

## Why GAO Did This Study

Every year, many people diagnosed with diseases such as leukemia and lymphoma require transplants of stem cells from umbilical cord blood or other sources. The Stem Cell Therapeutic and Research Act of 2005 authorized funding for banking 150,000 new units of high quality and genetically diverse cord blood and directed the Department of Health and Human Services (HHS) to contract with cord blood banks to assist in cord blood collection. HHS, through the Health Resources and Services Administration (HRSA), established the National Cord Blood Inventory (NCBI) program to support banking of cord blood units and contracted with 13 cord blood banks to bank these units. The 2010 reauthorization required GAO to report on efforts to increase cord blood unit collection for the NCBI. As of May 2011, HRSA had reimbursed banks for over 41,000 units banked for the NCBI.

In this report, GAO describes (1) practices identified to increase banking of cord blood units for the NCBI and related challenges and (2) practices cord blood banks are using to lower costs and improve the efficiency of cord blood banking and associated challenges. To do so, GAO reviewed relevant regulations and documents, and interviewed officials from pertinent organizations. These included officials from HRSA, the Food and Drug Administration (FDA), which is responsible for regulating cord blood used in transplants for patients who are not related to the donor, the National Marrow Donor Program (NMDP), which operates a national registry of cord blood units and other sources of stem cells, and the 13 banks with contracts to bank cord blood units for the NCBI.

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# NATIONAL CORD BLOOD INVENTORY

## Practices for Increasing Availability for Transplants and Related Challenges

## What GAO Found

The 13 banks with NCBI contracts reported various practices that could increase the number of cord blood units banked at existing and new collection sites, as well as increasing the diversity of the units collected. However, challenges to increasing collection for these banks include resource limitations, as well as competition from other cord blood banks, which collect units for use only by family members of the donor, and slowing growth in demand for U.S. cord blood units. Cord blood banks reported that increasing staff at collection sites, providing feedback to those who collect cord blood, and lowering the age for those donating could increase the number of units collected for the NCBI at existing sites. Expanding the number of collection sites could also increase the number and diversity of NCBI units. However, the banks in our review reported financial challenges related to increasing the number of units collected at existing or new collection sites, such as a limited ability to address the costs associated with hiring additional staff to cover more hours of collection or to support bank and hospital staff salaries at new sites. These banks identified additional practices for increasing the diversity of the units collected for the NCBI, but also reported that the units collected from some racial groups have lower volumes or cell counts compared to other groups, making such units less likely to meet standards for inclusion in the NCBI. Further, growth in sales of U.S. cord blood units, banks' primary source of funding, has slowed and could challenge banks' efforts. Demand for cord blood could increase or decrease depending on a number of variables, such as whether new research identifies ways to increase the benefits of cord blood or conversely, the development of alternative treatments to cord blood transplantation.

Most of the 13 banks with NCBI contracts reported adopting practices to reduce costs and improve the efficiency of cord blood banking, but also reported some uncertainty about the effect on costs and revenues of complying with FDA licensure regulations that now apply to cord blood. These banks reported practices such as using an early screening process to identify units that do not meet NCBI or the bank's own requirements prior to incurring the costs of processing these units. Further, banks with NCBI contracts reported that efforts to comply with applicable FDA regulations could increase the costs of banking cord blood. For example, some banks reported hiring external consultants or additional staff, reorganizing staff duties, beginning building renovations, or purchasing new processing equipment in attempts to comply with FDA regulations regarding cord blood manufacture and licensing. Some banks also said they were uncertain whether these efforts would comply with FDA requirements or if their collection sites would have to register with the FDA as an establishment that manufactures cord blood. However, FDA officials told GAO that neither individuals nor collection sites that have agreements with banks to collect units will be required to register, though banks must ensure the collection sites comply with FDA regulations. Further, some banks also reported that they were uncertain whether potential increased revenue from licensed units will offset their costs of cord blood banking.

HHS provided additional information regarding our findings, which was incorporated as appropriate.