Organizational Crisis: American Red Cross' Response to HIV and the Public's Perception in the Safety of the Blood Supply

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FOCUS AND REVIEW OF ISSUE

During the past ten years, the blood banking industry has had to react quickly to the deadly HIV virus. In the spring of 1982, the first case of hemophilia-associated acquired immunodeficiency syndrome (AIDS) came to the attention of the blood bank community.

As the disease spread and the number of cases mounted, so did public concern. The American people expressed this concern to their elected representatives in Congress. Congress, in turn, exerted increasing pressure on the U.S. Food and Drug Administration, which regulates blood banking.

By March of 1983, guidelines of the FDA prohibited blood donation by members of high-risk groups and those with symptoms or signs of AIDS (Pindyck, 1985). But, by summer there was near panic in segments of the public, with the few transfusion-related cases drawing considerable attention.

In an effort to "do something," blood bankers and regulators were considering surrogate testing when, in April of 1984, Dr. Gallo of the National Cancer Institute announced that AIDS was caused by a retrovirus, and that he and his associates had propagated it in a special cell line. A retrovirus contains RNA, not DNA, and produces a DNA analog of its RNA through the production of an enzyme known as "reverse transcriptase." Furthermore, Gallo described a test for the antibody to the virus which correlated highly with

viral exposure and indicated that the test could be available in less than 1 year (Morbidity and Mortality Weekly Report, 1985).

Officials of the United States Public Health Service (USPHS) licensed five manufacturers to produce test materials and clinical trials began in the fall of 1984. It seemed that licensure and mandatory donor testing were imminent; yet many blood donors, public health officers, physicians, gays, and ethicists were disturbed. Because the interpretation of a positive test result remained ambiguous, debate extended about whether donors, whose blood tested positive, should be informed what the responsibility of the collecting institution to the donor ought to be, and whether positive results should be entered onto deferral lists which might result in harm to the donor (Zuck, 1986).

The American Red Cross has had to react quickly to the HIV virus. Vast operational changes have occurred, and continue to occur, to protect the nation's blood supply from the HIV virus, as well as other blood transfused diseases. People's attitudes to these rapid changes are important to determine if the changes made within the Red Cross were enough.

This research will seek to ascertain the results of the operational changes that have taken place within the American Red Cross in response to the surfacing of the HIV virus, and, whether the changes made within the organization have made

the nation's blood supply as safe as possible, with respect to FDA regulations and public's perception as to the safety of the blood supply.

Blood Banks Respond.

Under the public spotlight, blood bankers developed new procedures to test and track their blood supply. Also, new questions were asked of the blood donors to assess groups at high-risk of exposure to HIV. Safeguards were established to maintain a clean blood supply, free from any blood-transfused viruses.(Olson) However, the standard screening tests for the HIV virus only detect antibodies to the virus. Because those antibodies typically do not show up in the blood for an estimated six weeks, a newly infected person may appear free of the virus.

Regulatory pressures on the blood industry have steadily increased and are expected to continue to increase in the future. In 1988, there were 288 licensed blood bank locations operating in the country. In the past two years, 40 of these have been either closed down by the FDA, or closed voluntarily due to difficulties in meeting standards of quality (Olson, 1991).

It is significant to note that only two of the 40 blood regions that were closed (Washington D.C., and Albany, New York), were operated by the American Red Cross. The operation of these two blood regions have been successfully

assumed by other nearby Red Cross blood regions. The American Red Cross collects just over 50% of all the blood used in the United States, so the FDA looked increasingly to the Red Cross to lead the way in ensuring the safety of the blood supply.

However, problems began to arise within the Red Cross system. Blood records appeared to be lost or not stored properly. The lines of accountability were vague. American Red Cross National Headquarters was losing control over the local blood regions. In 1988, the Red Cross entered into an agreement with the FDA, under which the Red Cross agreed to implement certain operational changes that would enhance ability of the Red Cross to ensure that all of its 53 blood regions meet the highest standards of quality and safety.

As a result of the 1988 American Red Cross/Food and Drug Administration agreement, on August 10, 1990, the American Red Cross announced operational changes, which represented a significant step in attempting to ensure the enforcement of uniform standards throughout the system. Prior to August 1990, the 53 Blood Regions of the Red Cross were governed by local volunteer Board of Directors, exercising its local authority to employ paid staff, who in turn operate the blood regions under guidelines provided by the National Red Cross. These guidelines were FDA approved.

But, in 1990, the National Red Cross Board of Governors determined that enforcement of uniform standards under the

guidelines of the FDA would be more effective if the Principal Officer in charge of each blood region is an employee of the National Red Cross, reporting directly to the Vice President, at National Headquarters. The National Board doubled its quality and regulatory assessment unit, and tripled the staff of its regulatory affairs unit. A new department of Education, Recruitment and Training was formed to increase the American Red Cross' commitment to quality assurance (Mueller, 1991).

On May 20, 1991, American Red Cross President Elizabeth H. Dole announced the most dramatic and far-reaching public safety step the Red Cross has taken in its 110 year history-- a total transformation of how the organization collects, processes and delivers blood.

"Instead of continuing to patch and bandage a system that evolved in the 1940s," (in 1940, there were two tests for blood) Dole said, "we will move to the next generation. (today, there are seven tests for each unit of blood). Drawing heavily on our people and our finances, we intend to expand the world of the possible. Rather than just meeting standards, we will raise them. Instead of just fixing problems, we will spend our time preventing them...for, because of the AIDS epidemic, nothing short of a transformation is needed" (Dole, 1991).

The transformation is described as a five-point plan that will be implemented over the next two-and-a-half years

at an estimated cost of $120 million. As outlined by Dole, the plan includes:

* The temporary closing of every Red Cross blood center, so each can be re-equipped. New standard operating procedures will be put into place and the staff trained. Only the distribution functions of the blood centers will remain open throughout the transformation so they can receive blood from other, operating Red Cross centers through a blood transport system. "We will ensure that blood is provided...so that not a single patient will go without the transfusion he or she needs," Dole said.

* Testing of blood will be moved from the 53 blood centers and placed in fewer than 10 regional laboratories, and the number of internal inspectors will be increased. Donor recruitment, blood collection and component production will then resume at the blood collection centers.

* One national computer system will be adopted for use by all blood centers throughout all Red Cross blood operations. At present, the Red Cross is operating 10 systems. These diverse computer systems were responsible for 25 percent of the citations made by the FDA in 1990, Dole said. In addition, development is underway of a new state-of-the-art donor deferral registry, through which one national computer system will record and archive any health history data or test results that categorize the donor as unsuitable.

* Customized patient services, such as special blood typing needs, tissue services or the return of a patient's own blood during surgery, that are currently provided only by some blood centers will be made available through all Red Cross blood centers. With this change, smaller hospitals will be able to receive the same advanced blood banking services as easily as larger hospitals.

* The oversight of all Red Cross Regional Blood Services will be separated from that of the local chapter, and newly formed Biomedical Boards of Directors at the local level will make the decisions that affect the safety and adequacy of the blood supply, determine the special patient needs in each community, and ensure that these are met.

The Red Cross plan received praise from Congressman John Dingell, Chairman of the House Energy and Commerce Committee, and Louis Sullivan, Secretary of Health and Human Services.

Dole stated that "their personal commitment to the safety of the nation's blood supply has proven to be a strong and useful catalyst to the Red Cross' own intensive self examination." Dole added, "the issue (safety of the blood supply) before us is bigger than the American Red Cross. It is a public policy issue" (Dole, 1991).

Since the American Red Cross is the largest public blood banking agency, and it touches the lives of so many U.S. citizens (97.6% of people who live to be 72 will require some type of blood transfusion or blood product in their lifetimes (Allen)), it is important that people are aware of the steps this organization is making to try to ensure the safety of everyone that needs a blood product or transfusion. Therefore, it is important to examine the organizational mechanisms and interview the leaders who influence the effectiveness of how the American Red Cross collects, processes, and distributes a clean, safe blood supply.

Blood Regulations.

The U.S. blood supply is regulated by the U.S. Food and Drug Administration and the American Association of Blood Banks. It is important to note the difference between the FDA and the AABB. The FDA is a federal agency, with the authority to close blood centers if they are not operating according to federal codes and

regulations. The American Association of Blood Banks is a membership association in which members must meet certain requirements that tend to involve higher standards of quality than mandated by the FDA. The AABB has no authority to close blood centers, but can revoke membership in the organization.

More important, operationally, is that specific standards for the manufacture of blood and blood components have been established by the FDA. These standards are referred to as Current Good Manufacturing Practices (CGMPs). Blood and blood products are regulated by two different sections of the Code of Federal Regulations (CFR): Part 606 for biologics and Part 211 for drugs. Drug manufacturers are primarily inspected according to their compliance with Part 211- Current Good Manufacturing Practice for Finished Pharmaceuticals.

CGMP requirements must be met during the maunfacturing process. In this way, standards for the quality of the product can be ensured without having to test each finished product. CGMP eliminiates different requirements among manufacturers of drugs. When all manufacturers of drugs adhere to one set of requirements, physicians can be assured that the product they prescribe for their patients is safe, pure, potent, and effective.

"These drug GMPs, until recently, were rarely cited in FDA communications involving blood

banks. It is interesting to note that 21 CFR 211.1 states, 'The current good manufacturing practice regulations in this chapter, ...as they apply to biological products for human use, shall be considered to supplement, not supersede the regulations in this part unless the regulations explicitly provide otherwise.'"(Solomon) Therefore, Part 211 takes precedence.

It has become clear, recently, that FDA inspectors have adopted the following excerpt as their regulatory credo. "Blood establishments are being cited for deficiencies under drug GMPs of which they were unaware because the relevant regulations do not appear in Part 606, the blood GMPs."(Solomon) In other words, the FDA is using a new set of standards, the 211 series, to inspect blood banks. More citations have occurred because of the change in philosophy of the FDA.

With this in mind, Compliance Officers and Principal Officers will be asked regulatory questions to determine the importance and the findings of the inspections by the FDA and AABB.

Lastly, the Five Point Transformation Plan will be studied to determine how the transformation will improve the safety of the blood supply. Over the next two-and-a-half years, the Red Cross will take on the major task of entirely overhauling the way it tests and tracks blood. Fifty-three testing centers will be consolidated into fourteen. There

will only be one national computer system for use by all Red Cross blood operations. In addition, there will be temporary closing of every Red Cross blood center to re-equip the enters and retrain the staff. Given the difficulty and scope of this transformation, interviews will be conducted to determine any foreseeable problems that could occur during and after the implementation of the transformation process. The transformation process will be a costly, complex, and very time consuming project. If everything is not thought out properly during the planning and implementation process, the transformation could be disastrous.

RESEARCH HYPOTHESES

Through questionnaires, the 1991 American Association of Blood Banks survey, and structured interviews, the following hypotheses statements will be tested:

1) People in the Wolverine Blood Region believe that blood in their region is safe, as measured by their opinion and donor screening questions:
    A) Before 1985.
    B) Between 1985-1990.
    C) Present.

2) People in the Wolverine Blood Region believe that blood in the nation is safe.

3) People in the Wolverine Region are confident that they would receive safe blood if they needed a transfusion.

4) People in the Wolverine Blood Region believe that the American Red Cross Transformation is a good idea.

5) People in the Wolverine Blood Region believe that the American Red Cross Transformation will be successful in increasing the safety of the blood supply.

6) The American Red Cross has a strong image in Blood Banking.

7) The American Red Cross should stay in the blood business.

From this research, I expect to find that: 1)from the blood donors', hospital administrators', and transfusion chairmens' opinions and perceptions, the American Red Cross has increased the safety of the blood supply and increased the level of trust in the safety of the blood supply; and 2)from the principal officers' and compliance officers' perceptions , the American Red Cross will lead the blood banking industry into the next decade with the successful implementation of the American Red Cross Blood Services Transformation.

METHODOLOGY

The scope of this research was the state of Michigan. The unit of measure consisted of people who are in some way affected by the operational changes in the American Red Cross Blood Services. The instruments used for data collection were a structured interview and a mailed

questionnaire.

The data collected came from two groups. In Group A, opinions and attitudes of American Red Cross clients (blood donors, hospital transfusion chairmen, and hospital administrators) were collected to formulate how the views of the nation's blood supply have changed since 1985 and what they presently think of the safety of the blood supply.

Blood donors were considered for their opinions because donors are the only resource for all pre-tested blood. The safety of the blood supply begins with the blood donor. Donors must be of good health, and must not take part in what could be considered risky behavior (IV drug users, prostitutional sex, etc.).

Hospital administrators were chosen for their opinions because most blood transfusions occur at the hospital. Therefore, administrators are aware of the liability of transfusions, cost of blood products, and the approximate number of cases involving complications from a blood transfusion.

Lastly, transfusion chairmen were chosen to be a part of Group A because they would be the most knowledgeable regarding the facts relating to blood, blood transfusions, and the liability associated with blood transfusions. The transfusion chairmen would also be quite knowledgeable about the facts relating to HIV-associated transfusions, and the

history of blood banking.

In Group B, American Red Cross Principal Officers and Compliance Officers in the state of Michigan were asked to evaluate the operational changes caused by the HIV virus and whether these were reasonable steps to assure a clean, safe blood supply.

Group A. All of the respondents from Group A came from the Wolverine Blood Region, which consists of 27 counties in the state of Michigan. The demographics of the area describe both urban and rural populations, with Genesee County being the largest county in the region (population: < 500,000).

A sample of two hundred and twenty-three blood donors from the Wolverine Blood Region were asked to express their views on donating blood since the discovery of the HIV virus, and on how HIV has affected the safety of the blood supply. They were also asked about their trust level in the safety of the blood supply.

A sample of seventeen transfusion chairmen in the state of Michigan who use blood products or transfusions on their patients were asked to respond to questions about the safety of the blood supply, since these individuals would be informed about HIV-related blood transfusions.

All thirty-five hospital administrators in the state of Michigan's Wolverine Blood Region were mailed questionnaires and asked to express their opinions and trust in the safety

of the blood supply since the surfacing of the HIV virus. The administrators were also asked to assess the safety of the blood supply during and after the implementation of the five point transformation plan.

Group B. American Red Cross Principal and Compliance Officers in the state of Michigan (n=6) were interviewed to express their opinions on the changes in accountability, quality assurance, regulatory affairs, and internal inspection mechanisms (and their view on the five point transformation plan) due to the HIV virus. They were also asked to give their opinion of what they think the public's trust level is in Red Cross to provide safe blood.

Design. The information gathered in this research is set up to cover three consecutive time intervals, before 1985, 1985-1990, and 1990 to present. Data were collected from three sources, structured interviews, a questionnaire, and secondary sources (AABB survey, articles). A a multi-dimensional survey and cross-sectional design were used to gather information on the respondents' opinions and attitudes regarding the operational changes within the Red Cross and the safety of the blood supply prior to 1985, 1985-1990, and 1990 to present.

Measures and Analysis. The primary dependent variables of this research were "safety" and "trust level". Safety, as it pertains to this research, is defined as freedom from harm or risk; and uncontaminated from infectious material (referring to blood and blood products). Trust level is the degree of confidence one places in the American Red Cross to provide safe blood.

RESULTS

Descriptives.

Blood Donors- A questionnaire was sent out to five different blood collection sites during a two week period of time to include donors of different demographics (i.e. community, age, etc.). A short description of each site is listed below.

SITE 1: **Fenton High School, Michigan.** Fenton High School is located in a mostly white, suburban area, located fifteen miles south of the city of Flint, Michigan. In 1990, the size of the school was 2,855 students.
Number of respondents: 24
Respondents' mean age: 19.91 years old (one adult donated during this blood drive, therefore, increasing mean age).

SITE 2: **Mayville, Michigan.** Mayville is a community blood program, located in Tuscola County. Mayville is a predominantly white, rural area, with a population of 1,048 (1990 census data).
Number of respondents: 96
Respondents' mean age: 39.06 years old

SITE 3: **Flushing, Michigan.** Flushing is a community blood program, located near the city of Flint, Michigan. Flushing is a predominantly white, suburban area, with a population of 8,542 (1990 census data).
Number of respondents: 34
Respondents' mean age: 38.88 years old

SITE 4: **Buick City, Michigan.** Buick City is an industrial complex where Buick automobiles are manufactured in the city of Flint. Donors are primarily hourly workers. There are approximately 3,400 workers at Buick City.
Number of respondents: 50
Respondents' mean age: 45.54 years old

SITE 5: **AC Rochester East Mini, Michigan.** AC Rochester Mini is an industrial complex located in the city of Flint, which manufactures General Motors parts. Donors are primarily hourly workers. There are approximately 9,000 workers at AC Rochester East Complex.
Number of respondents: 12
Respondent's mean age: 44.17 years old

Hospital Administrators- A questionnaire was mailed out to the thirty-five hospital administrators located in the Wolverine Blood Region. Twenty-seven of the thirty-five administrators returned the questionnaire. The respondents are listed below, along with the size and service/control classification of the hospital. The sizes and service classifications of the hospitals are listed to give some sense of the hospital settings. Smaller hospitals tend to be in more rural areas, where larger hospitals are usually found in more populated, urban areas.

HOSPITAL	*BEDS*	*CLASSIFICATION*
Alpena General Hospital	*176*	*General medical and surgical/county*

(Continued)

HOSPITAL	BEDS	CLASSIFICATION
Caro Community Hospital	46	Generalmedical and surgical/city
Charlevoix Area Hospital	40	General medical and surgical/non-profit
Flint Osteopathic Hospital	359	General medical and surgical/non-profit
Genesee Memorial Hospital	41	General medical and surgical/non-profit
Gladwin Area Hospital	42	General medical and surgical/non-profit
Grand Traverse Community Hospital	81	General medical and surgical/non-profit
Harbor Beach Community Hospital	67	General medical and surgical/non-profit
Hillsdale Community Health Center	68	General medical and surgical/city
Hurley Medical Center	540	General medical and surgical/city
Lapeer Regional Hospital	182	General medical and surgical/non-profit
Leelanau Memorial Hospital	n/a	n/a
Marlette Community Hospital	73	General medical and surgical/non-profit
McKenzie Memorial Hospital	31	General medical and surgical/non-profit
McLaren General Hospital	540	General medical and surgical/non-profit

(Continued)

HOSPITAL	*BEDS*	*CLASSIFICATION*
Munson Medical Center	*328*	*General medical and surgical/non-profit*
Northern Michigan Hospitals	*261*	*General medical and surgical/non-profit*
Paul Oliver Memorial Hospital	*n/a*	*n/a*
Rogers City Hospital	*89*	*General medical and surgical/city*
Scheurer Hospital	*47*	*General medical and surgical/non-profit*
St. Joseph Hospital (Flint)	*423*	*General medical and surgical/church operated*
St. Joseph Hospital (Tawas)	*67*	*General medical and surgical/non-profit*
Standish Community Hospital	*81*	*General medical and surgical/non-profit*
Tolfree Memorial Hospital	*92*	*General medical and surgical/city*
War Memorial Hospital	*157*	*General medical and surgical/non-profit*

Blood Transfusion Chairmen- Another questionnaire was mailed out to the thirty-five transfusion chairmen located in the Wolverine Blood Region. Of the thirty-five transfusion chairmen, seventeen responded to the questionnaire. The

responding hospitals are listed below (refer to hospital administrator's survey for size of hospital):

Standish Community Hospital (Flint)
Otsego Memorial Hospital
Tawas St. Joseph Hospital
Veteran's Administration Hospital
Wheelock Memorial Hospital
Northern Michigan Hospital
Genesee Memorial Hospital
War Memorial Hospital
McLaren General Hospital
St. Joseph Hospital
Flint Osteopathic Hospital
Marlette Community Hospital
Alpena General Hospital
Munson Medical Center
Hills and Dale Hospital
Harbor Beach Comm. Hospital
Hurley Medical Center

Principal and Compliance Officers- There are three American Red Cross Blood Regions in the state of Michigan. Each Principal Officer and Compliance Officer participated in the survey. Their names and designated regions are listed below:

Dr. Willys Mueller, Jr., M.D.
Principal Officer
Wolverine Blood Region

Ms. Sandra Anderson, R.N., BSN
Compliance Officer
Wolverine Blood Region

Dr. John A. Penner, M.D.
Principal Officer
Great Lakes Region

Ms. Patti Page
Compliance Officer
Great Lakes Region

Dr. A. William Shafer
Principal Officer
Southeastern Michigan Region

Ms. Martha Weaver-Dahm, MT(ASCP)SBB
Compliance Officer
Southeastern Michigan Region

(Verbal permission was granted by all POs and COs to quote them and use their names)

II. Public Perceptions.

The opinion survey of blood donors, hospital administrators, and transfusion chairmen were

The statement was phrased, "I think the blood supply before 1985 was safe," and they were asked to respond on the following scale: Strongly Agree, Agree, Disagree, or Strongly Disagree. The results are in Table 1.

Table 1. SAFETY OF BLOOD SUPPLY BEFORE 1985. (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
STRONGLY AGREE	12.5	8.0	6.3
AGREE	47.7	44.0	50.0
DISAGREE	37.0	40.0	37.5
STRONGLY DISAGREE	1.9	4.0	6.3
TOTAL RESPONDENTS	223	27	17

Table 2 compares the responses from the three groups when they were asked to respond to the following statement: "I think the blood supply between 1985-1990 was safe."

Table 2. SAFETY OF THE BLOOD SUPPLY BETWEEN 1985-1990. (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
STRONGLY AGREE	9.7	12.0	6.3
AGREE	66.2	66.0	87.5
DISAGREE	19.4	20.0	0.0
STRONGLY DISAGREE	2.3	4.0	6.3
TOTAL RESPONDENTS	223	27	17

Combining the percentages of the Strongly Agree and Agree responses in each group reflects a difference between the transfusion chairmen and the other two groups, the blood donors and the hospital administrators. 93.8% of the transfusion chairmen at least agree that the blood supply was safe between 1985-1990, compared to 78% of the hospital administrators and 75.9% of the blood donors who at least agree with the statement. When comparing this difference between the transfusion chairmen with the blood donors and hospital administrators in a t-test (see Glossary), $t=12.745$ ($p<.001$), with 42 degree of freedom. This shows a very high level of significance. Transfusion chairmen seemed more aware of the facts about the safety of the blood supply, or felt safer about the blood supply than the hospital administrators and the blood donors for the 1985-1990 period.

The next table, Table 3 shows the responses to the statement, "The blood supply in the region is safe."

Table 3. BLOOD SUPPLY IN THE REGION IS SAFE (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
STRONGLY AGREE	32.4	40.0	56.3
AGREE	65.3	56.0	37.5
DISAGREE	0.0	4.0	6.3
STRONGLY DISAGREE	1.4	0.0	0.0
TOTAL RESPONDENTS	223	27	17

Again, when combining the Strongly Agree and the Agree responses, 97.7% of the blood donors, 96.0% of the hospital administrators, and 93.8% of the transfusion chairmen at least agree that the blood supply in the Wolverine Region is safe. Generally speaking, the respondents agreed with this statement.

To broaden the scope, the respondents were asked to respond to the statement, "I think the blood supply in the nation is safe." The results are in Table 4.

Table 4. BLOOD SUPPLY IN THE NATION IS SAFE. (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
STRONGLY AGREE	13.4	16.0	12.5
AGREE	62.0	80.0	81.3
DISAGREE	22.2	4.0	6.3
STRONGLY DISAGREE	1.4	0.0	0.0
TOTAL RESPONDENTS	223	27	17

These data show a discrepancy between the blood donors and the other two groups, the hospital administrators and the transfusion chairmen. Twenty two percent of the blood donors surveyed believed that the blood in the nation is not safe, whereas, only 4.0 and 6.3 percent of the hospital administrators and transfusion chairmen believed that the nation blood supply is unsafe, respectively.

In the October 1991 American Association of Blood Banks

survey, conducted by the Gallup Organization, a similar question was asked from a national perspective, and generally speaking, 71 percent of the 1000 respondents felt the nation's blood is safe, and 27 percent felt the nation's blood supply to be unsafe.

A t-test comparing the results of the blood donors' responses to that of the hospital administrators' responses gave a t value equal to 112.4845 ($p<.001$), a very high level of significance.

The data seems to convey the message that the general public, including blood donors, have a concern about the blood supply of the nation. This is a very significant point. Although the respondents thought that the blood in their region is safe, the nation's overall blood supply is somewhat unsafe. This could be due to media attention given to the cases where patients received HIV tainted blood, the Dingell hearings, or other articles or news stories.

III. Internal Response to Public Image.

In accordance with the above statements and data, Principal Officers and Compliance Officers were asked to respond to the following question, "In regards to blood safety, do you believe the Red Cross has a damaged public image?" Beginning with the Principal Officers, their responses were mixed, with regard to the national blood supply.

Dr. John Penner, Principal Officer from the Great Lakes Region, stated that "our region, the Midwest, has not suffered from a damaged public image. Dr. A. William Shafer, Principal Officer from Southeastern Michigan Region, agreed with Dr. Penner. Dr. Mueller, Principal Officer of Wolverine Region, elaborated,

"I believe that the overall image of the Red Cross is sound, high in esteem, and high in trust, but did suffer some tarnishing during the public disclosure of erroneous releases and closure of blood centers, i.e. Nashville, Washington D.C., Albany, and Portland. It [Red Cross] was further tarnished during the Dingell hearings. Uncertainty as to the blood supply became a household concern. I believe the forthright approach of new leadership and the commitment to change has removed some of the tarnish. There is still concern about isolated cases of transfused-associated HIV that get published and prosecuted, when the cases occurred prior to HIV testing of blood. This raises undue concern as people perceive it to be a present case. These distortions are not clarified by the media."

As to the Compliance Officers, a summary of their response to the question, "Do you think the Red Cross has a damaged public image?", is listed in Table 5.

Table 5. DO YOU THINK THE RED CROSS HAS A DAMAGED PUBLIC IMAGE?

COMPLIANCE OFFICERS	RESPONSES
Sandra Anderson Wolverine Region	Responses would be different in different parts of the country. Trust our blood from our region but not other region's blood.
Marty Weaver-Dahm Southeastern Michigan	Bad press has given people the wrong idea, but not sure if people pay attention. Congress and FDA have attacked the Red Cross to use Red Cross as an example to entire blood banking industry, and it has worked very effectively. Elizabeth Dole has helped calm public's perception.
Patti Page Great Lakes Region	No. I don't believe the Red Cross has a damaged public image. The blood supply is as safe as it can be.

These responses convey the message that the overall image of the Red Cross, from an internal perspective, remains sound, even after some negative media attention. It is also interesting to note the response of Sandra Anderson, and others, who regionalized the question and hinted that the public perception would be different in different regions of the country.

IV. Confidence of Receiving Safe Blood.

Group A (Blood Donors, Hospital Administrators, and Transfusion Chairmen) were asked to respond to the following statement: "If I needed blood, I am confident that I would receive safe blood." The results are tabulated in Table 6.

Table 6. CONFIDENT OF RECEIVING SAFE BLOOD. (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
STRONGLY AGREE	28.7	28.0	31.3
AGREE	60.6	60.0	56.3
DISAGREE	8.8	12.0	12.5
STRONGLY DISAGREE	0.9	0.0	0.0
TOTAL RESPONDENTS	223	27	17

Most of these respondents showed some confidence in the blood supply when the question was more personalized. In the AABB survey, roughly half of the respondents felt it likely that AIDS could be contracted through blood transfusions, but it was not the number-one cited concern with regard to having surgery.

"The public is still confused about the risk of contracting the AIDS virus," said Dr. Claude Lenfant, MD, director of the National Heart, Lung and Blood Institute, National Institutes of Health. "The public needs to understand that, while there are risks involved in any medical procedure, the risk of getting AIDS from a blood transfusion is extremely low. The safeguards on our blood

supply now include seven screening tests for infectious disease and extensive questioning of the blood donors for risk factors."

To date, the Centers for Disease Control has documented 20 cases of AIDS contracted through blood transfusions since testing began in 1985, a period during which an estimated 20 million Americans received blood transfusions (AABB/Gallup Public Opinion Survey, 1991).

v. American Red Cross Transformation.

There has been rapid change throughout the blood banking industry within the past ten years. The Principal and Compliance Officers were posed with the difficult question, "What changes have you seen in blood banking in the last ten years, in regards to accountability, quality assurance, and regulatory affairs." The table below gives a synopsis of their responses to this broad and difficult question.

Table 7. CHANGES IN BLOOD BANKING IN THE PAST TEN YEARS.

Principal Officer	Response
Dr. Willys Mueller	More emphasis on quality assurance, and personal accountability. Also, more emphasis on compliance to CFRs, BSDs and SOPs [sic.]. Compliance office was stimulated by the FDA.
Dr. John Penner	Major changes. Change in time spent in quality assessment, and related documentation. Accountability, Quality

Table 7. (continued)

Principal Officers	Responses
	Assurance, and Regulatory Affairs all inter-related.
Dr. William Shafer	Night and day difference. Too broad too talk about. Accountability, Quality Assurance, and Regulatory Affairs all inter-related.

Compliance Officer	Response
Sandra Anderson	FDA holding the Red Cross more accountable. Looking for improvements in the system before incidents occur, instead of responding to them after the fact. Each department is more highly scrutinized.
Martha Weaver-Dahm	Much stricter regulations. Increased regulations by FDA. Gains in Quality Assurance in past ten years. Years of cost containment caused breakdown in checks and balances in system. Heading back toward more attention to checks.
Patti Page	More of an emphasis on the medical/technical side of industry. Prior to 1988, looked for cost containment measures, savings to the business.

Because of these changes in compliance areas, and stricter regulation by the FDA, the American Red Cross needed to refocus and reorganize the way they collect, process, test, and distribute blood. This major undertaking was named

"Transformation." Principal Officers and Compliance Officers gave their perspective of why Transformation was necessary. Table 8 shows that Transformation was necessary for two main reasons, a chang in philosophy about blood, and for the American Red Cross National Headquarters to gain control of the regions' procedures related to blood functions.

Table 8. WHY TRANSFORMATION WAS NECESSARY.

Principal Officer	Response
Dr. Willys Mueller	Change in philosophy about blood-procuring agencies/industries. Before, blood was looked at as a service. Now, blood is looked upon as a pharmaceutical product. Change from a service industry to a pharmaceutical industry. Transformation is the vehicle to get us there.
Dr. John Penner	Preserve national image. Provide protection from the FDA. Also, Red Cross recognized defects in their practices/procedures.
Dr. William Shafer	Refer to Elizabeth Dole news release.

Compliance Officer	Responses
Sandra Anderson	Regional centers were ignoring directives from National Headquarters. Regions were inventing their own method of doing things. Necessary to be uniform in procedures, according to our license.

Table 8. (continued)

Compliance Officer	Response
Martha Weaver-Dahm	Comply with the 1988 FDA/Red Cross agreement. Necessary for safety issues and the survival of the Red Cross. Limiting laboratories will increase control.
Patti Page	For National Headquarters to gain control over regions on regulatory functions. Operate under just one standard.

All three Principal Officers capsulated the goal of Transformation, from the perspective of their National Headquarters, in a sentence or two. Their overall responses are listed in Table 9.

Table 9. GOAL OF TRANSFORMATION

Principal Officer	Response
Dr. Willys Mueller	Increase efficiency, improve quality, improve system synergism, share resources, and improve supply.
Dr. John Penner	Increase safety, decrease risks. Provide back-up support to pass FDA inspections.
Dr. William Shafer	Develop blood service of the future. Make the safest, most efficient blood supply in the world.

Now that Transformation had been explained from an internal viewpoint, the blood donors, hospital

administrators, and transfusion chairmen were asked what they thought about Transformation.

First, the three groups were asked to respond to the question, "Do you think Transformation is a good idea?" Their response frequencies are shown in Table 10.

Table 10. IS TRANSFORMATION A GOOD IDEA (IN PERCENTAGES)

	DONORS	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
YES	45.4	84.0	68.8
NO	1.9	0.0	18.8
NO ANSWER	52.8	16.0	12.5
TOTAL RESPONDENTS	223	27	17

Although it appears that most of the respondents believed that the Transformation is a good idea, a large number of the respondent's did not believe that they were informed enough to answer the question adequately. This is especially evident in the blood donors group. Also, the data show that the transfusion chairmen appear to be more skeptical than hospital administrators as to the Transformation plan. Their skepticism is addressed in the following results.

Hospital administrators and transfusion chairmen were asked to predict the success of the Transformation. The results are tabulated below in Table 11.

Table 11. PREDICT THE SUCCESS OF TRANSFORMATION (IN PERCENTAGES)

	HOSPITAL ADMINISTRATORS	TRANSFUSION CHAIRMEN
EXCEEDS EXPECTATIONS	0.0	0.0
FULLY SUCCESSFUL	16.0	31.3
SUCCESSFUL	52.0	50.0
NEEDS IMPROVEMENT	4.0	18.8
DISASTROUS	4.0	0.0
TOTAL RESPONDENTS	27	17

Comparing the responses in the **Needs Improvement** category with a t-test, the result is $t=3.666$ ($p<.001$), with 42 degrees of freedom. Some of the concerns that were stated by the groups were:

Inadequate blood supply during and after Transformation
Improper testing
Improper tracking of units [i.e. location of units]
Poor service
Cost/benefit of the Transformation process
Increased costs [to hospitals]

Although a high percentage of the administrators and chairmen think that the American Red Cross Transformation will be successful, there is some skepticism and concern that there will be some issues that will still need to be addressed.

What happens to the American Red Cross Blood Services after Transformation? The Principal Officers and Compliance Officers were asked to where ARCBS (American Red Cross Blood Services) will be ten years from now. A synopsis of their

statements are reported in Table 12.

Table 12. ARCBS TEN YEARS FROM NOW

Principal Officer	Response
Dr. Willys Mueller	Multiple regional sites. Fewer regions than now, but supplying a larger area, with centralized testing labs which are state-of-the-art. Possibly between four to eight regions. Red Cross will diversify and not only supply blood and blood products, but filtering systems for blood. Also, if "artificial blood" is developed, the Red Cross will be a distributor. Possibly a transplantation service, depending on current need and current technology.
Dr. John Penner	Reduction in the total number of centers. Depending on management, sees downgrading to collection centers from testing and distribution centers. And then ten years after that, back to regional centers.
Dr. William Shafer	The Red Cross will be stronger than ever. Clearly the leader internationally.

Compliance Officers	Response
Sandra Anderson	Fewer regions. Larger testing centers. Control will be even more centralized. Between 30-35 regions.
Martha Weaver-Dahm	Very successful and the leader in blood bank industry.
Patty Page	A highly visible leader in blood banking.

Along with the predicted success for the Red Cross in the upcoming years, half of the officers see a significant change in the number of regions in the country. The consolidation of regions is expected, however, Dr. Penner added some concerns: "Communities will be unhappy with blood from other regions coming to them." Also stated by Dr. Penner, he sees that the business is cyclical, and that after consolidation of regions, ARCBS will then go back in the other direction and become more regionalized again.

Discussion

Overall, the responses to the questionnaires and structured interviews showed evidence that supported the research hypotheses. Also, the findings of this research closely paralleled the results of the American Association of Blood Banks survey (1991). There were a few exceptions where

there was discrepancy in the research and the hypotheses which are addressed below:

Hypothesis 1) **People in the Wolverine Region believe that blood in their region is safe:**

a) Before 1985: Group A showed concern about the blood during this interval with 37% of the donors, 40% of the hospital administrators, and 37.5% of the transfusion chairmen disagreeing with this statement.

Hypothesis 2) **People in the Wolverine Region believe that blood in the nation is safe:**

22% of the blood donors disagreed with this statement.

Hypothesis 4) **People in the Wolverine Region believe that the American Red Cross Transformation is a good idea:**

52% of the blood donors did not answer the question.
16% of the hospital administrators did not answer the question.
12.5% of the transfusion chairmen did not answer the question.

Hypothesis 5) **People in the Wolverine Region believe that the American Red Cross Transformation will be successful in increasing the safety of the blood supply:**

18.8% of the transfusion chairmen believe that improvements will still need to be made and expressed some concerns.

Limitations

Although only seventeen out of thirty-five transfusion chairmen responded to the questionnaire, the respondents that did return the questionnaire were from a good mix of urban and rural areas, larger and small hospitals. Therefore, the

responses are likely to be reasonably representative of the region.

Only six officers of the Red Cross were asked to express their opinions about the blood supply and Transformation. Since these are six different individuals, only from the state of Michigan, generalizations about their responses should not go beyond the state of Michigan.

Only one time frame was used to gather the results of this research. If these results were compiled over a longer period of time, the data would have been more significant. For future research, it would be interesting to ask the same questions five and ten years from now.

Although it would be difficult to study, it would be valuable to survey people who have received blood transfusions, and ask them similar questions to this research. Their views could have been compared to the blood donors to get a good idea of what level of trust people have in the American Red Cross.

Finally, if more than one blood region was used for responses in Group A, answers could have been compared from one region to another to see if there were differences in opinions to the question of the safety of the blood supply in the regions, and in the nation.

In hindsight, the donors, hospital administrators, and transfusion chairmen should have been asked the question that the Principal Officers and Compliance Officers were asked,

"What do you think the blood banking industry will look like ten years from now." This perspective would have been interesting to compare to that of the officers to see if each others' perceptions are closely related, or not. And, the public could have been polled to how many HIV blood transfusions they think there has been in the country before 1985, and 1985 to present. This data could have been compared to the facts.

Conclusion

Because of the HIV virus, and public's demands for safe blood, the blood banking industry has had to change its' values from a service industry to that of a pharmaceutical industry. The FDA began enforcing a new set of regulations on blood banks that were not previously used. Therefore, the American Red Cross has needed to make rapid, major changes in operations to stay a part of the industry.

A chronology of actions taken by the American Red Cross to improve the safety of the blood supply from HIV/AIDS is listed below:

"**January 1983:** With a single reported case of possible transfusion associated AIDS and fewer than 10 other reported cases of AIDS that appeared to be associated with hemophilic blood products, the Red Cross began expanding health history

interviews with donors to alert and defer donors who might be at risk for AIDS.

March/April 1983: Red Cross implemented (and continues to improve) nationwide donor screening recommendations proposed by the Public Health Service and the FDA to defer donors at potential risk for AIDS.

Spring 1985: Immediately upon FDA licensure of the first test to detect the antibody to HIV-1 (AIDS), Red Cross began testing all newly donated blood. Prior to this time, blood was tested for syphilis and Hepatitis B.

June 1986: Red Cross voluntarily initiated a "look back" procedure, in cooperation with hospitals, to notify recipients of blood transfused before HIV-1 antibody testing began, that had been collected from donors who, on subsequent donations, were found to have a confirmed positive test for HIV-1 antibodies.

March 1987: Red Cross recommended that patients who received blood transfusions prior to the advent of HIV-1 testing in 1985, discuss with their physicians the advisability of undergoing testing.

April 1987: Red Cross adopted the use of an improved, FDA-licensed HIV-1 test which effectively detects at least 80% of blood that is infected with HIV-2 -- a second AIDS virus. This began a 4-year study of HIV-2 infection in the United States blood donor population. Not one HIV-2-infected blood donor had been found in the survey.

February 1992: With the FDA licensure of an HIV-1/2 combination test, the Red Cross began implementation procedures in order to test more specifically for HIV-2, a new strain of the AIDS virus still very rare in this country" (Heubusch, 1992).

This research questioned the public and Red Cross leaders about the safety of the blood supply, trust in the (Red Cross) organization, and the Transformation.

The first hypothesis posed was that the people in the Wolverine Blood Region thought that the blood was safe during three time intervals, before 1985, between 1985-1990, and

presently. The results concluded that before 1985, there was strong concern for the safety of the blood supply, with 38.9% of the donors, 44% of the hospital administrators, and 43.8% of the transfusion chairmen disagreeing with the statement: "I think the blood supply was safe before 1985." These figures can be attributed to the number of HIV-transfused cases before testing was made available.

This has led to numerous court cases against the blood banking industry. One such case, in Colorado, is alleging that the blood bank industry should have taken additional steps to protect patients in 1983 and 1984. Plaintiffs' attorneys contest that the blood bank industry, by early 1983, had received enough warnings about possible AIDS transmission to adopt stronger measures to weed out blood donors infected with HIV. "For instance, the Federal Centers for Disease Control in December 1982 said studies had raised 'serious questions about the possible transmission of AIDS through blood and blood products'" (Wall Street Journal, 1992). These type of cases continue to plague the industry and still appear in national media coverage. Therefore, the public will always question the safety of the blood supply before 1985.

A smaller percentage of the respondents disagreed with the statement: "I think that the blood supply was safe between 1985-1990," with only 21.7% of the donors, 24% of the hospital administrators, and 6.3% of the transfusion chairmen

responding negatively. It is obvious that the transfusion chairmen were more knowledgeable about the safety of the blood supply during this time interval.

Presently, people in the Wolverine Blood Region strongly agree the blood in their region is safe, with only 1.4% of the donors, 4.0% of the hospital administrators, and 6.3% of the transfusion chairmen disagreeing with the statement. This shows significant trust in the blood supply of the region.

However, when the scope was broadened, and the question was asked, "I think the blood supply in the nation is safe", the percentages of the donors changed significantly, with 23.6% of the donors disagreeing with the statement. The hospital administrators and transfusion chairmen responded about the same as the previous statement about the region's safety. The donors' concern about the nation's blood supply might reflect publicity on past cases where patients received HIV tainted blood, the Dingell hearings, closing of blood centers, or other articles or news stories.

Next, the public was asked how confident they were of receiving safe blood if a transfustion was needed. 89.3% of the donors, 88% of the hospital administrators, and 87.6% of the transfusion chairmen felt confident that they would receive safe blood. These percentages are slightly lower than the percentages from the question about the safety of the blood supply in the region. The difference might be

attributed to personalizing the question. Overall, the public seemed confident that they would receive safe blood.

Recently, new FDA guidelines have changed the philosophy of the blood banking industry. Blood banking is no longer considered a "service industry," but a "manufacturing industry." Therefore, the American Red Cross must follow the same good manufacturing practices as pharmaceutical companies (CFR 211 series). This new philosophy and standards have made the Red Cross change the way it does business.

FDA intervention was brought on by public's concern to HIV-tainted blood transfusions. At first, the FDA looked to the blood banking industry for answers to public's mounting concern. However, with a system that was lacking in industry standards, (from the viewpoint of a pharmaceutical industry), the blood banking industry needed the extra push the federal regulators could enforce to deal with a problem of such magnitude. Working jointly to solve the HIV dilemma, the blood banking industry and the FDA sought solutions to calm public concern.

And, by May 1991, American Red Cross president, Elizabeth Dole, announced the most dramatic public safety steps the Red Cross has taken in its history-- a total transformation of how the organization collects, processes, and delivers blood. The transformation is a five-track plan that will be implemented over a two-and-a-half year period. The plan includes: retraining of <u>all</u> blood services staff, re-

equipping blood centers, scaling down from 53 blood testing sites to about ten, adopting one national computer system, creating a new Biomedical Board of Directors, and customizing patient services.

Principal Officers and Compliance Officers responded to the question of why transformation was necessary. Two themes were generated from their responses. First, there was a change in philosophy about blood. This change was brought on by the surfacing of the HIV virus in the nation's blood supply, and public's outcry for something to be done about it. The FDA responded by making blood banks adhere to two different sections of the CFR, the 606 series for biologics, and the 211 series for drugs. Secondly, the Principal Officers and Compliance Officers believed that American Red Cross National Headquarters needed to gain control of the regions' procedures relating to blood operations. Since the Red Cross operates under one FDA license, all Red Cross regions need to operate under the same uniform standards.

When Group A (blood donors, hospital administrators, and transfusion chairmen) was asked if they thought that the Red Cross transformation was a good idea, over half of the blood donors did not respond to the question. More hospital administrators and transfusion chairmen responded to the question than blood donors. It appears that blood donors were not informed on the topic of transformation. However, the people who answered the question believed that

transformation is a good idea. But, there was some skepticism from the transfusion chairmen. Some of their concerns were that there would be an inadequate blood supply at times, improper testing and tracking could occur, an increased turnaround time to test units, or a combination of the above.

The transformation of the American Red Cross Blood Services is important for the future of the industry, and the safety of the nation's blood supply. As this country moves into the unknown future, it is important for the blood industry to be ready for potentially, new infectious blood-borne pathogens. By reducing human err and standardizing all blood function procedures, the American Red Cross will be ready to lead the blood banking industry into the future.

This statement is supported by public's opinion of the American Red Cross. When the hospital administrators and the transfusion chairmen were asked if the Red Cross should <u>stay</u> in the blood business, 100% of the hospital administrators and 94.1% of the transfusion chairmen responded positively to this statement. Internally, the Principal and Compliance Officers remain confident that the overall image of the Red Cross is sound, despite some tarnishing between 1985-1990.

As technology increases, blood could become a product that is as safe as aspirin. In the form of Transformation, the American Red Cross is moving its resources toward that direction. With the help of the public and federal agencies,

the Red Cross remains accountable to its customers, the American people.

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GLOSSARY

Summary of Concepts and Components for Data Organization

Percentage: a part of a whole expressed in hundredths

$$\frac{x}{n} * 100 = \%$$ *where x=variable*
n=total number of repondents

t-test: used to determine a significant difference between two samples

$$t = \frac{(\bar{X}_1 - \bar{X}_2) - (\mu_1 - \mu_2)}{s(\bar{x}_1 - \bar{x}_2)}$$ *degrees of freedom= n + n - 2*