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A STUDY TO DEVELOP A METHODOLOGY DETERMINING THE FEASIBILITY OF ESTABLISHING A BLOOD COLLECTION PROGRAM IN AN ARMY HEALTHCARE FACILITY

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This study was conducted to develop a methodology for determining the feasibility of establishing a blood donor collection program in a Army hospital. Based on literature reviews and interviews with subject matter experts, the author devised an evaluation system for assessing cost effectiveness of establishment of a blood bank.

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A STUDY

TO DEVELOP A METHODOLOGY

DETERMINING THE FEASIBILITY OF

ESTABLISHING A BLOOD COLLECTION PROGRAM

IN AN ARMY HEALTHCARE FACILITY

A Graduate Research Project
Submitted to the Faculty of
Baylor University
In Partial Fulfillment of the
Requirements for the Degree
of
Master of Health Administration

by

Captain Rene A. Heidenheim, MSC

May 1985

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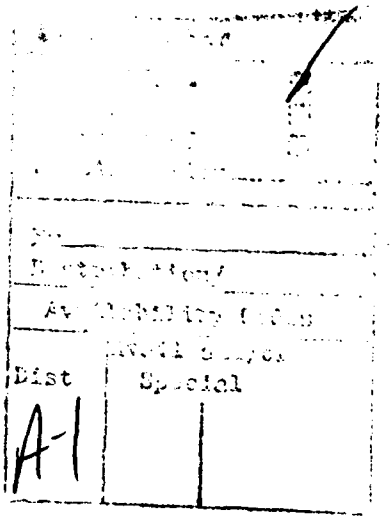

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CHAPTER I

INTRODUCTION

Overview

Blood--a powerful word. You can't say it without seeing the color. There is no true substitute for the genuine substance; the only source is the human body. Blood is such an integral part of health care that its' presence is almost taken for granted. Try to imagine a world without ready access to blood, or try to imagine a hospital where the appropriate quantity and quality of blood is not readily available. Few hospitals can function effectively without blood. Twelve million pints of blood are collected from eight million donors annually. The blood and blood products go to over three million people.[1]

The successful efforts of multiple activities and agencies have made it difficult to imagine a situation where there is a routine lack of blood. Red Cross, American Association of Blood Banks, and military efforts have allowed the majority of us to become complacent about availability of blood. Army Medical Department (AMEDD) officials stated the importance of blood in paragraph 12-1, Army Regulation (AR) 40-2: "The Army is charged with the responsibility of providing from its own resources the blood and blood component requirements for all patients receiving care in its' military medical treatment facilities without adverse impact on blood programs of civilian facilities."

awkward

The primary means of accomplishing this Army mission has been through blood collections on most larger installations. An alternative in use at several smaller installations has been to establish agreements with local blood programs. Cooperative agreements frequently have been the result of a compromise which were considered mutually beneficial to the parties

involved. Evaluation of the potential risks and benefits should have been an element in determining the final value of any agreement, as well as assuring that sufficient return would be received for the potential trade-off given in the compromise. This element, or management tool, for evaluation of benefits and risks, has not been officially developed or defined.

Evaluations of this nature should require recognition of a multitude of factors. The expense to the Army should be measured, not only in terms of dollars, but also in terms of training, mobilization readiness, rapidity of availability, space, and personnel costs, and other tangible and intangible factors. An evaluation should also seek the benefits of an in-house program. The research effort will develop a methodology to assess the feasibility of establishing an in-house blood donor collection program in a Medical Department Activity (MEDDAC) at an Army Continental United States (CONUS) installation. The purpose of this research is to provide a tool which could provide a systematic method for evaluating the risks and benefits of current and potential blood resource programs. This assessment tool will allow for the implementation of more efficient and effective feasibility studies at the installation level of management. The objectives of this study are to:

1. Describe the current blood management program of the Army;

2. Determine the mobilization requirements imposed on a MEDDAC with the addition of a blood collection mission;

3. Identify the legal aspects of a blood collection program;

4. Determine the cost effectiveness of a blood donor collection mission to a MEDDAC and to the installation;

5. Determine the amount of space required to draw blood;

6. Determine the training benefits of an in-house blood collection program;

7. Determine the feasibility of entering into a resource-sharing agreement with local Veterans Administration facility;

8. Identify blood acquisition alternatives available to the typical MEDDAC;

9. Identify the accrediting agencies and standards which a blood bank is required to satisfy in order to continue operating and determine if such accreditation is possible for MEDDAC;

10. Evaluate the validity of the data collected by a test of the methodology at a CONUS installation. Keywords: Health Administration Thesis (KT)

The methodology will incorporate the following when evaluating the feasibility of establishing an in-house blood collection program.

1. The installation can meet the Department of Defense (DOD) blood program standards for peacetime and during mobilization.

2. The potential legal risks are determined to be acceptable to the local governance.

3. A resource-sharing agreement with a Veteran's Administration hospital is not cost-effective.

4. The in-house program is cost-effective.

5. Sufficient space is available to draw blood.

6. The in-house blood collection program meets the minimal criteria established by the Army, the American Association of Blood Banks and the College of American Pathologists (CAP).

7. Blood and blood products will be therapeutically utilized prior to expiration.

8. Application of the methodology gives sufficient information to the administrative staff and command to permit following the recommended actions.

Several key assumptions need to be identified. First, significant technological developments affecting blood banking will either not be made, or will not affect the findings made. Secondly, in-house training programs will establish a more responsive staff during mobilization, the assumption which guides all Army training. Finally, one must assume that testing of the proposed methodology at one facility, Keller Army Community Hospital, West Point, New York, is indicative of the model. Limitations on this study are that medical mission requirements dictate that a medical clinical laboratory must have a type and match service and be able to store at least a fifteen day supply of blood. The study, therefore, cannot recommend that these services be eliminated. A further limitation is that the study applies only to CONUS installations with a co-located MEDDAC or Army Community Hospital.

To complete the study, the following methodology will be applied.

1. Description of the blood management program of the Army will be developed by means of a literature review. A brief narrative description will provide the reader with a clear understanding of the system as established by Army and Health Services Command directives, and as operated by the Military Blood Program Office.

2. Mobilization requirements will be determined by interviews with selected experts. At the local level, an interview will be conducted with the Hospital Commander and with the Clinical Laboratory Officer. At the Army level, interviews will be conducted with the Health Services Command Blood Program Manager (LTC Usry), the Department of the Army Blood Program Manager, (Colonel Spiker), and the Director, Camp Memorial Blood Center, Fort Knox, Kentucky (Major Frohman).

3. Some blood collecting procedures may result in adverse outcomes and legal action including: passing of hepatitis or Acquired Immune Deficiency Syndrome (AIDS) in the transfused blood; infecting the donor or recipient by infected equipment; and causing physical harm by improper technique. The methodology will establish the potential risk factors and the probability of risk. This will be accomplished by a literature research which will show historical risk data for each blood and blood products source.

4. Cost effectiveness is a measure of the alternative or combination of alternatives that gives the greatest expected effectiveness for the least cost. Cost data from alternative providers will be gathered through literature research and interviews. Hospital blood collecting costs will be determined by stratifying the elements of production and allocating a cost to each one. These costs will be totalled to give a unit cost which will then be compared to costs from alternative providers.

5. Space requirements will be determined by stratified area (reception, screening, drawing, recovery, processing, and administration). Each area will be described with a narrative on the function, approximate time needed by a

donor in each area, the supplies and equipment space requirements, and a total estimate of space required. Data will be acquired by observation of blood donor operations and by literature research.

6. The significant advantages and disadvantages of a resource sharing agreement with local Veterans Administration Medical Centers will be identified by means of literature research and interviews with subject matter experts.

7. Identification of the pertinent accrediting agencies and their respective standards will be by literature review. For specific validation of the methodology, interviews with the local Pathologist and Clinical Laboratory Officer will be conducted.

8. The methodology will be validated by a test application conducted at Keller Army Community Hospital, West Point, New York.

Footnotes

[1]Marilyn Chase, "Bad Blood", The Wall Street Journal, 12 Mar 84, p. 32.

CHAPTER II

DISCUSSION

Requirements and Programs

Army blood programs implement Department of Defense Directive 6480.5, Military Blood Programs. Responsibilities for processing and distribution of blood, procurement of blood from sources outside Department of Defense, maintenance of peacetime and emergency programs, personnel training, and supply maintenance sufficient to meet initial emergency requirements are included. Army blood programs are expected to provide blood and blood components for all patients treated. This is to be accomplished without adverse impact on blood programs in the local communities, and is further restricted to collecting blood only on a military installation from military personnel, family members, and civilian Federal employees.[1]

Providing volunteer donors for blood collection efforts is a command responsibility. Installation commanders are tasked to formally establish and operate an installation blood program at installation staff level to coordinate donors from all units. All commanders are required to develop educational and, if operational requirements permit, motivational programs to include three-day passes for military personnel and up to four hours of excused absence for civilian employees who have donated. Blood donors may not be provided in support of civilian blood programs and civilian communities without written authority of the Commander, USA Health Services Command to ensure that such a diversion of resources will not impact adversely upon the Army's capability to provide for its own needs.[2]

Health Services Command policy is to decentralize blood collection programs to the maximum extent possible.[3] Authority has been given to twenty-seven of thirty-eight Medical Department Activities (MEDDAC) to operate an in-house blood collection program. Rather than mandating such a program for all activites, however, eleven smaller MEDDACs have been given authority to rely on other military facilities or local civilian blood agencies to support their needs.[4] Why do the larger medical treatment facilities have blood collection programs?

One purpose of Army blood programs is to provide continuing training opportunity for technicians.[5] The Army has several blood banking training programs:

1. At the entry level for enlisted personnel, there is the Medical Laboratory Specialist Basic Course (311-92B10). This provides graduates with fundamental blood banking procedures skills, to include ABO groups, Rh types, antiglobulin tests, and compatibility testing with an acceptable degree of accuracy. The technicians do not receive training in actual blood donor procedures, however, and have no experience in drawing blood.[6]

2. Senior enlisted personnel may attend the Advanced Medical Laboratory Course (311-F1). This six week course provides personnel with a working knowledge of the principles and techniques of collecting, grouping, and processing whole blood in a large military blood bank center on a routine or emergency basis.

3. Officers who attend the Medical Technology courses offered at some major medical centers receive an eight week block of instruction on blood bank procedures. These individuals receive no on-the-job training if the facility to which they are subsequently assigned does not have a blood collection program.

4. The senior military program is The Blood Bank Fellowship at Walter Reed Army Medical Center. The goals of the Fellowship are to prepare career officers to:

- assume responsible positions in Military Blood Banking, especially as administrative and technical directors of large Military Blood Banks, and Transfusion Services; and
- To prepare the Fellows for certification examination as Specialists in Blood Banking.

5. Physicians in a pathology residency are taught clinical aspects of blood programs but receive no training in the administrative requirements or in blood donor recruitment techniques.

There are two significant training attributes of a military blood collection program which must be recognized in any evaluation. First, the staff must go through repeated hands-on work to develop and maintain proficiency. The single most important mission of military laboratory technicians during mobilization will be blood collection. For the hospital clinical laboratory, "our one lifesaving process is to give blood. Only an active blood collection program will give the level of skill required."[7]

Secondly, a blood collection program will give the installation a capability to respond rapidly in any local disaster. A major snowstorm, a tornado, an earthquake, or any other natural disaster may limit the availability of blood from routine sources. A major emergency operation may require quantities of blood faster than routine sources can provide it. A limited amount of blood can be made available rapidly if a mechanism is established and the procedures have been developed and refined through practice.

A further reason for Army blood programs is to establish a maximum capability for blood collection, processing, and storage to meet emergency needs and to support mass casualty plans, as well as applicable mobilization plans.[8] A typical small MEDDAC can be tasked, during mobilization, to expand blood collection capabilities to provide blood for local use and to ship up to fifty units of unprocessed whole blood on a daily basis to the Armed Forces Whole Blood Processing Laboratory (ASWBPL), McGuire Air Force Base, New Jersey, for shipment overseas.[9] ASWBPL active now in a limited mode for training purposes, is not a viable source of blood in CONUS because it is not their mission to provide it.[10]

Testing of Health Services Command mobilization plans has shown that rapid establishment of a blood collection program is extremely difficult if no program already exists. During an exercise conducted in November 1984, at Fort Campbell, Kentucky, the MEDDAC, which normally does not collect blood, was tasked to provide fifty units per day for one week. This MEDDAC had personnel rooms, beds, and equipment ready. The installation staff, however, could not respond by delivering troops to the hospital as required in the plans. This installation routinely provides blood donors for Camp Memorial Blood Center, which sends its' staff monthly in a mobile van to draw blood. Even this experience did not help the mobilization exercise. A further problem identified by the Fort Campbell MEDDAC laboratory staff was that much of their stock was out of date since it could not be rotated due to the lack of an in-house collection program.[11]

At Fort Dix, New Jersey, blood collection programs have been in effect for years. Coordination with the installation staff has resulted in a regular program of blood donations. Trainees in their fifth week report

to the blood collection facility on Thursday afternoon. The schedule even accounts for a phased arrival of units so that no unit training is affected for more than a few hours. The experience developed at this installation should be valuable during mobilization. A similarly positive program has been developed at Fort Ord, California. The laboratory staff has established a mobile program and gets support from the post staff in the form of regularly scheduled units. The blood goals are normally met easily, and expansion of this program during mobilization should be easily manageable.[12]

Health Services Command plans to enhance the training value of mobilization exercises commencing in 1985. Several MEDDACs will be tasked to actually draw up to twenty-five units per day for one to two weeks and ship the blood to Camp Memorial Blood Center as a test of their capability to respond adequately.[13]

There are several programs which have been developed to meet the daily mission requirements and which provide some of the training or emergency capability required. A brief description of these programs will now be valuable.[7] A more detailed evaluation of the advantages and disadvantages of the alternatives will follow later in the paper. The major sources of blood and blood products are:

1. Civilian regional blood centers.

- Let the agency draw blood on post in return for which blood and technical expertise will be made available either free or at manufacturing cost. Generally, these agencies do not like to use military personnel during blood draws because of state regulatory requirements.[14]

2. Self-supporting.

- Let the hospital blood bank fill all its own needs. This is generally impractical in small hospitals due to staff limitations. Blood supplies will also be hard to maintain in adequate levels and a back-up must be available for supplies, special testing, and technical advice.

3. Other Army facilities.

- Army medical centers and hospitals could possibly share a blood program. A box of blood can be shipped by Federal Express or equivalent services for approximately $28.00. Dependence on another hospital is risky, however, and distances may be an impossible obstacle in emergencies.

4. Camp Memorial Blood Center (CMBC), Fort Knox, Kentucky.

- The preferred method of using this scenario is for the small MEDDAC to draw blood and ship it unprocessed to CMBC. They would then process it and make small regular shipments back to the supplying hospital. If done weekly, the hospital can return aged blood and get fresh blood at a cost of only $28 per week. Although they do have sufficient technical expertise, emergencies cannot be supported in a timely fashion.

- Using this alternative, the blood bank may also have a choice about the type and amount of work it chooses to do. Blood may be fractionated into components if time is available or shipped whole if it is not. CMBC can do it all, but there are training opportunities to do some of the work in-house before shipping the blood. A second regional Army blood center is located at Fort Hood, Texas.

5. Veteran's Administration Medical Centers.

- The Veteran's Administration has a need for large quantities of blood. Because of the recent Congressional mandate to establish sharing

agreements (Public Law 97-174), this is a unique alternative which requires a separate discussion later in this paper.

6. Segment the installation population and let Red Cross (or other equivalent agency) draw some blood and the Army draw some.

- This has the advantage of satisfying some community responsibility while also controlling cost and providing training opportunities. Red Cross could serve as an emergency back up and provide technical expertise in this scenario. This alternative is in use at Fort Campbell, Kentucky. Red Cross volunteers access the 101st division on post, and Camp Memorial Blood Center staff comes on post monthly to draw blood from all non-divisional soldiers and civilians.

7. COMPASS program.

- COMPASS (which is not an acronym) is an agreement between the Army and the American Red Cross. It permits the Army to receive a "credit" for blood turned in to a Red Cross Blood Bank. Hospitals which need blood can then draw it from the Red Cross at which time the credit is deducted. The credit system is monitored by the Camp Memorial Blood Center.

8. Combinations of the above alternatives.

- Most hospitals will have to combine some of the above alternatives to gain maximum service support while still maintaining a mobilization training base at a minimal cost.

QUALITY ASSURANCE

While the need for an in-house blood collection program can be documented for training and mission requirements, a MEDDAC should not

implement such a program until several important issues can be satisfactorily addressed. Quality of the service is clearly one of the most important of these issues. One measure of quality is to earn licensure from the Food and Drug Administration, a major hurdle.[15] Once licensed, a blood bank is subject to unannounced inspections to determine whether services and products comply with existing statutes and regulations. The Food and Drug Administration has the only legal authority to immediately close an Army blood banking facility.[16] Successful completion of a Food and Drug Administration survey may be interpreted as a demonstration that the facility is in compliance with current statutes and regulations. Rules governing operations of a blood bank and blood collection program are contained in the Code of Federal Regulations, Title 21 - Food and Drugs. Applicable parts of this Title are:

-Part 606 -Current Good Manufacturing Practices for Blood and Blood Components;

-Part 607 -Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products;

-Part 610 -General Biological Products Standards; and

-Part 640 -Additional Standards for Human Blood and Blood Products.

In addition to licensure, voluntary accreditation is generally sought from professional associations such as the American Association of Blood Banks, the College of American Pathologists, and the Joint Commission on Accreditation of Hospitals. Earning accreditation from these peer groups enhances the confidence of end users through expert review and continuing education.[17] The Army has decided to use the standard operating procedures of the American Association of Blood Banks (AABB) as authorized by

21 CFR 606.100(d)(1). These may be found in Standards for Blood Banks and Transfusion Services.[18] This commercial publication has been adopted by the Army in Field Manual 8-70, with the same title. An extract of the standards is attached as Appendix A to demonstrate the complexity of the standards. AABB specific instructions, "hows" of blood banking, are included in the Technical Manual.[19] These also have been adopted by the Army in Technical Manual 8-227-3, also with the same title. An extract of this Manual is attached as Appendix B to show the detailed instructions.

Reviews include areas of technical proficiency, quality assurance procedures, documentation, equipment condition, and physical plant adequacy. The primary purpose of these inspections is to reduce the risk of injury or damage to blood donors and blood recipients, and to document that the facility personnel are not found to be negligent in their duties by a Court of Law.

"Negligence is the omission or commission of an act which a reasonable person would or would not do under given circumstances. It is a form of conduct caused by heedlessness or carelessness, which constitutes a departure from the 'standard of care' generally imposed upon members of our society.[20] The standard of care is a measuring stick representing the conduct of the average person, in the community, under the same circumstances as the one accused of the negligence. Violation of the standard is negligence.[21] "One is always responsible for his or her negligence".[22]

Negligence is either ordinary - the failure to do what a reasonably prudent person would do or not doing that which a reasonable person would not do, under the circumstances of the act or omission in question; or it is gross - an intentional or wanton omission of care which would be proper to provide

or the doing of that which would be improper to do. Four elements must also be present including: duty to use due care; breach of that duty; an injury resulting from the breach; and a close causal relationship between the improper conduct and the injury or damage.[23]

A court case clearly establishes the point.

> "In Brown v. Shannon West Texas Memorial Hospital, 222 S.W.2d 248 (1949), a blood donor sought to recover from a serious injury allegedly caused by the use of an unsterile needle. The court held that the burden of proof was on the plaintiff to show, by competent evidence, that the needle was contaminated when used and that it was the proximate cause of the alleged injury. The mere proof, said the court, that infection followed the use of the needle, or that it could possibly be attributed to the use of an unsterile needle, was insufficient."

There are several medical complications of blood potentially related to negligence. One of the most important is post transfusion hepatitis. Nationwide, there is approximately a seven percent prevalence of post transfusion hepatitis in patients receiving multiple blood products.[24] Three primary forms of hepatitis have been identified:

- Type A, a rare form of hepatitis, manifested as an inflammation of the liver, is acquired during epidemics from a virus spread the fecal-oral route.

- Type B hepatitis is acquired after parenteral exposure to infective blood or body fluids, or to needles or equipment contaminated with blood which has the hepatitis B virus. Type B hepatitis comprises about ten to fifteen percent of total post transfusion hepatitis.[25]

- Non A, Non-B hepatitis (a form of hepatitis for which no specific virus has yet been identified) causes ninety percent of the hepatitis transmitted through blood transfusions.[26]

A newly identified disease, Acquired Immune Deficiency Syndrome (AIDS), has generated fear throughout the United States. As of February 18, 1985, 8,495 cases of AIDS have been identified in total. Over 4,000 of the victims have died. There is no cure for the disease, and it apparently is one-hundred percent fatal. One hundred thirteen cases of AIDS have been linked to blood or blood products.[27] Misunderstanding of AIDS has caused the number of volunteer donors to drop sharply. There is however, no danger of acquiring AIDS from donating blood. Many patients became fearful of receiving blood transfusions. In this environment, there has been sharp pressure to develop a blood test screen. The Food and Drug Administration has recently licensed test kits to detect the antibody to the AIDS virus. The Public Health Service mandated HTLV-III testing in all federal facilities.[28]

Other risk factors are minimal. The risk of acquiring syphilis through blood transfusions is so rare that American Association of Blood Bank Standards have dropped the requirement to test for syphilis, although Federal regulations still require it. Malaria can be effectively screened out by excluding potential donors.[29] The risk of being infused with outdated blood is also rare. Outdated blood reports to Headquarters, Health Services Command, dropped to a low of nine-tenths of one percent (0.9) in MEDDACs for all of 1984.[30] Improper handling procedures such as inadequate refrigeration and storage of blood are also potential legal risks.

To minimize the element of negligence, the blood collecting facility must maintain records, and perform tests. Records must be maintained concurrently with the performance of each step of the processing. The records to be maintained are extensive. Deficiencies most frequently noted in inspections are record-keeping violations, either not properly completed, or not

available to inspectors.[31] Retention of records is for not less than five years for general blood products, ten years and six months for source plasma records, and indefinite for recovered plasma records.[32] Every donor must be checked against a registry. Camp Memorial Blood Center, for example, maintains a registry for every donor unit they ever collected.[33] According to Major Frohman, plasma has a ten year shelf life and AIDS can show up years after the transfusion. A recipient may not receive the infected plasma for ten years, contact AIDS ten years later, and therefore, after twenty years, file a claim against the Army for transmitting AIDS to him. This example shows the importance of preparing and maintaining good records.

All blood must be tested for determination as discussed at Appendix C. Military hospitals which receive blood from another collecting facility, must do confirmatory tests of ABO-group and Rh-group. When screening for AIDS antibodies, half of the positive results will be false positives. Seven percent of known AIDS victims have tested negative, possibly because of the time differential between contacting the disease and development of the antibody.[34] Although this screening is not as specific or as effective as may be desired, it is necessary.

A hospital will be liable for negligence if AIDS testing is not done. The principle has been tested in the blood banking industry. In an appeal of a judgment to the Supreme Court of Montana, a patient received blood which infected him with hepatitis.[35] He sued Blood Services of Montana for negligence in not using a laboratory test known as the SGOT test. The Supreme Court ruled that Blood Services of Montana was not negligent. In 1966, when the incident occurred, not a single blood bank in the nation had ever used the test to screen blood donors. "In other words, the standard of care established throughout the nation was not to use the SGOT test."

The standard of care principle demonstrated in this case is that if some blood banks do screen for the AIDS antibodies, then others may find themselves negligent for not following the standard of care. Already, many blood banks have determined that they will conduct the screening. Blood banks in Buffalo, Albany, Syracuse, and Rochester, New York have started to test blood for AIDS.[36]

SPACE REQUIREMENTS

Physical plant requirements for a blood collection facility are minimal. A physical description of each area is at Appendix C. Facilities adequate for a blood collection program may be found outside the hospital in any area with empty rooms, handwashing facilities, and toilets. An important aesthetic consideration is the design of a collection facility which is pleasing to the donor. Recruitment of donors is a challenging task, and a well-organized, well-run, and pleasing environment will facilitiate the return of donors.

The amount of space needed for an effective blood donor collection program is also minimal. Donor stations are normally set up as a semi-circle with three donor couches staffed by one technologist. Assuming a small program keeping two donor stations productive for two hours, approximately 60 units of blood can be collected. At many installations, potential donors are brought in a group, and complete the history forms together. To support this unit system, the reception area should have at least 30 chairs, a podium and tables with brochures. In locations which accept individual contributors, the reception area needs only two to three chairs per donor couch. Blood pressure

and hematocrit screening can be obtained by two technicians. Only one private screening station is necessary. Finally, the recovery area should have at least thirty chairs (for unit programs, ten for individual programs), plus tables for refreshments and a television.

TABLE 1

SPACE REQUIREMENT SUMMARY

TO COLLECT THIRTY UNITS OF BLOOD PER HOUR

AREA	SQUARE FEET REQUIRED
RECEPTION AREA	400
INITIAL SCREEN	40
HISTORY SCREEN	75
DONOR STATIONS	200
RECOVERY AREA	600
TOTAL	1315

As may be seen, space requirements, would not change significantly for a blood collection rate of thirty units per hour over the course of a longer period of time.

COST CONSIDERATIONS

The cost of collecting blood is an important part of the analysis. Major cost factors are identifiable in the Army accounting system and can be gathered relatively easily. Comparison to other systems is feasible. All Army hospitals must have a blood transfusion service in accordance with the standards of the Joint Commission on Accreditation of Hospitals (JCAH).[36] The functions of a blood collection service are generally easily differentiated from blood transfusion serivces, and therefore the costs should be kept separated.

The labor component of the cost analysis is taken from the College of American Pathologists Workload Recording Method.[38] The purpose of the Method is to provide a management aid to measure the productive time expended in the clinical laboratory. Not reflected is time spent by pathologists, or other doctoral level personnel. The Method is used in several thousand hospitals and independent laboratories.[39]

An expert opinion states that to draw only ten people in a day, perform all processing, and manufacture components, is the work of two people, or sixteen man-hours. Fifty people can be processed by four people in a full day of work or thirty-two man-hours.[40] As detailed at Appendix C, eighty (80) minutes per unit is needed for an approximate labor cost of $12.90 to $16.20.

Supply costs can be briefly summarized as the cost of blood bags and all other supply costs. There are four types of bags available:

- Single bags for whole blood ($3.80);
- Double bags for packed cells and one unit of plasma ($4.92);
- Triple bags for packed cells, platelet concentrate, and fresh-frozen plasma ($7.95);

- Quadruple bags, for packed cells, platelet concentrate, fresh-frozen plasma, and leuckocyte concentrate ($12.70).[41]

Other supplies are stratified into two categories. Supplies are needed for collecting blood (estimated cost - $3.00), and for processing blood (estimated cost $6.00 including AIDS screening). Emergency supplies and drugs also will be selected by the pathologist (as medical director) to be available in the donor bleeding area.

Equipment costs for the blood collection program of a small hospital could be quickly prohibitive. Fortunately, as shown at Appendix D, most of the equipment is already required for the blood transfusion service. Additionally, much of the equipment is required to be on hand for the mobilization mission of the MEDDAC. In determining the cost of a new collection program, the primary determination of cost will then be only for additional equipment, not already available, which is essential to start the blood collection program. These incremental costs will be relatively small compared to the total possible cost. They may be further controlled by modifying the amount of blood collected to a smaller level, by minimizing the time which blood is stored, or other techniques intended to prevent the initial expenditure of capital equipment dollars. Equipment costs, therefore, will be a minor obstacle for most MEDDACs.

The recurring costs of producing a unit of blood are summarized in Table 2. As a comparative indicator of what costs can be, the Veteran's Administration Hospital, Bronx, New York, will sell whole blood to an Army hospital for $26.00 per unit.[42] This also compares favorably to a price of $67.75 for buying whole blood from a civilian blood agency in the same region.[43]

TABLE 2

SUMMARY OF RECURRING COSTS

OF PRODUCING A UNIT OF BLOOD

ACTIVITY	LABOR	SUPPLIES	TOTAL
Collecting	$5.27	$8.57	$13.84
Processing	5.82	6.00	11.82
Manufacturing	1.64	-0-	1.64
Miscellaneous	1.82	-0-	1.82
TOTAL	$14.55	$14.57	$29.12

Prior to discussion of evaluating the feasibility of the alternatives, a discussion of Veteran's Administration Sharing Agreements is necessary because of their new and unique status. Inter-organizational arrangements to provide comprehensive quality care by shared service arrangements have recently gained credibility and popularity throughout much of the health-care sector. Recognizing a potential to benefit from this concept, the Federal government determined to implement shared services programs too.

Public Law 97-174 (Veterans' Administration and Department of Defense Health Resources Sharing and Emergency Operations Act) signed into law on May 4, 1982, had four objectives:[44]

- Greater sharing of healthcare resources which could result in reduced costs by minimizing duplication and underuse of healthcare resources;

- Improve the incentives to encourage such sharing of healthcare resources.

- Achieve sharing agreements without a detrimental effect on the primary healthcare beneficiaries; and

- Directing the Veterans' Administration to aid Department of Defense during and immediately after a period of war or national emergency with healthcare resources.

The law has been extremely effective. During Fiscal Year 1984, a total of 81 sharing agreements were implemented with 51 Veteran's Administration Medical Centers (VAMC) by 57 military facilities. Included in those, were 44 agreements for radiology (14 for CT scans), 37 for pathology, and 17 for nuclear medicine. Agreements extended into such mundane areas as contaminated waste disposal, maintenance of bio-medical equipment, vehicular maintenance, laundry, engineering, and transportation. Six agreements are in effect for blood products.[45]

If an agreement with a local Veterans' Administration Medical Center is possible, there are several distinctions which make such an agreement uniquely different from other alternatives previously identified. Among these unique features are:

1. Both are Federal government agencies. It is feasible for the two to work together more closely than is possible with civilian agencies such as the American Red Cross. The benefit of this is that a Veterans' Administration Medical Center blood collection team could come on an Army installation and draw blood under the direction and management of Army personnel. This gives a training benefit to the management staff of the Army facility Department of Pathology.

2. Army personnel may be able to work directly with the Veterans' Administration Medical Center team. Training benefits of performing all the work would therefore extend to the full laboratory staff. Since this discussion pertains to small hospitals, laboratory staffing is generally severely limited. The potential benefit is that the clinical laboratory officer can set up a blood donation date and be able to depend on Veterans' Administration Medical Center personnel to augment the MEDDAC staff if it is short, and yet can take advantage of as much hands-on training as staff is available.

3. Medical supply systems for the two agencies are very similar. A potential benefit is for the Veterans' Administration Medical Center to rotate fresher stocks into the MEDDAC for older stock, which the Veterans' Administration Medical Center will generally use rapidly.

4. Veterans' Administration Medical Centers are affiliated with medical schools. This permits them to rapidly adjust to new technologies which result in improved healthcare. The benefit to the Army is in personnel training.

5. Sharing agreements may include requirements for support during war or national disaster therefore setting up systems and providing the opportunity to practice working as a team during peace. There are many such arrangements in place for the Civilian-Military Contingency Hospital System (CMCHS). A wide range of medical services may be considered in the agreement. Sharing of blood in exchange for the use of under-utilized services of the Veterans' Administration Medical Center could provide significant cost advantages to both agencies.

6. The Veterans' Administration Medical Centers may be able to offer recruitment incentives not routinely available from other blood collecting services. The Veteran's Administration Medical Center, Bronx, New York, is considering a program which would guarantee a one year supply of free blood, including processing costs, for each donor. This would be a valuable incentive to the Department of the Army civilian work force.

Along with the advantages, there are potential disadvantages which must be evaluated in considering this alternative. A primary concern must be to establish clearly what it is that the Army facility would expect to gain by an agreemnt with a Veterans' Administration Medical Center. The cost to the Army, providing volunteer donors, while apparently low, is significant to the clinical laboratory officer. Donor resistance takes a significant effort to overcome. In a small hospital, half a man-year may be required just to recruit donors.[46] Another disadvantage is that the VA medical centers may not be able to provide timely blood services due to the requirements of their

own facility or because of supply or personnel shortages. Built into the agreement should be a clause which permits the hospital to withdraw if services promised by the Veterans' Administration Medical Center are not delivered.

EVALUATION OF ALTERNATIVES

The preceeding discussion gives a cognitive appreciation for many of the factors which impact on assessing the feasibility of establishing a blood collection program. The important task that remains is to evaluate the source alternatives identified earlier. Development of a list of criteria is important. Factors at each facility will cause criteria to vary. The following is a list of many of the important criteria from which a list may be tailored.[47]

1. Quality of blood and patient's safety

   - The proportion of transfusion reactions and the proportion of cases of serum hepatitis.

2. Adequacy of blood supply

   - Level of blood and blood products inventory by type.

3. Level of human errors

   - Number of erroneous crossmatches or clinical errors resulting in incorrect transfusion. When source is from outside the hospital, consider also the number of incorrect shipments by blood type.

4. Percentage use of components

   - Ratio of blood components to whole blood transfusions.

5. Response in emergencies

- Average time (in hours) of response to emergencies.

6. Outdating of blood

- Percentage of blood over 35 days old to the blood that is actually transfused.

7. Employee satisfaction

- Self-esteem generated by increased responsibility.

8. Crossmatch to transfusion ratio

- Ratio of number of crossmatches to the number of units actually transfused.

9. Delays in surgery

- A ratio of surgical delays caused by lack of blood compared to total surgeries performed where blood was available on time.

10. Workload on blood bank personnel

- Number of unit values measured by the CAP Method.

11. Community education

- Measured by the annual increase of volunteer donors.

12. Consultative services to hospitals

- The number of problems which must be referred out of the hospital for assistance (such as problem crossmatches).

13. Mobilization/emergency/disaster support

- An analysis of the mobilization/disaster plan ability to support mission requirements on little or no notice. Includes coordination problems, equipment and supply availability, and training.

14. Training level of blood bank staff

- How much is needed to start; what are the benefits (SQT); what are the costs?

15. Labor requirements

- Which alternative meets the most needs at the least cost in personnel.

16. Support of the total needs of the Army

- Looking beyond MEDDAC unique mission requirements, which alternative will best meet the long-range AMEDD mission.

17. Risk control

- Exposure to an increase degree of negligence.

18. Cost effectiveness

- Provides the best result for the least cost.

Once the hospital has identified the criteria which are most important to that facility, a method must be used to evaluate the alternatives. The Decision Matrix at Appendix E is a basic tool, but should be considered a reliable management tool. It has been expanded to include cost benefit and training/mobilization considerations. The matrix is established with the criteria listed vertically and the alternatives distributed horizontally. To use the table:

- The first step is to "weight" the criteria. This is done by a subjective command evaluation of the degree of importance of each criteria and numerically stratifying each one into its appropriate rank. If, for example, the risk of errors is more important than education of the population, then errors should have a value of two (2) and education a value of one (1). The range of weights should be kept between one (low) and five (high).

-Secondly, estimate the performance capability of each alternative by criteria. This is accomplished by a numerical scale of one (low) to ten (high). For example, if it is felt that a civilian blood bank is likely to produce very few errors, then they could be given a rating of nine, while a VA Medical Center may be given a rating of seven because of a local perception that it may produce more errors.

- The third step is to multiply the weight by the numerical evaluation. This will maintain a constant weight so that, in the previous example, errors at each alternative will always "weigh" more than education.

- Fourth, vertically add the values derived from step three.

- For step five, compare the totals for each alternative to establish a rank. At this point, one should also look for obvious errors, or unexpected deviation from what may have intuitively been anticipated and correct as required.

Two capabilities of this management tool make it very powerful. Once a preliminary evaluation is completed, it is easy to group or rank-order the alternatives, to drop an alternative which is clearly unfeasible, add a new combination of alternatives which now seem to be suitable, or make other changes, with a minimal investment of time. Secondly, this tool may be provided (with or without weight factors) to several key evaluators (e.g. DCCS, DCA, Chief Nurse, Pathology personnel, Comptroller, Chief, Logistics Division, etc.) and the results averaged to give a consensus summary. This method has the added advantage of focusing the discussion on areas of disagreement that require early resolution.

Footnotes

[1]Army Regulation 40-2, Army Medical Treatment Facilities, General Administration. p. 12-1.

[2]Ibid.

[3]Health Services Command Regulation 40-19, The United States Army Health Services Command Blood Program, 6 October, 1983, p. 5.

[4]Ibid, pp. 9-10.

[5]Army Regulation 40-2, p. 12-2.

[6]Interview with Captain Deborah Hampson, Clinical Laboratory Officer, USA MEDDAC, Fort Meade, Maryland, 4 December 1984.

[7]Interview with Captain Mark Gusack, M.D., Chief, Department of Pathology, USA MEDDAC, West Point, New York, 24 April 1985.

[8]Army Regulation 40-2, p. 12-2.

[9]Interview with Lieutenant Colonel Robert T. Usury, Blood Program Manager, Headquarters Health Services Command, Fort Sam Houston, Texas, 7 August 1984.

[10]Interview with Captain William W. Ward, US Air Force, Director, Armed Services Whole Blood Processing Laboratory, McGuire Air Force Base, New Jersey, 24 January, 1985.

[11]Telephonic interview with Captain Mark J. Wolcott, Clinical Laboratory Officer, USA MEDDAC, Fort Campbell, Kentucky, 20 March 1985.

[12]Telephonic interview with Major Richard Brown, Chief, Blood Bank, Fitzsimmons Army Medical Center, Aurora, Colorado, 9 October 1984.

[13]Interview with LTC Usury on 31 January 1985.

[14]Interview with Mr Scott Ferber, Administrator, Hudson Valley Blood Services, Valhalla, New York, 15 November 1984.

[15]Interview with Major Ellis M. Frohman, Director, Camp Memorial Blood Center, Fort Knox, Kentucky, 5-6 December 1984.

[16]Interview with Captain Deborah Miller, Clinical Laboratory Officer, Keller Army Community Hospital, West Point, New York, 24 January 1985.

[17]Francis K. Widmann, MD, Technical Manual (Washington, D.C.: American Association of Blood Banks, 1977). p. 316.

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[25]Ibid.

[26]Hospitals, 1 December 1984, p. 32.

[27]_____, "Feds Approve AIDS Blood Test", Middletown Sunday Record, 3 March 1985, p. 6.

[28]Letter, Military Blood Program Office, Subject: Military Implementation of Public Helath Service Provisional Recommendations Concerning Testing Blood and Plasma for Antibodies to HTLV-III, 13 March 1985.

[29]Technical Manual, p. 319.

[30]Letter, Headquarters Health Services Command, Subject: Blood Bank Information, 1 March 1985.

[31]Technical Manual, p. 372.

[32]Ibid, p. 373-4.

[33]Interview with Major Frohman, 5-6 December 1984.

[34]_____, Hospital Week, American Hospital Association Publishing Inc, 8 March 1985, p. 8.

[35]Hutchins v. Blood Services of Montana, Supreme Court of Montana, 1973, 506 P. 2d 449, extracted from Student Handout, GR 16-310-201 (075), "Cases and Comments on Liability of Health Care Providers", Health Care Administration Division, Academy of Health Sciences, United States Army, Fort Sam Houston, Texas, pp. 152-156.

[36]_____ _____, "Buffalo, Albany to Start Testing Blood for AIDS", Middletown Times-Herald Record, 23 March 1985, p. 8.

[37]Accreditation Manual for Hospitals (Chicago: Joint Commission on Accreditration of Hospitals, 1984), p. 120.

[38]_____, Manual for Laboratory Workload Recording Method, (Chicago: College of American Pathologists, 1984), pp. 143-6.

[39]Ibid, p. 1.

[40]Interview with Major Frohman, 5-6 December 1984.

[41]Interview with Mr. Steven Nestanpower, Assistant Administrator, Hudson Valley Blood Services, Valhalla, New York, 15 November 1984.

[42]Interview with Mr. Robert Simson, Director, Blood Bank, Veterans' Administration Medical Center, Bronx, New York, 8 April 1985.

[43]Letter, Greater New York Blood Program, Subject: Revised Fee Schedule Effective May 1, 1985, dated 29 March 1985.

[44]Public Law 97-174, "Veterans' Administration and Department of Defense Health Resources Sharing and Emergency Operations Act", 97th Congress, 4 May 1982.

[45]Interview with Sylvia Kuzniar, VA-DoD Sharing Agreements Program Manager, HQ, Health Services Command, 27 February 1985 (telephonic).

[46]Telephonic interview with Colonel James E. Spiker Jr., Department of the Army Blood Program Manager and Director, Military Blood Program Office, 10 October 1984.

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CHAPTER III

CONCLUSION

Application of the principles of the previous discussion will result in an effective examination of the feasibility of establishing a blood collection program. Analytical tools were described which will help to quantify most aspects of the problem. Subjective decisions will be made too, however, and they are an essential part of the study which should not be minimized.

Decentralization of the blood collection program provides an opportunity for each MEDDAC to tailor a system which will uniquely satisfy local requirements. The need for rapid expansion of blood collection efforts is clear. Formation of light-infantry divisions with a rapid deployment mission, events such as the Granada invasion on short notice, and the fact that forty-three percent of active Army forces are forward deployed,[1] dictate that MEDDACs cannot plan on a long period of time to develop functional blood programs during mobilization.

Training programs are essential for all personnel in a hospital clinical laboratory, from the pathologist to the military and civilian technicians. Military mobilization requirements and local emergency requirements dictate that the relatively small additional cost will be rewarded in a staff ready to respond to all needs. Training which satisfies the stringent standards of the accrediting agencies will benefit the Army in wartime. While these standards are called minimums, they require strict interpretation and careful attention to detail. Developing these careful habits in a blood collection program now will save lives later.

Risks associated with the establishment of a blood collection program can be controlled. Diligent adherence to the standards of the Food and Drug Administration and the professional associations will assure that the current standard of care is applied to the program. Military Personnel work in fixed medical facilities for the training value. Careful training of personnel and good supervision will control the risk of negligence. Good records to document the history and testing of donors will further satisfy a court that the operation is professionally operated and that there are no grounds for negligence. Lessons learned from such a stringent program will ultimately be tested and appreciated during the next disaster or mobilization.

While a cost of over $29.00 per unit of blood may appear to be prohibitive, for many facilities, at least most personnel resources will be from those already authorized. Therefore, the cost is significantly reduced to less than $15.00 per unit. Further reductions in cost will be found by the availability of some blood products which were previously purchased. Finally, the cost factor is further minimized by appreciating that the costs of whole blood and packed red blood cells acquired "free" through the COMPASS program are paid for by other Army hospitals in a form of cost-shifting.

Nevertheless, small hospitals cannot efficiently operate a blood management program in a vacuum. Determining which combination of alternatives is best will be the challenge offered. In some cases, this will require the fine art of compromise, trading off some value for potential benefit in another area. Compromise is necessary, as long as patient care is not

compromised, and training and mobilization capabilities can be improved cost-effectively. Veterans Administration - Department of Defense sharing agreements have demonstrated success for several years in multiple facilities. By establishing reasonable agreements which recognize that sharing services is not buying services from a supplier, significant advantages may be found in cost reduction, training benefits, and mobilization readiness.

The study was validated by an evaluation of the methodology at Keller Army Community Hospital, West Point, New York, and was demonstrably effective in assessing the feasibility of establishing a blood collection program and generating a decision from the Commander. It is a very complete tool, yet it is easily applied with only minor modifications for local conditions, prices, or other time related variables. Application to other hospital services is also feasible with particular attention to medical need being a primary focus modification.

Two issues have not been discussed. First, blood collection programs are a very politically sensitive issue in many locations. Regional blood banks are the for-profit arm of non-profit institutions (if they are not separate for-profit organizations). The Red Cross's non-profit blood programs forced many small commercial blood banks out of business in the 1970s.[2] Facts presented in the Project will assist in addressing the specific gains and losses created by various programs in a sensible, organized manner.

Secondly, effective communications will be vitally important in establishing a viable blood collection program if the study finds that it is feasible at the local installation. There may be a perception that such a

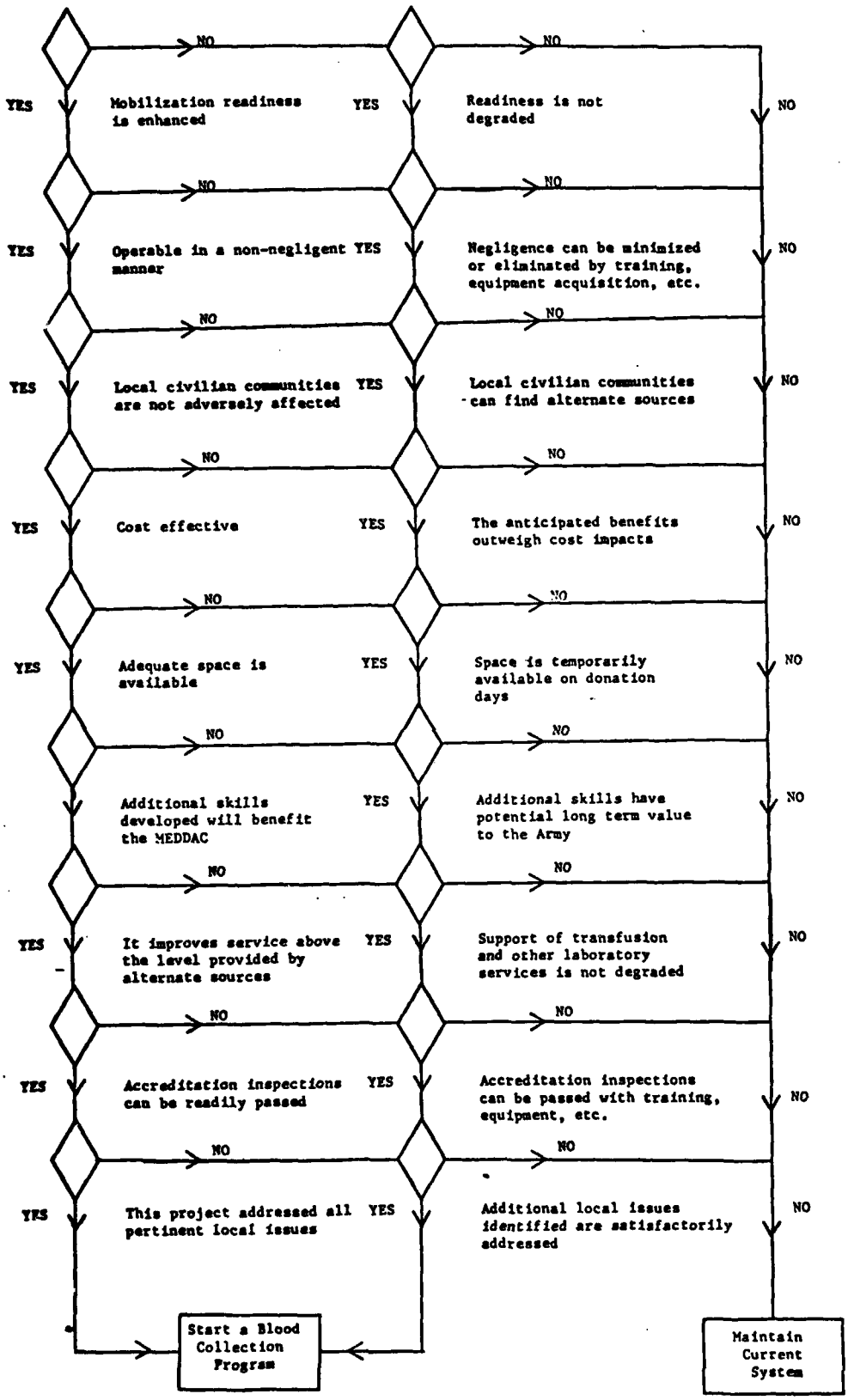
program will absolutely not work without additional personnel. This will have to be addressed very honestly by all parties. There may be a sense of danger as there frequently is with any proposal for changes. This will manifest itself in many ways, but it must also be faced with clear communications in a forthright manner. Communicating the need for a blood collection program to the installation staff will also be important to the initial success of the first blood drive. Finally, if a multiple agency alternative is employed, all parties must be made aware of all aspects of the program so that misunderstandings and jealousy will not prevail.

Focusing on the real problem during course of research and preparation of this project proved difficult. What appeared to be a MEDDAC mission concern became a training program need. Potential resource constraints transformed into making sure that excess resources, such as blood, blood products, and blood bags, did not go to waste. The evaluator should be aware of shifts in focus and take advantage of them by evaluating each one in the context of the whole problem to truly examine it in all its multiple facets.

Application of this Research Project should follow the flowchart at Figure 1. Upon completion of the study, a decision paper should be prepared for staffing in the MEDDAC and final action by the Commander. The study should be kept brief and follow the general form of the sample shown at Appendix E.

FIGURE 1

DECISION FLOWCHART



Footnotes

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APPENDIX A

EXTRACT OF FM 8-70, "STANDARDS FOR BLOOD BANKS AND TRANSFUSION SERVICES"

ARMY FIELD MANUAL
FM 8-70
NAVY PUBLICATION
NAVMED P-5120
AIR FORCE REGULATION
AFR 160-24

DEPARTMENTS OF THE ARMY, THE NAVY AND THE AIR FORCE

WASHINGTON, DC, *15 July 1981*

STANDARDS FOR BLOOD BANKS and TRANSFUSION SERVICES

1. This commercial publication has been adopted as a joint text for those military medical activities actively engaged as blood donor centers and those with a transfusion service.

2. It will serve as the basic text in the training of MOS 92B20 and 92B30, NEC HM-8506 and AFSC 904XO personnel and as the basic reference for the development of evaluation tests for those MOS, NEC and AFSC.

3. This civilian text establishes and maintains uniform blood banking standards for the military departments that are compatible with those of the civilian field of blood banking. Uniformity has become essential with the advent of the Food and Drug Administration's licensing of blood banks and issuance of the National Blood Policy by the Department of Health and Human Services.

4. The Code of Federal Regulations, CFR 21, Food and Drugs, Parts 600 to 799 are the primary standards applying to blood donor centers and transfusion service operations in military medical treatment facilities.

5. Following any transfusion, a copy of the SF518 (Medical Record—Blood or Blood Component Transfusion) will be attached to the recipient's chart, and a duplicate copy returned to and kept in the laboratory (see section M3.300).

This publication may be released to foreign governments (sec 1719, title 44, US Code).

* This manual supersedes FM 8-70/NAVMED P-5120/AFR 160-24, 1978.

STANDARDS

FOR

BLOOD BANKS

AND

TRANSFUSION SERVICES

Tenth Edition 1981

Prepared by
COMMITTEE ON STANDARDS
AMERICAN ASSOCIATION OF BLOOD BANKS
1828 L Street, NW Suite 608
Washington, DC 20036
Price $3.00

CONTENTS

A

GENERAL POLICIES

A1.000 All procedures and policies of the Blood Bank or Transfusion Service shall be under the direction of a licensed physician, qualified by training and/or by experience, who shall be responsible for all medical, technical and clerical services. These responsibilities shall include compliance with these Standards, recruitment and selection of blood donors, and the collection, storage, processing, distribution and, where possible, transfusion of blood and blood components. The medical director shall be responsible for providing or obtaining adequate consultation for special problems. Special services, such as phlebotomy for autologous transfusions, or pheresis technics, and any deviation from the Standards in this book, shall be approved by the medical director.

A2.000 There shall be an adequate and competent staff and patient-care consultative service under supervision of the medical director.

A3.000 Suitable quarters, environment and equipment shall be available to maintain safe, acceptable standards.

A4.000 Each Blood Bank and Transfusion Service shall maintain a detailed procedure manual. This manual may refer in specific instances to appropriate sections in the Technical Manual of the American Association of Blood Banks or other equally acceptable publications. Copies of the procedure manuals and publications used in lieu of written detailed procedures shall be available to the facility personnel at all times. There shall be evidence of review of the procedures at least annually by the medical director.

A5.000 Blood and its derivatives may contain infectious agents and, therefore, must be handled and discarded with precautions which recognize this potential hazard.

A6.000 All blood-letting devices capable of transmitting infection to the donor or recipient shall be disposable or sterilized prior to each use.

A7.000 All containers and anticoagulants used for preservation and storage of blood and blood components and all required reagents used for testing of blood samples shall meet or exceed appropriate Food and Drug Administration (FDA)* criteria.

A8.000 All Blood Banks and Transfusion Services shall utilize a program of quality control that is sufficiently comprehensive to ensure that reagents and equipment perform as expected, and that there is compliance with these Standards. Each Blood Bank and Transfusion Service shall participate in a proficiency testing program.

B

DONORS AND DONOR BLOOD

B1.000 *Criteria for Donor Selection*

B1.100 *Protection of the Donor*

On the day of donation the prospective donor's history shall be evaluated and the donor examined by a suitably qualified person trained to utilize the following guidelines in order to determine that the blood donation will not be detrimental to the donor.

B1.110 *General*

Prospective donors with active disease of the heart, kidneys, liver or lungs, or with a history of cancer, abnormal bleeding tendency or convulsions after infancy, shall be excluded subject to evaluation by a qualified physician.

B1.120 *Drug therapy*

Drug therapy, including antibiotics, may indicate that blood donation could be deleterious to the donor or

*Bureau of Biologics of the Food and Drug Administration, U.S. Department of Health and Human Services.

to the recipient; therefore, the clinical indication for such treatment should be determined.

B1.130 *Donation interval*

Except for reasonable qualifying circumstances, the interval between donations for a full unit of blood shall be at least eight weeks. Whole Blood donation must be deferred for at least 48 hours after pheresis.

B1.140 *Age*

Blood donors shall be between the ages of 17 through 65 (up to 66th birthday) with the following exceptions.

B1.141 Prospective donors who are considered minors under applicable law may be accepted only if written consent to donate blood has been obtained in accord with applicable law.

B1.142 After the 66th birthday, prospective donors may be accepted at the discretion of the Blood Bank physician.

B1.150 *Hemoglobin or packed cell volume (hematocrit)*

The hemoglobin concentration shall be determined with a sample of blood obtained by fingerstick or venipuncture.

B1.151 The hemoglobin shall be no less than 12.5 g per dl for prospective female donors, and no less than 13.5 g per dl for prospective male donors.

B1.152 The packed cell volume (hematocrit), if substituted, shall be no less than 38 percent for females, and no less than 41 percent for males.

B1.160 *Pulse*

The pulse shall reveal no pathological cardiac irregularity and should be between 50 and 100 beats per minute. If a prospective donor is an athlete with high exercise tolerance, a lower pulse rate may be acceptable.

B1.170 *Blood pressure*

The systolic blood pressure should be between 90 and 180 mm of mercury, and the diastolic pressure should be between 50 and 100 mm mercury. Prospective donors with diastolic blood pressure readings below 50 or above 100 mm mercury, or pulse pressures less than 30 or above 90 mm mercury, may be accepted only after evaluation by a qualified physician.

B1.180 *Pregnancy*

Known existing pregnancy shall preclude donation. Ordinarily a prospective donor shall be excluded for six weeks following delivery at term or during the third trimester.

B1.190 *Donor's weight and amount of blood collected*

Donors weighing 110 lbs (50 kg) or more ordinarily may give 450 ± 45 ml of blood, in addition to pilot samples which shall not exceed 30 ml. Donors weighing less than 110 lbs may be bled proportionately less in a reduced volume of anticoagulant provided the Standards outlined in B2.000 are met.

B1.200 *Protection of the Recipient*

On the day of donation the prospective donor's history shall be evaluated and the donor examined by a suitably qualified person trained to utilize the following guidelines in order to determine that the donor has no evidence of disease transmissible by blood transfusion.

B1.210 *General appearance*

The prospective donor shall appear to be in good health.

B1.220 *Temperature*

The oral temperature shall not exceed 37.5 C.

B1.230 *Immunizations or vaccinations*

Symptom-free prospective donors who recently have

been immunized may be accepted with the following exceptions:

Smallpox: Prospective donors are acceptable either after the scab has fallen off or two weeks after an immune reaction.

Measles (rubeola), mumps, yellow fever, oral polio vaccine, rabies and animal serum products: Prospective donors are acceptable two weeks after their last immunization.

German measles (rubella): Prospective donors are acceptable four weeks after their last injection.

Unlicensed vaccines: Prospective donors are acceptable one year after their last injection.

B1.240 *Donor skin*

The skin at the venipuncture site shall be free of lesions.

B1.250 *Receipt of blood or blood components*

Prospective donors who during the preceding six months have received blood, or those human blood components known to be a possible source of hepatitis, shall be excluded.

B1.260 *Infectious diseases*

A prospective donor shall be free from infectious diseases known to be transmissible by blood insofar as can be determined by usual examinations and history.

B1.261 *Viral hepatitis*

Prospective donors shall be permanently deferred for: (a) a history of viral hepatitis, (b) a history of a reactive test for hepatitis B surface antigen (HBsAg), or (c) donation of the only unit of blood or blood component transfused to a patient who within six months developed post-transfusion hepatitis and who received no other

blood derivative known to transmit viral hepatitis and there was no other probable source of infection. Prospective donors shall be deferred for 12 months after the last injection of Hepatitis B Immune Globulin (HBIG). Prospective donors who have a history of a tattoo or have had close contact with an individual with viral hepatitis during the preceding six months shall be deferred. The presence of an agent of viral hepatitis in donors cannot at present be excluded with certainty by any available means, including history, physical examination and laboratory tests (including a test for presence of HBsAg.)

B1.262 Malaria

Travelers who have been in areas considered endemic for malaria by the Malaria Program, Centers for Disease Control, U.S. Department of Health and Human Services, may be accepted as regular blood donors six months after return to the nonendemic area, providing they have been free of symptoms and have not taken antimalarial drugs. Prospective donors who have had malaria shall be deferred for three years either after becoming asymptomatic or after cessation of therapy. Prospective donors who have taken antimalarial prophylaxis shall be deferred for three years after cessation of therapy or after departure from the area, if they have been asymptomatic in the interim. Immigrants or visitors from endemic areas may be accepted as blood donors three years after departure from the area if they have been asymptomatic in the interim. Donations to be used for the preparation of plasma, plasma components or derivatives devoid of intact Red Blood Cells, are exempted from these restrictions.

B1.263 Tuberculosis

Prospective donors with clinically active tuberculosis are unacceptable. Prospective donors with a positive tuberculin skin test, but without other abnormality, may be accepted.

B1.270 *Alcohol, Narcotics*

Obvious stigmata of narcotic or alcoholic habituation or intoxication shall exclude a prospective donor. Both arms must be inspected for evidence of repeated venipunctures.

B1.300 *Information Provided to the Donor*

B1.310 *Requirement for consent*

The consent of the prospective donor must be obtained in writing after the procedure is explained in terms the donor can understand and after the donor has an opportunity to ask questions and to refuse consent.

B1.320 The donor must be instructed in postphlebotomy care and cautioned as to possible adverse reactions.

B1.330 *Notification of test results*

The medical director of the blood bank shall be responsible for a mechanism to notify donors of any clinically significant abnormalities detected during the predonation evaluation or during serological testing, including a reactive test for HBsAg.

B2.000 Collection of Blood from Donor

B2.100 *Method*

The removal of blood from the donor shall be by aseptic methods utilizing a sterile, closed system and a single venipuncture. Immediately after collection, the blood shall be placed at a temperature between 1 and 6 C unless platelets are to be harvested.

B2.200 *Protection Against Contamination*

The donor, as well as the future recipient, shall be protected by proper preparation of the site of the venipuncture. Preparation of the skin shall provide maximum assurance of an aseptic procedure and a sterile product. If more than one skin puncture is needed, another set and container must be used.

APPENDIX B

EXTRACT OF TM 8-227-3, THE TECHNICAL MANUAL OF THE AMERICAN ASSOCIATION OF BLOOD BANKS

Technical Manual

of the
AMERICAN ASSOCIATION
OF BLOOD BANKS

EIGHTH EDITION

1981

PRICE: $25.00

AMERICAN ASSOCIATION OF BLOOD BANKS
1828 L Street, NW, Suite 608, Washington DC 20036

Chapter 1

Blood Collection and Processing

BLOOD DONORS

BLOOD banks and transfusion services depend on voluntary donors to provide the basic ingredient necessary to meet the needs of the patients they serve. To attract volunteer donors initially and to encourage their continued participation, it is essential that conditions surrounding blood donations be as pleasant, safe and convenient as possible.

The donor area should be attractive, well lighted, comfortably ventilated, clean and open at convenient hours for donors. Personnel should be interested, friendly and understanding, as well as professional and well trained.

Each blood bank must prepare its own procedures manual, which covers all phases of activity in the donor area. These procedures must meet the requirements of the AABB *Standards*.[1] The manual should contain any local or state regulations pertaining to blood bank operation. The procedures manual must be reviewed annually by the medical director of the blood bank and should be available at all times to the personnel in the blood bank.

Registration[1,2]

The following information, which should make it possible to identify and recall the donor, must be initially recorded and kept constantly updated on a donor record (either single- or multiple-donation record), which is kept on file in the blood bank for at least five years or as required by local statutes, whichever is longer.

1. Date of donation
2. Name: Last, first, and middle initial
3. Address: Residence and/or business
4. Telephone: Residence and/or business
5. Sex
6. Age or date of birth: Blood donors must be between the ages of 17 through 65 years (up to 66th birthday) with the following exceptions:
   a. Donors who are considered minors under applicable law may be accepted only if written consent to donate blood has been obtained in accord with applicable law. Since these laws vary among jurisdictions, legal opinions should be obtained.
   b. After the 66th birthday, donors should be evaluated by the blood bank physician and this evaluation should be documented as part of the permanent record of that donation. Individuals 66 years or older may donate, with the blood bank physician's permission, if they meet other donor criteria.
7. Consent for the blood bank to take and use blood from a prospective donor must be obtained in writing. The consent form is part of the donor record and is usually completed at the time of registration. The procedure must be explained in terms the donor can understand. The donor must have an opportunity to ask questions and to decide whether or not to give consent by signing the form. The blood bank staff member then signs as witness to the donor's signature or notes his refusal (Fig. 1-1). This is not required but is common practice in most banks.
8. A record of reasons for previous deferrals, if any

The following information is not required but may be useful:

I am voluntarily donating blood to the .....Blood Bank to be used as decided by that Blood Bank. I certify that I have, to the best of my knowledge, truthfully answered questions regarding my health and medical history and understand that this information is important in determining whether I am acceptable as a blood donor.

A.M.
In witness Whereof, I have hereunto set my hand this .....day of .....19.... at .....P.M.

.....
(Donor)

.....
(Witness)

Fig. 1-1. Informed consent form (sample).

1. Additional identification such as social security or driver's license number. This information may be necessary for information retrieval in some computerized systems and provides additional identifying information.
2. Time of last meal: Most blood banks prefer it when donors have eaten within the past several hours. Many experienced donor room personnel feel that dizziness and other reactions occur more frequently in donors who have eaten nothing in the preceding four to six hours. A light snack from the refreshment area often alleviates this problem, although it may not be sufficient to prevent reactions if donors have not eaten in 18 hours or more. Donors who do not wish to do so, however, should not be required to eat.
3. Name of intended recipient or donor group:
   a. Full name of patient and hospital or donor group is important if a credit system is being utilized.
   b. Even if the donor is rejected, a record of rejected or deferred donors may be useful to the patient or to others concerned with donor recruitment or credit accounts.
4. Race: This information may be particularly useful when blood of a specific phenotype is needed to meet the needs of patients with unexpected antibodies.

Donor Selection[1,3]

A limited physical examination and medical history must be done on the day of and prior to each donation to determine whether giving blood will in any way harm the donor or if transfusion of the unit will in any way harm the recipient. Careful donor selection plays a major role in determining donor and recipient safety.

The medical history questions may be asked by a qualified interviewer or the donor may complete his own record, which must then be reviewed and initialed by a knowledgeable individual responsible to the blood bank.

The interview and physical examination should be performed in a manner that assures adequate privacy (auditory and visual), allays apprehensions and allows time for any necessary discussion or explanation. Answers to questions must be recorded "yes" or "no" with details explaining "yes" answers added as indicated. Results of all tests must be recorded.

Given below are:

1. Determinations to be included in the medical examination and some acceptable methods
2. Areas to be included in the medical history and sample questions
3. Allowable criteria in each area for acceptance, deferral or permanent rejection of the prospective donor

Physical Examination

Any exceptions must be evaluated individually by the blood bank physician.

1. Weight: Donors weighing 110 lb (50 kg) or more may ordinarily give 450 ± 45 ml of blood in addition to processing tubes not exceeding 30 ml. Donors weighing 100 to 110 lb may have a smaller amount of blood drawn (no less than 405 ml) without reducing the amount of anticoagulant in the primary bag, but it is important that there be an accurate measurement of the volume of blood withdrawn. If it is necessary to draw less than 405 ml, the amount of anticoagulant must be reduced proportionately by expressing the excess to an integrally attached satellite bag and sealing the tubing. The volume of blood drawn must be measured carefully and accurately. To determine the amount of anticoagulant to remove, the following formula may be used:

   Amount of anticoagulant to remove

$$= 63 \text{ ml} - \left[\frac{\text{donor's weight}}{110 \text{ lb}} \times 63 \text{ ml}\right]$$

   Amount of blood to draw

$$= \frac{\text{donor's weight}}{110 \text{ lb}} \times 450 \text{ ml}$$

2. Temperature: The oral temperature must not exceed 37.5° C (99.6° F). Caution: If a glass thermometer is used, it should not be in the donor's mouth when blood is obtained for hematocrit or hemoglobin determination.
3. Pulse: The pulse should be counted for at least 30 seconds. It should exhibit no pathologic irregularity, and should be between 50 and 100 beats per minute. However, if a prospective donor is an athlete with high exercise tolerance, a lower pulse rate may be acceptable. The blood bank physician should evaluate abnormalities of pulse before a donor is accepted.
4. Blood pressure: The systolic blood pressure should be between 90 and 180 mm Hg and the diastolic blood pressure should be between 50 and 100 mm Hg. Prospective donors with a pulse pressure (difference between systolic and diastolic figures) less than 30 mm Hg or greater than 90 mm Hg must be disqualified unless evaluated by a qualified physician and approved.
5. Skin lesions: The skin at the site of venipuncture must be free of lesions. Both arms must be examined for signs of narcotic habituation. The common findings would be needle puncture marks and/or sclerotic veins. Mild skin disorders such as acne, psoriasis or the rash of poison ivy are not necessarily cause for deferment unless present in the antecubital area or unusually extensive. Donors with boils, purulent wounds or severe skin infections anywhere on the body should be deferred.
6. General appearance: If the donor looks ill, appears to be under the influence of drugs or alcohol or is excessively nervous, it is best to defer.
7. Hematocrit or hemoglobin: The hematocrit value must be no less than 38% for female donors and no less than 41% for male donors. The hemoglobin value must be no less than 12.5 g/dl for female donors and no less than 13.5 g/dl for male donors. The preferred method is determination of the venous blood hemoglobin concentration, or its equivalent. Hemoglobin concentration may be determined by spectrophotometric methods, or the acceptable minimum value may be estimated by using copper sulfate.
   a. Copper sulfate method: Use solution of copper sulfate with specific gravity of 1.053 to test females (equivalent to 12.5 g/dl hemoglobin). Use copper sulfate with specific gravity of 1.055 to test males (equivalent to 13.5 g/dl hemoglobin). The solutions should be stored at room temperature in tightly

capped containers to prevent evaporation. For routine use, dispense 30 ml of solution into appropriately labeled, clean, dry tubes or bottles. Change solution daily or after 25 tests. Be sure the solution is adequately mixed before beginning each day's determinations.

This method is based on specific gravity. A drop of blood dropped into the solution is encased in a sac of copper proteinate, which prevents any change in specific gravity for about 15 seconds. If the drop of blood has a satisfactory specific gravity it will sink within 15 seconds. If not, the sinking drop will hesitate, remain suspended, or rise to the top of the solution. This is not a quantitative test and will show only whether the hemoglobin is below or above acceptable limits. Test results indicating satisfactory hemoglobin levels are usually accurate. Inappropriate rejections, however, occur fairly commonly. Measuring hematocrit or hemoglobin by a different method often reveals that the prospective donor is, after all, acceptable.

Blood obtained from an ear lobe puncture has a higher hemoglobin or hematocrit than blood from a fingerstick.[4] Some slightly anemic donors may be accepted if ear lobe punctures are done.

Test Procedure: Clean the site of skin puncture thoroughly with antiseptic solution and wipe dry with sterile gauze. If a finger is used, puncture vigorously, near the end but slightly to the side, with a sterile, disposable lancet. A good free flow of blood is important. Do not squeeze the finger repeatedly, as this may dilute the drop of blood with excess tissue fluid and give falsely low results. Collect blood in a capillary tube without allowing air to enter the tube. Let one drop of blood fall gently from the tube at a height of about 1 cm above the surface of the copper sulfate solution. Observe for 15 seconds.

Record results as greater or lesser than 12.5 g/dl for females, and greater or lesser than 13.5 g/dl for males.

b. Spectrophotometric methods: Use standard techniques.[5]
c. Hematocrit measurement: Use standard techniques.[5]

Medical History

Some very specific questions will be necessary, but a great deal of pertinent information can be obtained by using some general or leading questions in simple language that the donor can understand. The examples given below include all reqirements and are followed by suggested or required responses to information received.

1. Blood donation: Have you ever donated blood, platelets or plasma? Date of last donation?

   The interval between donations of whole blood must be eight weeks except in unusual circumstances and with the written permission of a physician. After plasmapheresis or cytapheresis, at least 48 hours must elapse before whole blood donation.
2. Rejection as a donor: Have you ever been rejected as a blood donor? When? Why?
3. Pregnancy: Are you pregnant? Have you been pregnant during the last six weeks?

   Defer during pregnancy and for six weeks after third trimester delivery. Exception may be made by the responsible physician for autologous transfusion or if the woman's blood is needed for exchange transfusion of her infant. Donors who have had abortions need not be deferred if they meet other donor criteria.
4. Surgical procedures or major illnesses: Have you had surgery or a major illness

in the last six months? When, what type? Are you under the care of a doctor for any reason? Why?

Donors who have had major surgery should be deferred for at least six months, partly to ensure complete recovery but largely because they may have received blood or components during the procedure. Minor surgery is disqualifying only until healing is complete. The determination of "major" and "minor" may have to be made by a physician, but the following common operations are generally classified as minor: closed reduction of fracture, repair of hernia, hemorrhoidectomy, appendectomy, tonsillectomy, minor gynecologic procedures, removal of pilonidal cyst or of small skin lesions, and varicose vein surgery.

Questionable answers that might indicate the donor is not in good health should be referred to the blood bank physician for further evaluation.

5. *Heart, lung, kidney, and liver diseases:* Have you ever had heart disease? When? What type? Do you ever suffer from chest pain, shortness of breath? Explain. Have you had tuberculosis or other lung disease? Explain. Do you ever cough up blood? Have you had any type of kidney disease? Explain. Have you had any type of liver disease? Explain.

   A history of coronary heart disease or rheumatic heart disease with known residual damage is cause for rejection unless evaluated and approved by the blood bank physician. A single episode of rheumatic fever or pericarditis, a heart murmur or repair of a congenital defect does not necessarily disqualify a donor.

   Active pulmonary tuberculosis is cause for rejection. Previous tuberculosis, successfully treated and no longer active, need not disqualify. Donors with a reactive tuberculin skin test, but without other abnormality, may be accepted.

   An active inflammatory or degenerative disease of the kidney or liver or one that might impair organ function may be cause for rejection of the donor. Chronic conditions must be evaluated by a physician.

6. Unexplained weight loss: Have you lost weight recently? How much? Why?

   Excessive unexplained weight loss could indicate undiagnosed serious illness, and should be investigated further and evaluated by a physician.

7. Drugs and medications: Are you taking any drugs or medications? Why? What?

   Marijuana (unless currently under the influence), oral contraceptives, mild analgesics, minor tranquilizers or psychic energizers, vitamins, replacement hormones or weight reduction pills are not usually cause for deferment or rejection.

   Aspirin or aspirin-containing compounds depress platelet function for one to five days. Platelets from a donor who has taken these drugs within five days should not be the only source of platelets for a patient. This applies to thrombocytapheresis concentrate for an adult patient or random-donor platelet concentrate for an infant recipient.

   History of recent or present therapy with antibiotics, corticosteroids, digitalis, insulin, quinidine, phenytoin (formerly called diphenylhydantoin or Dilantin), diuretics, nitroglycerin, anticoagulants or other potent drugs should be evaluated by a physician.

   Other drugs and medication should be carefully evaluated by the blood bank medical director. Listed below are some drugs and medical conditions that may be permitted in blood donors at the discretion of the medical director.[6] The approval to draw these donors may be (1) a general approval included in the facility procedures manual or (2) given individually as each problem arises, providing

verbal approval is documented on the donor's record

a. Tetracyclines and other antibiotics for acne
b. Topical steroid preparations for skin lesions not at the venipuncture site
c. Blood pressure medications, taken chronically and successfully, so that pressure is at or below allowable limits. The prospective donor taking antihypertensives should be free from side effects of the drug, especially episodes of postural hypotension, and should be free of any cardiovascular symptoms. Asymptomatic patients taking α-methyldopa (Aldomet) may have a positive direct antiglobulin test (see Chapter 15), in which case their blood should not be used for transfusion.
d. Isoniazid given because the tuberculin skin test has converted but without evidence of active tuberculosis
e. Over-the-counter bronchodilators and decongestants
f. Oral hypoglycemic agents in well-controlled diabetics without any vascular complications of the disease
g. Tranquilizers, under most conditions. A physician should evaluate the donor to distinguish between tranquilizers and antipsychotic medications. Donors taking antipsychotic agents should be deferred because their mental processes might be sufficiently disordered that it would be difficult to obtain a good, complete medical history from them
h. Hypnotics used sporadically at bedtime, or regularly at bedtime, but at no other times

8. Infectious diseases:

Hepatitis: Have you ever had hepatitis or yellow jaundice? Have you had a reactive test for hepatitis (HBsAg)? Have you had intimate contact with a person with hepatitis? When? Have you received injections of hepatitis B immune globulin (HBIG)? When? Have you been transfused with blood or blood components? When? Have you had a tattoo? When? Have you ever injected drugs into your veins or skin? (If ear piercing and/or acupuncture are commonly performed in the area and are not performed by a physician, the donor should be questioned about these procedures.)

The possible presence of the agent of viral hepatitis cannot at present be detected with certainty by any available means including history, physical examination or laboratory tests (including tests for HBsAg); therefore, strict regulations for donor acceptability must be established and followed.[1,2]

Reject permanently:

a. Donor with a history of viral hepatitis at any time
b. Donor who has ever had a positive test for HBsAg
c. Donor who is or has been a drug addict (involving injection of drugs). Check both arms.
d. Donor if his was the only unit of blood, blood component or derivative administered to a recipient who, within six months, developed post-transfusion hepatitis

Posttransfusion hepatitis after multiple transfusions is not cause for exclusion of all donors.

Defer for at least six months:

a. Recipient of blood, blood components or derivatives such as Factors II, VII, IX and X complex, or AHF (Factor VIII) concentrates. This includes donors who are in blood immunization programs.
b. Skin allografts and tattoo. (Ear piercing and acupuncture done under questionable conditions may be considered as reason for deferment.)
c. Donor who has had close contact with a person with viral hepatitis.

The type of contact that hospital personnel encounter in their routine work is not considered close contact and is not cause for deferral. Personnel in dialysis units have especially intense potential exposure to patients' blood. If the dialysis unit has a high proportion of patients positive for HBsAg, it may be wise to defer personnel who work there.

d. Inmates of penal or mental institutions

Defer for at least 12 months prospective donors who have received hepatitis B immune globulin. Any donor with a questionable history or one who has been implicated in more than one case of post-transfusion hepatitis should be referred to the blood bank medical director for evaluation.

Malaria: Have you ever had malaria? When? Are you a visitor or immigrant to the USA? How long have you been out of the malarial area? Have you ever been out of the USA? When? Where? Have you ever taken any medication to prevent malaria?

Travelers who have been in areas considered endemic for malaria by the Malaria Program, Centers for Disease Control, U.S. Department of Health and Human Services, may be accepted as regular blood donors six months after return to the nonendemic area, providing they have been free of symptoms and have not taken antimalarial drugs in the interim. (A recent World Health Organization list of the endemic areas should be available to the interviewing personnel.) Prospective donors who have had malaria must be deferred for three years after cessation of therapy, provided they have been asymptomatic for three years. Prospective donors who have taken antimalarial prophylaxis must be deferred for three years after cessation of therapy, or after departure from the malarial area, if they have been asymptomatic in the interim. Donations to be used for the preparation of plasma, plasma components or fractions devoid of intact red blood cells are exempted from these restrictions.

9. Abnormal bleeding tendencies: Do you bleed a long time when you have a cut or a tooth pulled?

   Prospective donors with an abnormal bleeding tendency may have cause for rejection, subject to evaluation by the blood bank physician. Such individuals may experience excessive bleeding at the site of venipuncture or may have received transfusion and may be hepatitis carriers. If there is deficiency of coagulation factors, their plasma would not confer expected therapeutic benefits.

10. Convulsions, fainting spells: Do you have epilepsy? Have you had convulsions or fainting spells? Last episode?

    Donors who have epilepsy or have had either convulsions or fainting spells, except for febrile convulsions in early childhood, may have a reaction or seizure if they donate.

11. Cancer: Have you ever had cancer? What type? Have you ever had any form of blood disease? What type?

    Prospective donors who have had cancer, other than minor skin cancer, should be carefully evaluated by a qualified physician before being accepted as a blood donor. Those donors who have or have had leukemia or lymphoma must be rejected. If the donor has another "blood disease," it should be evaluated by the blood bank physician.

12. Vaccinations, inoculations: Have you been vaccinated or had any shots in the past two months? What? When?

    Symptom-free donors who recently have been immunized need not be deferred, with the following exceptions:

    a. Smallpox: Donors are acceptable either after the scab has fallen off or

two weeks after an immune reaction.

b. Measles (rubeola), mumps, yellow fever, oral polio vaccine, rabies and animal serum products: Donors are acceptable two weeks after their last immunization.

c. German measles (rubella): Donors are acceptable four weeks after their last injection.

d. HBIG: Donors are acceptable 12 months after injection.

13. General health: Do you feel well now? Do you have other health problems?

The donor shall appear to be in good health. Pain, cough, sore throat, headache, nausea, dizziness, menstrual cramps or extreme nervousness may be cause for deferment, depending on severity and medical evaluation.

The record of physical examination and medical history must be identified with the examiner by initials or signature. The reason for deferral or rejection must be recorded and explained to the donor or referred to a physician, if indicated. Any abnormal findings, whether in the physical examination or medical history, are to be stated to the donor.

Donors who are accepted should be made aware there are risks to the recipient and should be asked to report any illness developing within a few days of donation, and especially to report hepatitis that develops within six months.

The size, shape and sequence of information on a medical history record should be designed to fit the needs of the blood bank and facilitate filing and retrieval.

Special Donor Categories

Exceptions to the usual requirements may be made for:

1. Therapeutic bleedings[1,2]:

This term is used when removing blood benefits the patient. The records should include the request of the patient's physician specifying the amount of blood to be drawn; the record may be a written request or documentation by blood bank personnel of a telephoned request. The blood bank physician must decide whether to accept responsibility for having these patients bled in the donor area. In most therapeutic bleedings it is advisable to bleed at a slower rate than usual and to extend the rest period following donation. If the patient is obviously ill, it may be advisable for his physician to be present during the procedure and to arrange the appointment when other donors are not present.

If the unit is not suitable for homologous transfusion, it must be labeled NOT FOR TRANSFUSION and either discarded or used for research purposes. If the unit is suitable for homologous transfusion (as determined by the medical director of the blood bank), it may be transfused after the usual processing, provided that the label indicates a therapeutic bleeding and specifies the donor's disease. The recipient's physician must agree to using the blood for transfusion and a record must be made of this agreement.

2. Autologous transfusion:

The indications and procedures for and advantages of autologous transfusion are discussed in Chapter 21.

3. Plasmapheresis:

Special requirements and recommendations for donors in a plasmapheresis program are detailed in Chapter 2.

COLLECTION OF BLOOD

Blood shall be collected from donors by trained personnel working under the direction of a qualified, licensed physician. The donor should never be left unattended during or immediately after the collection of blood. Blood collection must be by aseptic methods, utilizing a sterile, closed system and a single venipuncture. If more than one skin puncture is needed, another container and donor set

must be used. The phlebotomist must sign or initial the donor record, whether or not the phlebotomy resulted in a complete transfusion unit.

Materials and Instruments

Many items are available in sterile, single-use, disposable form. If these leak or the paper envelope is inadvertently wet by a nonsterile liquid, the contents must not be used. Items such as gauze, cotton balls, applicators, forceps and forceps holders may be adequately sterilized by steam under pressure for at least 30 minutes at 121.5° C, by dry heat for at least two hours at 170° C or by gas sterilization. Containers of sterilized items should be labeled and dated as to when they were sterilized and when they were opened. Transfer forceps should have at least the lower third immersed in an effective antiseptic solution (eg, 70% alcohol) and should be resterilized after one week. Unopened sterilized containers may be stored for two or three weeks if the container closure insures sterility of the contents if unopened. Open containers may be used for one week, but only if the lids are replaced after removal of contents and contents are removed with aseptic technique.

Blood Containers

The blood container must be pyrogen-free, sterile and contain sufficient anticoagulant for the quantity of blood to be collected. The anticoagulant must be one approved by the Food and Drug Administration (FDA),[2] or one that meets its regulations, and must be in the container when it is sterilized. The container must be sufficiently colorless and transparent to permit visual inspection of its contents. The container label must state the kind and amount of anticoagulant and the amount of blood collected. The name and address of the collecting facility must be on the container label, as well as the required storage temperature and a reference to the *Circular of Information* for further guidelines.

Identification

In each step from donor to final disposition, a numerical or alphabetical-numerical system shall be used to identify and relate the donor record, the processing tubes and the containers. Extreme caution is necessary to avoid any mix-up or duplication of numbers. All cards and labels should be checked for printing errors. Duplicate numbers must be discarded; it is good practice to record voided numbers. A separate work table by each donor chair decreases the likelihood of identification errors.

Before starting the phlebotomy:

1. Identify donor record with the donor by name.
2. Attach identically numbered labels to donor record, container and processing tubes. Attaching the numbers at the donor chair, rather than during the examination procedures, helps reduce the likelihood of identification errors.
3. Be sure that the processing tubes (to be used for laboratory tests other than crossmatching) are correctly numbered and that they accompany the container during the collection of blood. These may be attached in any convenient manner to the primary bag or may be placed in a container attached to the donor chair. Processing tubes must not be used for crossmatching.
4. Recheck all numbers.

Preparing Venipuncture Site

Blood should be drawn from a large, firm vein in an area that is free of skin lesions. It is often helpful to inspect both arms and, to make the veins more prominent, use either a tourniquet or a blood pressure cuff inflated to 40 to 60 mm Hg. Having the donor open

and close his hand a few times is also helpful. Once the vein is selected, the pressure should be released before the skin site is prepared.

There is no way to prepare a completely aseptic site for venipuncture; however, a state of surgical cleanliness can be achieved to provide maximum assurance of a sterile product, and two acceptable procedures follow. Other procedures may be equally satisfactory, however.

General Instructions for Both Methods

Prepare an area at least two inches in all directions from intended site of venipuncture. Use sterile materials and instruments. After the initial scrub, apply other solutions starting at the site of venipuncture and moving outward in a concentric spiral.

Method 1

1. Scrub vigorously with 15% aqueous (not alcoholic) soap or detergent solution for at least 30 seconds to clean away fat, oils, dirt, skin cells and other debris.
2. Remove soap and froth with 10% acetone in 70% isopropyl alcohol (one part acetone and nine parts isopropyl alcohol) and allow to dry.
3. Apply tincture of iodine (3–3½% in 70% ethyl alcohol) and allow to dry.

   Keep the tincture of iodine bottle tightly capped to prevent evaporation of alcohol. Higher concentrations of iodine may cause skin reactions.
4. Remove the iodine with 10% acetone in 70% isopropyl alcohol. (The iodine has served its purpose and will rarely cause any skin reactions if properly removed.) Allow the solution to dry.
5. If not ready to perform venipuncture immediately, cover site with dry sterile gauze.

Method 2

1. Scrub area for 30 seconds with 0.7% aqueous scrub solution of iodophor compound (eg, PVP-iodine or poloxamer-iodine complex). Excess foam must be removed, but the arm need not be dry before the next step.
2. Apply iodophor complex solution (eg, 10% PVP-iodine) and let stand for 30 seconds. This solution contains only 1% free iodine and need not be removed before completing venipuncture. It has the advantages of less odor and stain than tincture of iodine and seldom causes skin reactions even in iodine-sensitive individuals. Iodophor complexes may be substituted for tincture of iodine in method 1, step 3, above.
3. If not ready to do venipuncture immediately, cover the area with dry sterile gauze.

After the skin has been prepared, it must not be touched again. Do not repalpate the vein.

Phlebotomy and Collection of Samples for Processing and Compatibility Tests

1. Inspect bag for any defects. The anticoagulant solution must be clear.
2. Position bag carefully, being sure it is low enough to allow gravity collection. The bag may be hung upside down, so that blood entering the bag flows through the anticoagulant.
   a. If balance system is used, be sure counterbalance is level and adjusted for the amount of blood to be drawn. Unless metal clips and a hand sealer are used, make a very loose overhand knot in tubing. Hang the bag and route tubing through the pinch clamp.
   b. If balance system is not used, be sure there is some way to monitor the volume of blood drawn.
   c. If a vacuum-assist device is used, the manufacturer's instructions should be followed.

3. Reapply tourniquet or blood pressure cuff. Have donor open and close hand until previously selected vein is again prominent.
4. Uncover sterile needle and do venipuncture immediately. In order to obtain a clot-free, full collection of blood, it is most important to do a clean, skillful venipuncture. Tape the tubing to hold needle in place and cover site with sterile gauze.
5. Open the temporary closure between the interior of the bag and the tubing, if present.
6. Have donor open and close hand, squeezing a rubber ball or other resilient object slowly and repeatedly during collection.
7. Mix the blood and anticoagulant gently and periodically during collection. Mixing may be done manually, or by placing bag on a mechanical agitator, or by using vacuum-assist device.
8. Be sure blood flow remains fairly brisk, so that coagulation activity is not triggered. Units requiring more than eight minutes to draw may not be suitable for preparation of platelet concentrates or antihemophilic factor; however, if adequate blood flow is assured and constant agitation is maintained, rigid time limits are not warranted.
9. Monitor volume of blood being drawn. Blood flow will stop after the proper amount has been collected when using the balance or vacuum-assist methods. One milliliter of blood weighs at least 1.053 g (from females) and 1.055 g (from males). A convenient figure to use is 1.06 g; the final container should weigh 425 to 520 g (405 to 495 ml) plus the weight of the container with its anticoagulant.
10. Clamp tubing temporarily using a hemostat, metal clip or other temporary clamp. Deflate and remove tourniquet. Remove needle from arm. Apply pressure over gauze and have donor raise arm (elbow straight) and hold gauze firmly over phlebotomy site with the other hand.
11. Insert the needle through the stopper of a vacuum test tube, release the temporary clamp and allow the tube to fill.
12. Seal the tubing close to the needle assembly, using either a metal clamp and hand sealer or a dielectric sealer. Cut tubing and discard needle assembly into special container designed to prevent accidental injury and contamination to personnel.
13. Strip donor tubing as completely as possible into the bag, starting at seal. It is important to work quickly, before the blood begins to clot in the tubing. Invert bag several times to mix thoroughly, then allow tubing to refill with anticoagulated blood from the bag. Repeat this procedure a second time.
14. Seal into segments the tubing left attached to the bag. Knots, metal clips or a dielectric sealer may be used to make segments suitable for crossmatching. It must be possible to separate segments from container without breaking sterility of the container. Always begin sealing at the end of the tubing, where the needle assembly has been removed. If sealing is begun at the bag end, there may be excess pressure in the last segments, which may cause rupture, especially during centrifugation.
15. Reinspect container for defects.
16. Recheck numbers on container, processing tubes, and donor record. Be sure the expiration date of the unit is noted on the container label.
17. Place blood at appropriate temperature. Unless platelets are to be removed, whole blood should be placed at 1 to 6° C immediately after collection. If platelets are to be harvested, blood should not be chilled but should be maintained at room temperature (about 20 to 24° C)

until platelets are separated. Platelets must be separated within six hours after collection of the unit of whole blood. (The *Code of Federal Regulations*—21 *CFR* 640.24(b)—requires separation within four hours.)

Care of the Donor After Phlebotomy[1,2]

1. Check arm and apply bandage after bleeding stops.
2. Have donor remain reclining on bed or in donor chair under close observation by staff.
3. Allow donor to sit up when his condition appears satisfactory. DO NOT LEAVE DONOR.
4. Give donor instructions about postphlebotomy care. The medical director may wish to include some of the following suggestions:
   Eat and drink something before leaving.
   Do not leave until released by staff member.
   Drink more fluids than usual in next four hours.
   It is probably better not to have any alcohol until you have eaten something.
   Do not smoke for a half hour.
   If there is bleeding from phlebotomy site, raise arm and apply pressure.
   If you feel faint or dizzy, either lie down or sit down with head between your knees.
   If any symptoms persist, either return to blood bank or see a doctor.
   You may resume all normal activities after about a half hour if you feel well.
   It is probably better not to ride in fast elevators, do prolonged strenuous work or excessive exercises, or to visit a patient in the hospital until after you have eaten.
   Remove bandage after a few hours.
   Your blood volume returns to normal very rapidly [normal volume ranges from 4000 ml (8 pints) to 5500 ml (11 pints)], depending on size and weight.
5. Thank the donor for an important contribution, encourage repeat donation after proper interval and offer refreshments to the donor. The personnel on duty throughout the donor area should be friendly and qualified to observe for any signs of delayed reaction, competent to interpret instructions and answer questions, and responsible for releasing donor in good condition.
6. Note on the donor record any adverse reactions that occurred and, if the donor leaves the area before being released, note this on the record.
7. Be sure there is a mechanism to notify donors of any clinically significant abnormalities detected in either predonation evaluation or in postdonation laboratory tests, especially a positive test for HBsAg.

Donor Reactions[7]

Most donors tolerate giving blood very well, but occasionally an adverse reaction may occur. Personnel must be trained to recognize reactions and treat some of them. Many blood banks require their donor room personnel to be trained in cardiopulmonary resuscitation (CPR).

Causes and Symptoms

Syncope (fainting or vasovagal syndrome) may be caused by the sight of blood, by watching others give blood or by individual or group excitement. Whether caused by psychologic factors or by neurophysiologic response to blood donation, the various symptoms may include weakness, sweating, dizziness, pallor, loss of consciousness, convulsions and involuntary passage of feces or urine. The skin feels cold and there is a fall in blood pressure (systolic level may drop as low as 50 mm Hg or the blood pressure may

APPENDIX C

THE BLOOD COLLECTION PROCESS

(HOW IS IT DONE?)

APPENDIX C

THE BLOOD COLLECTION PROCESS

(HOW IS IT DONE?)

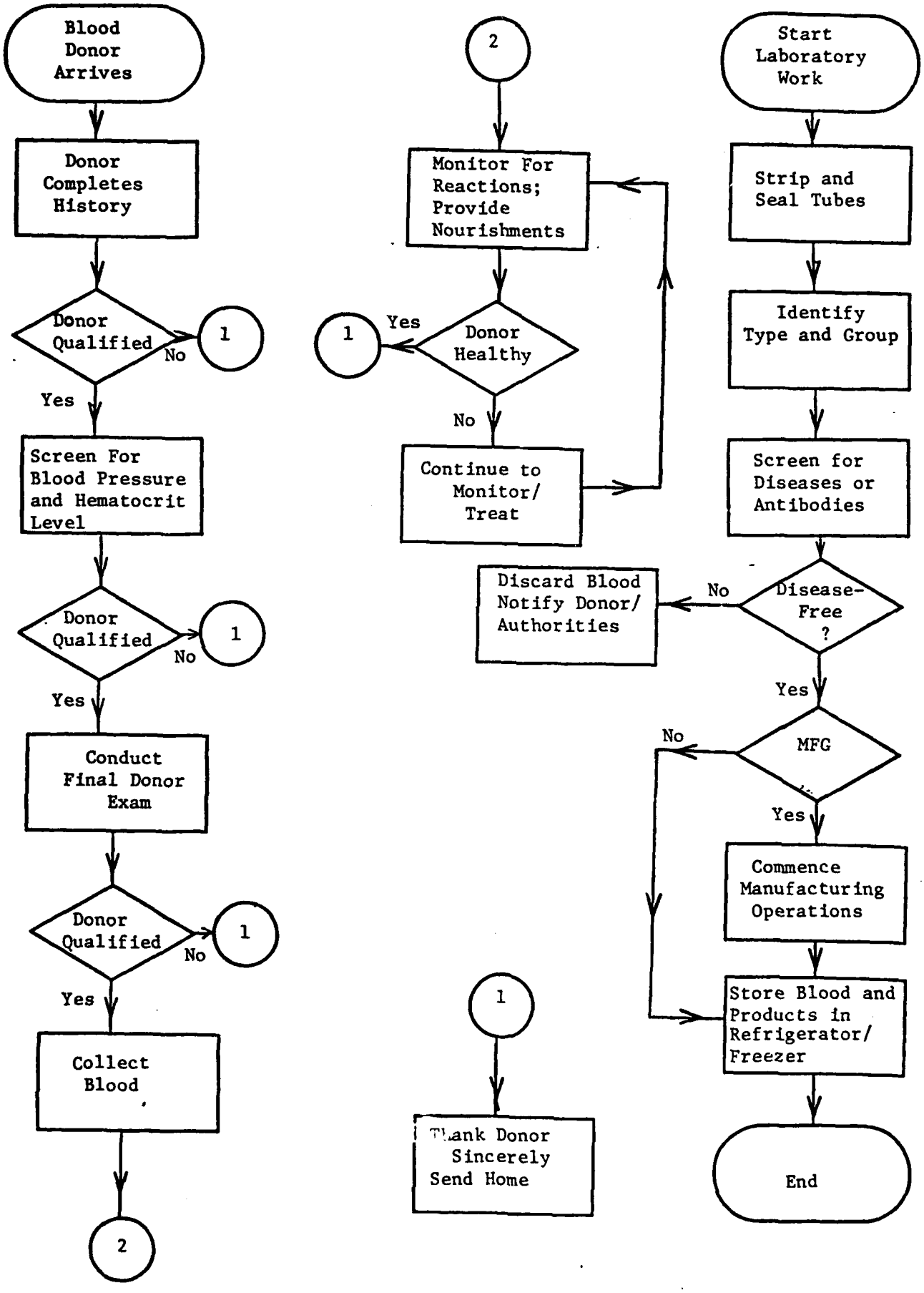
Given an acceptable physical plant and a medically efficacious scenario, this appendix outlines the routine blood collection process and shows time standards for each function. Five areas are generally recognized: reception and briefing; physical exam; screening; phlebotomy; and recovery. Additionally, two areas are needed in the laboratory. A larger area may be needed for the preparation of blood components, and an administrative area will be needed for records and blood donor recruitment activities.

The time elements are extracted from the College of American Pathologists (CAP) Manual for Laboratory Workload Recording Method[1], hereafter known as the CAP Method. This is designed as an aid which will measure productive time expended by technical, clerical and aide staff and may assist in making decisions regarding, space, staffing, and equipment. The CAP Method is in use in several thousand hospitals and numerous separate laboratories and is used for interhospital comparisons by the American Hospital Association.[2]

Labor starts with preparing the donation site by transporting supplies and equipment, setting up the various areas, and making sure the facility is appealing to the donors. This administrative type labor is not included in the CAP Method, and will be highly variable depending on the activity. Once potential donors arrive, events follow the flowchart shown at Figure 2. A reception area is needed for donors. In this location they will fill out a history. In most military units, the history is completed as a group with the

FIGURE 2

BLOOD DONOR COLLECTION FLOWCHART



staff explaining each entry and waiting for the group to complete entries before going on. This will also screen out some individuals who may not donate blood due to current illness or past history of hepatitis. This process will take fifteen to twenty minutes. Time spent assisting the group fill out questionnaires is not recognized by the CAP Method. Space is needed for donor seating, while they prepare history forms, an instructor podium, and a table with brochures intended to show the process and recruit future donors. No other specific equipment is required in this area.

Donors move to an initial screening area where blood pressure and pulse readings are recorded and where they are evaluated for hematocrit level. Needed in this area is equipment for the blood pressure station (a table and two chairs for each technician), and the hematocrit station (which is often done by the same technician at one station). A private screening area or room is required next for an accurate examination of individuals to determine their suitability as donors.[3] The private screening station does not have to be in a separate room (although there should be voice privacy and a screen) and requires only two chairs, a table, and a person weighing scale. Donors who pass this screening will then return to the reception room or go directly to a donor station. The CAP Method recognizes eleven minutes per donor for this portion of the process.[4]

Once at the donor station, the donor is issued a bag and the Laboratory Technician will prep the arm, do the venipuncture, observe the blood flow, remove and seal the bag when it is full, tape up the donor's arm, and tag the bag. An assistant will then transport the bag to a central site where tubes attached to the bag will be stripped (to mix the blood into the

anti-coagulent) and the tubes will be sealed into sections for later testing and identification purposes. The bag is then placed in storage. If the blood is to have platelets removed it is stored at room temperature, if not, it should be refrigerated immediately.[5] Eleven minutes is granted by the CAP Method for this portion of the process.

Donation stations are normally set up with three beds or couches set up in a semi-circle for each phlebotomist. Within this area is a small stand used to hold supplies used to prep an arm for the puncture. Attached to each donor couch is a scale mechanism to identify a full bag. Normally, a bag will be filled in five minutes. Under no circumstances should a donor be required to attempt donation for more than twelve minutes.[6] Giving each donor couch three to four donors per hour, one phlebotomist with a minimum of experience will be able to draw nine to twelve donors per donor collection station. The College of American Pathologist guideline for the phlebotomy is eleven minutes, yielding a maximum efficiency per station of 15 donors per hour (5 donors x 3 couches). Between stations there should be wide corridors of at least ten feet for donors and staff to walk through without accidentally bumping donors.

Donors will then move to a recovery area. Donor nourishments are to be provided in this area to assist in preventing minor donor reactions and as a gratuity to the donors.[7] These nourishments are normally cookies or doughnuts, with juices and coffee to drink. Several tables will be needed for the nourishments. Donors should have a place to sit comfortably, possibly around a television set. A curtained off area should also be available with two extra beds to permit some donors to recover while lying down if needed.

They will have to remain in this area a minimum of twenty minutes, and a half-hour is average. A toilet facility in this area is also essential. This area must be staffed at all times to monitor donors for delayed reactions, however, no time is expressly recognized by the CAP Method.

Once blood is collected, it must be processed and manufactured. Processing is the work involved with identifying the blood and testing it for certain diseases and antibodies. ABO classification and the Rh group must be determined by testing red blood cells and the serum or plasma.[8] The CAP Method recognizes five minutes per specimen for these tests. All donor blood must be tested for HBsAg, for which the CAP Method gives a (temporary) value of 1.6 minutes. Donors with a previous history of transfusion or pregnancy should be tested for unexpected antibodies, preferably at the time of processing. Most blood banks test all donor blood regardless of history.[9] Finally, as discussed earlier, standard of care criteria require all blood banks to test for AIDS. This test will take 2.4 minutes.

Blood which is found to be free of disease may then be fractionated (separated) into components. This is also known as manufacturing components. As shown at Table 3, there are several options available and the times to perform this processing is highly dependent on the level of separation work desired, and whether blood can be separated in groups of four units or singly.

TABLE 3

SUMMARY

ACTIVITY	TIME	CAP CODE NO
	COLLECTION	
Set-up time	2 min (est)	None
Group History Preparation	5 min	None
Donor Exam (BP, Hematocrit, Screen)	11 min	86825
Phlebotomy	11 min	86133
SUB-TOTAL (to draw blood)	29 min	
	PROCESSING	
ABO/Rh Typing	5 min	86081
Antibody Detection	20 min	86140
Hepatitis Confirmation (ELISA)	1.6 min	86176
Syphilis	3.0 min	86430
AIDS	2.4 min	None
SUB-TOTAL (to process)	32 min	
	MANUFACTURING COMPONENTS (assumes four or more units are prepared simultaneously)	
Fresh-Frozen Plasma Preparation	4 min (t)	86801
Packed Red Blood Cells	2 min (t)	86796
Platelet Concentrate Preparation	3 min (t)	86390
(Note: Other manufacturing, such as for cryoprecipitates has been intentionally omitted due to the amount of manufacturing time required.)		
SUB-TOTAL (to manufacture these three components)	9 min	
	MISCELLANEOUS	
Blood, Component or Derivative (issue or receive)	2 min	86134
Donor Accounting, per Unit	8 min	86820
SUB-TOTAL	10 min	
GRAND TOTAL	80 minutes	

TABLE 4

ESTIMATED LABOR COST PER

UNIT OF BLOOD

EMPLOYEE CATEGORY	PER HOUR	PER UNIT
Civilian (GS-7, Step 5)[1]	$ 9.68	$12.90
Military (E-5)[2]	12.14	16.20
Average (time documented CAP Method)	10.91	14.55

[1]Cost of civilian labor is the actual salary multiplied by a factor of 1.273 to cover various fringe benefits (HSC Regulation 750-2, appendix B).

[2]Letter, ACOA, DACA-FAP-A, 19 March 1985, subject: FY 85 Military Composite Standard Rates - CA Letter No. 85-3.

Footnotes

[1] _____, Manual for Laboratory Workload Recording Method, 1985 Edition, (Chicago, Il., College of American Pathologists, 1984).

[2] Ibid, p. 1.

[3] US Department of Health, Education, and Welfare. Food and Drug Administration. 21 CFR 606.4 (a) (1). 1 April, 1978.

[4] CAP Manual, p. 145.

[5] Technical Manual, pp. 11-12.

[6] Interview with Major Frohman, 5-6 December, 1984.

[7] Army Regulation 40-2, p. 12-1.

[8] Technical Manual, p. 14.

[9] Ibid, p. 15.

[10] Interview with Robert Simson, 8 April, 1985.

APPENDIX D

EQUIPMENT AND SUPPLIES

APPENDIX D

EQUIPMENT NEEDED IN A BLOOD COLLECTION FACILITY[1]

	Collections Per Session		
	25	50	100
1. Blood Bank refrigerators	1	2	2
2. Blood Bank freezers	1	1	1
3. Alarms for above two	2	3	3
4. Centrifuge for serologic testing variable speed, variable time	1	1	1
5. Refrigerated Centrifuge	1	1	1
6. Cell washers (automated)	1	1 or 2	2
7. Water bath	1	1	1
8. Heat blocks	1	2	3
9. Electric sealers	1	1	2
10. Ice machine	1	1	1
11. Scale, person weighing	1	1	2
12. Chairs, student	10	20	40
13. Microscope	1	1	1
14. Donor bed, portable	3	6	9
15. Equipment table	1	2	3
16. Sphygmomanometer	6	9	12
17. Stethoscope	3	3	6
18. Weighing mechanism, blood	3	6	9

[1]CPT Miller

SUPPLIES NEEDED FOR COLLECTING
ONE UNIT OF BLOOD

MATERIALS	UNITS	COST FOR UNITS SHOWN (EST)
Acetone Alcohol	2 ea	$0.206
Albumin	6 drops	.038
Alcohol Swab	1 ea	.010
Anti Sera A	1 drop	.034
B	1 drop	.034
AB	2 drops	.070
Capillary Tube	1 ea	.024
Coombs	6 drops	.190
Copper Sulfate	1 ml	.006
Gauze, 2x2	2 ea	.028
Gauze, 4x4	2 ea (pkg)	.024
Iodine Swab	1 ea	.278
Lancets	1 ea	.016
PipeHes	3 ea	.268
Rh Control	2 drops	.156
Refreshments	1 coke and cookies	.750
Saline	50 ml	.072
Scrub Swab	1 ea	.296
Sealing Clips	1 ea	.040
Tubes 12x75	16 ea	.600
13x100	2 ea	.014
TOTAL		$2.974

APPENDIX E

DECISION MATRIX

#	ALTERNATIVES / CRITERIA		CIVILIAN BLOOD SERVICES	SELF-SUPPORTING	OTHER MILITARY HOSPITAL	CAMP MEMORIAL BLOOD CENTER	VETERAN'S ADMIN SHARING AGREEMENT	CIVILIAN VA SELF COMBINATION		TOTAL POSSIBLE (10X WEIGHT)					
1	QUALITY														
2	ADEQUACY														
3	ERRORS														
4	COMPONENTS														
5	EMERGENCIES														
6	OUTDATING														
7	EMPLOYEE SAT														
8	CROSSMATCH/TRANSFUSIO														
9	DELAYS														
10	WORKLOAD														
11	EDUCATION														
12	CONSULTS														
13	MOBILIZATION														
14	TRAINING														
15	LABOR														
16	TOTAL ARMY														
17	RISK CONTROL														
18	COST														
	TOTAL														
	PERCENT														

GENERAL PURPOSE DATA SHEET

(TO BE USED AS A WORKSHEET OR FOR COPY PREPARATION - NOT TO BE OVERPRINTED)

ARMY-WR-Bul- 1000-68

APPENDIX F

SAMPLE DECISION PAPER

SUMMARY SHEET

ROUTING						ROUTING					
	OFFICE	DATE	CONCUR	NON-CONCUR	SEE TAB....		OFFICE	DATE	CONCUR	NON-CONCUR	SEE TAB....
1	Clinical Lab Off					6	C, Dept of Nurs				
2	Pathologist					7	C, DPCCM				
3	C, Dept of Surg					8	DCA				
4	Comptroller					9	Admin Resident				
5	C, CSD					10					

ACTION OFFICE: HSUD
OFFICER/PHONE: 4832/4833

SUBJECT: Establishment of a MEDDAC Operated Blood Collection Program at West Point, New York

DATE: 1 Jun 85

SUMMARY

PURPOSE: To recommend to the Commander, USA MEDDAC, West Point, New York, that a limited blood collection program be initiated by Department of Pathology.

DISCUSSION: In recent years there has been significant interest at Keller Army Community Hospital in the blood collection program. This interest resulted in certain significant changes in its relationship with the Hudson Valley Blood Services, a civilian regional blood bank. While this has resulted in reducing the direct cost of the blood acquired, there was still a need to evaluate the total needs of the MEDDAC and to determine if other blood collection programs would be feasible.

The author has completed such a Research Project as a requirement of the course of study leading to a Master's Degree from the US Army-Baylor University Program in Health Care Administration. A brief discussion of the specific application of this methodology to West Point is at Tab A. A copy of the Project Paper is attached at Tab B for detailed material as directed.

RESOURCE IMPACT: A constraint, imposed by the Commander, to the local study was that personnel resources could not be expanded. The limited program proposed in the discussion satisfies this constraint. Supply costs, per unit of blood collected, are $14.57. Labor costs, estimated at $14.55, will have no direct effect as no increase in staff is anticipated. No significant equipment costs are anticipated although there will be some minor purchases required of less than $1,000.

RECOMMENDATION: A limited MEDDAC operated blood collection program, as identified at TAB C, is feasible for the significant training and mobilization benefits discussed. Implementation of this limited program will be in the best interest of the US Army Health Services Command, and the MEDDAC, West Point, New York.

RENE A. HEIDENHEIM
CPT, MS
Administrative Resident

DECISION OFFICE

- ☐ APPROVED
- ☐ APPROVED AS MODIFIED
- ☐ DISAPPROVED
- ☐ SEE ME

INITIALS..... DATE.....

USMA FORM [illegible]

TAB A

BLOOD DONOR COLLECTION PROGRAM
FEASIBILITY ASSESSMENT FOR
USA MEDDAC, WEST POINT, NEW YORK

Food and Drug Administration Regulations prevent MEDDAC staff from routinely collecting blood until a license is awarded. Blood collection programs at West Point generate blood primarily for a regional civilian blood bank, the Hudson Valley Blood Services, a division of the Greater New York Blood Program, an organization affiliated with the American Red Cross. This organization operates two blood drives annually which, in 1984, produced 5,899 pints (units) of blood. Additionally, they collect blood at Stewart Army Sub-post. A third blood drive conducted on West Point proper, is operated by Walter Reed Army Medical Center once a year. In 1984 this drive yielded approximately 800 units.

There are no direct cost-benefits derived from Hudson Valley Blood Services in return for blood donations. West Point receives whole blood and packed red blood cells at no cost as a result of other Army installations contributing blood to Red Cross blood banks through the COMPASS program. All other products and services rendered are reimbursable. These other costs are kept to a minimum by careful management and by acquiring fresh-frozen plasma and cryoprecipitates from Walter Reed Army Medical Center or Camp Memorial Blood Center, Fort Knox, Kentucky.

"Our one life-saving process is to give blood", says Captain Mark Gusack, M.D., Chief, Department of Pathology. There are three aspects, he continues, to the need for a blood collection program. Training technologists is one

of the most important missions of Army pathology. Gaining a basic understanding of donor recruitment and collection is the second aspect. Technicians graduating from the Medical Laboratory Specialist Basic Course receive no training in the drawing of blood. Senior enlisted personnel attending the Advanced Medical Laboratory Course do receive this training but need to maintain skills by hands-on practice. Clinical Laboratory Officers also have no opportunity to maintain skills without a blood collection program. An important mission of the MEDDAC is to develop and maintain medical skills of all personnel. A blood collection program would provide important training to help meet that mission. This training cannot be simulated, but can only be accomplished by going through the motions of the actual process. The third aspect, finally, is that pathology residencies provide little to no training in the management aspects of a blood collection program so that pathologists need the training experience too.

The mobilization mission for West Point MEDDAC is currently under review due to other installation missions and lack of space. There remains a possibility that even if the hospital mission is modified or deleted, there will still be a requirement to provide up to fifty units of unprocessed blood per day during mobilization. Experience at other Army installations demonstrates that there are too many variables to successfully accomplish this mission without training. LTC Usury, the Blood Program Manager for Health Services Command, has indicated that West Point will be tasked to actually collect twenty-five units of blood per day for a week during mobilization exercise this fall as a realistic test of mission readiness. These factors demonstrate a need to actively establish a program which will require the Department of Pathology to prepare itself for any mission.

Training and mobilization readiness will not be enhanced at the cost of poor service. "One is always responsible for his or her negligence", according to MAJ Kevin E. O'Brien, Counsel at the Office of the Staff Judge Advocate, West Point. The Department of Pathology has a proven record of accuracy and reliability which demonstrates clearly that they are fully capable of undertaking this additional mission. A small blood collection program may provide an additional skill level which will minimize risks if a larger program must ever be initiated on short notice. Maintenance of records is an extremely important part of minimizing negligence in a good blood collection program and will be an especially important part of the program.

Hudson Valley Blood Services provides blood to thirty-nine hospitals in a seven county region. Approximately ten percent of the blood they provide comes from West Point. Clearly, a major change in provider availability would have to be carefully coordinated. A minor program such as the one proposed, will not adversely affect the number of donors currently available, and community responsibilities will not be affected by a change in the mission.

TABLE 1

BLOOD AND BLOOD PRODUCTS USED DURING 1984

ITEM	UNITS
Whole Blood	4
Packed Red Blood Cells	271
Fresh-Frozen Plasma	24
Cryoprecipitates	25
Platelets	18

As a further check, a telephonic interview with Ms. Laura Reinholz, Blood Bank Manager for Cornwall Community Hospital, confirmed that she is not highly dependent on the active duty military population. Any change, therefore, will have no significant adverse impact on the local community.

Costs per unit of blood collected are high. As shown at Table 2, recurring costs per unit will be approximately $29.12. There will be additional costs incurred as a result of donor recruitment activities, records keeping, and excess management.

TABLE 2

RECURRING COSTS

PER UNIT OF BLOOD COLLECTED (ESTIMATED)

Blood bags	$5.57	(Approximate, depending on type bag used)
Supplies		
-for collecting	3.00	
-for testing	6.00	(includes $3.00 for cost of AIDS test)
Sub-total supplies	$14.57	
Labor	14.55	(computed at 80 minutes)
TOTAL	$29.12	

These costs can be minimized. Among the methods possible:

-Labor will be from in-house resources. Therefore, there will be no actual increase in civilian pay, and a supply cost of only $14.57 per unit.

-Over $2,100 was used during Fiscal Year 1984 for the purchase of blood products from Hudson Valley Blood Services. Blood products purchased include:

* 24 units at $35.25 of fresh-frozen plasma;

* 25 units at $24.50 of cryoprecipitate;

* 18 units at $35.75 of platelets.

-Cryoprecipitate and fresh-frozen plasma can be acquired free of charge from Camp Memorial Blood Center or Walter Reed Army Medical Center. Increased inventories are now kept on hand to reduce emergency requirements from Hudson Valley Blood Services. With a donor program on post, there may be a possibility that even some platelets will be available when needed.

-As will be detailed later in this discussion, a sharing agreement with a Veteran's Administration Medical Center is a viable option. A program of this sort is potentially cost-effective.

The final area of significant cost potential is for equipment. Because there is a transfusion service already in place, however, only few items must be purchased (TAB E) for a one-time cost of less than $1,000 to start a program.

As recommended at TAB C, an in-house collection program would collect twenty to forty units per month for a total recurring supply cost of approximately $3,500 to $7,000 per year. This is an increase of only twenty-two to forty-four percent compared to a total blood bank cost of $16,000 during Fiscal Year 1984.

A blood collection program can be set-up outside the hospital. The only essential facility requirements are toilets and hand-washing facilities. An optimal facility at West Point would provide four rooms: a reception area; screening & history area; a donor collection area; and finally a recovery area. To collect from thirty donors in an hour requires only 1,315 square feet in total. The collection station should be placed near the Central Area for the convenience of the donors. Temporary use of facilities in the Cadet Health Clinic on collection days would be preferred. Use of Eisenhower Hall, while feasible, would adversely affect the number of donors available. The use of the main hospital would be equally hard to reach for donors.

The Department of Pathology has passed numerous inspections by the College of American Pathologists, the Joint Commission on Accreditation of Hospitals, the Inspector General, and the Food and Drug Administration (for the transfusion service). Accreditation of a blood collection program is feasible.

Alternatives

Five alternatives initially appeared to have some feasibility at West Point:

1. Continued use of Hudson Valley Blood Services with no change to current systems. Reliability, proximity, and an outstanding consulting service are the primary benefits. Total lack of training opportunity and mobilization preparation are the primary disadvantages.

2. Establish a self-supporting program. While clearly advantageous for training and mobilization purposes, this alternative is extremely costly and would be extremely difficult to support.

3. Share a blood collection program with another military hospital. Total Army mission requirements would be enhanced by the training and procedures which could be set up. The nearest facility, however, is at Fort Dix, New Jersey. This is too far to plan on dependable support in case of an emergency, would not provide the consult services needed, and cannot be depended upon to have adequate supplies of all types. Walter Reed Army Medical Center is also too far to be of routine support for consult or product service. West Point has used cryoprecipitates and fresh-frozen plasma provided by Walter Reed to control costs.

4. Receive support from Camp Memorial Blood Center. Quality and quantity service is virtually guaranteed. Distances again make total dependence on this facility unfeasible. West Point has ordered blood products from the Center to reduce expenses.

5. Establish a sharing agreement with a Veterans' Administration Medical Center (VAMC). In an interview with the Director, Blood Bank, Bronx VAMC, several attractive proposals were made if West Point provided donors:

-VAMC would keep the first 25 units collected, and divide the rest of the donated blood evenly;

-VAMC would pay for all expendables;

-VAMC would bring up a mobile unit and process and manufacture on site;

-West Point personnel could maintain full direction and control of the program;

-VAMC would exchange all old blood collection stocks in Materiel Branch for fresh stock at no cost;

-VAMC would stipulate in an agreement that they would support mobilization and mobilization training requirements on 24 hours notice;

-VAMC would study the feasibility of providing Department of the Army civilians free blood and blood products for one year after they make a donation.

-VAMC would provide a full range of clinical laboratory services for transfusion associated problems.

Each alternative was evaluated against a set of eighteen criteria as shown at TAB D. No single alternative provides for all the needs of the West Point community and MEDDAC. There are many clear and evident reasons which mandate that Hudson Valley Blood Services continues to provide the full range of services which they have provided in the past under any alternative. The disadvantages identified can be offset by a combination of several alternatives as explained in the final recommendation at TAB C.

TAB B

GRADUATE RESEARCH PROPOSAL

THE GRADUATE RESEARCH PROPOSAL WOULD BE PLACED AT TAB B

IF YOU WERE TO USE THIS DECISION PAPER AS YOUR FORMAT.

TAB C

RECOMMENDATION FOR THE ESTABLISHMENT

OF A BLOOD COLLECTION PROGRAM AT

USA MEDDAC, WEST POINT, NEW YORK

A blood collection program at Keller Army Community Hospital, West Point, New York, should consist of the following elements:

1. Hudson Valley Blood Services should continue to be the primary provider of whole blood, packed red blood cells, and special clinical laboratory services. The current blood collection programs they operate should not be altered.

2. Walter Reed Army Medical Center annual blood drives should continue without change.

3. The Department of Pathology staff should initiate a small blood collection program which would attempt to recruit approximately ten to twenty donors every other week. Recommended location for this program is in Cadet Health Clinic. This small program will provide a valuable start to a training program and mobilization capability.

4. A sharing agreement should be initiated with the Veteran's Administration Medical Center (VAMC), Bronx, New York. This agreement should specify inclusion of the items discussed at TAB B. The shared program should operate on a quarterly basis until sufficient donor awareness will make the donor recruitment mission (fifty to sixty donors) of the Clinical Laboratory Officer feasible on a monthly basis (approximately six months).

5. Blood products currently purchased from Hudson Valley Blood Services should be included as a service provided by the VAMC, or if sufficient lead time is available, from a military facility.

TAB D

EVALUATION MATRIX

#	ALTERNATIVES / CRITERIA	CRITERIA WEIGHT	HUDSON VALLEY BLOOD SERVICES	SELF-SUPPORTING	OTHER MILITARY HOSPITAL	CAMP MEMORIAL BLOOD CENTER	VETERAN'S ADMIN SHARING AGREEMENT	HVBS VA SELF COMBINATION		TOTAL POSSIBLE (10X WEIGHT)
1	QUALITY	3	7 / 21	6 / 18	6 / 18	7 / 21	6 / 18	7 / 21		30
2	ADEQUACY	3	7 / 21	4 / 12	3 / 9	5 / 15	5 / 15	8 / 24		30
3	ERRORS	4	7 / 28	7 / 28	6 / 24	7 / 28	6 / 24	6 / 24		40
4	COMPONENTS	2	7 / 14	5 / 10	5 / 10	7 / 14	6 / 12	7 / 14		20
5	EMERGENCIES	4	7 / 28	6 / 24	4 / 16	4 / 16	5 / 20	7 / 28		40
6	OUTDATING	2	7 / 14	3 / 6	4 / 8	5 / 10	6 / 12	7 / 14		20
7	EMPLOYEE SAT	3	3 / 9	7 / 21	3 / 9	4 / 12	6 / 18	6 / 18		30
8	CROSSMATCH/TRANSFUSIO	2	6 / 12	7 / 14	6 / 12	6 / 12	6 / 12	6 / 12		20
9	DELAYS	3	7 / 21	6 / 18	5 / 15	5 / 15	6 / 18	7 / 21		30
10	WORKLOAD	2	5 / 10	7 / 14	5 / 10	5 / 10	6 / 12	6 / 12		20
11	EDUCATION	1	6 / 6	7 / 7	4 / 4	4 / 4	7 / 7	8 / 8		10
12	CONSULTS	4	8 / 32	4 / 16	5 / 20	6 / 24	6 / 24	8 / 32		40
13	MOBILIZATION	4	3 / 12	8 / 32	6 / 24	5 / 20	7 / 28	7 / 28		40
14	TRAINING	3	3 / 9	7 / 21	6 / 18	4 / 12	7 / 21	7 / 21		30
15	LABOR	3	7 / 21	4 / 12	5 / 15	5 / 15	6 / 18	6 / 18		30
16	TOTAL ARMY	3	3 / 9	8 / 24	7 / 21	7 / 21	6 / 18	7 / 21		30
17	RISK CONTROL	2	8 / 16	7 / 14	6 / 12	7 / 14	7 / 14	7 / 14		20
18	COST	2	3 / 6	2 / 4	4 / 8	4 / 8	5 / 10	4 / 8		20
	WEIGHTED TOTAL		290	295	253	270	301	337		500
	PERCENT		58%	59%	51%	54%	60%	67%		100%

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INSTRUCTIONS FOR COMPLETING THE DECISION MATRIX

A. Definitions:

1. Quality of blood and patient's safety

- The proportion of transfusion reactions and the proportion of cases of serum hepatitis.

2. Adequacy of blood supply

- Level of blood and blood products inventory by type.

3. Level of human errors

- Number of erroneous crossmatches or clinical errors resulting in incorrect transfusion. When source is from outside the hospital, consider also the number of incorrect shipments by blood type.

4. Percentage use of components

- Ratio of blood components to whole blood transfusions.

5. Response in emergencies

- Average time (in hours) of response to emergencies.

6. Outdating of blood

- Percentage of blood over 35 days old to the blood that is actually transfused.

7. Employee satisfaction

- Self-esteem generated by increased responsibility.

8. Crossmatch to transfusion ratio

- Ratio of number of crossmatches to the number of units actually transfused.

9. Delays in surgery

- A ratio of surgical delays caused by lack of blood compared to total surgeries performed where blood was available on time.

10. Workload on blood bank personnel

- Number of unit values measured by the CAP Method.

11. Community education

- Measured by the annual increase of volunteer donors.

12. Consultative services to hospitals

- The number of problems which must be referred out of the hospital for assistance (such as problem crossmatches).

13. Mobilization/emergency/disaster support

- An analysis of the mobilization/disaster plan ability to support mission requirements on little or no notice. Includes coordination problems, equipment and supply availability, and training.

14. Training level of blood bank staff

- How much is needed to start; what are the benefits (SQT); what are the costs?

15. Labor requirements

- Which alternative meets the most needs at the least cost in personnel.

16. Support of the total needs of the Army

- Looking beyond MEDDAC unique mission requirements, which alternative will best meet the long-range AMEDD mission.

17. Risk control

- Exposure to an increase degree of negligence.

18. Cost effectiveness

- Provides the best result for the least cost.

B. Filling in the Numbers:

1. "Weight" the criteria. This is done by a subjective command evaluation of the degree of importance of each criteria and numerically stratifying each one into its appropriate rank. If, for example, the risk of errors is more important than education of the population, then errors should have a value of two (2) and education a value of one (1). The range of weights should be kept between one (low) and five (high).

2. Estimate the performance capability of each alternative by criteria. This is accomplished by a numerical scale of one (low) to ten (high). For example, if it is felt that a civilian blood bank is likely to produce very few errors, then they could be given a rating of nine, while a VA Medical Center may be given a rating of seven because of a local perception that it may produce more errors.

3. Multiply the weight by the numerical evaluation. This will maintain a constant weight so that, in the previous example, errors at each alternative will always "weigh" more than education.

4. Vertically add the values derived from step three.

5. Compare the totals for each alternative to establish a rank. At this point, one should also look for obvious errors, or unexpected deviation from what may have intuitively been anticipated and correct as required.

TAB E

EQUIPMENT NEEDED IN A

BLOOD COLLECTION FACILITY

EQUIPMENT NEEDED IN A BLOOD COLLECTION FACILITY

	REQ	ON-HAND	SHORT
1. Blood Bank refrigerators	1	1	
2. Blood Bank freezers	1	1	
3. Alarms for above two	2	2	
4. Centrifuge for serologic testing variable speed, variable time	1	1	
5. Refrigerated Centrifuge	1	1	
6. Cell washers (automated)	1	1	
7. Water bath	1	1	
8. Heat blocks	1	1	
9. Electric sealers	1	1	
10. Ice machine	1	0	1*
11. Scale, person weighing	1	1	
12. Chairs, student	10	0	10*
13. Microscope	1	1	
14. Donor bed, portable	3	1	2
15. Equipment table	1	0	1*
16. Sphygmomanometer	2	1	1*
17. Stethoscope	2	1	1*
18. Weighing mechanism, blood	3	2	1

*Available from elsewhere on loan

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