United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Commerce, House of Representatives

For Release on Delivery
Expected at 9:30 a.m.
Thursday, September 23, 1999

BLOOD SUPPLY

Availability of Blood

Statement of Janet Heinrich, Associate Director
Health Financing and Public Health Issues
Health, Education, and Human Services Division

GAO/T-HEHS-99-195

Summary

While there is cause for concern about shortages of certain blood types or in certain regions, the blood supply as a whole is not in crisis. Although a recent report by the National Blood Data Resource Center (NBDRC) projected that the demand for blood will outstrip the available supply by next year, we believe that this study overstates the decline in the blood supply. Moreover, most of the decline found by NBDRC was in donations targeted for specific individuals—not in the community supply of blood available to anyone in need—and the projection relies on data from only 2 years.

At the same time, the Department of Health and Human Services (HHS), which oversees the nation's blood supply, has initiated a major policy change—and is considering another—that could further affect the blood supply. Specifically, the Department's Food and Drug Administration has recommended prohibiting blood donations from individuals who spent a total of 6 months or more in the United Kingdom between 1980 and the end of 1996 because of concerns over the possible transmissibility of the human form of "mad cow" disease. The U.K. donor exclusion policy has been estimated to reduce the blood supply by approximately 2.2 percent. Blood banks fear that the actual loss due to this exclusion will be greater, but it is not possible to assess the accuracy of these estimates.

HHS has also proposed removing barriers to donation by individuals with hemochromatosis—and iron-overload disease that may be treated by drawing blood—to make up some of the loss from the decreasing donations and possible losses from the U.K. donor exclusion. While the estimates of the potential increase in the blood supply from donations by individuals with hemochromatosis vary widely, most of these increases could not occur until current regulations are changed. Therefore, such donations would not affect the available blood supply for some time.

Blood Supply: Availability of Blood

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here as you discuss the availability of blood to meet the nation's requirements as well as recent and proposed policy changes regarding blood donation that may affect the future supply.

A recent report by the National Blood Data Resource Center (NBDRC), a group representing blood banks, projected that the demand for blood will outstrip the available supply by next year. At the same time, the Department of Health and Human Services (HHS), which oversees the nation's blood supply, has initiated a major policy change—and is considering another—that could further affect the blood supply. Specifically, the Department's Food and Drug Administration (FDA) has recommended prohibiting blood donations from individuals who spent a total of 6 months or more in the United Kingdom between 1980 and the end of 1996 because of concerns over the possible transmissibility of new variant Creutzfeldt-Jakob disease (nvCJD), the human form of "mad cow" disease. HHS has also proposed removing barriers to donation by individuals with hemochromatosis—an iron-overload disease that may be treated by drawing blood—to make up some of the loss in blood donations from the decreases in donations and losses that may result from the U.K. donor exclusion.

In light of these developments, you asked us to discuss the results of our recent correspondence on the blood supply.[1] In that report, done at the Committee's request, we provide information on (1) recent trends in blood donation and the demand for blood transfusions, (2) the expected effect of a ban on donors who have traveled to the United Kingdom, and (3) the potential effect of policy changes to allow units of blood collected from individuals with hemochromatosis to be distributed. The points I will present today are discussed in more detail in the correspondence.

In summary, we found that, while there is cause for concern about shortages of certain blood types or in certain regions, the blood supply as a whole is not in crisis. We believe that the NBDRC study overstates the decline in the blood supply. Most of the decline found by NBDRC was in donations targeted for specific individuals, rather than in the community supply of blood available to anyone in need. Further, the projection of a shortage relies on data from only 2 years. The U.K. donor exclusion policy has been estimated to reduce the blood supply by approximately 2.2

[1]Blood Supply: Availability of Blood to Meet the Nation's Requirements (GAO/HEHS-99-187R, Sept. 20, 1999).

percent. Blood banks fear that the actual loss due to this exclusion will be greater, but it is not possible to assess the validity of their concerns. Estimates of the potential increase in the blood supply from donations by individuals with hemochromatosis vary widely, from 300,000 to 3 million units. Regardless, use of such donations will require changes to current regulations, which may delay their availability for some time.

Background

About 8 million volunteers donate approximately 12 million units of whole blood each year. Sixty percent of the population is eligible to donate, and about 5 percent of the eligible population actually donate each year.[2] There are four sources of whole blood from volunteer donors for transfusion. The first, allogeneic donations, is the most important category, accounting for roughly 90 percent of the blood supply. Blood from allogeneic donations is available to any patient in need, and efforts to increase the blood supply usually focus on increasing participation in blood drives or otherwise raising the number of allogeneic collections. Second, autologous collections involve blood taken from patients before a medical procedure for their own use. Third, directed collections involve blood donated for use by a particular patient. A small portion of the autologous and directed collections ultimately are "crossed over" to the general supply. Finally, less than 2 percent of the total blood supply is imported.

Blood banks maintain a supply cushion to meet the uncertain demand for blood. Local demand for particular blood types varies over the course of the year, and blood banks want to ensure that trauma patients and others who may require many units of blood can be treated promptly whenever the need arises. The supply cushion means that some blood is discarded—in 1997, for example, about 4 percent of the allogeneic blood supply expired without being transfused.

New variant CJD is a chronic, progressive neurodegenerative disease that is inevitably fatal. It has a long, but unknown, incubation period. As of August 1999, there had been 43 confirmed cases—41 in the United Kingdom, 1 in France, and 1 in Ireland. It is suspected that all of these individuals contracted nvCJD from eating contaminated tissues from cattle infected with bovine spongiform encephalopathy ("mad cow" disease) in the United Kingdom, probably prior to 1990. Estimates of the number of U.K. residents who will ultimately manifest nvCJD range from the

[2]To be eligible to donate, a person should be at least 17 years of age, weigh at least 110 pounds, be in good physical health, and pass a physical and medical history examination.

hundreds to more than 500,000. In the United States, there have been no documented cases of nvCJD.

Hemochromatosis is the most common genetic disease in Americans of European descent—about 1 in 10 may carry the gene for this disease, and as many as 1 million Americans have evidence of hemochromatosis.[3] The proportion of individuals, however, who have the mutations associated with hemochromatosis and later develop the disease is unknown because not all of these individuals become ill. Treatment of hemochromatosis has two phases: (1) iron depletion therapy, in which the patient receives a therapeutic phlebotomy, or drawing of blood, about 1 to 2 times a week for several months up to 3 years to remove excessive iron stores, and (2) maintenance therapy, in which the patient continues to undergo therapeutic phlebotomies but less frequently (2 to 6 times a year) to keep body iron stores low and iron levels normal for the remainder of the patient's life.

Recent Trends in Supply and Demand

The blood supply has decreased over the last decade, and there is some evidence that in recent years the demand for blood has increased. However, any conclusions about the trends in the blood supply are hampered because information about the blood supply has not been gathered routinely. The last systematic survey of the blood supply was conducted by NBDRC in 1998, which measured units collected and transfused in 1997. NBDRC will release the results of a new survey of blood collections this November, and the National Heart, Lung, and Blood Institute of the National Institutes of Health (NIH) has recently arranged for NBDRC to collect data on blood donations on a monthly basis from a sample of blood centers.

Earlier this year, NBDRC projected that the demand for blood will outstrip supply by next year.[4] We found that current evidence indicates the blood supply has declined more slowly than assumed for that projection. NBDRC's projection rests on the overall 5.5 percent decrease in the blood supply from 1994 to 1997 and on the observed 3.7 percent increase in the number of units transfused during those years. (See table 1.)

[3]There are two genetic mutations, C282Y and H63D, associated with hemochromatosis. C282Y is considered the major mutation; fewer data are available on the prevalence of hemochromatosis in other populations.

[4]This projection did not consider the consequences of excluding travelers to the United Kingdom from donating blood or of any other policy changes that may affect the blood supply.

Table 1: Blood Supply Trends

	1989	1992	1994	1997	Percent change (1994-1997)
Total units collected	14,229,000	13,794,000	13,340,000	12,602,000	–5.5
Total community supply	13,296,000	12,303,000	12,075,000	11,837,000	–2.0
Total units transfused	12,059,000	11,307,000	11,107,000	11,517,000	+3.7

Our analysis of the blood supply data found that the 5.5 percent figure suggests a more serious decline than actually occurred in the community supply of blood (available to anyone in need). Most of the 5.5 percent decrease came from a drop in blood not included in the community supply, which decreased only about 2 percent from 1994 to 1997. The number of units designated for particular transfusion patients, both autologous and directed donations, decreased by 37 percent from 1994 to 1997, accounting for two-thirds of the overall 5.5 percent decline. Indeed, there was an even larger decline in the number of such units that had been collected but not used.[5]

While other evidence seems to indicate that the blood supply cushion has narrowed, it is difficult to determine if shortages are worse now than in earlier years because blood banks have no incentive to collect more blood than can be used. The American Red Cross informed us that the number of days' supply decreased below the comfort level in many of its centers and gave us data showing less than 1 day's supply on hand for some blood types in some regions at one point this summer. America's Blood Centers reported anecdotal evidence of shortages in many of its affiliated blood banks this year. Shortages occur more frequently in some regions, as do shortages of blood types O and B. Furthermore, the 1998 NBDRC survey found that at least some surgeries and medical procedures have been postponed due to blood shortages. Specifically, 8.6 percent of the hospitals surveyed indicated that elective surgeries were cancelled on 1 or more days in 1997 due to blood shortages; 24.7 percent of hospitals said that they were unable to meet nonsurgical blood requests on 1 or more days in 1997.[6]

Blood banks can mitigate the effects of local blood shortages by transferring blood from regions with an excess supply to those with

[5]The number of autologous and directed units collected but not transfused dropped 63 percent between 1994 and 1997.

[6]Among all hospitals responding to the survey, the mean number of days with surgeries cancelled was 0.44 and the mean number of days with unmet nonsurgical blood requests was 2.1.

shortages. The American Association of Blood Banks' National Blood Exchange and the American Red Cross together moved about 1.1 million units of blood between blood centers last year. This blood is purchased by centers in shortage areas from centers with surpluses of particular types of blood.

Estimates of the future demand for blood are also uncertain. On the one hand, persons aged 65 and older receive twice as much blood per capita as younger individuals, so the aging of the population may increase the demand for blood products. Further, some procedures requiring blood are being performed with increasing frequency, and the range of treatments requiring blood or blood products is increasing. On the other hand, some evidence indicates that the use of blood can be substantially reduced. The amount of blood used for the same procedures varies widely among hospitals, and at least one pilot program has shown that clinical outcomes would not be affected if the use of blood were substantially reduced. Similarly, improved surgical techniques and better understanding of the clinical thresholds that trigger blood transfusions has reduced the demand for blood in some instances.

Expected Effect of Excluding Donors Who Have Resided or Traveled in the United Kingdom

Last month, FDA issued guidance recommending that collections be prohibited from donors who had traveled or resided in the United Kingdom for a total of 6 months or more between 1980 and 1996—because of the theoretical risk of transmitting nvCJD through blood transfusions—which has raised concern among some about the effect such a policy would have on the blood supply. FDA will review this policy at 6-month intervals, to consider any new scientific information and the policy's effect on the blood supply.

While it has not been shown that nvCJD is transmissible by blood transfusion, animal research suggests that infection by blood is theoretically possible—in some cases, direct injection of blood from a contaminated animal into the brain of another has caused infection. However, no cases of transmission by blood in humans have been documented. In the United Kingdom, 4 donors subsequently diagnosed with nvCJD gave blood that was transfused into 10 recipients. None of these recipients have developed nvCJD to date, although they may later because of the long incubation period.

Effect on the Blood Supply

The 6-month U.K. residence interval was selected to balance the twin goals of minimizing losses to the blood supply and eliminating as much risk as possible. A survey of blood donors by the American Red Cross found that 23 percent of donors had traveled to the United Kingdom between 1980 and 1996. Only one-fifth of the blood-donor travelers had been in the United Kingdom for more than 30 days, and just 1 in 10 of them had a cumulative stay of 5 months or more. The Red Cross analysis estimated that the 6-month exclusion criterion would result in a 2.2 percent reduction in the blood supply and eliminate 87 percent of the risk of collecting blood from a person infected with nvCJD.

Blood banks have expressed concern that this exclusion will result in more than a 2.2 percent loss. First, there is the possibility that some potential donors will fail to attend to the details of the policy and not donate blood even though they are eligible to do so. For example, donors who traveled to the United Kingdom only in 1997 may stop donating even though they remain eligible to do so. Second, there is concern that potential donors may become discouraged because their friends or neighbors are excluded, heightening the sense that it is difficult to pass all the screening criteria for giving blood. Third, there is worry that excluded U.K. travelers will not return to donate blood if, and when, the restriction is lifted.

Blood banks are also concerned about other burdens imposed by this exclusion. For example, according to research conducted by the American Red Cross, donors who resided or traveled in the United Kingdom are disproportionately repeat donors. Without these donors, the blood banks will need to recruit a large number of first-time donors to replace them because first-time donors are roughly twice as likely to have disqualifying medical conditions as regular donors. Second, the effect will vary by blood center, as those with a larger proportion of U.K. travelers will lose more of their donors than other blood collection centers. The Red Cross survey found that the proportion of donors affected in some blood centers were 35 percent greater, and others 50 percent less, than the overall average.

Risk Reduction

Estimates of the degree of risk reduction achieved by this exclusion are problematic. First, the degree of potential risk to be mitigated is unknown. Second, because the prohibition applies only to future donations, some blood from donors who would now be excluded has entered the blood supply in the recent past. Third, because so little is certain about how nvCJD is acquired, estimates of the beneficial effect of any prohibition

threshold—other than a complete ban on potential donors who have traveled to the United Kingdom at all—are uncertain. For example, the Red Cross estimate assumed that the risk of acquiring nvCJD increased directly with each day spent in the United Kingdom. Any change in this assumed relationship would lead to a significantly different risk reduction estimate. Indeed, HHS told us that the Department did not totally agree with the Red Cross risk formulation and that its choice of the 6-month threshold was based on other information. In particular, HHS told us that all of the individuals in the British cases (41 of the 43 known cases) were born in the United Kingdom and resided there for at least 10 years between 1980 and 1996; thus, the Department reasoned that any exclusion threshold of 1 year or less would reduce the presumed risk tenfold or more.

Potential for Blood Donations From Individuals With Hemochromatosis

In April 1999, the Public Health Service's Advisory Committee on Blood Safety and Availability recommended that policy changes be made to allow blood collected from individuals with hemochromatosis to be distributed for transfusion.[7] Making hemochromatosis patients eligible to donate would essentially guarantee an increased number of donors because they have to periodically have blood drawn to treat their condition. Members of the advisory committee concluded that blood products from individuals with hemochromatosis carry no known increased risk to recipients. Therefore, they recommended that HHS change its policies and remove any barriers to the use of this blood. At the same time, the advisory committee recommended that HHS take steps to eliminate any financial incentive for these individuals to donate blood. Since individuals with hemochromatosis may have to pay to have their blood drawn through therapeutic phlebotomy,[8] there would be a financial incentive to avoid this cost by donating blood. Unless this incentive is removed, FDA is concerned that these potential donors will not truthfully answer screening questions about risk factors that would disqualify them from donating, thereby compromising the safety of the blood supply.

According to one survey, most individuals with hemochromatosis are insured or partially insured for therapeutic phlebotomies. However, even

[7]Hemochromatosis is a disease of iron regulation that results in excessive iron absorption and accumulation, leading to organ damage. The human body cannot excrete excess iron, so it remains in the body unless it is lost through menstruation, childbirth, hemorrhage, or blood donation. Iron is highly toxic when an excessive amount is absorbed. Some clinical chronic conditions associated with hemochromatosis include severe fatigue, diabetes mellitus, heart disease, cirrhosis of the liver, and cancer.

[8]Therapeutic phlebotomy is the removal of a full unit of blood from an individual, about 500 mls, for the purpose of treating a disease.

though therapeutic phlebotomies are a necessary medical treatment for some individuals, insurance does not always cover the costs. The average cost of the procedure per unit of blood ranges from $52 at blood centers to $69 at physician offices and $90 at hospitals, with an average out-of-pocket cost of $45 for all respondents to the survey.[9] These out-of-pocket costs are a financial incentive for persons with hemochromatosis to not disclose any disqualifying conditions and volunteer for blood donations. In one study, 37 percent of the hemochromatosis patients surveyed reported being voluntary donors before their diagnosis and 54 percent of the individuals attempted to donate blood after diagnosis.[10] The results from the National Donor Research and Education Study sponsored by NIH show that about half of the individuals who responded that they had hemochromatosis (only 0.4 percent of those surveyed) were volunteer donors. At present, there is no routine screening for this disease.

In the United States, blood obtained by therapeutic phlebotomy from individuals with hemochromatosis is currently discarded. Although hemochromatosis is inherited, not transmitted, and there is no evidence that the use of hemochromatosis blood for transfusion carries any risks to recipients,[11] hospitals and physicians hesitate to use this blood. FDA permits the use of blood from individuals with hemochromatosis, as long as they meet the same donor suitability criteria as any other donor, but it requires that this blood be labeled as coming from a hemochromatosis donor, which effectively impedes the use of this blood. Some in the U.S. blood industry consider hemochromatosis donors to be the same as paid donors, implying a decreased level of safety.[12] In 1996, the American Association of Blood Banks issued standards discouraging transfusion of blood from donors who had therapeutic phlebotomies. Because many blood centers conform to these standards, this policy effectively excludes most individuals with hemochromatosis from donating blood.

FDA has agreed to make the necessary regulatory changes to remove barriers to donation once financial incentives for hemochromatosis

[9]S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis," Transfusion, Vol. 39 (1999), pp. 651-6.

[10]S. M. McDonnell and others, "A Survey of Phlebotomy Among Persons With Hemochromatosis."

[11]The processing of whole blood units into packed red cells removes most of the iron-enriched serum.

[12]Data show that blood from paid donors is more likely to transmit disease than that from volunteer donors; R. A. Sacher, "Hemochromatosis and Blood Donors: A Perspective," Transfusion, Vol. 39 (1999), pp. 551-4.

patients are removed.[13] There are several different requirements that would need to be changed. FDA currently requires an 8-week interval between donations to prevent iron depletion of donors, but individuals with hemochromatosis at the initial stage of treatment undergo therapeutic phlebotomies 1 to 2 times a week. FDA also requires blood from therapeutic bleeding, including for hemochromatosis, to be labeled with the disease for which the bleeding was performed, which discourages health care providers from using this blood.

As an initial step, FDA recently agreed to consider case-by-case exemptions to existing regulations on blood labeling and frequency of blood collection for blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient. However, FDA officials have publicly stated that in making these exemptions, they will require a commitment from blood collection facilities to concurrently provide safety data, including viral marker rates, incidence of transmissible infections based on seroconversion rates, frequency of postdonation reports of undisclosed risks, and reports of adverse events.

Individuals with hemochromatosis have the potential to make up some of the loss in blood donations due to the U.K. donor exclusion policy. Estimates of increases in the blood supply through donations by these individuals vary widely, from 300,000 to 3 million units—although the former is generally considered a better estimation. Regardless, changes to current regulations affecting blood from hemochromatosis patients will occur considerably later than FDA guidance to exclude donors, which has already gone into effect. It seems unlikely that the issue of coverage of therapeutic phlebotomies by insurers will be quickly addressed and that anything less than full reimbursement may be considered undue donor incentive. Therefore, unless blood centers absorb the costs of providing therapeutic phlebotomies to persons with hemochromatosis, it is also unlikely that FDA will revise current regulations.

Conclusions

On the basis of the information we reviewed, we conclude that the blood supply is not in crisis. However, there is cause for concern about the possibility of some regional shortages and shortages of some types of blood. These may be exacerbated somewhat by the U.K. donor exclusion policy, which will affect blood banks differently. Potential additions to the blood supply from hemochromatosis patients cannot occur for some time,

[13]The American Association of Blood Banks has also indicated that, if FDA changes the regulations, it would make changes to its standards related to the use of blood from patients with hemochromatosis, so that centers could remain in compliance with the association's requirements.

since blood from these individuals will not be entered into the community supply until issues related to who pays the costs of therapeutic phlebotomies are resolved and regulatory changes are implemented.

This concludes my prepared statement, Mr. Chairman. I will be happy to respond to any questions that you or Members of the Subcommittee may have.

Contacts and Acknowledgments

For future contacts regarding this testimony, please call Janet Heinrich at (202) 512-7119. Key contributors to this testimony include Marcia Crosse, Martin T. Gahart, and Angela Choy.

Ordering Information

The first copy of each GAO report and testimony is free. Additional copies are $2 each. Orders should be sent to the following address, accompanied by a check or money order made out to the Superintendent of Documents, when necessary. VISA and MasterCard credit cards are accepted, also. Orders for 100 or more copies to be mailed to a single address are discounted 25 percent.

Orders by mail:

U.S. General Accounting Office
P.O. Box 37050
Washington, DC 20013

or visit:

Room 1100
700 4th St. NW (corner of 4th and G Sts. NW)
U.S. General Accounting Office
Washington, DC

Orders may also be placed by calling (202) 512-6000 or by using fax number (202) 512-6061, or TDD (202) 512-2537.

Each day, GAO issues a list of newly available reports and testimony. To receive facsimile copies of the daily list or any list from the past 30 days, please call (202) 512-6000 using a touchtone phone. A recorded menu will provide information on how to obtain these lists.

For information on how to access GAO reports on the INTERNET, send an e-mail message with "info" in the body to:

info@www.gao.gov

or visit GAO's World Wide Web Home Page at:

http://www.gao.gov

United States
General Accounting Office
Washington, D.C. 20548-0001

Bulk Rate
Postage & Fees Paid
GAO
Permit No. G100

Official Business
Penalty for Private Use $300

Address Correction Requested