

# 3 Community Blood Center of the Carolinas: Donations, Donations, Donations

Tom Hassett, group vice president for Carolinas Healthcare System, was responsible for studying the laboratory service line for his hospital system in 2002 (one of 17 service lines with escalating costs). He recalled, "Our costs were actually going down from vendors who were working with us in a very tight time for health care in general and hospitals specifically. But blood costs kept increasing. In just one year, our cost for blood doubled! Discussions with the Red Cross – which was the dominant supplier of blood in our area – went nowhere. I think there were a couple of reasons for that. Charlotte is headquarters for a blood services region for the Red Cross and one of eight national blood testing labs is located





This case was written by Linda E. Swayne, The University of North Carolina at Charlotte and Thomas Hassett, Group Vice President for Carolinas Healthcare System. It is intended as a basis for classroom discussion rather than to illustrate either effective or ineffective handling of an administrative situation. Used with permission from Linda Swayne.



here, but all business decisions are made in St. Louis and they don't appreciate our problems since they have problems of their own. They're trying to cover the costs for all the activities required by the consent decree. The St. Louis guys told us if we didn't like their prices we should get our blood elsewhere. That's when we really got serious about an independent blood center."

# **Discussions Begin**

"We began to talk with hospitals in our immediate area about their experiences and found them to be similar to our experience. As informal word got around, more hospitals called to express their interest in looking at an alternative. Then we discovered America's Blood Centers – a national group serving as the umbrella organization for some 75 independent community blood centers spread around the country. When we approached them, ABC suggested that we contact two or three members about their centers and their willingness to help our group look at how we might set up an independent community blood center," Hassett explained.

He continued, "We then found out some interesting things. The Red Cross had a blood center in Springfield, Missouri that the hospitals there were not very happy with. When discussion began about a community blood center in Springfield, the Community Blood Center of Greater Kansas City was contacted for assistance. Don Thomson, CEO of the Red Cross center was hired to become the executive director of the Springfield area center, named the Community Blood Center of the Ozarks. Not long afterward, almost the entire staff of the Red Cross resigned and moved to the Community Blood Center of the Ozarks. This caused such a wrangle that the Red Cross filed lawsuits against the Ozarks and brought in a Red Cross executive by the name of Bob Carden. After an unfruitful battle against the community blood center, Bob resigned from the Red Cross, switched sides, and became the executive director at Virginia Blood Services, a community blood center in Richmond, Virginia.

"With the Ozark group's experience in mind, we pulled together the 22 hospitals that had indicated interest in a community blood center and asked these two gentlemen to speak to our group. Certainly, the event in Springfield became a model for what could happen with the start-up of a new center – both positively and negatively. Shortly thereafter, the North Carolina Hospital Association became interested in what was going on. At a meeting they organized for the state, some 60 hospitals attended to hear these same speakers, as well as Bill Coenen, the CEO of Community Blood Center of Greater Kansas City."

Although a statewide effort did not emerge, ten Charlotte-area hospitals committed to work together to develop a community-based blood organization. It was the first time that there had been such collaboration. Hassett recalled, "The hospitals worked extremely well together to resolve a common problem. The rising cost of blood was an issue for us all and blood is critical to all hospitals' operations. Although there is pretty intense competition among some of us, we had a common need and blood was neutral territory."







# Charlotte Area Hospitals Agree to Investigate

Hassett continued, "Although the Red Cross says it has 'national pricing,' Premier did a study that documented the variation in the cost of blood across the United States. The lowest costs were in places where there was competition. We decided that we needed the competition in the Charlotte area and, despite some misgivings over tackling the Red Cross, we decided to investigate an independent blood center."

The hospitals' leadership group commissioned Astraea, Inc., parent company of Virginia Blood Services (VBS) in Richmond, Virginia, to evaluate the feasibility of starting an independent blood center to serve the Charlotte region. The VBS study showed that more than 1.5 million people lived in the region and if 60 percent of the population was eligible and able to donate blood, there were 900,000 potential donors in the area. Typically, about 5 percent of the population actually donated (75,000 people).

# **CBCC Begins**

Community Blood Center of the Carolinas, the first community blood center in North Carolina, was the result of the collaboration by the hospitals. Because licensing generally takes three years to complete and the hospitals were anxious to begin operations, CBCC began by working under Virginia Blood Center's US Food and Drug Administration blood license. CBCC focused on serving the needs of blood donors, patients, and health care providers in the Charlotte region. (See Exhibit 3/1 for an overview about blood and blood collection.)

#### Exhibit 3/1: Blood: The River of Life

Using human blood to treat disease and trauma began in France in 1667 when Jean-Baptiste Denis documented a direct human blood transfusion. These early direct donor-to-patient transfusions were often unsuccessful because it was not possible to predict donor-recipient blood type compatibility. In 1901, a German scientist, Dr. Karl Landsteiner, discovered that there were different blood groups. Since he found that all humans fall into one of these groups, the ABO system provided an answer to the puzzle of why some transfusions had worked and others failed.

Blood had no substitute. Individuals who donated blood literally saved lives – more than 4.5 million American lives each year. Someone needed blood every three seconds. One pint (unit) of donated blood could save three lives. One out of ten hospital patients needed blood. Car accident and blood loss victims often needed transfusions of 50 pints or more of red blood cells. Bone marrow transplant patients needed platelet donations from about 120 people and red blood cells from about 20 people. Severe burn victims typically needed 20 units of platelets during their treatment.

The amount of blood in the body of an average adult was ten pints. Blood made up about 7 percent of a person's body weight. Sixty percent of the US population was eligible to donate blood but only 5 percent did so. About 32,000 pints were used each day in the United States.

When patients had organ transplants, cancer treatments, gastrointestinal disease, trauma, aneurysms, anemia and clotting disorders, accidents, open heart surgeries, burns, and so on, blood was required. However, blood from anyone would not necessarily be what the patient required.







#### Exhibit 3/1: (cont'd)

#### **BLOOD TYPES**

Blood came in four different types – A, B, AB, or O – and differed by Rhesus factor (RH) as either positive or negative (approximately 15 percent of the population had negative blood). Nearly half of the blood "ordered" by hospitals was O– because it was the universal donor, meaning that everyone could safely receive O– type blood. Patients with any of the positive blood types could safely receive O+ blood, but only O– could be used safely with all blood types. The most common type of blood was O+ (37.4 percent of the population) and the least common was AB– (0.6 percent).

Blood types in the population were as follows:

Type	Percent of the population		
AB-	0.6		
B-	1.5		
AB+	3.4		
A-	6.3		
O-	6.6		
B+	8.5		
A+	35.7		
0+	37.4		

Blood type compatibility was as follows:

Type	Could be transfused to patients with blood type:
0+	O+, A+, B+, AB+
A+	A+, AB+
B+	B+, AB+
AB+	AB+
0-	O+, A+, B+, AB+, O- , A- , B- , AB-
A-	A+, AB+, A- , AB-
B-	B+, AB+, B- , AB-
AB-	AB+, AB-

#### THE PROCESS

Volunteers were screened to determine whether they were likely to be successful blood donors. The screening process became far more arduous after the emergence of HIV/AIDS and the discovery that numerous patients were infected from blood transfusions and organ transplants. Volunteer donors used to answer about 15 questions. After belatedly understanding that HIV was carried in transfusions, screening intensified. With the advent of mad cow disease, SARS, and West Nile virus, the number of questions increased to 50 or more, covering health, travel, and sexual history.

Blood was withdrawn from the volunteer to fill several vials and a one pint plastic bag (each marked with a unique bar code to match a particular donor's record and to track it electronically until the pint was delivered to a hospital and administered to a patient). The actual blood donation only took about 10 to 20 minutes, although the entire process took from 45 minutes to an hour. The blood was kept refrigerated until it reached a lab, where the unique bar code was read into the computer for tracking and monitoring of test results. The vials were used to type the blood (O, A, B, AB, plus RH factor) and to determine whether there were any transmissible diseases present. Fourteen tests (11 for infectious diseases) were performed on each unit of donated blood.

The pint of blood was separated into its components: leukocytes (white blood cells), red blood cells, platelets, and plasma. (Some patients required whole blood, but some did not. By separating the blood into these components, as many as three patients' lives could be saved from one donated unit.) Then the blood was stored under refrigeration until the test results were received. Testing generally took 12 to 16





#### Exhibit 3/1: (cont'd)

hours and the results were returned electronically, enabling the blood to be distributed for use generally within 24 hours. Hospital professionals transfused the blood (or blood components) to the patient.

#### **Blood Components**

Patients seldom required all the components of whole blood. The request for blood transfusion was specified based on the blood component needed for the patient's condition or disease. Thus, several patients benefited from a single pint of donated blood.

Apheresis, an increasingly common procedure, was the process of removing a specific component of the blood, such as platelets, and returning the remaining components, such as red blood cells and plasma, to the donor. This process allowed more of one particular part of the blood to be collected than could be separated from a unit of whole blood. Apheresis was also performed to collect red blood cells, plasma (liquid part of the blood), and granulocytes (white blood cells). The apheresis donation procedure took longer than the 45–60 minutes for whole blood donation; an apheresis donation might take between one to two hours. Not only were blood components different in the benefits they offered to patients, they had different shelf lives.

Red blood cells – Red blood cells had a shelf life of 21 to 42 days and could be treated and frozen for up to ten years. Red blood cells were particularly needed by patients who had chronic anemia, malignancies, gastrointestinal bleeding, and those with major blood loss from trauma.

Patients scheduled for surgery might be eligible to donate blood for themselves, a process known as autologous blood donation. In the weeks before nonemergency surgery, an autologous donor could have blood drawn that was stored until the surgical procedure.

White blood cells (leukocytes) – White blood cells protected the body from invasion by bacteria and viruses but they were also a factor in making some patients intolerant to blood transfusions. Therefore, much whole blood was filtered to remove leukocytes. The filtration had to occur within 48 hours of donation. However, for immunosuppressed patients, one type of white blood cells – granulocytes – were used to attempt to improve resistance to infection. Granulocytes were collected through apheresis donation or through centrifuging whole blood. White blood cells had to be transfused within 24 hours.

Plasma – Plasma was 90 percent water and contained albumin (protein), fibrinogen (helps with clotting), and globulins (antibodies). Although it looked like dirty river water, plasma maintained blood volume and pressure, supplied critical proteins for blood clotting and immunity, and provided a medium of exchange for vital minerals. This liquid component of blood was frozen soon after donation and could be stored for up to one year.

*Platelets* – Platelets helped to clot blood (stop the bleeding). They were collected by apheresis (or plateletpheresis) and through centrifuging whole blood. Platelets could be stored for up to five days at room temperature, provided that temperature was maintained at 72°F and the platelets were kept moving to avoid sticky clumps.

#### **Blood Testing**

Blood was tested for a variety of diseases that were determined to be transmitted (or theoretically could be transmitted) through blood donation. Prior to identification of the HIV/AIDS virus, blood was tested for syphilis and hepatitis B. During the 1980s, a number of tests were added: HIV/AIDS antibody tests (starting in 1985, with additional tests in 1992, 1996, 1999), hepatitis C (with additional tests for hepatitis A in 1986 and hepatitis B in 1987), human T-cell, and human lymphotropic virus. During 2000, blood tests and screening questions were added for SARS; in 2003, tests were added for West Nile virus.

The tests were performed to maintain a safe blood supply, but many blood collection organizations were concerned that the increased number of deferrals (healthy individuals who are not permitted to donate because of their travel or place of residence) would decrease the number of blood donors and endanger the blood supply.

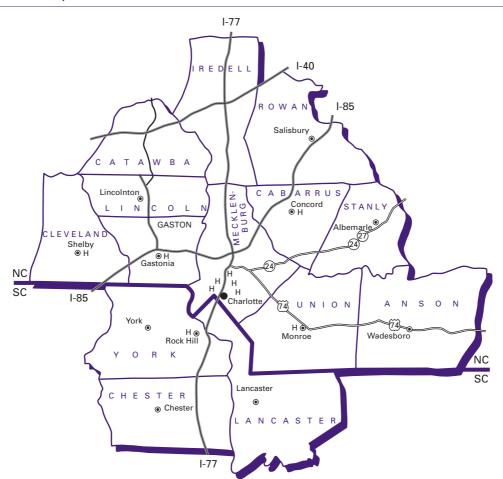






As a blood center, CBCC gathered blood donations – the raw material for its operations – from people in the community and after breaking down the whole blood into red cells, plasma, platelets, and other components and testing for safety, the blood was returned to the community that donated it. CBCC planned to serve residents in York, Chester, and Lancaster counties in South Carolina; and Anson, Cleveland, Cabarrus, Catawba, Gaston, Iredell, Lincoln, Mecklenburg, Rowan, Stanly, and Union counties in North Carolina (Exhibit 3/2 maps the service area). Residents in these counties were served by the ten hospitals that originally developed the plans to establish CBCC (see Exhibit 3/3 for a brief description of the hospitals). The CBCC partner hospitals had 2,985 beds and used about 62,000 units of red blood and about 6,000 platelet doses annually.

Exhibit 3/2: Map of CBCC's Service Area







#### Exhibit 3/3: Hospitals that Formed CBCC

Ten hospitals came together to form the Community Blood Center of the Carolinas.

Carolinas Healthcare System, a not-for-profit, self-supporting organization, was the largest health care system in the Carolinas and one of the largest publicly owned systems in the nation. CHS was a vertically integrated system that owned and managed hospitals, nursing homes, physicians' practices, and physical and radiation therapy facilities in both North and South Carolina. It was comprised of more than 4,900 beds and employed more than 23,000 people. Its physicians' network included approximately 640 primary care doctors and other providers. The flagship hospital, *Carolinas Medical Center*, was named in *US News & World Report's* 2002 America's Best Hospitals list. *CMC Mercy Hospital*, *CMC – University*, and *CMC – South* were three partner hospitals to Carolinas Medical Center, the region's only Level 1 Trauma Center.

Gaston Memorial Hospital, with 1,543 employees, was operated by CaroMont Health and located in Gastonia, North Carolina (to the west of Charlotte). The 442-bed, independent, not-for-profit hospital was recognized nationally as one of the 100 top hospitals in the country. The growth of specialty services, such as the CaroMont Heart Center, the Comprehensive Cancer Center, and Women's and Children's Services, along with the addition of state-of-the-art surgical and treatment options, underscored Gaston Memorial Hospital's commitment to meeting the region's health care needs.

NorthEast Medical Center was established in 1937. This private, not-for-profit medical facility offered state-of-the-art services in affiliation with Duke University School of Medicine and Johns Hopkins. Offering a broad scope of services, 457 licensed beds, 275 skilled physicians and 3,500 employees, NorthEast Medical Center was a leading health care facility located in Kannapolis, North Carolina (in the north Charlotte region).

As one of the 118 hospitals owned by Tenet Healthcare, *Piedmont Medical Center*, located in Rock Hill, South Carolina, prided itself in keeping health care affordable, accessible, and effective for all families. With a staff of 1,400 employees combining advanced technology and highly skilled doctors, Piedmont provided a comprehensive care facility offering a wide variety of programs including cardiac surgery, neonatology services, emergency medical care, a cancer center, and a sleep disorder center.

Based in Charlotte, Presbyterian Healthcare was in the Southern Piedmont Region of Novant Health, the largest private, not-for-profit health care system in North Carolina. Presbyterian was comprised of four hospitals, *Presbyterian, Presbyterian Matthews, Presbyterian Orthopaedic Hospital* (one of the top 100 orthopedic hospitals in the nation), and *Presbyterian North* (opened in fall 2004). Novant's Southern Piedmont Region had 581 licensed beds and 5,772 employees, a skilled-nursing facility, physician division, and ancillary services.

# The Organization

Gregory A. Ball was hired as the first executive director in November 2002 to start the Center. A native of Gastonia, he had worked for the American Red Cross for 26 years before doing consulting work in the blood industry. At the Red Cross he was credited with starting one of the first automated platelet-collection programs in the industry and building four local offices or manufacturing facilities. He had managed eight different Red Cross business units around the country. As a consultant, Ball worked with Astraea, Inc. (Virginia Blood Services) to develop the feasibility study for CBCC. He was then hired as the first executive director responsible for start-up, from identifying a local board of directors and a medical advisory board to finding a facility and beginning production.







In November, Ball stated his goals: "I need to hire 50 people necessary to staff CBCC, find the Center's first Charlotte collection facility, draw the first unit of blood by spring 2003, raise the percentage from the typical 5 percent of the population donating in Charlotte to 9 percent, and bring in revenues of \$3.4 million in the first year."

In addition to Greg Ball, CBCC was led by a group of local business people who served as its board of directors and advised about the organization's business decisions – the products offered, where those products were to be sent, and how much they would cost. A medical advisory committee, comprised of local professionals, counseled the directors about medical concerns. Experts on this team – business and medical – were entrusted as stewards of local health care resources and were responsible for ensuring that the community received the most value possible for its health care dollars. (Exhibit 3/4 lists the 2004 board of directors and the medical advisory board.)

# Start-Up

Temporary housing for the Center was in Presbyterian Hospital. The Center handled its first unit of blood on August 15, 2003. Ball estimated that a facility of 20,000 sq. ft. was needed initially, but 32,000 sq. ft. would be needed when CBCC was collecting 60,000 units per year – the community's annual need for blood. A 30,000 sq. ft. facility was found on South Boulevard, a major artery near Charlotte's city center, less than five miles from the two major hospitals in Charlotte and with easy Interstate access for the other hospitals. Leased for seven years, the price was \$3.50 per sq. ft. in the first year and escalated over the period of the lease to \$7.00 per sq. ft. (Exhibit 3/5 has a schematic of the facility.)

Ball stated at a September 19, 2003 open house for the new facility, "My requirements are two: compliance and customer service. Compliance requires that we have the size and the capabilities to keep the blood supply protected. Customer service has enabled us to have one to three blood drives a day with about one-third of the donors not having participated in a drive previously."

CBCC became a member of America's Blood Centers (ABC) because the group subscribed to the same philosophy as CBCC – community-focused blood banking – meaning that community donors knew that the blood they gave stayed in the community to help family members, friends, and neighbors. Only excess supply was shared with other communities when needed. CBCC was a member of the American Association of Blood Banks (AABB) as well. (Exhibit 3/6 contains an overview of these organizations.)

## **CBCC Mission**

CBCC's mission was to provide local control of the blood supply, ensuring that local needs were met first. This local control provided greater choice for blood







#### Exhibit 3/4: CBCC Board of Directors and Medical Advisory Committee

Each of the five hospital systems involved with CBCC had a permanent seat on the board of directors. The remaining CBCC directors were elected to represent the communities served. These volunteer members of the board were business leaders and medical experts who made decisions to benefit the patients and donors in the greater Charlotte community. Board members included:

Jennifer Appleby – President and Chief Creative Officer, Wray Ward Laseter Advertising Agency. Steven Burke – Vice President, Ancillary Services, Presbyterian Hospital\* and CBCC Board Chair. Jeffrey Canose, MD – Vice President, Medical Services Division, Gaston Memorial Hospital.\* Bob Carden – President/Chief Executive Officer, Virginia Blood Services.

John Cox – Chief Executive Officer, Cabarrus Regional Chamber of Commerce.

Scott Gollinger - Vice President, Clinical Services, NorthEast Medical Center.\*

Mark Keener - Regional Chief Financial Officer, Carolinas Healthcare System.\*

Edward Lipford, MD – Carolinas Pathology Group.

Kim McMillian - Vice President, Marketing/Public Relations, Allen Tate Realty Co.

Mark Patafio - Vice President, Small Business Sales Leader, Wachovia Bank.

Jeff Smyre - Senior Manager, PricewaterhouseCoopers CPA.

Joseph Stough - Vice President, Piedmont Medical Center.\*

\*System permanent seats.

The CBCC medical advisory committee advised the board on medical matters. The medical advisory committee members were:

Linda Boggs - Transfusion Medicine Section Chief, Presbyterian Hospital.

Pam Clark, MD - Medical Director, Community Blood Center of the Carolinas.

Beth Curtis - Blood Bank Specialist, NorthEast Medical Center.

Rita Duffy - Blood Bank Supervisor, Gaston Memorial Hospital.

Stephen D. Harris, MD – Presbyterian Pathology Group.

Philip Leone, MD - Leone Pathology, Gaston Memorial Hospital.

Ned Lipford, MD - Carolinas Medical Center Laboratory.

Barbara McElhiney – Manager, Transfusion Services, Carolinas Laboratory System, Carolinas Healthcare System.

Beth Prichard, MD - NorthEast Medical Center Department of Pathology.

Rita Tate – Technical Director, Community Blood Center of the Carolinas.

Rob Thomas, MD - Piedmont Medical Center.

Kelly Ware - Transfusion Services Team Leader.

Jennifer Carpenter - Laboratory Director, Piedmont Medical Center.

products and services. Local doctors could select products and services that best met the needs of their patients. And for the first time in the region, donors had a choice of where they gave blood. CBCC was a customer-focused organization, and its service philosophy was to exceed expectations.

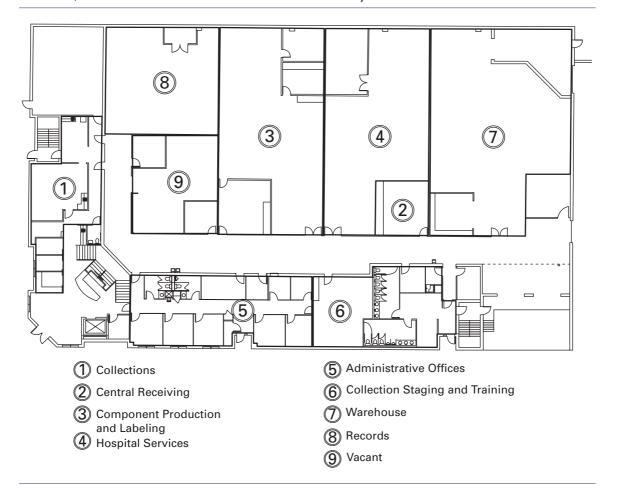
Ball said, "Control and choice lead to lower costs. CBCC is committed to offering services of the highest quality at more affordable and predictable pricing. Lower costs reduce patient charges and help our hospitals to control costs, become better stewards of resources, and improve patient care." CBCC emphasized regulatory







#### Exhibit 3/5: Plan of the CBCC South Boulevard Facility



#### Exhibit 3/6: Blood Banking Organizations

#### AMERICAN ASSOCIATION OF BLOOD BANKS

Founded in 1947, the American Association of Blood Banks (AABB) was organized to support and encourage continued blood research, promote exchange of scientific information, and develop standards of practice for blood banks. The AABB was an international association of blood banks, including hospital and community blood centers, transfusion and transplantation services, and individuals involved in activities related to transfusion and transplantation medicine. The AABB supported: high standards of medical, technical, and administrative performance; scientific investigation; clinical application; and education. It was dedicated to encouragement of voluntary donations of blood and other tissues and organs through education, public information, and research. The AABB member facilities were responsible for collecting virtually all of the nation's blood supply and transfusing more than 80 percent.

The AABB's mission statement was to establish and promote the highest standard of care for patients and donors in all aspects of: blood banking; transfusion medicine; hematopoietic, cellular, and gene therapies; and tissue transplantation. The AABB International's mission statement was to







#### Exhibit 3/6: (cont'd)

coordinate and promote improvements in blood banking and transfusion safety internationally by supporting: (1) the development of national and/or regional standards in blood banking; transfusion medicine; hematopoietic, cellular, and gene therapies; tissue transplantation; and (2) the development of mechanisms for assessing compliance with those standards.

More than 2,200 institutions (community and hospital blood banks, hospital transfusion services, and laboratories) were AABB members (AABB accreditation was a requirement for institutional membership). More than 8,500 individuals were members of the AABB (anyone interested in or actively involved in transfusion medicine and related biological therapies was eligible for individual membership, including physicians, scientists, administrators, medical technologists, blood donor recruiters, and public relations personnel). Members were located in all 50 states and 80 foreign countries. The AABB's active membership provided direction to the Association through its elected board of directors and more than 30 committees of volunteer professionals.

#### Accreditation

The AABB Accreditation Program strove to improve the quality and safety of collecting, processing, testing, distributing, and administering blood and blood products. The Accreditation Program assessed the quality and operational systems in place within the facility. The basis for assessment included compliance with Standards, Code of Federal Regulations, and federal guidance documents. This independent assessment of a facility's operations helped the facility to prepare for other inspections and served as a valuable tool to improve both compliance and operations. Accreditation was granted for: collection, processing, testing, distribution, and administration of blood and blood components; hematopoietic progenitor cell activities; cord blood activities; perioperative activities; parentage testing activities; immunohematology reference laboratories; and specialist in blood bank schools. Since 1957, the AABB has been a leader in the development of standards for voluntary compliance in blood bank blood component collection, processing, and transfusion. Standards for Blood Banks and Transfusion Services was developed by experts in blood banking and transfusion medicine. Standards were based on good medical practice and, when available, scientific data, principles associated with good manufacturing practices and quality assurance that were consistent with FDA regulations. These standards, along with the requirements specified in the Accreditation Information Manual provided the basis for the AABB Accreditation Program.

#### **AMERICA'S BLOOD CENTERS**

In 1962, seven community-based blood centers came together with the help of local hospitals, physicians, and civic groups to establish America's Blood Centers (ABC). Medical expertise, customer service, and a community-first blood banking philosophy were the founding principles of America's Blood Centers. The community-based blood banking philosophy meant that community donors knew that the blood they gave stayed in that community first – helping family members, friends, and neighbors. Any excess supply was shared with other communities that needed it most.

America's Blood Centers became an international network of 76 community-based blood centers around the United States and Canada. ABC members collected 7.5 million units of whole blood in 2003 – nearly half of the United States as well as 25 percent of the Canadian blood supply. ABC members yearly provided more than 10 million blood components (including red blood cells, platelets, and plasma) to hospital customers.

ABC members supplied a majority of the nation's tissue, bone marrow, stem cell, and transfusion services. In addition, America's Blood Centers members received the majority of blood-related NIH research funds. Fifteen members managed cord blood banks for transplantation. The New York Blood Center operated the largest cord blood bank in America.

ABC's national office provided members with support for national awareness campaigns, lobbying with the government, information on medical issues of concern to the blood banking community, blood resource sharing, group purchasing, educational programs, fund-raising support, blood center quality management issues, and federal regulation training programs.

Six ABC centers were located in South Carolina; Community Blood Center of the Carolinas was the only ABC center in North Carolina.







and quality assurance standards to help make certain that only the highest quality blood products were collected and used, and ensured that the safety and well-being of donors and patients were protected. Residents of the region had an alternative to the Red Cross.

## The American Red Cross<sup>1</sup>

Clara Barton and a circle of acquaintances founded the American Red Cross (ARC) in Washington, DC on May 21, 1881. Barton first heard of the Swiss-inspired International Red Cross Movement while visiting Europe following the Civil War. After returning home, she campaigned for an American Red Cross Society and for ratification of the Geneva Convention protecting the war-injured. She was successful on both.

Prior to World War I, the ARC introduced first aid, water safety, and public health nursing programs. With the outbreak of war, ARC staffed hospitals and ambulance companies, and recruited 20,000 registered nurses to serve the military. Additional Red Cross nurses came forward to combat the worldwide influenza epidemic of 1918. As a member of the International Federation of Red Cross and Red Crescent Societies, which it helped found in 1919, the American Red Cross joined more than 175 other national societies in bringing aid to victims of disasters throughout the world.

After World War I, ARC focused on service to veterans and enhanced its programs in safety training, accident prevention, home care for the sick, and nutrition education. In addition, it provided relief for victims of major disasters such as the Mississippi River floods in 1927 and severe drought and the Depression during the 1930s.

The Red Cross provided extensive services once again to the US military, Allies, and civilian war victims during World War II. It enrolled more than 104,000 nurses for military service. At the military's request, the Red Cross initiated a national blood program that collected 13.3 million pints of blood for use by the armed forces. After World War II, the Red Cross introduced the first nation-wide civilian blood program that supplied nearly 50 percent of the blood and blood products in the United States. In addition, the Red Cross expanded its role in biomedical research and entered the new field of human tissue banking and distribution.

# ARC's Biomedical Services<sup>2</sup>

The biomedical services division of the Red Cross comprised blood services, tissues services, plasma services, and research. Blood Services was the most visible of ARC's Biomedical Services Divisions and collected about 50 percent of the blood donated in the United States through 36 blood services regions. The Red Cross estimated that the United States needed 38,000 units of blood





per day (over 13 million units annually). In fiscal year 2003, 6.42 million units were collected through the Red Cross – a decrease of 2.6 percent compared with fiscal 2002.

#### ARC Blood Services Division Has Its Problems

Although the Red Cross was known for its disaster relief as well as its blood products, it was the blood services division that caused its headaches.

# BLOOD SAFETY<sup>3</sup>

The Red Cross had been under a court-supervised consent decree since 1993 to eliminate safety problems in its blood program. In the 1993 consent decree, the Red Cross agreed to establish clear lines of managerial control over a newly established, comprehensive, quality assurance program in all regions; to enhance training programs; and to improve computer systems, records management, and policies for reporting problems, including adverse reactions.

In February 1999, the ARC had completed its "Transformation," a \$287 million program that reengineered its Blood Services' processing, testing, and distribution system and upgraded its computer system for tracking blood products (among other management activities). As a result of this investment, the ARC's Biomedical Services had:

- a single, standardized computer system that efficiently maintained its blood donor database;
- a network of eight national testing laboratories;
- a biomedical institute that provided training and other educational resources to Red Cross Blood Services' personnel;
- a quality assurance/regulatory affairs department to assure compliance with FDA regulations; and
- a centrally managed blood inventory system to ensure the availability of blood/ blood components throughout the country.

Poor donor screening, the release of mislabeled blood, collecting blood from disqualified donors, flawed procedures aimed at keeping unsuitable blood in quarantine, falsified records, retaliation against employees who reported problems, poor inventory controls, computer errors in tracking blood, and failing to ask donors about risky health practices were some of the issues that the FDA had identified over time in various ARC facilities or its home office in Washington, DC. An FDA inspection of the Red Cross headquarters in December 2002 revealed that the ARC failed to correct deviations from the last inspection, that the ARC's lack of quality assurance oversight led to the release of unsuitable blood products, and that the lack of inventory control led to the unknown disposition of blood products. Thus, the FDA was ready to sue for a revised consent decree.







The revised consent decree stemmed from "FDA concerns arising from inspections over the past 17 years revealing persistent and serious violations of blood safety rules." The revised consent decree included the following fines if the ARC failed to comply with blood safety rules and the revised requirements:

- \$10,000 per event for any violation of the ARC's standard operating procedures (FDA mandated and approved written procedures designed to help ensure product quality), the law, or consent decree requirements and timeline.
- \$50,000 for the preventable release of each unit of blood if the FDA determined that there was a reasonable probability that the product might cause serious adverse health consequences or death, as well as \$5,000 for the release of each unit that might cause temporary problems, up to a maximum of \$500,000 per event.
- \$50,000 for the improper re-release of each unsuitable blood unit that was returned to inventory.
- \$10,000 for each donor inappropriately omitted from the National Donor Deferral Registry, a list of all unsuitable donors.

In February 2004, the FDA informed the ARC of its intention to assess fines because the ARC's Problem Management Standard Operating Procedures, submitted October 2003, did not meet the terms of the Amended Consent Decree. The Red Cross issued a statement that it "continues to share with the FDA the steadfast commitment to the safety and availability of the blood supply" and was "working diligently to review and implement satisfactory SOPs" that would bring it to "swift regulatory compliance." In addition, the Red Cross stated that it had made provisions within its operating funds to cover the cost of the penalties and that "no monetary donations will be used to pay these penalties."

# September 11, 2001: Attacks and Discarded Blood Units<sup>5</sup>

According to *The Washington Post*, the General Accounting Office reported that the vast amount of blood collected from new donors was not needed by victims of the terrorist attacks – fewer than 280 units were used of the approximately 572,000 additional pints collected. In the end, one in every three pints was thrown away – about 208,000 pints. The *Los Angeles Times* reported that critics had faulted the Red Cross for its "unrelenting call for blood donors after September 11th resulting in more than 250,000 pints being discarded because it was too old to use."

The Red Cross was criticized for continuing to collect tens of thousands of pints after it was clear the blood would not be needed by the victims of the September 11 attacks and after many members of America's Blood Centers had halted collections rather than accept surplus blood. The Red Cross defended its actions and said it continued collections because it needed to build inventories in case of future attacks and wanted to enable Americans to do something for their country. In addition, the Red Cross said it planned to freeze more than 100,000 pints for future emergencies, but ended up freezing about 9,000 units.







Because of the bad publicity over the discarded blood, a backlash occurred, resulting in apathy toward donating. These first-time donors did not return. The Red Cross had 276,423 first-time donors within weeks of the attacks, but fewer than one in 20 returned.

#### Red Cross Research

The Red Cross national research program was established to make contributions to biomedical science, blood safety, plasma-derived therapeutics, and transfusion technology. Red Cross scientists were engaged in research to develop the next generation of blood products and services. Each year, the Red Cross invested more than \$25 million in research projects seeking to improve the safety, purity, and efficacy of blood.

Recent examples of research results were the actions taken for leukocytes and cellular therapy. Ordinarily, leukocytes (white blood cells) help fight off foreign bodies, such as bacteria, viruses, and abnormal cells, to avoid sickness or disease; however, when transfused to another person, these foreign leukocytes in whole blood were often not tolerated well by some patients and have been associated with transfusion complications. Although not required by many patients, the Red Cross moved to a system-wide, pre-storage leukocyte reduction to improve patient care. Within 48 hours of donation, all blood was filtered to remove leukocytes, adding about \$65 to the cost of processing each unit of blood.

Cellular therapy involved collecting and treating blood cells from the patient or another blood donor. The treated cells were then returned to the patient to help revive normal cell function; to replace cells that were lost as a result of disease, accidents, or aging; or to prevent illnesses. Cellular therapy might prove to be helpful for patients undergoing treatment for cancer, because researchers hoped that treated cells would battle cancerous cells.

# ARC's Carolinas Blood Services Region<sup>7</sup>

Headquartered in Charlotte, North Carolina, Carolinas Blood Services was established to serve a population of more than 6 million people from 82 counties in North Carolina and parts of South Carolina, Georgia, and Tennessee. In addition, Charlotte was the location for one of eight Red Cross national testing laboratories. The Red Cross estimated that more than 1,500 units of donated blood were needed daily in the Carolinas region; between 1,500 and 1,600 blood products were distributed daily to more than 100 hospitals. Blood was collected from ten permanent sites (Asheville, Cary, Charlotte, Durham, Greensboro, North Raleigh, Raleigh, Wilmington, and Winston-Salem in North Carolina and Johnson City, Tennessee) and more than 10,000 blood drives each year involved businesses, churches, schools, shopping malls, and so on. In 2002, individuals donated more than 400,000 units of whole blood and more than 50,000 apheresis products. The Carolinas Blood Services Region led the nation in collections from 1997 through 2003.







Additional services offered by the Carolinas Blood Services Region included: two reference labs (operated 24/7); frozen units of rare blood (the American Red Cross maintained the National Rare Blood Registry); therapeutic apheresis; perioperative autologous salvage (recycling of a patient's blood during surgery); and bone marrow, stem cell, and sickle cell programs (typing for matching, and so on).

# **Blood Challenges**

ARC collected about 45 percent of the blood supply, ABC-related organizations collected about 45 percent, and hospitals collected about 10 percent. Estimates were that approximately 32,000 units of blood were needed daily in the United States.

# Number of Donors

The major challenge in blood banking was to increase the number of donors as well as increase the number of donations made by each individual donor. A healthy person could donate blood every 56 days (six times per year). Only 5 percent of the population donated blood. During the late 1990s and the early years of the new millennium, the advent of mad cow disease, SARS (severe acute respiratory syndrome), and the West Nile virus severely impacted the number of potential donors.

Donors had to be at least 17 years old, 110 pounds or more, and meet the requirements of the screening process. As the number of screening tests performed and the restrictions on donors increased, blood donors decreased. Screening for HIV/AIDS and hepatitis had been done for some time, but new tests were required for mad cow disease, SARS, and West Nile virus.

#### Screening for Mad Cow Disease

In 2002, because of mad cow disease, the FDA enacted restrictions on blood donations from anyone who lived in the United Kingdom for three months or more between 1980 and 1996; spent five years or more in Europe since 1980; spent six months or more from 1980 to 1990 on a military base in Belgium, the Netherlands, Germany, Spain, Portugal, Turkey, Italy, or Greece; or who received a blood transfusion in the UK since 1980.

#### SCREENING FOR SARS

The first SARS case was identified in November 2002 and in April 2003 the FDA recommended guidelines for donations:

 Individuals who had traveled to high-risk areas for SARS (People's Republic of China, Hong Kong, Hanoi, Vietnam, Singapore, Taiwan, and Toronto, Ontario)





were deferred from giving blood for 14 days after returning even if they showed no symptoms of infection.

- Individuals who had close contact with someone who had SARS were deferred for 14 days following the last close contact.
- Individuals who had SARS or were suspected of having SARS were deferred for 28 days after complete symptom resolution and termination of medical treatment.
- Recent donors who experienced a SARS related exposure were encouraged to report the information up to 14 days after donation.

#### Screening for West Nile Virus

The first West Nile virus cases in the United States occurred in 1999. Over the three years till 2001 there were 18 deaths. Then, in 2002, the number jumped to over 4,000 cases and 284 deaths. At least 23 people were infected by the virus through blood transfusion and four more through organ transplants. Nucleic acid amplification tests (NATs) of collected blood were required by the FDA as of July 1, 2003. Although donors were specifically asked if they had experienced fever with headache during the seven days prior to donation, only about 20 percent of individuals who had been exposed to the virus actually developed symptoms (flu-like, with headache, fever, and muscle aches). Individuals were deferred for 14 days after the last occurrence of symptoms (headache and fever) or if the NAT identified the presence of the virus.

# Cost of Blood

Although donated blood is free, there are significant costs associated with: collecting, testing, preparing components, labeling, storing, and shipping blood; recruiting and educating donors; and quality assurance. As a result, processing fees are charged to recover costs. Hospitals charge for any additional testing that may be required, such as cross matching, as well as for the administration of the blood. When CBCC began operations in 2002, the Red Cross charged about \$200 per unit and CBCC charged \$150. For CBCC hospitals, the difference amounted to a \$3 million saving. In 2004, the differential remained about the same.

# Demand Exceeding Collections

The blood supply level fluctuated throughout the year. During holidays and in the summer, supplies tended to fall because donations declined, but demand remained stable or even increased. Persons 69 years and older accounted for approximately 10 percent of the population, but they required 50 percent of all whole blood and red blood cells transfused, according to the National Blood Data Resource Center. Using current screening and donation procedures, a growing number of blood banks found blood donation by seniors to be safe and practical.







# **Reality Sets in for CBCC**

Trouble in collection volume became apparent in October 2003. Ball's estimates for blood collection were not being met (700 units collected versus 1,400 projected per month) and costs were considerably higher than budgeted. In November 2003, CBCC was required to undergo some "rightsizing." The board replaced Ball with an interim executive director, Linda O'Neal, who was director of marketing and strategic planning at Virginia Blood Services. O'Neal traveled to Charlotte each week from November to May, when chairman of the board, Tom Hassett, became the interim director.

Hassett had been intimately involved with CBCC since its inception. He flatly stated, "The critical success factors for CBCC are donations, donations. The regulatory part is critical but it's a given. We need to be as near perfect as humanly possible. But if we don't have donations, it doesn't matter."

He continued, "When the budget was so bad, the board reduced the staff from 50 to 31. Blood requires a highly specialized staff and if they are not kept busy, we can't reduce the time they work per week because they will quit and go elsewhere – and there are plenty of places that will hire them."

One concern in particular to Hassett was that the board found it necessary to wipe out the marketing budget at a time when it was so necessary to get CBCC's name out to the community. He went on to describe other cost-cutting measures: "We have two apheresis machines that lease for \$4,000 per month. We are not using those machines sufficiently and I'm trying to get out from one of the leases until we build the number of apheresis donors. In addition, several of the hospitals wanted us to do autologous blood collection at the hospital. We had three set up with that capability but it really made more sense for us to centralize that process. Now we have autologous collection, apheresis collection, and whole units collected at the Center."

Hassett expressed some frustration in CBCC's inability to attract donors. He commented, "The Red Cross is really entrenched here. They have had drives at companies and churches for years. We were warned that it would be challenging for CBCC to get started, but I don't think any of us realized how hard it would be. That's why we put back some marketing money in our tight budget. We began the '100 Sponsors in 100 Days' campaign that ran from April to August 5, 2004." Exhibit 3/7 shows one of the ads that ran in local newspapers.

Hassett summarized, "We ended up with 112 new sponsors, bringing the total number to 285 organizations. We are trying to contact new organizations that do not have pre-set ideas about only donating to the Red Cross. We are happy when anybody gives blood because it saves lives – but we would like more donors to give through CBCC. We've had some success going to high schools. Kids have to be over 17 to donate, but there are a good number of seniors who are. Targeting them is really a long-range strategy because we hope that over their lifetime they will continue to donate to CBCC."

He continued, "We collected about 1,000 units a month – by fiscal year end 2004. In 2004–05, CBCC is satisfying 70 percent of the need for blood in the





Exhibit 3/7: 100 in 100 Ad

# If you just gave a pint of blood, why is it the hospitals feel so weak?

For a number of years, local hospitals have been struggling to have a voice in their blood program. Their doctors have asked for a choice in products and services to best meet the needs of their patients. They've sought predictable blood prices to help contain rising healthcare costs in our community. That's why 10 of those hospitals you trust for your healthcare decisions made just that – a decision. They decided to put the needs of local patients, donors and doctors first.



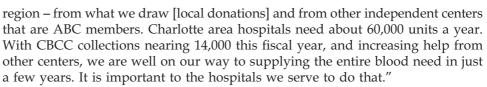
To sign up your organization, please call 704/972-4701.
Or visit 100in100.org. Because the value of a pint of your blood is immeasurable.

Hence, the creation of Community Blood Center of the Carolinas and the 100 in 100 blood drive challenge. During the next 100 days, we'll be contacting organizations like yours to secure 100 new blood drives so local donors will have opportunities to help save local patients.



100 days to secure blood drive commitments with 100 additional organizations

Carolinas HealthCare System • Caromont Health • NorthEast Medical Center • Piedmont Medical Center • Presbyterian Healthcare



Some ABC blood centers were fortunate enough to collect more blood than they regularly use. CBCC contracted with some of them for excess blood for one year; contracts with others were by the quarter. Because it was excess blood for the centers, the price was reduced. Hassett said, "We don't want to rely on blood from other centers, but for now it is an effective bridge to help us get where we need to be."

#### Financial Concerns

"We have three crews that handle our drives," explained Hassett. "We need to keep them and the Center staff busy to lower our costs of production. We have also been talking with hospitals in western North Carolina and Greensboro that might start community blood centers and ship blood to us for processing. It seems logical that we don't all need processing facilities and ours is certainly large enough.







I don't know if we can make that work, but it is an interesting scenario. Right now our hands are full managing our operations and building the number of donors.

"Our original budget (see Exhibit 3/8) was optimistic. When we didn't hit the numbers, we were fairly drastic in 'rightsizing.' We cut staff – from 50 employees to 31 – and reviewed all ways to manage more efficiently. Despite

#### Exhibit 3/8: Initial Budget

#### A: Forecasted Collections FY 2003 (April through September) Oct. Nov. Dec. Jan. Sep. **Total** Feb. Mar. Apr. May Jun. Jul. Aug. **Collections** Whole Blood 400 400 600 700 700 800 3,600 Autologous 150 150 150 150 150 750 **Apheresis** 25 50 75 150 1,025 **Total** 400 550 750 875 900 4,500 FY 2004 Oct. Nov. Dec. Jan. Feb. Mar. Apr. May Jun. Jul. Aug. Sep. **Total** Collections 1,000 1,200 1,350 1,400 1,450 Whole Blood 700 800 900 1,100 1,500 1,500 1,600 14,500 75 75 75 75 75 75 75 75 75 Autologous 75 75 75 900 **Apheresis** 10 20 30 40 40 40 50 50 50 50 50 10 440 1,215 **Total** 785 885 995 1,105 1,315 1,465 1,525 1,625 1,625 1,725 1,575 15,840

#### B: CBCC Summary P&L (Forecasted) (\$)

	FY 2003	FY 2004		FY 2003	FY 2004
Revenue			Education	7,200	0
Blood Products			Public Relations	153,330	104,000
Red Blood Cells (RBCs)	513,000	2,493,909	Services Purchased	448,365	711,785
RBCs Leukoreduced	0	4,743,920	Utilities	45,000	85,325
RBCs-Auto's	168,750	200,475	Business Expense	54,690	27,700
Random Donor Platelets	54,530	272,655	Insurance	39,328	146,122
Fresh Frozen Plasma	98,800	1,060,245	Depreciation	70,487	123,680
Recovered Plasma	24,273	0	Interest Expense	68,956	100,380
Apheresis Platelets	20,000	230,400	Duplication Expense	59,618	4,460
Total Revenue	879,353	9,001,604	Building Repair	0	0
Oneveting Evnences			Renovations	0	0
Operating Expenses Salaries	1 220 400	1 000 440	Shipped-in-Blood	0	5,107,544
	1,338,480	1,882,440	Postage	11,250	6,000
Salaries O/T	88,316	55,680	Contributions	0	0
Bonus Benefits	0	227.241	Freight	32,528	28,992
	285,359	327,341	Taxes	20,000	0
Professional Services	391,360	503,100	Lease/Rent	128,749	207,479
UNCAP Equipment	16,862	1,500	Purchase Expense	6,270	0
Equipment Rentals	17,472	48,000	Total Operating Expense	3,498,696	9,819,008
Equipment Repair	27,364	15,925		(0.040.040)	(047.404)
Supplies	187,712	331,555	Net Income (Loss)	( <u>2,619,343</u> )	(817,404)





the loan guarantees from the hospitals that created CBCC, projections were that we might run out of cash by September."

Hassett's task during the summer of 2004 was straightforward:

- Increase cash flow to keep the Center alive.
- Increase the number of donors and sponsors.
- Increase the level of customer service.
- Hire a highly talented and energetic executive director.

#### CASH FLOW

With a projection of running out of credit in September, the hospitals agreed to institute a fast-pay program – CBCC submitted invoices daily and was paid weekly. Consequently, days in accounts receivable were significantly reduced and the Center was positioned to stay alive while the other cost-reduction strategies were implemented.

#### Sponsors and Donors

The "100 in 100" campaign was given major focus with a very positive outcome of signing 112 new sponsors in 100 days. Because of new sponsors, future donations would increase because of the relationships being built.

#### Customer Service

Every drive needed to be as near perfect as possible. Collecting blood was nearly identical no matter whether it was the Red Cross or a community blood center because the process was so heavily regulated by the FDA. The difference would be seen in donor satisfaction and sponsor satisfaction. Survey instruments were implemented so that CBCC could score and track satisfaction. The reports pointed out where improvement could be made and provided positive feedback to the collection and support staff. Satisfaction scores increased to the level of between "very satisfied" and "extremely satisfied."

#### EXECUTIVE DIRECTOR

With cash flow in order, the number of sponsors significantly increased, and donor satisfaction high, it was time to recruit a permanent executive director. First, the board defined the qualities desired in CBCC's top executive. A proven track record of success in a sales-oriented business was considered to be of utmost importance. Secondly, the individual's personality would need to exhibit passionate energy for the community role and success of CBCC. Thirdly, it would take someone who could manage operations well. Because of the expertise of Virginia Blood Services regarding all regulatory and quality functions, the board felt that the executive director did not have to be an expert in the science of blood banking but he or she would certainly have to have a healthy respect for the need to be outstanding in the areas of quality and regulation and to assure compliance.







# What's Next?

Challenges remained for CBCC. Although the budget for the Center called for breakeven operations by September 2005, it also called for a 40+ percent increase in the number of collections. It was considered doable, but challenging. The largest companies and government agencies in the region had a long history of sponsorship with the Red Cross; it continued to fight to maintain its market share despite 70 percent of the blood collected in the Charlotte area being sold across the country. CBCC had to earn its way to increased blood drive sponsors by proving over and over its commitment to the local community and telling its story by every avenue possible.

After an extensive search, Martin Grable was hired as executive director in September 2004 (see Exhibit 3/9 for the news release announcing the appointment). In accepting the position, he stated, "It's all about donor development – there is nothing else. CBCC is meeting the quality and service standards. Clearly we have to build the donor and sponsor base."

He continued, "The fiscal year has just started. Three days after I arrived one of the recruiting managers resigned. We can't get behind the curve in October

#### Exhibit 3/9: News Release

#### CBCC APPOINTS NEW EXECUTIVE DIRECTOR

Charlotte, NC – Community Blood Center of the Carolinas' Board Chair, Steven Burke, announces the appointment of Martin A. Grable of Charlotte as Executive Director. Mr. Grable has 17 years of experience delivering consulting, financial, and professional services to large corporations. Most recently, he was cofounder, president and CEO of Matrix Absence Management, Inc. of San Jose. Founded in 1985, Matrix is a national benefits administrator providing professional services to many of the Fortune 500 companies – a number of which have remained with the company since its beginnings. The first seven Matrix clients – Philips Semiconductor, University of the Pacific, Amdahl, LSI Logic, National Semiconductor, Sun Microsystems and Intel Corporation – have remained as clients. He sold the company in 1998 to Delphi Financial Group and agreed to remain as President and CEO for three years.

In 2002, Martin Grable had the good fortune to travel and reflect on the opportunities that might lie ahead. He did an exhaustive search for the right community for his family – one that was growing, with a diverse economic base, in a good location with a great climate and a major airport, and a strong sense of community. After many visits to a number of locations, he became a Charlottean by choice.

His interest in doing something different that would make a difference led Grable to apply for the position of Executive Director at CBCC. Grable stated, "I came to CBCC because I recognized the importance and value a community blood center brings to the community. The blood supply is a community asset, best managed locally, with the interests of the local community as the top priority." CBCC was established in 2003 through the collaborative efforts of ten area hospitals to better provide for the blood needs of the communities in the Charlotte area. Steven Burke, CBCC Board Chair said, "The Board is really excited that Martin Grable is bringing both his concern for the community and his entrepreneurial spirit to assist in meeting the blood needs for our community."

Grable was born and raised in Kansas and attended the University of Kansas. He is married to Cathy and they have three children: Lauren 20, Nicole 26, and Heather 30.







because the months of November and December are traditionally slow months for donations. I have to figure out what to do now – the immediate plan. Then, determine a mid-range plan for the next two quarters, followed by a longer term strategic plan . . . But, they all have to work together or there will be a mixed message to donors and sponsors and that won't help us at all."

He concluded, "I like the odds. We'll have a few bumps in the road, but I like the geometry of the hospitals, the community, and the blood center. We are a service to the community and we will develop that sense of community."

#### **NOTES**

- This section is taken from "A Brief History of the American Red Cross," http://www.redcross.org/ museum/history/brief.asp, accessed July 10, 2004.
- Information in this section is from "Biomedical Services," http://www.redcross.org/services/biomed/, accessed July 10, 2004.
- "American Red Cross Agrees to Revised Consent Decree to Improve Blood Safety," FDA News at http:// fda.gov/bbs/topics/NEWS/2003/NEW00891.html, accessed September 18, 2004.
- 4. "American Red Cross Statement on FDA Adverse Determination Letter of Feb. 6, 2004," http://www.redcross.org/pressrelease/0,1077,0\_314\_2271,00.html, accessed September 18, 2004.
- 5. Gilbert M. Gaul and Mary Pat Flaherty, "Troubled Times for Red Cross; Blood Bank Faces Shortages, Dispute over Safety Violations," *The Washington Post* (September 16, 2002), p. A-2.
- Charles Ornstein, "FDA Cites Concerns over Red Cross' Handling of Blood," Los Angeles Times (December 11, 2001), p. A-44.
- This section is adapted from "About Us," American Red Cross Carolinas Blood Services Region at http:// www.redcrossblood.org/about.htm, accessed on July 10, 2004.



