported by available evidence and that public banking is the recommended method of obtaining cord blood. In addition, the importance of contribution from all ethnicities and races to public banks is highlighted.

Recommendations

The American College of Obstetricians and Gynecologists makes the following recommendations regarding umbilical cord blood banking:

- Umbilical cord blood collected from a neonate cannot be used to treat a genetic disease or malignancy in that same individual (autologous transplant) because stored cord blood contains the same genetic variant or premalignant cells that led to the condition being treated.
- The routine collection and storage of umbilical cord blood with a private cord blood bank is not supported by the available evidence.
- The current indications for umbilical cord blood transplantation are limited to select genetic, hematologic, and malignant disorders.
- Private umbilical cord blood banking may be considered when there is knowledge of a family member with a medical condition (malignant or genetic) who could potentially benefit from cord blood transplantation.
- Public umbilical cord blood banking is the recommended method of obtaining umbilical cord blood for use in transplantation, immune therapies, or other medically validated indications.

- Families of all ethnicities and races should consider the societal benefit of public umbilical cord blood donation to increase the availability of matched cord blood units for people of all backgrounds.
- Obstetrician–gynecologists and other obstetric care providers should be aware of state and local laws regarding umbilical cord blood banking, including the law in some states that requires physicians to inform patients about umbilical cord blood banking options.
- Health care providers with a financial interest in private umbilical cord blood banking should disclose these interests, incentives, or other potential conflicts of interest.
- If a patient requests information about umbilical cord blood banking, balanced and accurate information regarding the advantages and disadvantages of public and private umbilical cord blood banking should be provided.
- A variety of circumstances may arise during the process of labor and delivery that may preclude adequate collection.
- Umbilical cord blood collection should not compromise obstetric or neonatal care or alter routine practice of delayed umbilical cord clamping with the rare exception of medical indications for directed donation.
- It is important to inform patients that the medical condition of the woman or neonate may prevent adequate umbilical cord blood collection.

Introduction

Historically, umbilical cord blood had no identified value and was disposed of with the placenta. Umbilical cord blood is now known to contain hematopoietic stem cells that have potential life-saving benefit. When used in hematopoietic stem cell transplantation, umbilical cord blood offers several distinct advantages compared with bone marrow or peripheral stem cells. Biologically, a greater degree of human leukocyte antigen (HLA) mismatch is tolerated by the recipient and the incidence of acute graft-versus-host reaction is decreased when umbilical cord blood is used compared with unrelated donor bone marrow (1, 2). The predominant disadvantage of umbilical cord blood use is that there is often a low yield of stem cells acquired per unit. Only 8–12% of umbilical cord blood units have sufficient cell volume for transplant to a person weighing 80 kg (176 lb) (3). However, the use of combined units of umbilical cord blood allows for the expansion of umbilical cord blood volume (and increased number of stem cells) to be used for adult hematopoietic transplants. Since the first successful umbilical cord blood transplant in 1988, it has

been estimated that more than 35,000 transplants have been performed in children and adults for the correction of inborn errors of metabolism, hematopoietic malignancies, and genetic disorders of the blood and immune system (4, 5). Most patients undergoing umbilical cord blood transplantation are adults who lack a HLA-matched donor (5). Umbilical cord blood stem cells also are being studied in the areas of regenerative medicine and infectious disease. The regenerative potential of transplanted umbilical cord blood stem cells remains an area of research and should be considered only in the setting of an Institutional Review Board-approved protocol.

Types of Umbilical Cord Blood Banking: Public and Private

Two types of banks have emerged for the collection and storage of umbilical cord blood: 1) public banks and 2) private banks. In general, a private umbilical cord blood bank is a for-profit company that allows storage of umbilical cord blood for personal use. There is an associated cost for collection and storage and no guarantee that the umbilical cord blood from an individual will be useful to treat a medical condition in that same person (autologous umbilical cord blood transfusion) or a family member. In contrast, public umbilical cord blood banks offer gratuitous cord blood banking for individuals who meet the donation requirements. Public banks generally are supported by federal or private funding, which allows them to provide collection and storage at no cost to a family. Unlike private banks, public cord blood banks do not allow directed storage. This allows the umbilical cord blood to be available to all patients for transplant (allogeneic umbilical cord blood transfusion) and not uniquely available to a specific person or family. All collected units of umbilical cord blood must meet rigorous standards of donor screening and infectious disease testing as outlined by the U.S. Food and Drug Administration. Although the FDA does regulate umbilical cord blood differently depending on the source and intended use, private and public umbilical cord blood banks must register with the FDA and comply with tissue-handling requirements. Umbilical cord blood intended for personal use does not require FDA approval before use, although cord blood intended for an unrelated donor must meet additional FDA requirements before use. There is no contact between donor and recipient.

The benefits and limitations of public versus private umbilical cord blood banking should be reviewed with the patient because they serve different purposes. This patient discussion also should include the concept of autologous and allogeneic use of umbilical cord blood. Umbilical cord blood collected from a neonate cannot be used to treat a genetic disease or malignancy in that same individual (autologous transplant) because stored cord blood contains the same genetic variant or premalignant

cells that led to the condition being treated (6, 7). The estimated lifetime probability of an individual to develop an indication for autologous umbilical cord blood transplant ranges from 1 in 400 to 1 in 2,500 (8–10). Private banks advertise directly to consumers and often encourage parents to bank their infants' umbilical cord blood as a form of "biological insurance" against future disease. Such routine storage of umbilical cord blood for this purpose is not recommended by the American Academy of Pediatrics, given the lack of scientific data to support its use and availability of allogeneic transplantation (6); the American College of Obstetricians and Gynecologists concurs with this recommendation. Further, there is no current evidence to support the use of an autologous umbilical cord blood sample in regenerative medicine. The routine collection and storage of umbilical cord blood with a private cord blood bank is not supported by the available evidence (6).

The current indications for umbilical cord blood transplantation are limited to select genetic, hematologic, and malignant disorders. Private umbilical cord blood banking may be considered when there is knowledge of a family member with a medical condition (malignant or genetic) who could potentially benefit from cord blood transplantation. Patients should be made aware of the quality control and regulatory organizations that provide oversight for the process of umbilical cord collection and storage (6, 11). Private umbilical cord banks are not subject to the same regulatory mechanisms as public umbilical cord blood banks and may not produce samples that meet the expected standards, with resultant decreased usefulness (12). Health care providers also should review the financial obligation for processing and the annual storage fees related to private and public umbilical cord blood banks.

Public umbilical cord blood banking is the recommended method of obtaining umbilical cord blood for use in transplantation, immune therapies, or other medically validated indications (6). There are currently 28 public umbilical cord blood banks identified in North America (13). Public banks promote allogeneic (related or unrelated) donation, which is analogous to the current collection of whole blood units in the United States. The National Marrow Donor Program maintains a list of participating hospitals that work with the network of public umbilical cord blood banks. Every unit of unrelated donor cord blood to be transplanted in the United States must be licensed or covered under an investigational new drug application approved by the FDA (14). Initial HLA typing of these units allows them to be entered into computerized registries so that when the need arises, a specific unit can be rapidly located for a patient. Families of all ethnicities and races should consider the societal benefit of public umbilical cord blood donation to increase the availability of matched cord blood units for people of all backgrounds. Minority populations are significantly underrepresented in public and private banks.

Collection Technique

To ensure that there will be enough cells for transplantation, at least 40 mL of cord blood must be collected. Collection can be performed before or after removing the placenta. In either case, thorough cleansing of a section of umbilical cord is performed, and blood is obtained from the umbilical vein by venipuncture and allowed to drain by gravity into a bag supplied by the bank. Blood should be collected as soon as feasible after birth to minimize coagulation and maximize volume (15). If the specimen is not sterile or is not of sufficient quantity, the bank will discard it.

Health Care Provider and Patient Information

Obstetrician–gynecologists and other obstetric care providers should be aware of state and local laws regarding umbilical cord blood banking, including the law in some states that requires physicians to inform patients about umbilical cord blood banking options. Health care providers with a financial interest in private umbilical cord blood banking should disclose these interests, incentives, or other potential conflicts of interest.

If a patient requests information about umbilical cord blood banking, balanced and accurate information regarding the advantages and disadvantages of public and private umbilical cord blood banking should be provided. Umbilical cord blood collection is not part of routine obstetric care. A variety of circumstances may arise during the process of labor and delivery that may preclude adequate collection. For example, patients should be aware that delayed umbilical cord clamping significantly decreases the volume and total nucleated cell counts of cord blood donations. Nonetheless, umbilical cord blood collection should not compromise obstetric or neonatal care or alter routine practice of delayed umbilical cord clamping with the rare exception of medical indications for directed donation (16). Therefore, it is important to inform patients that the medical condition of the woman or neonate may prevent adequate umbilical cord blood collection.

For More Information

The American College of Obstetricians and Gynecologists has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at www.acog.org/More-Info/CordBloodBanking.

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's website, or the content of the resource. The resources may change without notice.

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